The effect of mindfulness on stimulus over-selectivity and selective attention to threat following acquired brain injury

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Overall abstract for thesis portfolio

Objective: The thesis portfolio aimed to explore the effect of mindfulness on cognition in an acquired neurodisability population.

Methods: A systematic review of the literature was conducted to determine the effect of mindfulness-based interventions on cognition for those with acquired brain injury, traumatic brain injury and multiple sclerosis. Further to this, a parallel randomised control design was used to explore the effect of a 10-minute mindfulness exercise on stimulus over-selectivity and selective attention to threat in a sample of 42 individuals with acquired brain injury, compared to an unfocused control condition. Computerised measures of stimulus over-selectivity and selective attention to threat (an emotional Stroop) were administered pre- and post-intervention.

Results: Six studies met criteria for the systematic review and included participants who had experienced traumatic brain injury, stroke or unspecified acquired brain injury. Results across studies were mixed with regards to effects on different cognitive domains, with the most promising results for selective and sustained attention. However, all papers were at moderate-high risk of bias. In the empirical paper, mindfulness was not found to improve stimulus over-selectivity or selective attention to threat in this sample of individuals with acquired brain injury.

Conclusions: More good-quality research is needed to investigate the effect of mindfulness on cognition following acquired neurodisability. It would be particularly beneficial to identify mechanisms of change to establish which aspects of mindfulness work on which cognitive processes for whom. Additionally, more research is needed to further understand specific attentional biases in this population, such as stimulus over-selectivity and selective attention to threat.

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Introduction to the thesis portfolio

The thesis portfolio consists of two main papers: a systematic review and an empirical study. Both papers looked at the effect of mindfulness on cognitive difficulties following acquired neurodisability. Within the portfolio there is also a bridging chapter and finally an overall discussion chapter, which synthesises the findings from both main papers.

Neurodisability has been defined as: *a group of congenital or acquired long-term conditions that are attributed to impairment of the brain and/or neuromuscular system and create functional limitations… Conditions may vary over time, occur alone or in combination, and include a broad range of severity and complexity* (Morris, Janssens, Tomlinson, Williams & Logan, 2013). This portfolio focuses on acquired neurodisability, which can have a sudden onset and result from a number of acquired brain injuries (ABI), including: traumatic brain injury (TBI), stroke, aneurysm, haemorrhage, tumour, encephalitis, hydrocephalus, hypoxia or anoxia. Multiple Sclerosis (MS) was also included in the systematic review, which although typically progressive, can also have a sudden onset and is the most common non-traumatic acquired neurological disease among young adults (Crescentinia, Urgesia, Fabbroa & Eleoprac, 2014).

Cognitive impairments following acquired neurodisability are common and can include, but are not limited to, difficulties with attention, language, visuospatial processing, speed of processing, memory and executive functioning (EF; Dams-O'Connor & Gordon, 2010; Ponsford et al., 2014b). These have been found to have a significant negative impact on quality of life (Chiaravalloti and DeLuca, 2008; Djikers, 2004), and occupational and interpersonal functioning (Ponsford et al., 2014b).

Additionally, those with acquired cognitive impairments are at increased risk of emotional disorders (Bombardier et al., 2010; Ozen et al., 2016). It is well understood that attentional bias to emotional material is a causal and maintenance factor in affective disorders (Harvey, Watkins, Mansell & Shafran, 2004). For example, selective attention to threat (SAT) is when threatening stimuli in the environment are selected over neutral stimuli for processing, resulting in an increased perception of threat (Bar-Haim, Lamy, Pergamin, Bakermans-Kranenberg & van IJzenoorn, 2007). Acquired attentional and EF deficits due to neurological damage could cause and maintain emotional difficulties by increasing emotion-processing biases, such as SAT.

The debilitating cognitive deficits that are caused by acquired neurodisability and the link between these and other significant psychosocial problems, such as increased risk of emotional disorders, highlight that effective interventions are needed to improve cognitive difficulties for this population. There is now emerging exploration into the use of mindfulness-based interventions to treat cognitive difficulties in acquired neurodisability. However, study design and methodology seem to vary and findings are mixed.

The systematic review explored existing evidence regarding the effect of mindfulness-based interventions on cognition following acquired neurodisability. This was prepared for submission to the journal: *Neuropsychological Rehabilitation*. Journal guidelines can be found in Appendix A. The empirical paper's focus was more specific, investigating the effect of a brief mindfulness exercise on an attentional process, stimulus over-selectivity, and attentional control under emotional load, SAT, in individuals with ABI. This was prepared for submission to the journal: *Neuropsychology*. Journal guidelines can be found in Appendix B.

Chapter 1

Systematic review

Prepared for submission to *Neuropsychological Rehabilitation*

The effectiveness of mindfulness-based interventions on cognition in individuals with acquired neurodisability. A review of neuropsychological findings.

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Abstract

Cognitive difficulties following acquired neurodisability have a detrimental impact on individuals, yet standardised evidence-based treatments are lacking. This paper aimed to review the effect of mindfulness-based interventions on cognition following acquired neurodisability, including participants with acquired brain injury, traumatic brain injury and multiple sclerosis. In May 2017 a search was conducted in MEDLINE, CINAHL, Psychinfo and Scopus. Studies were included if they used an objective measure of cognition and if they had a control condition or were a well-designed single-case experimental design. Six studies met criteria and included participants who had experienced traumatic brain injury, stroke or unspecified acquired brain injury. Results across studies were mixed with regards to effects on different cognitive domains, with most promising results for sustained and selective attention. However, all papers had multiple domains of moderate-high risk of bias, so conclusions need to be taken with caution. More high-quality research is needed to determine the effectiveness of mindfulness-based interventions on cognition following acquired neurodisability. Due to the heterogeneous nature of acquired neurodisability, well-designed proof of principle studies are vital in order to establish the mechanism of change that mindfulness may cause on specific cognitive processes for which individuals.

Keywords – Mindfulness, Attention, Cognition, Brain, Neurodisability

Introduction

Acquired neurodisability

Neurodisability is a commonly used term for a range of functional problems and diagnoses of neurological origin, yet the term is poorly defined (Morris, Janssens, Tomlinson, Williams & Logan, 2013). Morris et al. (2013) propose the definition for neurodisability as: *a group of congenital or acquired long-term conditions that are attributed to impairment of the brain and/or neuromuscular system and create functional limitations… Conditions may vary over time, occur alone or in combination, and include a broad range of severity and complexity.*

This review specifically looked at acquired neurodisability, which can result from acquired brain injury (ABI), specifically: traumatic brain injury (TBI), stroke, aneurysm, haemorrhage, tumour, encephalitis, hydrocephalus, hypoxia or anoxia. There were 348,934 admissions to hospital for ABI in 2013-2014 (Headway, 2015), and in 2017 there were over 1.2 million stroke survivors in the UK (The Stroke Association, 2017). Multiple Sclerosis (MS) can also have a sudden onset and is the most common non-traumatic acquired neurological disease among young adults (Crescentinia, Urgesia, Fabbroa & Eleoprac, 2014), with an estimated 100,000 people with MS in the UK (MS Society, 2016).

Cognitive deficits

People with ABI have lasting cognitive, physical and psychological difficulties (Konrad et al., 2011; Masel & DeWitt, 2010). Cognitive deficits can include difficulties with attention, language, visuospatial processing, speed of processing, memory and executive functioning (EF; Dams-O'Connor & Gordon, 2010). Attentional impairments are common, irrespective of ABI severity or aetiology (Ponsford et al., 2014b; Sivan,

Neumann, Kent, Stroud & Bhakta, 2010) and EF impairments are characteristic following TBI (Tate et al., 2014). Cognitive deficits are present in approximately one-third of individuals who have had a stroke (Nair & Lincoln, 2007). Specifically, aphasia, attentional neglect, slowed information processing and EF impairments have been found to be common post-stroke (Cumming, Marshall & Lazar, 2013). Cognitive impairments of this kind have been found to reduce quality of life (Djikers, 2004), increase the risk of developing depression (Ozen et al., 2016), and have a negative impact on both occupational and interpersonal functioning (Ponsford et al., 2014b).

In 40-65% of individuals with MS, difficulties have been found with processing speed, attention, working memory, EF and general memory (Chiaravalloti & DeLuca, 2008; Jongen, Ter Horst & Brands, 2012; Guimarães & Sá, 2012), which significantly reduce an individual's quality of life (Chiaravalloti & DeLuca, 2008).

Cognitive rehabilitation

The debilitating cognitive deficits that are caused by acquired neurodisability and the link between these and other significant psychosocial problems, highlight that effective interventions are needed to improve cognitive difficulties for this population.

Cognitive rehabilitation encompasses a wide range of interventions for different cognitive deficits. The aim is to promote generalisation and improve functioning in an individual's everyday environment (Bayley et al., 2014). Generally, cognitive rehabilitation can be divided into efforts to retrain and restore impaired skills or develop compensatory strategies to reduce the impact of deficits. Both approaches are recommended for the rehabilitation of cognitive deficits in TBI (Bayley et al., 2014). However, specific guidelines for EF and attentional difficulties recommend the use of metacognitive compensatory strategies, over retraining interventions. This is because the latter appear to facilitate improvement on specific cognitive tasks (e.g. dual attention

tasks), but effects are not transferrable to day-to-day functioning (Ponsford et al., 2014a; Tate et al., 2014).

Compensatory interventions involving metacognitive strategy instruction (MSI) for EF deficits are intended to teach individuals to *think about their thinking* and plan, implement, and evaluate strategic approaches to learning and problem solving (Palincsar, 1986). The most extensively researched and widely used MSI is goal management training (GMT; Robertson, 1996), which is used to address sustained attention difficulties and impaired goal management. There is a strong emphasis on self-awareness and self-monitoring of current feelings, behaviour and goal states, with mindfulness meditation often incorporated to promote this (Levine et al., 2011). Comprehensive rehabilitation programs incorporating GMT with other approaches were found to be effective at improving EF deficits following ABI, but insufficient evidence was found to recommend GMT as a stand-alone intervention (Krasny-Pacini, Chevignard and Evans, 2014).

Hallock et al. (2016) found that rehabilitation was successful at improving overall cognition, verbal memory and EF for TBI. It was also found to improve individuals' daily functioning by retraining functional skills and introducing compensatory mechanisms. Another review found mixed results for cognitive interventions dependent on attentional process and ABI aetiology (Virk, Williams, Brunsdon, Suh and Morrow,2015). Amato et al. (2012) reviewed and concluded that research into the effectiveness of cognitive rehabilitation programs for those with MS to either slow or improve impaired cognitive decline are limited and provide mixed results.

Generally, the literature into the effectiveness of cognitive rehabilitation post-acquired neurodisability appears promising but mixed, and stronger evidence is needed to support current clinical practice recommendations (Tate et al., 2014). Currently, there is a lack of consensus as to what components cognitive rehabilitation encompasses

(Hallock et al., 2016), but compensatory interventions, such as GMT, seem to have a greater evidence base for improving functioning, over interventions to restore deficits.

Mindfulness and neurodisability

Mindfulness is characterised by full attention to and awareness of the present moment, without judgement (Chambers, Chuen Yee Lo & Allen, 2008). Mindfulness-based interventions combine the Buddhist practice of mindfulness with aspects of Western psychology and are becoming increasingly used to improve attentional control (Chiesa, Calati & Serretti, 2011) and treat emotional disorders in a neurologically healthy population (Hofmann, Sawyer, Witt & Oh, 2010). In their systematic review, Chiesa et al. (2011) found support for mindfulness improving sustained and selective attention. Teper, Segal and Inzlicht (2013) propose that present-moment awareness and subsequent non-judgemental acceptance promotes attentional control and EF. This is done by encouraging an openness and sensitive awareness to subtle changes in affect, alerting the individual to goal conflict and the need to employ executive attentional control.

It has been proposed that mindfulness is associated with increased activity of underlying neural mechanisms that play key roles in enhanced attention monitoring and emotion regulation: the anterior cingulate cortex (ACC), prefrontal cortex (PFC) and insular cortex (IC; Holzel et al., 2011). Teper and Inlicht (2013) also found increased brain potential generated by the ACC in mindfulness-meditators. The ACC is believed to exert 'top down' control over lower neuroaxis brain structures, regulating attention. The IC and ACC are both involved in switching of attention, via different neural networks (Shapiro, Carlson, Astin & Freedman, 2005). Holzel et al. (2011) argue that changes in activity of these neural mechanisms during mindfulness interventions are of potential clinical importance in conditions where EF and attention are impaired.

So, it could be hypothesised that mindfulness interventions could be effective for those with acquired neurodisability, particularly where there are attention or EF difficulties. Additionally, as mindfulness has been linked to changes in brain structures and neural mechanisms, it may be that such interventions could be used as a restorative and retraining intervention within cognitive rehabilitation. Components of existing MSI interventions for EF and attentional control, like GMT, arguably already incorporate elements of mindfulness, including self-awareness and self-monitoring (Levine et al., 2011). It may be that this is an active component of such approaches.

There is a growing body of evidence investigating the use of mindfulness-based interventions to improve functioning and wellbeing in a neurodisability population, including on emotional, psychosocial and physiological outcomes (Bedard et al., 2014; Johansson, Bjuhr & Ronnback, 2012; Lawrence, Booth, Mercer & Crawford, 2013; Simpson et al., 2014). However, despite possible mechanisms of change of mindfulness via improving attentional control and EF and potential changes in brain structure, there seem to be fewer studies with mixed findings and varying methodology which have investigated the impact of mindfulness-based interventions on cognition following acquired neurodisability. Additionally, mindfulness-based meditation is not recommended in current guidelines for attentional deficits post-TBI (Tate et al., 2014).

Review aims

Given the growing interest in mindfulness-based interventions, and their potential to change underlying cognitive and neural mechanisms, this review aimed to answer the question: are mindfulness-based interventions effective at improving cognition in individuals with acquired neurodisability? As a secondary aim, this review looked at the strength of evidence between different neurodisabilities.

Method

Search strategy

In May 2017 a systematic search for studies was conducted in four electronic databases: MEDLINE, CINAHL, Psychinfo and Scopus. To identify any additional studies, PsychBITE and Google Scholar were also searched. Reference lists from published reviews and already obtained papers were checked. To identify further theses, ProQuest Dissertations, Thesis Database and OpenThesis were searched.

Searches were performed using the following key words. For the intervention: mindfulness, mindfulness-based interventions, mindfulness-based cognitive therapy, MBCT, mindfulness-based stress reduction, MBSR, mindfulness meditation, mindfulness intervention, mindfulness training, and mindfulness therapy. For the outcome measurement: cognition, cognitive, attention, memory, executive function, executive functioning, goal neglect, self-regulation, inhibition, dysexecutive syndrome, and executive processes. For the population: neurodisability, brain injury, brain damage, brain trauma, stroke, cerebrovascular accident, acquired brain injury, traumatic brain injury, sudden onset, encephalitis, multiple sclerosis, and subarachnoid haemorrhage. To be eligible, papers had to include at least one key word from each area (intervention, outcome measurement and population) in its title, abstract or key words.

Selection criteria

Studies were included if they fulfilled the following criteria:

- Participants had an acquired neurodisability. Acquired brain injury and MS were included due to similar cognitive deficits experienced, the sudden initial onset, and due to the lack of good quality research in one specific group.
- Participants were aged 18 years and older.

- Outcome measures were a neuropsychological assessment, psychometric or validated measure of cognition. This allowed for a more robust assessment of effect on cognition.
- Interventions were a mindfulness-based intervention, rather than other types of meditation practice. There were no criteria for intensity, length or delivery method, due to the high variation in the literature.
- The dominant component of any psychologically-based intervention was mindfulness, for example MBCT or MBSR, rather than Acceptance and Commitment Therapy (ACT) or Dialectical Behaviour Therapy (DBT).
- Studies included a control condition, either active or non-active. Or used a control phase if a single case experimental design (SCED), either using a withdrawal or reversal design (for example: ABA, ABAB or ABACAD); multiple baseline; alternating treatment; or changing criterion (Tate et al., 2013).

Studies were excluded if they met any of the following exclusion criteria:

- Participants had a neurodevelopmental or neurodegenerative condition (for example, dementia).
- Qualitative reports.
- Uncontrolled studies.
- Speculative reports.
- Meditation practice inappropriately described as mindfulness methods.
- Case descriptions, pre-post designs and multiple measurement AB designs. They lack sufficient experimental control (Tate et al., 2013).
- Reviews and meta analyses.
- Papers not written in English.

Data extraction and critical appraisal

Data was screened and extracted by one reviewer (K.V.), on study design, participants, intervention, control group, cognitive outcome measures and results and conclusions from these measures.

Five studies were critically appraised for risk of bias using a tool developed by the author (Appendix C) compromised of the Cochrane Collaboration tool for randomised control trials (RCTs; Higgins et al., 2011), Sign50 (Scottish Intercollegiate Guidelines Network, 2015) and the 25-item RCT of Psychotherapy Quality Rating Scale (Kocsis et al., 2010). Eligibility criteria allowed inclusion of study designs other than RCTs, so a wider range of items were required for assessing risk of bias. The SCED was quality assessed using the Risk of Bias in N-of-1 Trials (RoBiNT) scale (Tate et al., 2015). Using both scales, each risk domain was judged to either be low, moderate or high risk of bias.

If there were missing data to either include in the data extraction table or in order to fully assess risk of bias, study authors were contacted. The quality assessment process for all papers was conducted by one reviewer (K.V.) and a selection of three papers were independently assessed by a second reviewer (a final year Trainee Clinical Psychologist). Any disagreements were then discussed and resolved consensually. See Appendix D for inter-rater agreement data.

Analysis

A narrative synthesis was chosen over meta-analysis to answer the review's questions, due to the heterogeneity in study design in this area of research.

Results

The database searches retrieved 246 papers. Six papers were eligible for inclusion in the review (Figure 1): Johansson et al. (2012); Johansson, Bjuhr, Karlsson, Karlsson & Rönnbäck (2015); McHugh and Wood (2013); McMillan, Robertson, Brock and Chorlton (2002); Nassif (2013); and Orenstein, Basilakos and Marshall (2012). A further paper (Grossman et al., 2010) met criteria, but post-intervention cognition scores were not presented in the paper and the author did not supply missing information when contacted. Therefore, the study was not able to be included in this review. See Appendices E and F for papers excluded after a full review of papers.

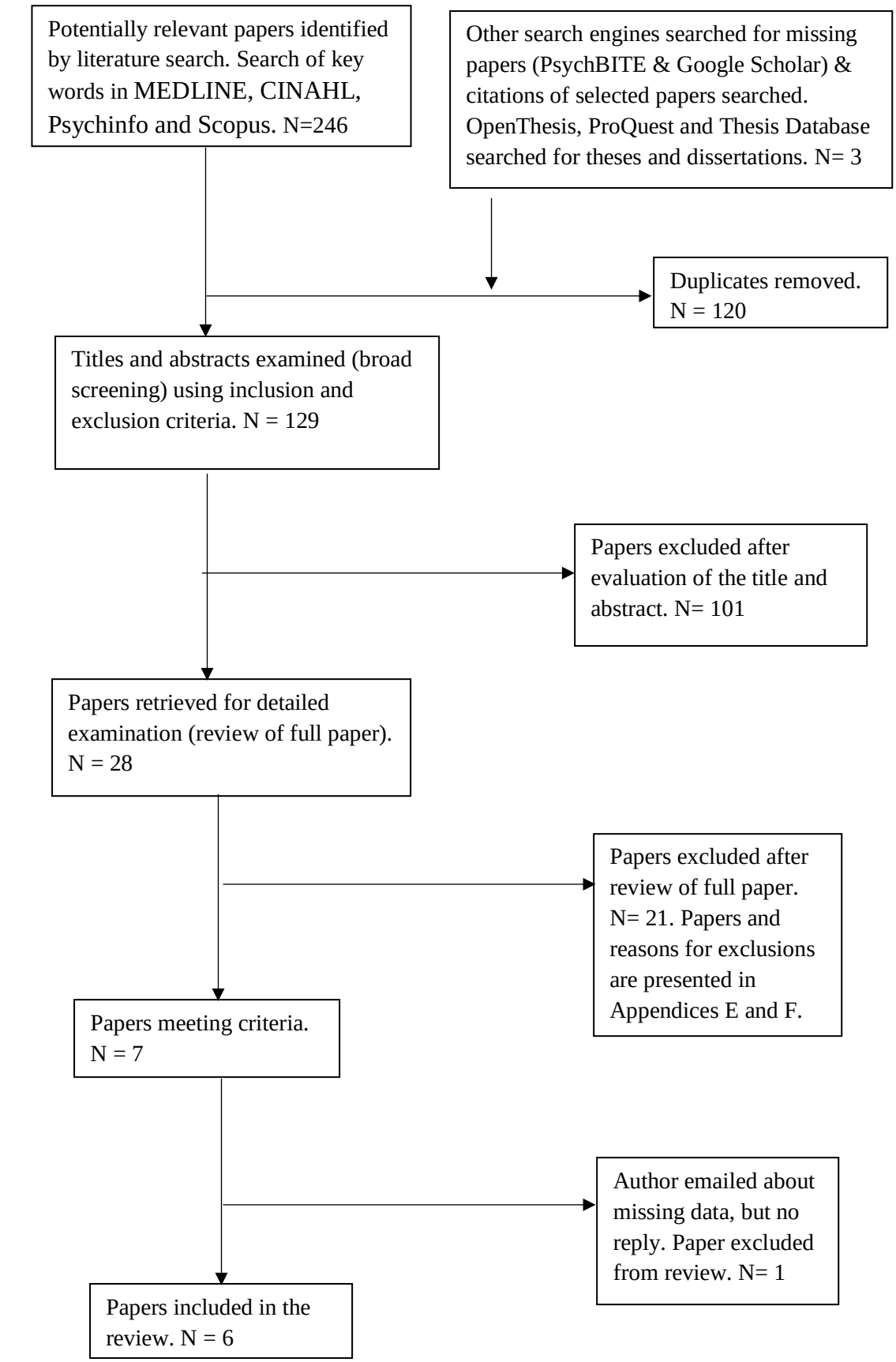

Figure 1. PRISMA flow chart for literature search.

Study characteristics

Key characteristics of the studies are presented in the data extraction table (Table 1).

Design

Three studies were randomised control trials (RCTs; Johansson et al., 2012; McMillan et al., 2002; and Nassif, 2013). Other studies employed a mixed within-between-subjects design (Johansson et al., 2015), a between-subjects design (McHugh and Wood, 2013) and a multiple baseline single case experimental design (SCED; Orenstein et al., 2012).

Participants

Across all studies, a total of 252 participants were recruited into either a mindfulness or control condition: 38 had experienced a stroke, 211 traumatic brain injury (TBI) and 3 unspecified acquired brain injury (ABI). There were no papers meeting criteria that included a multiple sclerosis (MS) sample. Two studies used mixed samples of TBI and stroke (Johansson et al., 2012; Johansson et al., 2015), and three studies used participants exclusively with TBI (McHugh & Wood, 2013; McMillan et al., 2002; Nassif, 2013). Orenstein et al. (2012) recruited three participants with left-hemisphere brain damage and aphasia.

Time since ABI varied between groups with McMillan et al. (2002) only including participants who were three months – one-year post injury and McHugh and Wood (2013) recruiting people who were 11 months – 5.5 years post-injury. Johansson et al. (2015) recruited participants who were up to forty-two years post-ABI. Johansson et al. (2012) do not report the range of time since injury in their sample, but only recruited those who were more than 12 months post-ABI. Nassif (2013) and Orenstein et al. (2012) did not consider time since injury.

Nassif (2013), Orenstein et al. (2012) and Johansson et al. (2015) did not report injury severity. Johansson et al. (2012) only included participants who scored in the moderate disability range (5) on the Glasgow Outcome Scale. McHugh and Wood (2013) reported the Glasgow Coma Scale (GCS) range of their TBI sample to be 3-15 (severe-mild) and McMillan et al. (2002) do not report the range of severity but acknowledge their sample included a wide range of TBI severity (also based on GCS).

Intervention

Both Johansson et al. (2012) and Johansson et al. (2015) used an eight-week mindfulness-based stress reduction (MBSR) programme. Johansson et al. (2015) also included a MBSR internet intervention group. McMillian et al. (2002), Nassif (2013) and Orenstein et al. (2012) used interventions of varying lengths and intensities based on MBSR. McHugh and Wood (2013) used a one-off 10-minute mindful awareness of breath exercise.

Outcome measures

Some used validated measures of cognition, including Johansson et al. (2012), Johansson et al. (2015), McMillan et al. (2002) who used neuropsychological assessment measures (see Table 1). Other studies used objective measures of cognition but were tasks created by the authors or were less well validated on the population of study (McHugh & Wood,2013; Nassif, 2013; Orenstein et al., 2012).

Table 1.

Data extraction table, detailing study characteristics

Author & date	**Study design**	**Participants (neurodisability type, number, recruitment, attrition)**	**Intervention (type, duration, format, materials, practice)**	**Control condition(s)**	**Outcome measures of cognition**	**Main findings regarding cognition**
Johansson, et al., 2012	RCT	Total recruited, N = 29 Stroke, N = 18 TBI, N = 11 Recruited from an advertisement in a local newspaper. Randomised to intervention group, N = 15 Attrition, N = 3 (20%) Randomised to control group, N = 14 Attrition, N = 0 Control group later went on to receive intervention, N=10 Attrition, N = 4 (28.6%) Overall study attrition rate, N= 7 (24.13%)	MBSR Eight-week programme of weekly 2.5-hour group sessions. A one day-long retreat between weeks six and seven. A guided CD was given to participants and 45-minute home practice six days a week was encouraged. Intervention delivered by Clinical Psychologist and trained MBSR teacher.	No treatment – wait list control	Neuropsychological assessments were secondary measures: Digit Symbol-Coding (WAIS-III) Digit span FAS verbal fluency test Trail Making Test A, B, C & D Dyslexia screening tool	The MBSR group performed Trails Making Tests B and C faster than controls (ANCOVA, TMT B: F=7.39, p=0.013; TMT C: F=4.84, p=0.039). However, after adjustment for processing speed (TMT A covariate), the effect disappeared. Paired t-tests within the MBSR group revealed a significant improvement on TMT B, TMT C and Digit Symbol-Coding after MBSR (TMT B: p=0.017; TMT C: p=0.001; digit coding: p=0.026). No significant changes over time were detected for the control group on waitlist. A significant increase in word fluency over time in the MBSR group (p=0.050), but not for the control group (p=0.081). No significant changes were found for working memory, TMT A, D and reading speed. The second MBSR group (those in the control group who went on to complete MBSR) also found some significant within-group changes (paired t-test): TMT C (p=0.007), Digit-Symbol Coding (p=0.028), word fluency (p=0.044). The paper concludes that MBSR seems to have improved attention and processing speed.

Johansson, et al., 2015	Within-between subjects	Total recruited, N=38 Stroke, N=20 TBI, N=18 Recruited from an advertisement in a local newspaper or from the study's website. Face-to-face intervention group, N = 12 Attrition, N = 0 Internet intervention group, N = 16 Attrition, N = 3 (18.8%) Control, N = 10 Attrition, N = 1 (10%) Control group later completed internet intervention, N = 9 Attrition, N = 3 (22.2%) Overall study attrition rate, N= 7 (18.4%)	1) MBSR face-to-face. Eight-week programme of weekly 2.5-hour group sessions. A one day-long retreat between weeks six and seven. A guided CD was given to participants and 45-minute home practice six days a week was encouraged. Intervention delivered by Clinical Psychologist and trained MBSR teacher. 2) MBSR internet Same intensity, duration and material as face-to-face condition. Delivered via computer. Used online meetings, allowing participants to interact with MBSR instructor and each other.	Walking group Eight-week programme of weekly 1.5-hour walking group. Led by a facilitator. Encouraged to take daily walks in-between meetings.	Cognitive assessments were part of primary measures: Digit Symbol-coding (WAIS-III) Attentional blink task	Significant improvements for the MBSR Internet group were found for processing speed on coding (p=0.031). There was improved temporal attention on the attentional blink task, resulting in more correct T2 responses at 504ms (p=0.024) and 756ms intervals (p=0.037). But no significant changes at 252ms. The face-to-face MBSR group improved significantly on the attentional blink task and made more correct T2 responses after the 504ms interval (p=0.038), but not at 252ms or 756ms. The walking group improved significantly on coding (p=0.001). Significant changes were not found on the attentional blink task at any time interval. The control group who later attended the MBSR internet programme showed improved attentional blink performance with significantly more correct T2 responses at the 756ms interval post-intervention (paired t-test, p=0.015). No other significant changes were found. Authors suggest that it is possible to deliver a live online MBSR program, including the entire curriculum, with positive results.
McHugh & Wood, 2013	Between-subjects design	Total recruited, N = 24 TBI only	Focused attention exercise Recording played to participants of a three-	Inactive control group Received no instruction.	Computerised over-selectivity task.	Difference between the most and least correctly selected stimuli was greater in the control group compared to the experimental group. This implies mindfulness reduced over-selectivity. One-tailed

		Recruited from the Tertiary Head Injury Clinic at Swansea University for neuropsychological assessment and rehabilitation advice. Randomised to intervention, N = 12 Attrition = 0 Randomised to control, N = 12 Attrition = 0	minute *mindful awareness of breathing* exercise. A reminder was then delivered approximately every 30-seconds, with the exercise totalling 10-minutes in duration.			independent t-test revealed this to be significant, $t(22)=1.74$, $p<0.05$. Authors conclude that over-selectivity can be elicited in a TBI population and that a mindfulness induction procedure can reduce levels of stimulus over-selectivity. A similar mindfulness intervention could be used to improve deficits in attentional lapses of memory (forgetfulness) and decision-making.
McMillan, et al., 2002	RCT	Total recruited, N = 145 TBI only Recruited from the Neurosurgical Unity at Atkinson Morley's Hospital & St George's Hospital in London Randomised to intervention, N = 50 Attrition post-intervention, N = 6 (12%) Further attrition at 12-month follow-up, N = 7 Randomised to active control (1), N = 47	Attentional Control Training Five 45-minute sessions of clinician-supervised practice over 4 weeks. A recording of a breathing-based mindfulness procedure taken from MBSR was delivered in each session. Daily practice encouraged.	1) Physical exercise fitness training Five 45-minute sessions of clinician-supervised practice over four weeks. Physical exercise fitness training delivered by audiotape. Daily practice encouraged. 2) Control group of no treatment	Cognitive tests were primary outcome measures: Test of everyday attention (subtests: map search, elevator counting, telephone search, telephone search dual task and lottery) Adult Memory and Information Processing Battery Paced Auditory Serial Addition Test	There were no significant differences between the three treatment groups on all objective cognition measures pre-treatment, post-treatment or at follow-up. Attentional control training of this duration and intensity could not be recommended as a routine treatment for patients suffering attentional problems following closed head injury.

		Attrition post-intervention, N = 9 (19%) Further attrition at 12-month follow-up, N = 3 Randomised to inactive control (2), N = 48 Attrition = 0 Attrition at 12-month follow-up, N = 10 (21%) Overall study attrition immediately post-intervention, N = 15 (10.3%)		and no therapist contact.	Trail Making Test	
Nassif, 2013	RCT	Total recruited, N = 13 TBI only Recruited from the Washington, DC Veterans Affairs Medical Centre (DC VAMC). Randomised to intervention, N = 8 Attrition, N = 4 (50%, includes drop outs and exclusion from analysis) Randomised to control, N = 5 Attrition = 0	iRest Eight-week mindfulness meditation programme. Two one-hour sessions per week. Encouraged to practice daily using audio recordings. Delivered by therapist who had received iRest training from the Integrative Restoration Institute.	Treatment as usual No description given. N recruited=5 N completed=5 Attrition=0%	Cognition measures were secondary outcomes: Conners' Continuous Performance Test (CPT-II)	Two-factor mixed ANOVA used. For the CPT II, experimental group improved on vigilance (sustained attention). Significance was detected from pre- to post-intervention for both the main effect of time, $F(1,7)=14.49$, $p=.004$, $\eta 2=.218$ and interaction of time and group, $F(1,7)=22.29$, $p=.002$. Effect size, $\eta^2=.278$ (large). T-tests then used to compare pre- and post-reaction times for each group. Values for reaction time by block decreased from baseline (M=53.81, SD=3.62) to endpoint (M=41.56, SD=2.31) in the experimental group, indicating that participant responses became faster as the test progressed. This difference in reaction time was significant for the experimental group, $t(3) = 9.95$, $p=.002$ as compared to no change for the control group, $t(4) = -0.332$, $p=.757$.

		Overall study attrition, N = 4 (31%)				No other measure on the CPT II (inattention, impulsivity) was found to be significant. Author concludes that vigilance (sustained attention) and reaction time improved in the iRest group from pre- to post-intervention.
Orenstein, et al., 2012	Multiple baseline single-subject ABA design	Total recruited, N = 3 Non-specified ABI with left-hemisphere brain damage and aphasia. Attrition = 0	Phase B - Mindfulness meditation taken from MBSR programme. Weekly sessions. The length of mindfulness meditations increased - beginning with five minutes of practice and building to 30 minutes. Practice encouraged in between sessions.	Phase A – baseline measures Phase A2 - maintenance phase	Cognitive outcomes were primary measures: Divided attention task Boston Diagnostic Aphasia Examination (BDAE)	Results showed no changes in performance on the divided attention task or on BDAE. All 3 participants exhibited high performance on the divided attention task with no obvious changes observed as a result of the implementation of mindfulness meditation.

Methodological quality

All authors except Nassif (2013) were contacted for missing information, but not everything requested was given. Based on the information available, all RCTs, between-within and within subject designs were deemed to have multiple areas of moderate-high risk of bias (Table 2). Rated using the RoBiNT, Orenstein et al. (2012) was deemed to have multiple areas of high risk of bias with regards to both internal and external validity (Table 3 & Table 4).

RCTs, between-within- and between-subjects designs

Selection bias

All papers stated appropriate inclusion and exclusion criteria. The majority of studies used appropriate methods for recruitment and screening, for example use of a random number table and qualified neurologists to conduct screening. Thus, the sample was representative of the neurodisability investigated. In one study (McMillan et al., 2002) risk of bias was rated high as the descriptions were incomplete on how many people were screened and excluded and who conducted the screening. Johansson et al. (2012) were rated as moderate risk of bias due to some missing information. In one study (Johansson et al., 2015) not all participants were randomised introducing high risk of bias. Risk of bias from group allocation concealment were rated as high in all studies apart from one rated as moderate risk (McHugh and Wood, 2013), as participants were kept naïve to the study's purpose.

Performance bias

Blinding of participants and research personnel to group membership did not happen in any of the five studies.

Detection bias

A strength of three studies was the use of measures validated in the study population (Johansson et al., 2012; Johansson et al., 2015; McMillan et al. 2002).

Remaining studies used measures not validated in brain injury (McHugh & Wood, 2013; Nassif, 2013). High risk of detection bias was introduced in two studies, as assessors and researchers analysing results were not blind to treatment group (Johansson et al., 2012 & Johansson et al., 2015). This bias was minimised in McHugh and Wood (2013) and Nassif (2013) as they used computerised outcome measures, and McMillan et al. (2002) did blind assessors to group membership. However, those analysing results in all studies were aware of which interventions groups received.

Attrition bias

Risk of attrition bias was moderate - high across all five studies. Johansson et al. (2012) had a high overall attrition of 24.2%. Others had uneven attrition between groups, with a difference higher than 20% (Johansson et al. 2012 & Johansson et al., 2015) and there was extreme uneven attrition in Nassif (2013) where there was a 50% difference. Some studies did not report how they dealt with missing data (Johansson et al. 2012 & McMillan et al. 2002) and in one study only 50% eligible to take part did so (McHugh & Wood, 2013).

Reporting bias

Moderate risk of reporting bias was introduced in four papers. One article failed to report results from all outcome measures and used multiple statistical analyses without using corrections for this (e.g. Bonferroni's Correction), increasing the risk of a type one error (Johansson et al., 2015). All studies, apart from McMillan et al. (2002) had small sample sizes meaning statistical analyses may have been underpowered, particularly Nassif (2013; N in active group = 4; N in control = 5). Most of the articles failed to comment on the power of statistical tests used (Johansson et al., 2012; Johansson et al., 2015; McHugh & Wood, 2013; McMillan et al., 2002). Effect sizes and whether data met parametric assumptions for statistical tests were not reported in four papers (Johansson et al., 2012; Johansson et al., 2015; McHugh & Wood, 2013;

McMillan et al., 2002). McMillan et al. (2002) did not state which statistical tests they used for all analyses, therefore were rated as high risk of reporting bias.

Other bias

Generally, study design was strong across papers. Johansson et al. (2012), McMillan et al. (2002) and Nassif (2013) used RCT designs and Johansson et al. (2015) employed a within-between design. McHugh and Wood (2013) had the weakest design as they did not take pre-intervention measures and used a between-subjects design.

The suitability of control groups, with regards to population and intervention length were a particular strength in four studies. However, McHugh and Wood's (2013) paper was rated as moderate risk of bias as they did not use a comparable intervention and instead employed an inactive control group. Therefore, it is difficult to determine if any change on outcome measures was due to the specific mindfulness intervention or generally time spent listening to a recording.

Studies did not report fidelity of treatment. Hence, some bias could be introduced here as it is not certain if the intervention being delivered, is the specific treatment under investigation. McHugh and Wood (2013) and McMillan et al. (2002) used a recorded audiotape to deliver the intervention, so it is implied this was standardised across participants. Only Johansson et al. (2012), Johansson et al. (2015) and Nassif (2013) gave details of adequate training and qualifications of the therapist delivering the intervention.

Table 2.

Risk of bias in RCTs, between-within and between-subjects designs.

	Selection bias				Performance bias	Detection bias		Attrition bias	Reporting bias			Other bias		Global risk rating
Author & date	**Nature of sample**	**Screening of sample**	**Random sequence generation**	**Allocation concealment**	**Blinding of participants and personnel**	**Blinding of outcome assessment**	**Reliable, valid, outcome measures**	**Incomplete outcome data**	**Selective reporting**	**Conclusions reported**	**Fidelity of treatment groups**	**Suitability of control group**	**Study design**	**(out of 24)**
Johansson et al., 2012	Low	Moderate	Low	High	High	High	Low	High	Moderate	Moderate	High	Low	Low	Moderately high risk (13 points)
Johansson et al., 2015	Low	Low	High	High	High	High	Low	High	Moderate	Moderate	Moderate	Low	Low	Moderately high risk (13 points)
McHugh & Wood, 2013	Low	Low	Moderate	Moderate	High	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderately high risk (14 points)
McMillan et al., 2002	Low	High	Low	High	High	Moderate	Low	Moderate	High	Moderate	Moderate	Low	Low	Moderately high risk (14 points)
Nassif, 2013	Low	Low	Low	High	High	Moderate	Moderate	High	Moderate	Moderate	Moderate	Low	Low	Moderate risk (15 points)

Note. High risk of bias = 0 points; moderate risk of bias = 1 points; low risk of bias = 2 points.

Table 3.

Risk of bias of Orenstein, Basilakos & Marshall (2012) using RoBiNT internal validity subscale

Design	**Randomisation**	**Sampling behaviour**	**Blinding patient & therapist**	**Blinding assessors**	**Inter-rater reliability**	**Treatment adherence**
Moderate	High	Low	High	High	Moderate	High

Table 4.

Risk of bias of Orenstein, Basilakos & Marshall (2012) using RoBiNT external validity subscale

Baseline characteristics	**Therapeutic setting**	**Dependent variable**	**Independent variable**	**Raw data record**	**Data analysis**	**Replication**	**Generalisation**
High	Moderate	Low	Moderate	Low	High	Low	Moderate

SCED ratings

Internal validity

Risk of bias ratings on the RoBiNT internal validity scale are presented in Table 3. Orenstein et al. (2012) met criteria for a well-designed SCED (Tate et al., 2013). However, they only utilised two demonstrations of the treatment effect (i.e. ABA), rather than three or more, so there is still moderate risk of bias introduced within the design. A strength of the study was the collection of at least five data points in each phase.

However, the authors did not randomise phase onset, instead they determined the movement between phases based on reaching a required time of mindfulness practice and stability on the dependent variable. They did not blind participants, personnel or assessors, and there were neither subjective nor objective treatment adherence measures used. Consistency of assessment of outcome measures was not checked using inter-rater reliability, but some risk was reduced due to the use of objective measures.

External validity

Risk of bias ratings on the RoBiNT external validity scale are presented in Table 4. Strengths of Orenstein et al. (2012) included a well operationalised dependent variable and sufficient description of the outcome measures. The study also included a detailed raw data record, as graphs displayed each variable scored at each time point for each phase. The SCED was replicated with three participants, as recommended by the RoBiNT. However, moderate risk of bias was introduced as some information on the intervention and its location was missing. Additionally, the study was rated at high risk of bias as they did not evaluate baseline characteristics of participants, nor report sex, age, ABI aetiology or severity for each individual participant. Study results were

defined by the RoBiNT as *unstructured visual analysis* and the study did not statistically consider phase mean, slope of the fitted line or variability.

Effect of mindfulness interventions on cognition

Attention

Significant improvements were found on an attentional blink task measuring selective attention in Johansson et al. (2015). However, this effect was only found in both MBSR groups over the control group when the temporal distance between targets was 504ms, rather than 252ms or 756ms. This may suggest improvement only at a certain level of conscious processing, but the authors do not discuss possible reasons for this. McHugh and Wood (2013) found that over-selectivity reduced following mindfulness compared to an inactive control group. Nassif (2013) found a significant group-time interaction on a computerized task of sustained attention, but their sample size was extremely small.

The version of the Trails Making Test (TMT) A used in Johansson et al. (2012) and McMillan et al. (2002) is considered a measure of sustained attention, visual scanning, sequencing and psychomotor speed (Salthouse, 2011). Johansson et al. (2012) found a significant improvement in performance on TMT A in the MBSR groups over control, whereas no significant difference was found between groups in McMillan et al. (2002). McMillan et al. (2002) did not find an effect on TMT B, which was considered a test of divided attention in both articles. Johansson et al. (2012) claim that MBSR improved performance on TMT B, as they found a significant improved result for MBSR group one using within-group analysis. However, when conducting an ANCOVA with TMT A as a covariate in between-group analysis, the effect found on TMT B disappeared. Johansson et al. (2012) included two further TMTs in their paper: TMT C and TMT D, both constructed to evaluate higher demands on dual tasks (i.e.

multi-tasking). Although they found significant improvements using within-group analysis for the two MBSR groups, they found the significant effect between groups on TMT C also disappeared after including TMT A as the covariate. No difference was found on TMT D.

Further to this, McMillan et al. (2002) found no difference between the mindfulness and control group on other measures of attention: six subtests of the Test of Everyday Attention (TEA) which looked at a range of attentional processes; and the Paced Auditory Serial Addition Test (PASAT) which assessed sustained and divided attention. Subtests of the TEA were: map search, elevator counting, telephone search, telephone search dual task and lottery. Orenstein et al. (2012) found no differences pre- to post-mindfulness intervention for all three participants on a divided attention task.

Processing speed

Nassif (2013) found that reaction times in their attentional task decreased over time in the mindfulness group compared to the control group, indicating increased processing speed. Both Johansson et al. (2012) and Johansson et al. (2015) found significant differences on digit-symbol coding from the WAIS-III and coding from the WAIS-IV between MBSR groups and control. However, this effect was only found for the MBSR internet group and not the MBSR face-to-face group in the Johansson et al. (2015). Therefore, it is not possible to conclude that MBSR improved processing speed based on this outcome. Additionally, McMillan et al. (2002) found no difference between groups on their measures of processing speed: PASAT or Adult Memory and Information Processing Battery (AMIPB).

Other

Improvement in verbal fluency was found following MBSR but not wait-list control in Johansson et al. (2012), a measure of EF and verbal functioning (Shao, Janse, Visser & Meyer, 2014). But no difference following MBSR was found on working

memory. Additionally, Orenstein et al. (2012) found no significant differences on outcomes of language.

Discussion

To the authors' knowledge, this is the first systematic review that has aimed to determine the effectiveness of mindfulness-based interventions on cognition following acquired neurodisability. Six papers met criteria and included participants with traumatic brain injury (TBI), stroke or unspecified acquired brain injury (ABI). Results found on cognition were mixed and all studies were deemed to have multiple domains of moderate – high risk of bias. Therefore, it is not possible to answer the review question with any certainty.

However, there was some indication that selective and sustained attention improved following mindfulness-based interventions in an ABI population. Although papers investigated different attentional processes, attention was the most widely explored. This could be a consequence of the growing body of evidence that has explored the effects of mindfulness on attentional processes in a neurologically healthy population (Chiesa et al., 2011). Improvement was found on EF on a verbal fluency task, but no other effect was found on divided attention, switching of attention or multi-tasking. The mixed results and weaknesses of included studies therefore provide only partial support to the emerging evidence-base that argues mindfulness can impact on neural mechanisms involved in regulating attention, and hence help those with EF and attentional impairments (Holzel et al., 2011).

There is also some preliminary evidence to suggest that mindfulness could improve processing speed, but once again results in this area were mixed and studies

had areas of moderate – high risk of bias. Other areas that found no effect of mindfulness, but were also much less extensively researched, included working memory and language. Importantly, no evidence of harm caused by mindfulness was found in any study.

Weaknesses of reviewed studies

Overall, weaknesses in study methodology and statistical analyses for all six studies mean that conclusions drawn from results should be taken with caution. None of the six studies kept participants, therapists and assessors blind to group allocation. Although this is not always possible with this type of intervention, potential bias could be reduced by keeping outcome assessors and those analysing data blind to group membership and participants blind to study hypotheses.

In four of the randomised control trials (RCTs), between-subjects and between-within-subjects designs, small sample sizes were likely to have reduced the statistical power of analyses employed and this was not considered by all of the papers. Low power increases the likelihood of a type two error. It also reduces the likelihood that statistically significant results found in the studies reflect a true effect (lowers the positive predictive value) and potentially has led to an exaggeration of effect size, as studies with low power are only able to detect larger effect sizes (Button et al., 2013). The larger study (McMillan et al., 2002) did not find any significant effects of mindfulness on cognition. However, this paper had weaknesses, including no reporting of statistical analyses used.

Generally, there was uneven attrition between groups, which can create systematic differences between active and control groups. In two studies attrition was only found in mindfulness-intervention groups and not controls (Johansson et al, 2012; Nassif 2013), whereas in others it was mixed between conditions. Some studies did not

explore attrition or comment on how they dealt with it in the analysis. This meant they may have missed potential common characteristics of participants that could have led to attrition, potentially leading to biased estimates of true intervention effects (Deke, Sama-Miller & Hershey, 2015).

Interventions were all variations of or taken from mindfulness-based stress reduction (MBSR), but ranged in length and intensity, from full programmes, to individual 10-minute exercises. This makes them difficult to compare. There was no fidelity reporting in any of the six studies, hence we cannot conclude that the intervention intended to be investigated was the one that was delivered. Some interventions were delivered by therapists, whereas others were played on an audiotape. It has been argued that the therapist-client relationship is important for improving mindfulness levels post-intervention (Bowen & Kurz, 2012). Suitable training and supervision for those delivering interventions was also not considered by all papers.

Additionally, there was also considerable variation in cognitive processes investigated and which outcomes were used to measure these, as well as aetiology of brain damage, making it difficult to compare study outcomes. Furthermore, there were no studies that investigated the effect of mindfulness on cognition in multiple sclerosis (MS) that met eligibility criteria for this review, suggesting the evidence-base in this population is generally weaker and lacking.

Implications for future research

Findings from this review suggest that more high-quality research is needed to fully assess the impact of mindfulness on cognition following acquired neurodisability. This includes more large-scale RCTs, with high power to detect small to large effect sizes to reduce reporting bias. Additionally, well-designed proof of principle studies and

more robust single case experimental designs (SCEDs) are needed, addressing areas of potential bias in papers in this review.

Only one study met criteria for a well-designed SCED and this had many areas of internal and external validity which were rated as moderate-high risk of bias. Not only are SCEDs ranked by the Oxford Centre for Evidence-Based Medicine as level one evidence for treatment decision purposes in individual patients (Howick et al., 2011) but they are of particular value in an acquired neurodisability population due to the heterogeneous nature of the conditions it encompasses (Tate et al., 2013). Larger scale RCTs are logistically difficult when investigating such a complex intervention within a complex population, so well-designed SCEDs will also be vital to contribute to the evidence base.

As well as more robust designs for future research, possible moderators and mediators of treatment response need to be investigated. Time since brain injury may impact on ability to engage and therefore the effectiveness of mindfulness-based interventions. Interestingly, the only paper which did not find significant results (McMillan et al., 2002) included a sample who had the shortest time since injury (although time since injury was unknown in Orenstein et al., 2012 and Nassif, 2013). Awareness and degree of acceptance of cognitive impairments has been found to decrease engagement in therapy in those with moderate-severe TBI (O'Callaghan, McAllister & Wilson, 2012). It may be that those who have the shortest time since injury are the least adjusted to and accepting of their difficulties. More research is needed to investigate this further.

Even though mindfulness has been found to improve sustained and selective attention in a neurologically-healthy population (Chiesa et al., 2011) it may be that those with acquired cognitive deficits from neurodisability interact and respond differently to mindfulness. Mindfulness encompasses many components and aims to

build a number of skills, for example earlier meditation practices aim to focus attention on explicit objects, whereas later exercises aim to teach self-monitoring and develop reflexive awareness (Lutz, Slagter & Dunne & Davidson, 2008). These skills require a number of cognitive processes to perform, some of which may be impaired to a significant level following neurodisability, which may prevent certain individuals from benefitting from the process. It may be that those with greater severity of injury or those with certain cognitive deficits engage and react differently to mindfulness-based interventions.

Additionally, there is no definitive indication when reviewing these papers, as to whether intervention length and intensity, or method of delivery (including therapist training) had an impact on outcome and needs further exploration. In their review, Chiesa et al. (2011), proposed that moderately brief mindfulness interventions seem to have an impact on selective and sustained attention, but that attention switching may be insensitive to mindfulness generally, or require a more advance and prolonged mindfulness intervention. They also found that with increasing amount of mindfulness meditation experience, there was increased enhancement in cognitive abilities and brain structural changes.

Medical Research Council (2008) guidelines on complex interventions with multiple components, such as mindfulness-based interventions, state that to be effective and used appropriately, it is important to identify how the intervention works by identifying active ingredients and how they are exerting their effect. This seems particularly vital to gain a greater understanding of with regards to this review area, due to the heterogeneous nature of acquired neurodisability. It is difficult to conclude any mechanisms of change of mindfulness on cognition following ABI from the papers in this review. Although there is some suggestion in the existing literature that mindfulness acts on sustained and selective attention in neurologically healthy individuals (Chiesa et

al., 2011) and attentional control and EF (Teper et al., 2013), more good quality proof of principle studies are needed to fully understand and determine the effect of mindfulness-based interventions on cognition following acquired neurodisability.

Implications for clinical practice

The scarcity of research that is both relatively weak and found mixed results in this area prevents a recommendation to incorporate mindfulness-based interventions into current practice to improve cognitive difficulties following acquired neurodisability. This does not mean mindfulness-based interventions could not make improvements for other psychosocial difficulties, but this is beyond the scope of this review.

Limitations of this review

One limitation of the current review is that most of the process was undertaken by one individual. It has been suggested that studies should be rated by at least two reviewers (Thomas, Ciliska, Dobbins & Micucci, 2004), whereas, only a selection of three papers were independently assessed for risk of bias by a second reviewer (a final year Trainee Clinical Psychologist). Therefore, possible bias may have occurred and it must be acknowledged that conclusions made are from the perspective of one individual.

This review aimed to include as many well-designed studies as possible to answer the review question, so criteria was opened up to include designs other than RCTs and conducted a search of dissertations and theses. However, it should be highlighted that the review did not include unpublished literature or studies not published in English. Hence publication bias may mean some evidence to answer the review question is missing and perhaps reduce generalisability of review findings.

Conclusion

There may be some benefit of mindfulness-based interventions on selective and sustained attention and processing speed following ABI. However, more high-quality research is needed to assess this further, including more large-scale RCTs, well-designed proof of principle studies and robust SCEDs. Due to the heterogeneous nature of ABI and the complexity of mindfulness-based interventions, to fully understand the impact of mindfulness-based interventions on cognition following acquired neurodisability, knowledge of specific mechanisms of change on certain cognitive processes for which individuals is needed. Hypotheses concerning the proposed mechanism of change on sustained and selective attention (Chiesa et al, 2011) and attentional control and EF (Teper et al., 2013) need to be tested.

Disclosure of interest

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Chapter 2

Bridging chapter

Bridging Chapter

The systematic review focused on reviewing the literature to ascertain whether mindfulness-based interventions are effective at improving cognitive difficulties experienced as a result of acquired neurodisability. The review found that evidence was mixed and papers had multiple domains of moderate – high risk of bias. However, the most promising evidence was found for improving selective and sustained attention and processing speed in acquired brain injury (ABI). Evidence for other cognitive processes was either mixed, weak or minimal, and evidence for those with multiple sclerosis was lacking.

The systematic review concluded that in order to truly assess the effect of mindfulness-based interventions on cognition following acquired neurodisability, more high-quality research is needed. The current evidence-base includes participants that vary in acquired neurodisability etiologies and characteristics (e.g. injury severity), mindfulness-based interventions used and cognitive processes investigated, measured by a range of different outcome measures. Therefore, results were difficult to compare, and the review was unable to conclude what intervention works on which cognitive process for whom. Due to the heterogeneous nature of acquired neurodisability, it was deemed vital for future research to investigate specific mechanisms of change of mindfulness on specific cognitive processes, for which individuals.

Therefore, the following empirical paper aimed to begin to address this. It aimed to explore the effects of a 10-minute mindfulness of breath and body scan exercise on specific attentional processes within a sample of participants who had suffered an ABI. The attentional processes investigated were stimulus over-selectivity and selective attention to threat (SAT). Stimulus over-selectivity was investigated by one of the papers included in the systematic review (McHugh and Wood, 2013), where a positive

effect of a mindfulness exercise was found. The following research study aimed to address their limitations and design weaknesses.

Selective attention to threat is an attentional control process that occurs under emotional load. It has been found to cause and maintain anxiety in a neurologically healthy population (Harvey, Watkins, Mansell & Shafran, 2004). Research suggests that those with executive functioning (EF) deficits display decreased emotion regulation (Williams et al., 2009) and hence those with EF deficits and poor attentional control post-ABI could potentially experience increased SAT. To the author's knowledge this is the first paper to look at the effect of mindfulness on SAT within an ABI population. This seems particularly important, as those with ABI have been found to be at increased risk of developing an emotional disorder (Bombardier et al., 2010). If mindfulness interventions could target attentional deficits, as well as attentional biases to emotional material causing emotional regulation difficulties following ABI, this would be particularly beneficial.

Chapter 3

Empirical paper

Prepared for submission to *Neuropsychology*

The effect of mindfulness on stimulus over-selectivity and selective attention to threat following acquired brain injury.

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Abstract

Objective: This study aimed to explore the effects of a brief mindfulness exercise on stimulus over-selectivity and selective attention to threat in a sample of individuals with acquired brain injury. It aimed to contribute towards understanding mechanisms by which mindfulness-based interventions may benefit those with acquired brain injury with both specific cognitive and emotion difficulties.

Method: A parallel randomised control design was used. Forty-two participants (27 traumatic brain injury, 9 stroke and 6 other acquired brain injury; 35.7% female and mean age of 45.6 years) were randomised into two conditions. Groups received either a 10-minute mindfulness exercise or unfocused attention control exercise. Computerised measures of stimulus over-selectivity and selective attention to threat (emotional Stroop) were administered pre- and post-intervention.

Results: Two mixed ANOVAs found non-significant interactions between group and time for stimulus over-selectivity: Wilks' Lamda = .996, $F(1,34)=.15$, $p=.70$, partial eta squared = .004, and selective attention to threat: Wilks' Lamda = .997, $F(1,35)=.11$, $p=.75$, partial eta squared=.003.

Conclusions: Compared to an unfocused control condition, mindfulness was not found to improve stimulus over-selectivity or selective attention to threat in this sample of individuals with acquired brain injury. However, methodological weaknesses mean that results were difficult to interpret, and clinical recommendations cannot be proposed. Future avenues of research should include developing greater understanding of stimulus over-selectivity and selective attention to threat, as well as specific mechanisms of change of mindfulness-based interventions on cognitive processes following ABI.

Keywords: mindfulness, brain injury, attention, emotion

Introduction

People who have suffered an acquired brain injury (ABI) often experience cognitive deficits and are at increased risk of developing an emotional disorder (Bombardier et al., 2010; Dams-O'Connor & Gordon, 2010). Cognitive and emotional difficulties following ABI have a significant negative impact on quality of life and are associated with difficulties in occupational tasks and increased fatigue (Djikers, 2004; Ponsford et al., 2014; Ziino & Ponsford, 2006). Impairments of these kind have been connected to poor outcomes and high social costs (National Co-ordinating Centre for NHS Service Delivery and Organisation R&D, 2007; Spitz, Ponsford & Rudzki, 2012).

Cognitive difficulties include impairments in attentional processes and executive functioning (EF; Dams-O'Connor & Gordon, 2010; Ponsford et al., 2014). EF allows individuals to problem-solve, generate strategies for complex actions, follow through with plans and override and regulate behavioural and emotional responses to engage in goal-directed behaviour (Williams, Suchy & Rau, 2009). Those with traumatic brain injury (TBI) have been found to display stimulus over-selectivity (McHugh & Wood, 2013), where individuals attend to one aspect of the environment but miss other information. This can be problematic, as decision-making and behaviour is then guided by this selective attention bias.

It is well understood that attentional bias to emotional material is a causal and maintenance factor in affective disorders (Harvey, Watkins, Mansell & Shafran, 2004). Selective attention to threat (SAT) is when threatening stimuli in the environment are selected over neutral stimuli for processing, increasing perception of threat (Bar-Haim, Lamy, Pergamin, Bakermans-Kranenberg & van IJzenoorn, 2007). Heightened anxiety lowers the threshold for perceiving information as threatening, causing increased SAT (Cisler & Koster, 2010). There is strong evidence finding SAT in a neurologically-

healthy population with clinical anxiety and depression, using experimental paradigms such as the emotional Stroop and dot probe (Bar-Haim et al., 2007; Epp, Dobson, Dozois & Frewen, 2012; Phaf & Kan, 2007).

Physical threat and negative social evaluation have been found to be particularly salient for those with ABI, which may lead to anxiety (Riley, Brennan & Powell, 2004). Gracey, Longworth and Psaila (2015) argue that individuals post-TBI experience threats to self-identity and subsequent selective attention to these threats, which could be influenced by acquired deficits in attentional control and EF. Williams et al. (2009) found that neurologically-healthy individuals with inferior EF are vulnerable to enhanced stress exposure, suggesting poor EF leads to increased emotion dysregulation. Therefore, an interaction between cognitive deficits and emotional problems post-ABI can be hypothesised. Specifically, acquired attentional and EF deficits could cause and maintain emotional difficulties by increasing emotion-processing biases, such as SAT. However, there is a paucity of research investigating this, and subsequent lack of guidance regarding interventions that might be helpful for these attentional biases, in ABI.

Mindfulness

Cognitive and emotional difficulties post-ABI are common, result in poorer quality of life for individuals and place strain on services. Furthermore, the potential interaction between attentional and EF deficits and emotional processes highlights the importance of finding interventions that effectively target these post-ABI difficulties.

Mindfulness is characterised by full attention to and awareness of the present moment, without judgement (Chambers, Chuen Yee Lo & Allen, 2008). Mindfulness-based interventions combine the Buddhist practice of mindfulness with aspects of Western psychology. Such interventions have been found to reduce depression and

anxiety symptoms and improve sustained and selective attention in a neurologically healthy population (Chiesa, Calati & Serretti, 2011; Hofmann, Sawyer, Witt & Oh, 2010). Mindfulness-based interventions could have the same effect on attention and emotion processes following ABI and there is a growing interest in the use of mindfulness-based interventions for this purpose.

Neuroimaging and possible mechanisms

It has been argued that affective attentional control, cognitive appraisal and selective attention rely on the dorsolateral prefrontal cortex (PFC), the inferior parietal cortex (IPC) and anterior cingulate cortices (ACC; Banich et al., 2009; Holzel et al., 2011). These areas exert downward regulatory effects on lower systems involved in regulating attention, hence improving attentional control and EF. They also regulate the amygdala, involved in emotional appraisal (Ochsner & Gross, 2008). These regions have been found to be hypo-activated in a neurologically healthy population with affective disorders (Price and Drevets, 2012). Mindfulness training has been found to improve PFC regulation of amygdala activation via the ACC (Lazar et al., 2005). Mindfulness has also been found to directly decrease the activation of the amygdala in response to emotional stimuli (Desbordes et al., 2012).

Additionally, research within a neurologically healthy population, has proposed that mindfulness enacts change by improving sustained and selective attention (Chiesa et al., 2011), or by improving attentional resource allocation processes (Malinowski, 2013). Additionally, Teper, Segal and Inzlicht (2013) propose that mindfulness training improves attentional control and EF by promoting present-moment awareness and acceptance, which in turn improves emotion regulation.

Current evidence

Although minimal with some mixed results, initial evidence is promising for mindfulness being a useful intervention post-ABI for both cognitive and emotional

difficulties. McHugh and Wood (2013) found that a 10-minute mindful breathing exercise decreased stimulus over-selectivity in a TBI population. Others have found some improvement on selective and sustained attention, EF and processing speed following Mindfulness-based Stress Reduction (MBSR; Johansson, Bjhur & Rönnbäck, 2012; Johansson, Bjuhr, Karlsson, Karlsson & Rönnbäck, 2015; Nassif, 2013). This intervention is an eight-week programme, incorporating a range of meditation practices (Kabat-Zinn, 1990). Bedard et al. (2014) found that mindfulness-based cognitive therapy (MBCT) reduced symptoms of depression in people with TBI. This incorporates mindfulness practice with cognitive therapy techniques to prevent the consolidation of ruminative and negative thinking patterns (Segal, Williams, & Teasdale, 2002). However, in a large scale randomised control trial (RCT), McMillan, Robertson, Brock and Chorlton (2002) found no effect of mindfulness for those with TBI on cognitive function or mood.

Varying mindfulness-based interventions and meditations have been researched which makes it difficult to determine the mechanism of change. Medical Research Council (2008) guidelines on complex interventions state that it is important to identify how interventions work by identifying active ingredients and how they are exerting their effect. This line of research has begun in a neurologically healthy population (Chiesa et al., 2011; Malinowski, 2013; Teper et al., 2013), but there is a considerable lack of evidence in ABI. There is only one study (McHugh & Wood, 2013) which looks towards identifying an effective mechanism of the intervention on a specific cognitive process. But, the lack of active control group for comparison means it is unclear whether the effects were just due to receiving an intervention. The use of a between-subjects design meant baseline scores on the cognitive task were unknown. Additionally, no identified studies specifically examine how mindfulness works on cognitive processes linked to processing emotional material in an ABI population.

Study aims

Therefore, the current study aimed to explore the effects of a brief mindfulness exercise on a specific attentional process: stimulus over-selectivity, addressing design weaknesses of McHugh and Wood (2013). As well as on attentional control under emotional load, investigated by focussing on SAT. It was hypothesised that:

1. The mindfulness group would display significantly reduced levels of stimulus over-selectivity on an experimental task from pre- to post-intervention, compared to the unfocused attention control group.
2. The mindfulness group would display significantly reduced levels of SAT on an emotional Stroop task from pre- to post-intervention, compared with an unfocused control group.

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Method

Design

A parallel randomised control design was used. Participants were randomised into two groups (mindfulness or unfocused attention control). Experimental tasks were administered pre- (T1) and post-intervention (T2).

Participants

Participant inclusion criteria were: aged 18 – 65 years; medical evidence of acquired brain injury (ABI) with attention or executive functioning (EF) difficulties; time since ABI to be 9 months or greater; and ABI severity to be moderate to severe, determined using the Mayo classification system (Malec et al., 2007). If this

information was unavailable, then there needed to be clinically significant difficulties resulting from ABI to have used brain injury services. Participants had self-reported or clinician-identified emotional difficulties adjusting to circumstances post-ABI, to detect an effect on the emotional Stroop which relies on the presence of emotional difficulties (Bar-Haim et al., 2007). Exclusion criteria were any confounding variables that would prevent valid engagement in experimental tasks, specifically: significant, severe and enduring presence of mental health difficulties or substance misuse; perceptual, language, communication, reading or motor difficulties; the presence of developmental or acquired dyslexia; severe cognitive difficulties; and/or the presence of pre-existing or comorbid disorders that may affect cognitive functioning (other than ABI).

Participants were recruited from a combination of brain injury National Health Service (NHS), voluntary sector and private sector community and inpatient providers. Forty-nine individuals were identified and expressed interest in taking part. Forty-two were recruited: 27 traumatic brain injury (TBI), 9 stroke, and 6 other ABI (hypoxic injury, tumour or hydrocephalus); 35.7% female, with a mean age of 45.6 years (SD=13.8). Of those identified who did not take part, three individuals did not have enough time to meet with the researcher and four people did not reply to attempts to contact them.

Intervention tasks

The 10-minute mindfulness task was verbally introduced to participants. A recording of a three-minute mindfulness breathing exercise and body scan (Williams & Penman, 2011) was played to participants. Language was modified to account for cognitive difficulties following ABI. This was followed by a task-reminder instruction approximately every 30 seconds for a total of 10 minutes (Arch and Craske, 2006; McHugh and Wood, 2013): *Focus on the actual feelings of breath entering and leaving*

the body. There is no need to think about the breath, just experience the feeling of it. When you notice that your attention is no longer on the breath, gently bring your attention back to the feelings of breathing.

The control group was verbally introduced to, then played a recorded 10-minute unfocused attention task (McHugh, Simpson and Reed, 2010). This included a reminder of task instructions approximately every 30 seconds: *Simply think about whatever comes to mind. Let your mind wander freely without trying to focus on anything in particular.*

Measures

Baseline measures

Information was gathered on participants' educational background, employment history, injury severity, damaged brain areas, and time since injury. Participants were assessed at baseline on measures that could influence performance on experimental tasks or response to the intervention: anxiety, depression, mindfulness, sustained and selective attention and pre-morbid general intellectual functioning, using:

- The Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983).
- The Five Facet Mindfulness Questionnaire (FFMQ; Baer, Smith, Hopkins, Krietemeyer & Tony, 2006).
- Elevator counting and elevator counting with distraction from the Test of Everyday Attention (TEA; Roberston, Ward, Ridgeway & Nimmo-Smith, 1994).
- The Wechsler Test of Adult Reading (WTAR; Wechsler, 2001).

Experimental tasks

Memory load task

Immediately prior to the over-selectivity task, a memory load task was administered to induce as much over-selectivity as possible (McHugh and Wood, 2013; Reed and Gibson, 2005). Participants were given 20 seconds to memorise a grid containing four shapes (Figure 2) and then instructed to draw this out from memory after the over-selectivity task. Different versions of the task were used pre- and post-intervention, where the same shapes were placed in different segments of the grid. The order was counterbalanced across participants.

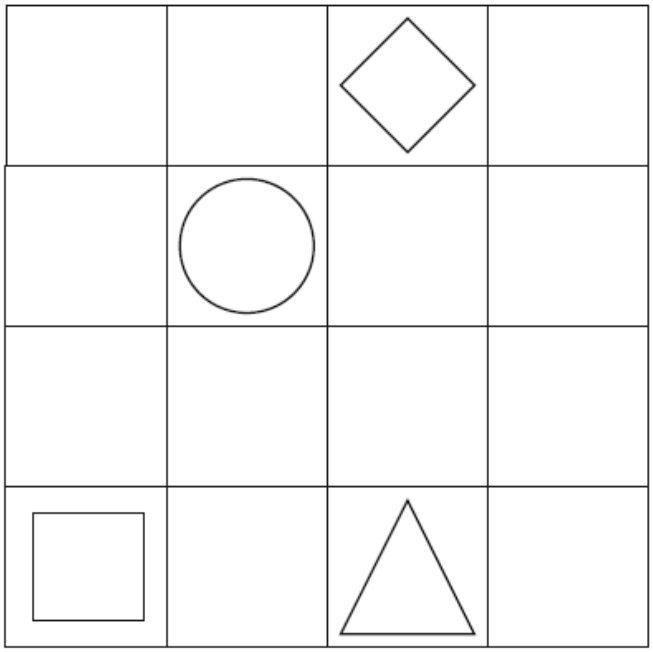
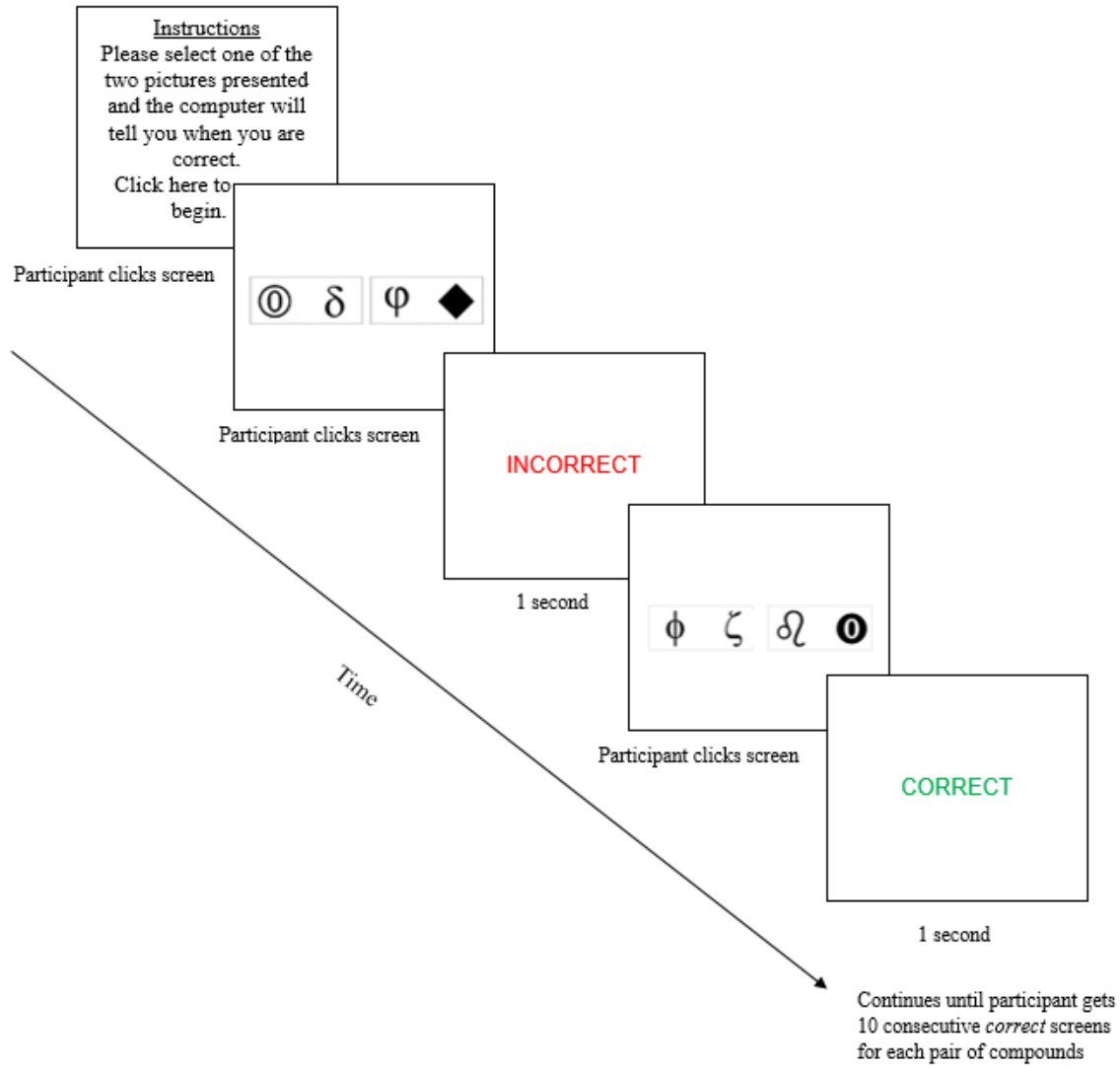


Figure 2. Grid shown to participants in the memory load task

Over-selectivity task

The computerised over-selectivity task was developed by McHugh and Wood (2013; Figure 3). A laptop running Windows 10 was used to present the task and record participants' responses.

Practice phase



Test phase

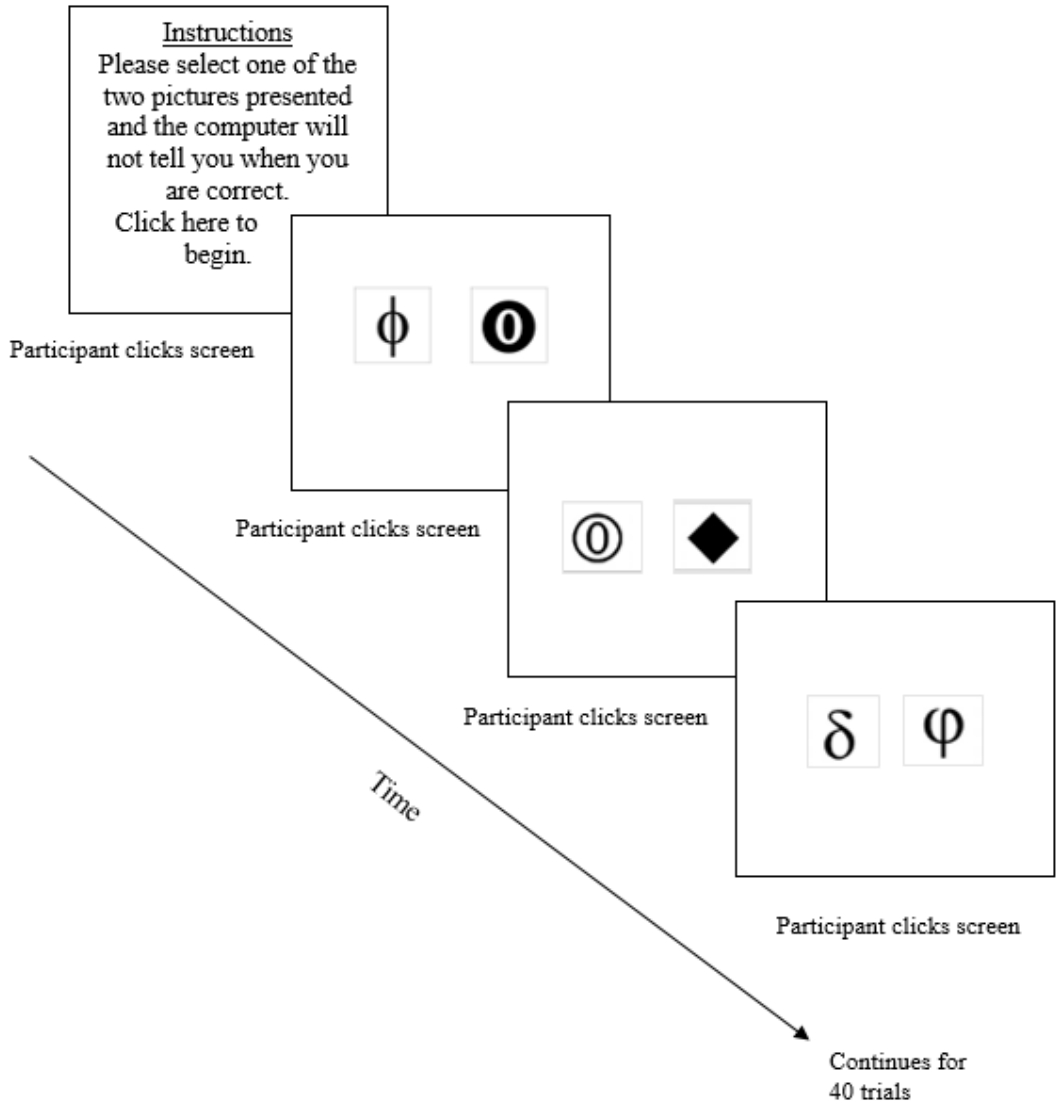


Figure 3. The computerised over-selectivity programme.

In the practice phase, participants were presented with two compounds simultaneously (Figure 4) and instructed to select one of the compounds. Participants learned which were the correct compounds from feedback given: their choices were either reinforced (correct) or punished (incorrect). There were two different pairs; four compounds that were made up of eight different stimuli. Each pair was presented an equal number of times and the practice phase was complete when each correct

compound was selected on 10 consecutive trials. The reinforced compound was presented equally to the left and right positions.

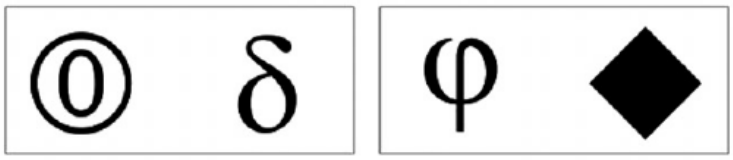


Figure 4. One pair of compounds (pair one) from the practice phase of the over-selectivity task

In the subsequent test phase, participants were presented with two single stimuli simultaneously, one from the reinforced compound and one from the punished compound (Figure 5). They were instructed to select one of the stimuli, but no feedback was given. Pair one stimuli were only presented with other pair one stimuli and the same for pair two stimuli. Each combination of single stimuli pairings was presented for five trials, totalling 40 trials in the test phase. The reinforced stimuli were presented as often in the left position as the right position and the order of stimuli and pairings was randomised by the computer programme.

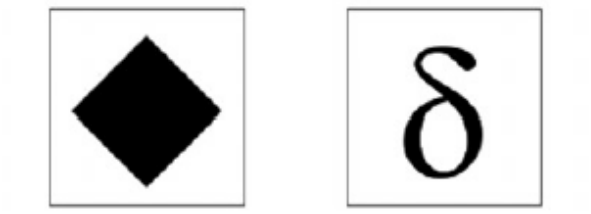


Figure 5. Two single stimuli presented to participants in the test phase of the over-selectivity task

Over-selectivity was demonstrated if participants failed to learn one of the stimuli in the reinforced compound during the practice phase and therefore failed to

select this stimulus when completing the test phase. The primary over-selectivity outcome for each participant was the difference between the number of most and least correctly chosen reinforced stimuli in the test phase.

Emotional Stroop

The same laptop running Windows 10 was used to present and record responses on the emotional Stroop. The task was created and run with *OpenSesame* (Mathôt, Schreij & Theeuwes, 2012). It consisted of a practice phase, where participants received feedback on their responses (correct or incorrect), followed by two experimental phases, where no feedback on response was given (Figure 6). The order of the experimental phases was counterbalanced across participants.

Participants were instructed to name the colour of the word as quickly as possible, whilst ignoring the word's meaning. Each subsequent trial began with the presentation of a black fixation cross in the centre of a white screen for 750ms. Following this, a single word was displayed in the centre of the screen for 500ms, or until the participant logged their response. The colour of the word was either red, blue or green and the meaning of the word was either threatening or neutral. Participants logged their colour-naming response by pressing the relative labelled key on the laptop keyboard (z;v;m). The practice phase consisted of 24 neutral and 24 threatening words. Each experimental phase contained 36 neutral and 36 threatening words. The order and colour of the words was randomised by the computer programme. Selective attention to threat was inferred when reaction time (RT) to word colour-naming was greater (slower) for threatening words relative to neutral (Bar-Haim et al., 2007).

Threatening words for the task were generated based on physical threat and negative social evaluation, as these areas are particularly salient for those with ABI (Riley et al., 2004). Words were selected from previously published research in social phobia (Ononaiye, Turpin & Reidy, 2007) and have also been used in previous theses at

the University of East Anglia. Each threatening word was matched with a neutral word on length and frequency, which were chosen based on their low threat value (Ononaiye et al., 2007).

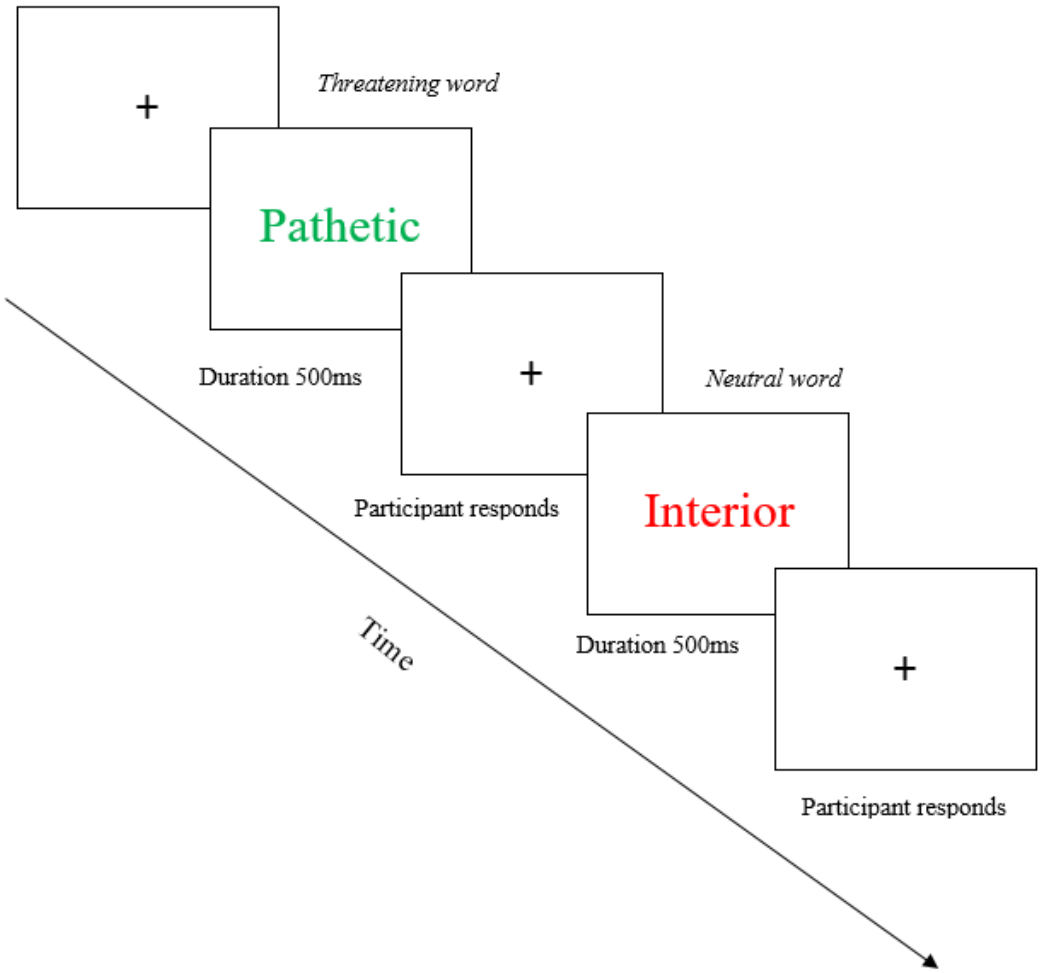


Figure 6. The experimental phase of the computerised emotional Stroop task

Procedure

Ethical approval was gained by the NHS Research Ethics Committee and NHS Health Research Authority (Appendix G; Appendix H). Study capability and capacity for recruitment was granted by local NHS Research and Development departments or non-NHS research departments for each site (Appendix I).

Participants were randomly allocated to one of two groups (mindfulness or unfocused attention control). Participants were assigned a research number when they gave consent to take part in the study, which had previously been randomised using the programme *Randomizer* (Urbaniak & Plous, 2013). Participants were not informed of the study's hypotheses. Demographics and details of participants' brain injury were obtained from a recent medical report.

One of the research team (K.V.) met with participants to complete the HADS, WTAR, subtests of the TEA and FFMQ. All participants completed the memory load task, followed by the over-selectivity task, and the emotional Stroop. Participants completed the mindfulness or unfocused attention exercise, then repeated the experimental tasks. The order was counterbalanced across participants.

Analysis plan

Data was analysed using Statistical Package for the Social Sciences (SPSS; IBM corp., 2013).

Recruitment

Using existing findings on mindfulness, stimulus over-selectivity and the emotional Stroop, a medium effect size was estimated. G-Power analysis (Erdfelder, Faul & Buchner, 1996) was conducted to determine 42 participants in total were needed for sufficient power (0.8).

Comparison of groups at baseline

To determine if there were any confounding significant differences between groups, groups were compared using Chi-square, independent t-tests or Mann Whitney U tests on demographics, ABI characteristics and baseline scores on: HADS, WTAR predicted FSIQ, FFMQ and TEA subtests. For the emotional Stroop, groups were compared at T1 on overall mean RT, number of incorrect responses, as well as on the

primary outcome measure. For the over-selectivity task, groups were compared on how many trials it took to complete the practice phase and the primary outcome measure.

Main hypotheses

To obtain the stimulus over-selectivity score, the most and least correctly selected reinforced stimuli in the test phase were identified for each compound and the difference between these were calculated for each participant. The difference for both compounds were then added together, for each time point. A greater score represented a higher level of over-selectivity. For the emotional Stroop, the mean RT for emotional and threatening words, followed by the difference between these RTs, was calculated for each participant at each time point. A negative value represented a quicker RT to neutral words compared to threatening words, therefore represented SAT.

To test the study's main hypotheses, a 2x2 mixed-design ANOVA for each task was used. Alpha level was corrected using Bonferroni Correction (α=0.025).

Data preparation

Error rate (participants responded with the incorrect coloured key) and RT was explored within emotional Stroop data. High error rate (outliers in dataset) and overall slow mean RT irrespective of word meaning (over 2,500ms) was suggestive of difficulties with information processing that may have invalidated responses on the emotional Stroop. Participants meeting either of these criteria were excluded from analysis. Further to this, all emotional Stroop trial data were screened and individual trials in which an incorrect response was made were removed from the analysis. This led to the exclusion of 132 trials (1.24%). Any trials that were considered outliers (RTs -/+2SDs from the mean RT for each participant) were removed from data analysis, as these were considered anticipatory errors or concentration lapses. This removed a further 362 trials following previous removal of errors (3.4%).

Five participants had missing data on the over-selectivity task, due to a failure of the computer programme to record some trial responses. Imputation using analysis of patterns was attempted. There is no established cut off for an acceptable percentage of missing data in a data set for valid imputation. However, the most agreed upon range in the literature seems to be 5-10% (Dong & Peng, 2013). Others argue that consideration of the missing data mechanisms and patterns are more important than proportion of missing data (Tabachnick & Fidell, 2012).

Results

Recruitment ran from June 2017 to January 2018. Forty-two participants were randomly allocated to either the mindfulness or control condition. Two participants (one from each condition) completed the baseline measures, but then dropped out of the study. One participant became too physically unwell to continue and one was found to meet exclusion criteria, *severe cognitive difficulties*, so was withdrawn. One participant in the mindfulness condition was unable to complete the practice phase of the over-selectivity task, so this was terminated. Three other participants' over-selectivity data were removed at the point of analysis because of missing responses; two from the mindfulness condition and one from the control. One participant was excluded based on too much missing data (22.5%) and two due to unclear arbitrary patterns in the data. Three participants were excluded in the analysis of the emotional Stroop; two from the mindfulness and one from the control condition. This was due to a high number of incorrect responses (26%, 11% and 8%), and one of these participants also had a mean overall RT of greater than 2500ms. Figure 7 demonstrates participant flow for each group.

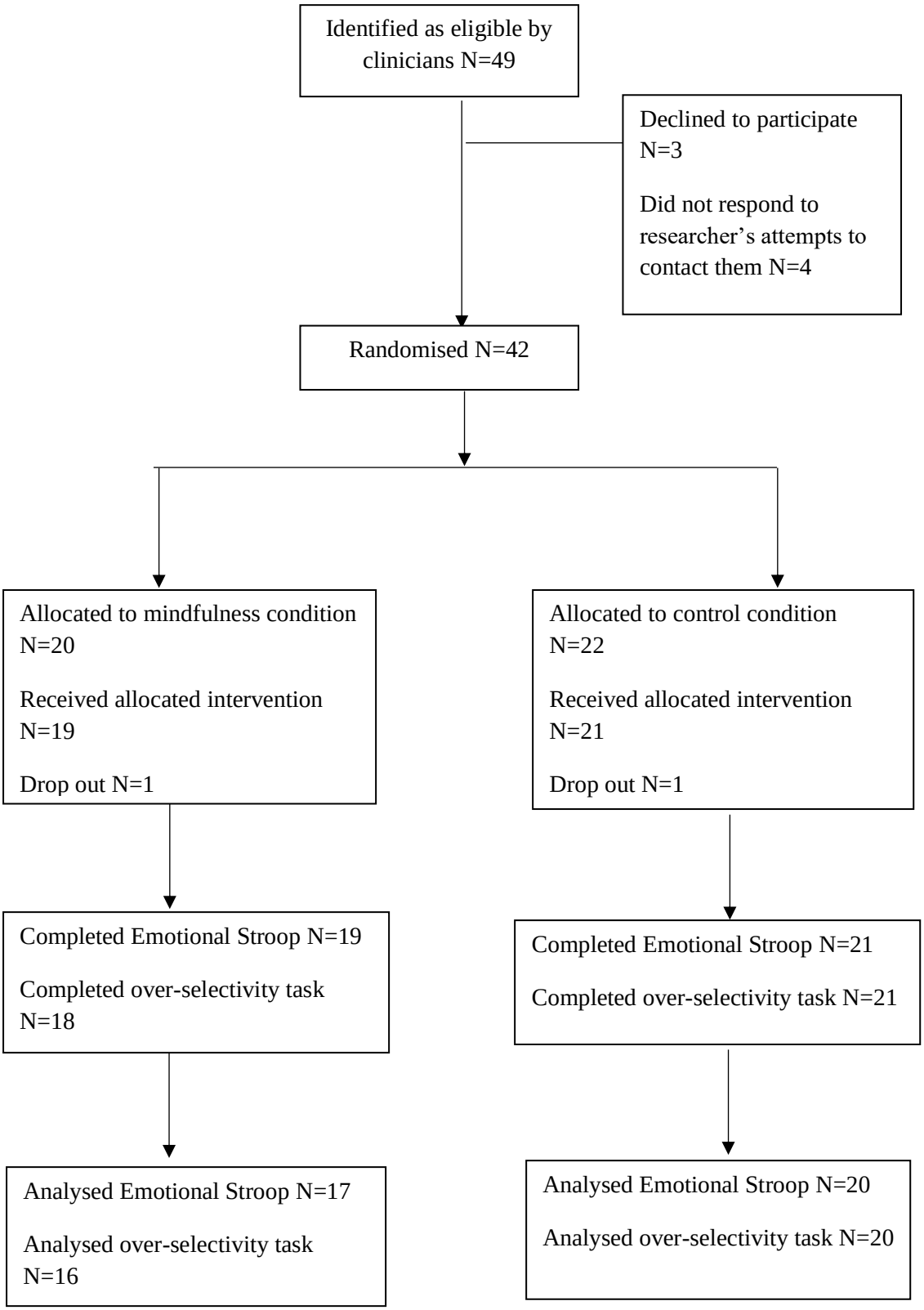


Figure 7. Participant flow diagram

Comparisons of groups at baseline

Demographics and acquired brain injury (ABI) characteristics for the 42 participants who began the study are shown in Table 5 and scores on baseline measures are in Table 6. There were no significant differences between the mindfulness or control group.

Table 5.
Sample demographic and ABI characteristics for all 42 participants recruited into the study

	Whole sample (baseline N=42)			Mindfulness (baseline N=20)			Control (baseline N=22)		
Variable	N (%)	M	SD	N (%)	M	SD	N (%)	M	SD
Gender									
Female	15 (35.7)			6 (30.0)			9 (40.9)		
Male	27 (64.3)			14 (70.0)			13 (59.1)		
Age		45.6	13.8		46.0	14.6		45.3	13.3
Education									
No qualifications	10 (23.8)			4 (20.0)			6 (27.3)		
GCSEs	18 (42.9)			8 (40.0)			10 (45.5)		
A-levels/ college	3 (7.1)			2 (10.0)			1 (4.5)		
Undergraduate	7 (16.7)			3 (15.0)			4 (18.2)		
Postgraduate	3 (7.1)			2 (10.0)			1 (4.5)		
Unknown	1 (2.4)			1 (5.0)			0 (0.0)		
Employment									
Full time paid	29 (69.0)			14 (70.0)			15 (68.2)		
Part time paid	4 (9.5)			1 (5.0)			3 (13.6)		
Homemaking	2 (4.8)			2 (10.0)			0 (0.0)		
Full time education	2 (4.8)			1 (5.0)			1 (4.5)		
Unemployed	5 (11.9)			2 (10.0)			3 (13.6)		
ABI type									
Stroke	9 (21.4)			6 (30.0)			3 (13.6)		
TBI	27 (64.3)			10 (50.0)			17 (77.3)		
Hypoxic	2 (4.8)			2 (10.0)			0 (0.0)		
Tumour	2 (4.8)			2 (10.0)			0 (0.0)		
Hydrocephalus	2 (4.8)			0 (0.0)			2 (9.1)		
Damaged areas									
Temporal	6 (14.3)			2 (10.0)			4 (18.2)		
Frontal	5 (11.9)			4 (20.0)			1 (4.5)		
Diffuse	2 (4.8)			2 (10.0)			0 (0.0)		
Frontotemporal	5 (11.9)			2 (10.0)			3 (13.6)		
Other	3 (7.1)			0 (0.0)			3 (13.6)		
Combination	9 (21.4)			4 (20.0)			5 (22.7)		
Unknown	12 (28.6)			6 (30.0)			6 (27.3)		
Time since injury		9.3	10.1		7.3	8.0		11.1	11.5

Table 6.
Baseline scores for all 42 participants recruited into the study

	Whole sample (baseline N=42)			Mindfulness (baseline N=20)			Control (baseline N=22)		
Variable	N (%)	M	SD	N (%)	M	SD	N (%)	M	SD
HADS anxiety		9.3	4.4		9.1	4.3		9.5	4.5
Normal	20 (47.6)			9 (45.0)			11 (50.0)		
Mild	5 (11.9)			3 (15.0)			2 (9.1)		
Moderate	11 (26.2)			6 (30.0)			5 (22.7)		
Severe	6 (14.3)			2 (10.0)			4 (18.2)		
HADS depression		7.6	4.1		6.9	3.8		8.3	4.4
Normal	17 (40.5)			8 (40.0)			9 (40.9)		
Mild	17 (40.5)			10 (50.0)			7 (31.8)		
Moderate	5 (11.9)			1 (5.0)			4 (18.2)		
Severe	3 (7.1)			1 (5.0)			2 (9.1)		
WTAR (FSIQ)		95.8	12.5		96.8	12.3		94.9	13.0
Borderline	3 (7.1)			1 (5.0)			2 (9.1)		
Low average	12 (28.6)			5 (25.0)			7 (31.8)		
Average	19 (45.2)			10 (50.0)			9 (40.9)		
High average	8 (19.0)			4 (20.0)			4 (18.2)		
TEA elevator									
Normal	29 (69.0)			12 (60.0)			17 (77.3)		
Abnormal	13 (31.0)			8 (40.0)			5 (22.7)		
TEA elevator counting with distraction		6.2	2.1		6.6	2.8		6.0	1.4
FFMQ		115.7	17.9		115.3	17.1		116.2	19.1

Of the participants included in data analysis, the mean number of practice trials on the over-selectivity task for the mindfulness group was M = 85.69 (SD = 52.65) and M = 74.70 (SD = 44.18) for the control group. A Mann Whitney U test found the between-group difference was not significant, p= .48. The mean primary outcome score on the over-selectivity task at T1 for the mindfulness group was M = 5.00 (SD = 4.12) and M = 7.50 (SD = 5.12) for the control group. An independent samples t-test revealed the difference was non-significant: t(34) = -1.84, p=.074, d=0.54.

For the emotional Stroop task, the mean reaction time (RT) for correctly identifying the colour of the word in the mindfulness group was M = 744.88ms (SD = 357.10) and M = 670.62ms (SD = 306.54) for the control group. An independent samples t-test revealed the between-group difference was non-significant, t(35) = .68,

p=.50. The mean number of incorrect responses in the mindfulness group was M = 2.12 (SD = 2.22) and M = 2.65 (SD = 3.79) in the control group. A Mann Whitney U test found this difference was non-significant, p = .75. The mean score (primary outcome measure) on the emotional Stroop at T1 for the mindfulness group was M = -6.85 (SD = 58.72) and M = -12.18 (SD = 66.85) for the control group. A Mann Whitney U test revealed this difference was non-significant, p = .96.

Effect of mindfulness on stimulus over-selectivity

The mean over-selectivity score (difference between the most and least selected reinforced stimuli) and standard deviations for the two groups at T1 and T2 are presented in Table 7. The change in mean over-selectivity score pre- to post-intervention for each group is represented in Figure 8.

A mixed ANOVA determined there were no statistically significant main effects for group, F(1, 34) = 2.50, p = .12, partial eta squared = .07 or time, Wilks' Lamda = .91, F(1, 34) = 3.3, p=0.08, multivariate partial eta squared = .09. The interaction between group and time was also found to be non-significant, Wilks' Lamda = .996, F(1, 34) = .15, p = .70, multivariate partial eta squared = .004. Residuals were slightly skewed for the post-mindfulness group, so results were interpreted with caution.

Table 7.
Descriptive statistics for scores on the over-selectivity task pre- and post- intervention for each group.

	Mindfulness			Control		
	N	Mean	SD	N	Mean	SD
Pre-intervention	16	5.00	4.12	20	7.50	5.12
Post-intervention	16	4.81	4.70	20	6.65	5.48

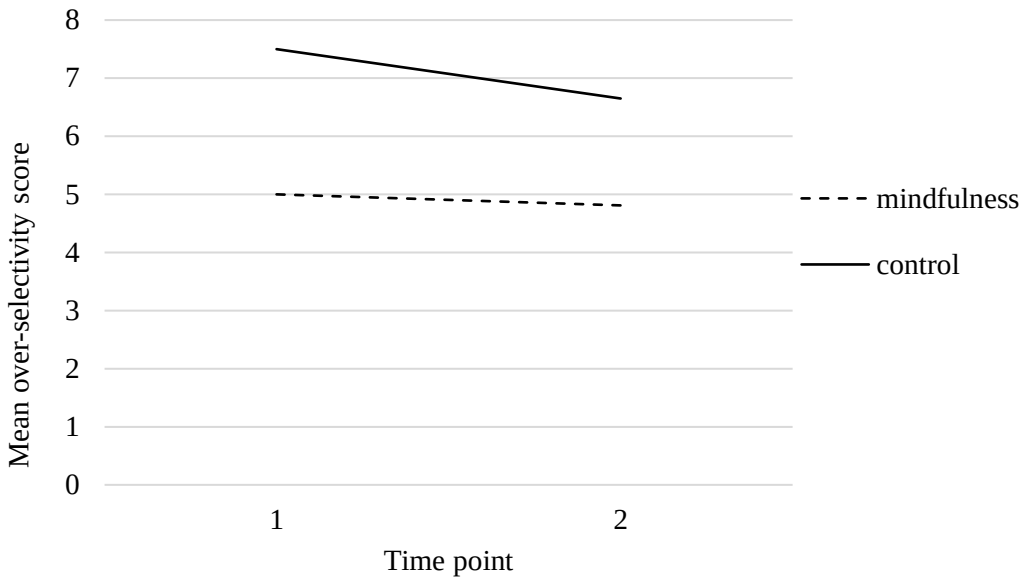


Figure 8. The change in mean over-selectivity score pre- to post-intervention for each group.

Effect of mindfulness on selective attention to threat

The mean SAT score (difference between RT response of threatening and neutral words) and standard deviations for the two groups at T1 and T2 are presented in Table 8. The mean change in SAT for each group over time is represented in Figure 9.

A mixed ANOVA concluded there were no statistically significant main effects for group, $F(1, 35) = .80$, $p=.38$, partial eta squared $=.02$ or time, Wilks' Lamda $=1.0$, $F(1, 35) =0$, $p=1.0$, multivariate partial eta squared $=.00$. The interaction between group and time was also found to be non-significant, Wilks' Lamda $=.997$, $F(1, 35) =.11$, $p =.75$, multivariate partial eta squared $=.003$. Residuals were minimally skewed so results were interpreted with caution.

Table 8.

Descriptive statistics for scores on the emotional Stroop pre- and post- intervention for each group.

	Mindfulness			Control		
	N	Mean	SD	N	Mean	SD
Pre-intervention	17	-6.85	58.72	20	-12.18	66.85
Post-intervention	17	-2.20	38.95	20	-16.82	49.00

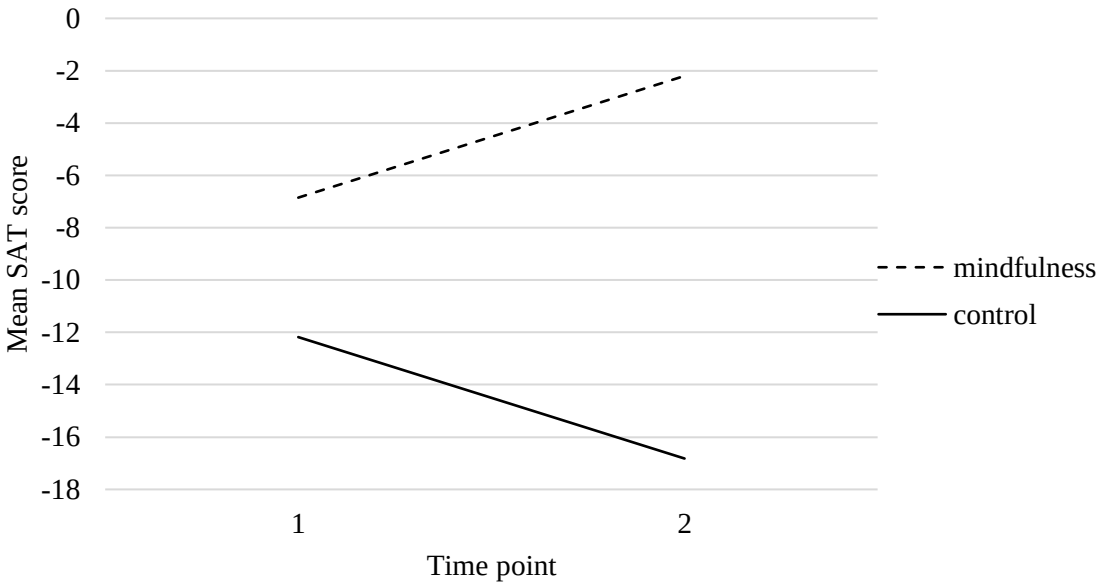


Figure 9. The mean change in SAT for each group over time. A greater negative value represents greater SAT.

Discussion

This study attempted to identify mechanisms by which mindfulness-based interventions may benefit those with acquired brain injury (ABI) with specific cognitive and emotion difficulties. It aimed to explore the effects of a brief mindfulness exercise on stimulus over-selectivity and selective attention to threat (SAT). Neither of the main hypotheses were supported, as compared to an unfocused attention control exercise,

mindfulness was not found to reduce stimulus over-selectivity or SAT in an ABI sample. These findings contradict those found by McHugh and Wood (2013) who found that a 10-minute mindfulness of breath exercise reduced stimulus over-selectivity in a traumatic brain injury (TBI) sample compared to an inactive control group.

The study's results cannot provide evidence towards a mechanism of change of mindfulness on attentional control processes following ABI. It cannot add to research that has been conducted within a neurologically healthy population that argues mindfulness enacts change by improving sustained and selective attention (Chiesa et al., 2011), improves attentional resource allocation processes (Malinowski, 2013), or improves attentional control and executive functioning (EF; Teper et al., 2013).

Study limitations

Methodological limitations need to be considered when interpreting the results. The study did not recruit a sample size that satisfied power requirements; a common challenge in ABI research (Carroll, Cassidy, Holm, Kraus & Coronado, 2004). Although no statistical differences between groups were found at baseline on SAT or over-selectivity task performance (dependent variable), these statistical tests were underpowered to detect effects. Analysis was reaching statistical significance (p=.074) when comparing the two groups at baseline on the stimulus over-selectivity task, with a medium effect size. This suggests that there may be an undetected difference between groups, and potentially some systematic bias was introduced during the randomisation process.

The ANOVA for the over-selectivity task was underpowered and the main effect for time for this task approached significance (p=0.08). It may be that, due to study design, participants learned the objective of the stimulus over-selectivity task at T1 so at T2 they knew to attend to both stimuli in the compounds presented during the practice

phase, causing practice effects. Additionally, there may be possible floor effects on both measures, which would have reduced the possibility of being able to find a valid difference on the task between groups.

The chosen 10-minute mindfulness intervention exercise may have been insufficient to impact on task performance and a longer exercise might have found different effects. Studies have found a significant positive correlation between the amount of mindfulness practice and levels of mindfulness post-intervention (Bowen & Kurz, 2012). Greater mindfulness experience was found to be associated with greater enhancement of cognitive abilities and brain structural changes (Chiesa, et al., 2011), and activation of different brain networks compared to novice practitioners (Tang & Posner, 2009).

McHugh and Wood (2013) did find an effect on stimulus over-selectivity following a similar recorded 10-minute mindfulness exercise. However, they used a mindfulness of breath exercise, whereas this study incorporated mindfulness of breath and a full body scan. Hence, shifting and broadening the focus of attention. Additionally, there was no evidence of adherence to either intervention exercise by participants and potentially those in either condition may have focused their attention on external phenomena, rather than follow task instructions. Chiesa et al. (2011) hypothesise that subtle differences in meditation instructions could be related to significantly different neuropsychological findings. For example, focused attention exercises are arguably more likely to specifically improve selective and divided attention (Chiesa et al., 2011), and attentional control and EF used to regulate thoughts and feelings (Posner, Sheese, Odludas & Tang, 2006).

So, focused attention mindfulness exercises could be hypothesised to be particularly beneficial for those with EF or attentional control deficits (Holzel et al., 2011). It may be that this study's sample did not have these difficulties, due to the

variation in ABI aetiology recruited, and may not have had the characteristics to benefit from the 10-minute focused attention mindfulness intervention used.

Additionally, McHugh and Wood (2013) recruited those with TBI only, in contrast to this study. However, it is difficult to further compare the two samples as, although the title of their paper claims they explored stimulus over-selectivity in a sample of individuals with temporal brain injury, neither their inclusion criteria nor results refer to area of brain damage. It may also be that the sample in this paper did not have as much difficulty with over-selectivity to begin with. The control group in McHugh and Wood (2013) were displaying a higher amount of over-selectivity post-intervention compared to this study's sample at baseline. However, they do not measure over-selectivity pre-intervention. It may be that only those with specific damage following TBI (potentially temporal lobe damage) have specific difficulties with over-selectivity.

It is well documented in the literature that those with greater clinical anxiety and depression display more SAT and larger effect sizes on the emotional Stroop (Epp et al., 2012; Phaf & Kan, 2007). In this study, even though selection criteria specified the need for participants to have difficulties with emotional adjustment post-ABI, 47.6% of the sample fell within the normal range on HADS anxiety subscale, and 40.5% on the depression subscale. It can be hypothesised that this study's sample was not sufficiently depressed or anxious to display enough SAT at T1 to detect an effect.

Although the emotional Stroop is an established paradigm to measure SAT, to the authors' knowledge there is only one other paper that has used the task in an ABI population (Coates, 2007). It may be that those with cognitive difficulties perform differently on the emotional Stroop compared to a neurologically healthy population, as it relies on other general cognitive and attentional processes to complete, including, word-processing, processing speed and psycho-motor processing. Although it is beyond

the scope of this study to investigate the impact of specific cognitive deficits following ABI on performance on the emotional Stroop, it is worth noting that 31% of this study's sample fell out of the normal range on a measure of sustained attention at baseline, potentially impacting emotional Stroop performance. However, RTs on the emotional Stroop in this study do not seem to differ significantly from other studies using neurologically healthy controls (Buodo, Sarlo & Palomba, 2002; Dresler, Mériau, Heekeren & van der Meer, 2009).

Furthermore, the emotional Stroop was created by one of the authors, based on factors that have found the largest effect sizes for SAT within the emotional disorders literature. However, these characteristics have not been validated on an ABI population. Additionally, it has been found that SAT is detectable when the content of the stimuli is congruent with the concerns associated with the emotional disorder (Bar-Haim et al., 2007). In previous studies, participants have rated a list of proposed threatening words and the most salient have been used in the task. The current study did not do this.

Future directions

No clinical recommendations can be made based on results from this study, but there are some avenues of future research that have been highlighted. Further understanding of stimulus over-selectivity and SAT is needed within an ABI population. Research should investigate whether ABI aetiology, specific brain damage or cognitive deficits have an impact on whether stimulus over-selectivity and SAT present for individuals. Attentional control and EF have been linked to increased emotion regulation difficulties and proposed to increase SAT (Gracey et al., 2015; Williams et al., 2009), and these difficulties are often common following TBI (Tate et al., 2014**).** Specifically recruiting those with TBI may mean the sample has more

difficulty with stimulus over-selectivity and SAT at baseline, addressing the limitation of floor effects within this study.

Furthermore, it needs to be determined if findings from the emotional disorder literature with regards to attentional bias to emotional material apply to ABI. For example, if severity of clinical depression and anxiety are related to higher SAT. This could be done by using more stringent inclusion and exclusion criteria to obtain a clinically anxious and/ or depressed sample. Future research also needs to refine and validate experimental tasks, such as the emotional Stroop, used to investigate these concepts in an ABI population.

A greater understanding of stimulus over-selectivity and SAT following ABI, as well as refinement of tasks used to measure outcomes of these, will allow more reliable analysis of the mechanism of change within mindfulness-based interventions to affect these potential attentional processes. The specifics of how types of mindfulness exercise impact on neural networks on the brain should be established. This can then lead on to further exploration of how specific mindfulness practices can impact on those with certain neurocognitive profiles, as well as specific processes like stimulus over-selectivity and SAT following ABI.

Conclusion

Although the study's hypotheses on the effect of a brief focused attention mindfulness exercise on stimulus over-selectivity and SAT in an ABI sample were not supported, methodological weaknesses mean the results are difficult to interpret and no clinical recommendations can be proposed. However, this study has highlighted that more understanding of stimulus over-selectivity and attentional biases to emotional material (like SAT) is needed in an ABI population. Additionally, more research into specific mechanisms of mindfulness-based interventions on specific cognitive processes

and neural mechanisms on different neurocognitive profiles within ABI are vital. Only then can it be established who these interventions would be effective for and on what deficits following ABI.

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Chapter 4

Additional method and results section for empirical paper

Additional method

This additional method chapter includes details of the method and procedure not covered in the main paper due to the limited word count.

Participants

The National Health Services (NHS) participants were recruited from were: the Evelyn Community Head Injury Service and the Oliver Zangwill Centre in Cambridge Community Services NHS Trust, the Community Brain Injury Service within Northampton Healthcare NHS Trust and the Colman Hospital in Norfolk Community Health and Care NHS Trust. Charitable organisations included: St Andrew's Healthcare in Northampton; Headway in Essex, and Norfolk & Waveney; and Icanho, Livability, in Suffolk.

Some services were contacted for recruitment but did not identify any suitable participants. Within the NHS this was the Peterborough Community Neurorehabilitation Service within Cambridge and Peterborough Foundation Trust. Non-NHS services were: Brain Injury Rehabilitation Trust (Fen House); and services within Priory: Elm Park, Grafton Manor and Burton Park.

Intervention tasks

The modified Williams and Penman (2011) mindfulness exercise script can be found in Appendix J.

Measures

Baseline comparison measures

Severity of anxiety and depression symptoms was measured using the Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983), a self-report measure consisting of 14 items. As greater anxiety and depression have been linked to higher levels of selective attention to threat (SAT; Epp, Dobson, Dozois & Frewen, 2012; Hofmann, Sawyer, Witt & Oh, 2010), levels of anxiety and depression could impact performance on the emotional Stroop. For those with TBI, Cronbach's alpha for the measure was found to be .94 for the overall HADS scale and .88 for depression and .92 for anxiety subscales, indicating homogeneity of the scales (Whelan-Goodinson, Ponsford & Schönberger, 2009).

The Five Facet Mindfulness Questionnaire (FFMQ; Baer, Smith, Hopkins, Krietemeyer & Tony, 2006) is a self-report measure, consisting of 39 items. Baer et al. (2008) found alpha coefficients ranged from .75 to .91, which shows an adequate to good internal consistency. Although research has not validated the FFMQ in acquired brain injury (ABI), it has been increasingly used to measure mindfulness in this population (for example, Krzeczkowski, Robb & Good, 2017; Nassif, 2013).

Attention was measured using two subtests from the Test of Everyday Attention (TEA; Roberston, Ward, Ridgeway & Nimmo-Smith, 1994). Elevator counting is a measure of sustained attention and elevator counting with distraction is a measure of selective attention. The elevator subtests have been found to be valid and have good test-retest reliability on those with stroke and traumatic brain injury (TBI; Robertson, Nimmo-Smith, Ward & Ridgeway, 1994).

The Wechsler Test of Adult Reading (WTAR; Wechsler, 2001) has been found to be a valid measure of premorbid intelligence post-ABI (Green et al., 2008).

Participants read a list of 50 words with irregular pronunciations to assess previous learning of the words.

Experimental measures

Emotional Stroop

There is strong evidence finding SAT in those with clinical anxiety and depression, using experimental paradigms such as the emotional Stroop and dot probe (Bar-Haim, Lamy, Pergamin, Bakermans-Kranenberg & van IJzenoorn, 2007; Epp et al., 2012; Phaf & Kan, 2007). The emotional Stroop was chosen as the experimental paradigm in this study, as it has yielded the greatest effect sizes in the literature. In their meta-analysis of 125 studies, Bar-Haim et al. (2007) showed the emotional Stroop found the biggest effect size (d=0.45) compared to the dot probe (d=0.38), suggesting that the dot probe is less sensitive at detecting SAT. This was important for the current study due to the common difficulty of recruitment in ABI studies (Carroll, Cassidy, Holm, Kraus & Coronado, 2004) and power considerations.

The emotional Stroop was designed and created by one of the authors (K.V.). The following were considered in its design: Bar-Ham et al. (2007) found emotional Stroop tasks using words had a bigger effect size (d=0.48) than those with pictures (d=0.25) and supraliminal exposure was greater (d=0.5) than subliminal (d=0.32). Existing papers on the emotional Stroop were referred to when choosing the number of words shown. A full list of words used it the task can be found in Appendix K.

Procedure

Clinical teams were initially contacted via email or telephone and a gatekeeper for each service was identified. Dependent on the preference of the gatekeeper, the researcher either attended the service in person to explain the study in more detail to the

clinical team and distributed inclusion and exclusion criteria. Otherwise, the researcher liaised with the gatekeeper only.

Clinicians gave potential participants the participant study information sheet (Appendix L) and asked if they consented to being contacted by the researcher. Written consent for this was obtained (Appendix M). If consent was obtained, the researcher contacted the potential participant to answer any questions, give more information and, if appropriate, arrange a time and place to meet. There was a minimum of 24-hours after the potential participant was given the study information sheet and the researcher contacting them. On occasions, potential participants did not want to be contacted by the researcher directly, instead requesting to communicate via a member of their clinical team. This was given as an option to potential participants on the consent to contact form.

The study took place over one or multiple visits at the participant's home or in a clinic room. When the researcher contacted participants to arrange the time and location of the study, participants were able to choose between the number of visits and location.

When the researcher first met participants, written informed consent to take part in the research was obtained (Appendix N). The first part of the study involved administering baseline measures. This took approximately 45 minutes – 60 minutes for each participant. This was the point at which participants could rearrange another visit to complete the second part of the study.

In the second visit, participants completed the memory load task, over-selectivity task and emotional Stroop. This was followed by completing either the mindfulness or control exercise, depending on which group participants had been allocated to. They then completed the experimental tasks again. Experimental tasks were counterbalanced across participants. The second part took approximately 60 minutes to complete for each participant, so the study totalled 120 minutes. Participants

were offered regular breaks to manage fatigue. Fatigue has been shown to affect performance and confound results on cognitive tasks (Johansson, Bjuhr & Ronnback, 2012).

At the end of the study, participants were debriefed and given the opportunity to ask the researcher any questions. Participants were asked for feedback on how they found the procedure and the tasks they carried out. This will be taken on board for future research in this area, adding to patient and public involvement in research. Participants were also given a handout about where to find further information on mindfulness (Appendix O) and asked if they wanted to receive a lay summary of the results once all data had been analysed.

A letter was sent to the participant's GP to inform them that their patient took part in the study. Information was obtained by the researcher from the referring clinical team from a recent medical report with regards to: participant's current age, educational background, age at injury, injury severity, time since injury and which brain areas are damaged.

Ethics

Patient and Public Involvement

Prior to the design of this study, a member of the research team (F.G.) held discussions with individuals involved with Headway and CSS NHS Trust services who have experienced an ABI. These meetings determined that emotional adjustment and cognitive and emotional difficulties post-ABI are key difficulties they experience. These individuals expressed that it is of interest to them for these areas to be investigated in research.

In the planning and development of the study, a meeting between the researcher (K.V.) and staff and clients at Headway Norfolk and Waveney was carried out to obtain

feedback on the project and accessibility of the participant information sheet. Additionally, during the project, feedback from each participant on the study's protocol was obtained in the debrief in order to use this when designing future research in this area.

Informed consent

All participants had some cognitive difficulties and so were given as much support as possible to understand the nature and purpose of the study to ensure they were able to give informed consent (British Psychological Society, 2010; BPS). For example, the researcher discussed the study with potential participants and asked them to repeat back instructions to check their understanding. All potential participants were given written information about the study in the participant information sheet, which was produced using less complex and more concrete sentences, use of bullet points and using short paragraphs. The readability age score for the participant information sheet was nine years old (checked using http://gunning-fog-index.com/). The information sheet was reviewed by those with a brain injury. Participants were given the option to consent or decline taking part without coercion.

At each visit, participants were reminded they had the right to withdraw at any point during the study up until the point of data being anonymised and analysed, as at this point data would be impossible to withdraw. Participants were made aware of this in the consent form that they signed.

Mental Capacity

The Mental Capacity Act states that mental capacity should always be presumed (Department of Health, 2005), but damage to the brain can sometimes mean that an individual lacks capacity to make certain decisions, which could include taking part in research. Given the possible impact of cognitive difficulties, information about the study was made as accessible as possible to participants. Those with cognitive and

communication difficulties too severe to engage in experimental tasks, and therefore who lack the ability to take part, would have been screened out in selection for the study by the relevant clinician and gatekeeper. This excluded those with cognitive difficulties too severe to give informed consent to take part in the study and hence lack capacity to decide to take part. These individuals would be unable to produce meaningful results on the experimental tasks and it is not ethical to put participants through research that will yield meaningless results. Clinicians and the researcher also used their clinical judgement to determine potential participants' capacity to take part in the research. Capacity and wellbeing of participants were monitored throughout the study by the researcher.

Confidentiality

The Data Protection Act (Department of Health, 1998) was adhered to at all times. Data were anonymised once collected using the participant research number as identification on datasets and questionnaires. Personal and identifiable information was securely stored on an encrypted memory stick by the researcher. Hard copies of documents remain in a locked draw at the UEA. After the study is complete and peer review paper written up, all research data will be archived at UEA and then destroyed following 10 years after study completion. Personal and identifiable information will be destroyed as soon as possible; either once data has been collected, or once the study is completed if participants wish to have a summary of the results and they have been posted a copy. Participants are told about all the information that will be collected in the participant information sheets.

Risk

There were no disclosures of risk during the study, but if there had then confidentiality would have been broken and a member of the participant's care team informed. Participants were told about this in the information sheet and the consent

form and reminded verbally at each visit. Some scores on the Hospital Anxiety and Depression Scale (HADS) identified those with significant anxiety or depression symptoms (scores above 15 on either subscale). Participants were informed that confidentiality needed to be broken and a member of the referring care team informed.

If participants had become distressed at any point during the study, they would have been informed that they could discuss any issues with the researcher in the short-term. If necessary, participants would have been encouraged to contact a member of their care team or GP. If participants were highly distressed, then the researcher would have informed a member of their care team. This would have been discussed with the participant first and was mentioned on the participant information sheet. They would have been reminded that they had the right to withdraw from the study at any point. Participants were always debriefed at the end of each visit.

When meeting one participant to begin the study, the researcher had some concerns regarding their mental health. A risk assessment was carried out by the researcher, who did not deem them to be at any immediate risk of harm to themselves or others. The researcher chose not to carry out the study with the participant, instead contacting their care team to pass on their concerns. The participant was informed and gave consent for this to happen.

Analysis plan

Statistical analysis assumptions

Categorical data were explored to see if they met assumptions for Chi-squared. If categories violated the assumption of lowest expected frequency in 80% of cells to be five or more, Fisher's Exact was used instead (Clark-Carter, 2010). Continuity Correction was used to compensate for the overestimation of the Chi-square value with 2x2 table where necessary (Pallant, 2001).

Data were checked for outliers using box plots and assessed for parametric assumptions using histograms and Shapiro-Wilk tests. Parametric tests are robust to some violation of normality (Rasch & Guiard, 2004), but where necessary, transformations of data were initially attempted before use of non-parametric tests. For t-tests, homogeneity of variance was checked using Levene's Test of equality of variance. For mixed ANOVAs, normality of residuals were checked using histograms and Shapiro-Wilk tests and homogeneity of correlations and homoscedasticity were checked using Box's M statistic and Levene's Test.

Main hypotheses

If any demographic or questionnaire scores significantly differed between groups (determined from t-tests and χ^2 previously) or if performance on an experimental task at T1 differed significantly between the two groups, then the relevant scores would have been inputted as a covariate and an ANCOVA would have been used. However, this was unnecessary as no significant differences between groups were identified.

There is not a non-parametric equivalent of a 2x2 mixed ANOVA or ANCOVA. So, if the data did not meet parametric assumptions then an ANOVA would still need to have been used, but limitations would have been acknowledged. It is worth noting parametric tests are robust to some skew in the data (Rasch & Guiard, 2004). Alternatively, if there was extreme violation of assumptions, separate Wilcoxon tests would have been used to determine any significant difference between scores on both tasks at T1 and T2 for each condition. The differences in performance for each task between the two groups would be determined using two Mann-Whitney U tests.

Data preparation

On the emotional Stroop, those with a mean reaction time (RT) of over 2,500ms were removed from the dataset as it suggested difficulties with information processing that may have invalidated responses on the task. This was based on existing literature,

that has used 1500ms-3000ms as RT cut-offs (Egloff & Hock, 2003; Fackrell, Edmonson-Jones & Hall, 2013; Kindt, Bierman & Brosschot, 1997; Putman, Arias-Garcia, Pantazi & van Schie, 2012). Individual trials were removed if they were -/+2SDs from the mean RT for each participant. This method of identifying outliers was based on existing literature using the emotional Stroop (Bertsch, Böhnke, Kruk & Naumann, 2009; Thomas, Johnstone & Gonsalvez, 2007).

Data imputation

Imputation using analysis of patterns of data was possible for two participants with missing data on the stimulus over-selectivity task. All reinforced stimuli were labelled by the task output as either A, B, E or F. One participant had one missing data at T1 (2.5% of total data) and two missing data at T2 (5.0%). At T1 their response for a F stimulus was missing, as all other F stimuli were correctly identified by the participant in other trials, a correct response was inferred for the missing data. At T2, responses for one B and one E stimuli were missing, all other B and E responses were correct, therefore correct responses for these missing data were also inferred. A further participant had one E response missing at T2 (2.5%), all other E responses were correct, so a correct response was inferred.

Additional Results

This chapter contains additional information about checking data for parametric assumptions. It also includes some further exploratory analysis regarding selective attention to threat (SAT) and over-selectivity between groups, as well as within the acquired brain injury (ABI) sample as a whole. The benefits of using mixed ANOVA

over independent samples t-tests to determine any statistically significant change in SAT or over-selectivity over time between the two groups is considered.

Parametric assumptions and rationale for analysis

Demographics and baseline data

Groups were compared on gender and TEA elevator category using Chi-square analysis with Continuity Correction: age, x^2_{Yates}=.172, p=.68 and TEA elevator category, x^2_{Yates}=.766, p=.381. Fisher's Exact was used to compare groups on: education, p=.90; employment, p=.69; ABI type, p=.51; damaged brain areas, p=.22; HADS anxiety category, p=.83; HADS depression category, p=.51 and WTAR predicted FSIQ, p=.97.

Using box plots on SPSS three possible outlier data were identified for time since injury; two outliers for FFMQ score; and three for TEA distraction. Raw data were checked and there were no errors in the dataset. These outliers were causing skew in the data (see tests for normality below), but it was decided to include all data in baseline comparisons rather than exclude outliers. These outliers were believed to reflect the heterogeneous nature of an ABI sample and it was deemed important to keep these in to assess whether there were any genuine differences and therefore any bias between the groups at baseline.

HADS anxiety, HADS depression and WTAR predicted FSIQ were shown to be normally distributed, and so independent samples t-tests were used to assess differences between groups on these variables. Age was slightly negatively skewed in the mindfulness group, but it was deemed t-tests would be robust enough to still be valid (Rasch & Guiard, 2004). Homogeneity of variance was met by all data. Those with outliers were found to be significantly skewed. Groups were compared on these variables using Mann Whitney U tests.

No significant differences were found between groups on any continuous variable using independent-samples t-tests: age, t(40), p=.88; HADS anxiety, t(40), p=.72; HADS depression, t(40), p=.29; and WTAR predicted FSIQ, t(40), p=.64. No significant differences between groups were found using Mann Whitney U tests on any of the following variables: time since injury, p=.73; FFMQ, p=.27; and TEA distraction SS, p=.91. These analyses were underpowered and so results interpreted with caution. However, none were approaching significance.

Data were positively skewed for scores at baseline on the over-selectivity task and so transformed using square root formula before an independent t-test was used to compare groups. Data were skewed for both baseline incorrect responses and primary outcome measure for the emotional Stroop. Transformations were unsuccessfully attempted and Mann Whitney U tests were conducted.

Main hypotheses

Stimulus over-selectivity

No outliers were identified, and data were transformed using square root formula due to slight positive skew. This improved distributions, but the post-intervention mindfulness group remained positively skewed. Therefore, mixed ANOVA was used with transformed data and residuals checked for normality post-analysis. Once again, all residuals were normally distributed, apart from skew in the post-mindfulness group. Therefore, results from the ANOVA were interpreted with caution. Homogeneity of correlation assumptions were met by the data.

Selective attention to threat

Due to the mixed direction of skew of the data for groups at different time points, transformations could not be used. Therefore, original data was used in analysis, given the robustness of parametric assumptions to some skew. Subsequently, the distribution of residuals was checked following ANOVA. These also showed some

slight skew, therefore results were interpreted with caution. Homogeneity of correlations and homoscedasticity assumptions were met by all data.

Over-selectivity following ABI

Baseline levels of over-selectivity were considered, in order to establish if this was present in the ABI sample. The over-selectivity paradigm used in this paper does not have any norms and therefore, there is no 'cut off' score to demonstrate over-selectivity. However, a score of zero represents no degree of over-selectivity on the task and a greater positive score from zero represents higher rates of over-selectivity. The whole sample at T1 had a mean score of M = 6.39 (SD = 4.81), range 0-16. This would suggest that on average, the sample were displaying some over-selectivity. However, there were three individuals who obtained a score of zero, suggesting that not everyone post-ABI has difficulties with stimulus over-selectivity. Future research is needed to explore this further, either to obtain norms for the paradigm, or use a control group from a neurologically healthy population to see if there are significant differences on over-selectivity scores between these two populations.

Selective attention to threat following ABI

Exploratory analysis was undertaken to further investigate if the whole sample were displaying SAT at baseline, in order to investigate if SAT is a problem following ABI. In the main paper, SAT was conceptualised as the difference between the RT of threatening and neutral words, which was calculated for each participant. In this exploratory analysis, the difference between RTs to neutral and RTs to threatening words for all participants at T1 was compared to see if there was a significant difference between RTs dependent on word valence.

Data for both neutral and threating RTs were positively skewed and so both sets of data were transformed using square root formula, resulting in normal distributions. The mean RT for neutral words was M = 667.45 (SD = 296.96) and for the control group M = 677.18 (SD= 322.65). Although this meant RT to neutral words was quicker, suggesting the correct direction for SAT, this difference was found to be non-significant by a matched pairs t-test: t(36)=-.70, p=.487, Cohen's d=.03. This implies that the difference in RTs was in fact very small, hence implying that the sample was perhaps experiencing minimal SAT at T1. As discussed in the main paper, this highlights difficulties with floor effects on the emotional Stroop.

Anxiety, depression and SAT

Previous research suggests a strong relationship with anxiety and SAT (Bar-Haim et al., 2007), and there is also evidence to suggest a relationship between depression and SAT (Epp et al., 2012). Therefore, the relationship between HADS anxiety score and HADS depression score with SAT (difference between threatening and neutral words at T1) in the sample was explored using correlation analysis. Data were normally distributed and the assumptions of linearity and homoscedasticity were checked using scatter graphs for both HADS anxiety and HADS depression compared with pre-intervention score. Both anxiety and depression graphs showed similar patterns and did not violate either assumption. However, two outliers were identified in each of the scatter plots. But as there was no mistake in the raw data and as this was exploratory analysis, it was decided to include these data. The scatter plots did not suggest any strong relationship between the variables.

The relationships between HADS anxiety score and SAT, and then HADS depression and SAT, were investigated using Pearson product-moment correlation coefficient. There was a weak, but non-significant, correlation between the HADS

anxiety and SAT: r=-.17, p=.32, with high anxiety related to greater SAT. However, the correlation is likely to be underpowered due to the small sample size and weak relationship. G-power was used to calculate that, based on this r value, the sample size of 37 and a significance level of p=0.05, achieved power was 0.26. There was also a weak, non-significant, relationship between HADS depression and SAT, r=-.26, p=.12, with high depression related to greater SAT. G-power was used to calculate that achieved power was 0.5. Therefore, once again this correlation could have been underpowered to detect the relationship.

It may be that a more anxious or depressed sample would have displayed higher levels of SAT at baseline, allowing for more of an effect pre- to post-intervention. This adds support to points discussed in the main paper regarding the nature of the study's sample, and other research in a neurologically healthy population that suggests greater anxiety and depression is associated with greater SAT. The exploratory correlational analysis conducted in this study tentatively adds support to this, as it found a weak but non-significant relationship between high anxiety and depression and SAT. Although these relationships were non-significant, the analysis was underpowered to find a result. Some statisticians argue that the direction and strength of relationship is more important than significance value for correlational analysis (Pallant, 2002). However, this result should be taken with caution and future research is needed to explore the relationship between clinical anxiety and depression and SAT in an ABI population, as discussed in the main paper.

Use of mixed ANOVA

When testing the main hypotheses for SAT and stimulus over-selectivity, the use of independent-samples t-test was considered to determine if mindfulness and control groups significantly differed on the change in pre- to post-intervention scores. This

analysis could have been used as an alternative to mixed ANOVA. However, a power calculation was undertaken and the mixed ANOVA had significantly more power (0.75) than the t-test (0.31), based on the study's sample, a predicted detection of a medium effect size and the use of Bonferroni's correction for multiple tests (p=.025). Therefore, ANOVA was chosen to analyse results.

Chapter 5

Overall thesis portfolio discussion

Overall thesis portfolio discussion

This chapter will synthesise the findings from both the systematic review and empirical paper, and how they relate to previous research and the wider literature. A critical evaluation of both papers is included, followed by suggestions of how the work can be improved and extended. Avenues of future research are suggested.

Main findings

The thesis portfolio aimed to explore the effect of mindfulness on aspects of cognition in an acquired neurodisability population. Firstly, by conducting a systematic review of the available existing literature on this topic, which included an evaluation of the strength of evidence. Secondly, an empirical research project was conducted that specifically looked at the impact of a brief mindfulness exercise on attentional processes: stimulus over-selectivity and selective attention to threat (SAT), in an acquired brain injury (ABI) population.

Systematic review

It became apparent from the systematic review that there is limited good-quality research that has investigated the effectiveness of mindfulness-based interventions on cognition following acquired neurodisability, providing mixed results. All papers meeting criteria for review used an ABI sample: a mixture of traumatic brain injury (TBI), stroke or unspecified ABI. No papers that used a multiple sclerosis (MS) sample employed a robust enough design to meet criteria for the review. Hence, it can be concluded that the evidence-base is weaker and lacking in this population. Attentional processes were the most explored in the literature. This may be due to the strongest evidence to date for improvement of selective and sustained attention after mindfulness in a neurologically healthy population (Chiesa, Calati & Serretti, 2011). In agreement

with this, although conclusions should be taken with caution, the most promising results of mindfulness appeared to be on selective and sustained attention following ABI. Less support was found for improvement on divided attention, switching of attention and inhibition. There was also some preliminary, but mixed, evidence of a positive impact on processing speed.

However, all papers reviewed had multiple areas of moderate – high risk of bias, hence conclusions made by papers should be taken with caution. Additionally, the current evidence-base in an ABI population uses a great variation of length, intensity and delivery method of mindfulness-intervention. Many different cognitive processes are investigated and varying outcome measures are used to assess them. This made results across studies difficult to compare. Hence, the main conclusion from the systematic review was that more high-quality research is needed to fully assess the effectiveness of mindfulness-based interventions on cognition following acquired neurodisability.

Empirical paper

The research paper in this portfolio then aimed to address some of the weaknesses within papers in the current literature and further explore the impact of mindfulness on cognition following acquired neurodisability. It specifically focused on a 10-minute mindfulness of breath and body scan exercise, and its impact on specific attentional processes in an ABI population. The attentional processes included stimulus over-selectivity, when people focus on certain aspects of the environment, missing other information. This was investigated previously by a paper included in the systematic review (McHugh and Wood, 2013). Secondly, the empirical paper in this portfolio concentrated on an attentional process under emotional load, SAT. This is when threatening stimuli in the environment are selected over neutral stimuli for processing, resulting in an increased perception of threat (Bar-Haim, Lamy, Pergamin, Bakermans-

Kranenberg & van IJzenoorn, 2007). This is a well-known casual and maintenance factor in emotional disorders (Harvey, Watkins, Mansell & Shafran, 2004).

The empirical paper hypothesised that, compared to an unfocused attention control group, the mindfulness group would display significantly less stimulus over-selectivity and SAT from pre- to post-intervention. This was measured using two computerised paradigms: an over-selectivity task and an emotional Stroop. Neither hypothesis was supported by results. This contradicted findings by McHugh and Wood (2013) who found that a 10-minute mindfulness of breath exercise reduced stimulus over-selectivity in a TBI sample compared to an inactive control group. These results are discussed in more detail in relation to the wider literature below, and strengths and limitations of the portfolio discussed later in the chapter need to be taken into account when interpreting the empirical paper findings.

Mechanisms of change in mindfulness-interventions

Mindfulness-based interventions are made up of multiple components. They combine the Buddhist practice of mindfulness (full attention to and awareness of the present moment, without judgement) with aspects of Western psychology (Chambers, Chuen, Yee Lo & Allen, 2008). This has culminated in interventions such as Mindfulness-based Stress Reduction (MBSR; Kabat-Zinn, 1990), an intervention originally created to treat chronic pain. It is an eight-week programme, incorporating a range of meditation practices and is increasingly being applied to treat other difficulties in a range of populations. Mindfulness-based cognitive therapy (MBCT; Segal, Williams & Teasdale, 2002) incorporates mindfulness practice with cognitive therapy techniques to prevent the consolidation of ruminative and negative thinking patterns, in order to prevent relapse of depression.

Within these interventions, a number of mindfulness meditations are included, ranging from focused attention exercises on internal stimuli, such as mindfulness of breath exercises, to broadening awareness and focus to external stimuli and exercises promoting self-awareness and self-monitoring (Lutz, Slagter, Dunne & Davidson, 2008). Hence, it can be inferred that different mindfulness exercises act on different cognitive processes and neural networks in the brain. This is supported by Chiesa et al. (2011)'s review of mindfulness training on cognitive abilities in a neurologically healthy population. They suggest that meditation practices involving the narrowing of attentional focus are more likely to improve selective and executive attentional control, whereas exercises promoting the open monitoring of stimuli are likely to improve upon sustained attention. Additionally, this would suggest that different mindfulness exercises are working upon different attentional networks, as proposed by Posner, Sheese, Odludas and Tang (2006). Exercises promoting open monitoring may act upon the alerting network, involved in acquiring and sustaining an alert state. Whereas, exercises narrowing attentional focus could be acting upon networks involved in executive attentional control, responsible for the resolution of conflict between neural systems and regulating thoughts and feelings.

Others have attempted to model mechanisms underlying effects of mindfulness training on emotion regulation. Teper, Segal & Inzlicht (2013) suggest mindfulness improves executive control via the executive control network as it fosters present moment awareness and acceptance. This in turn improves emotion regulation, as it enhances experience of and attention to transient affects (cues to use executive control) that arise from competing goal tendencies. Malinowski (2013) supports this, arguing that mindfulness practice results in changes to early stimulus processing, by improving attentional selection and control mediated by improved resource allocation and conflict resolution processes. Holzel et al. (2011) highlighted mindfulness training improves

activation of the dorsolateral prefrontal cortex (PFC) and anterior cingulate cortices (ACC), which improve regulation of the amygdala. This improves attentional control and emotional appraisal of emotional material.

In addition, it may be that increased experience and practice of mindfulness techniques lead to different mechanisms of change. Novice mindfulness meditators use more mental effort to focus their attention and open their mind, which will require more executive functioning (EF) and capacity which heavily involves the PFC. As practice continues and expertise develops, less effortful control is required, and the autonomic nervous system becomes more active. Tang and Posner (2009) hypothesise that this is when the ACC is activated more to maintain the balance of cognitive control and autonomic activity.

Mechanisms and stimulus over-selectivity and selective attention to threat

Over-selectivity describes an attentional bias where only a limited amount of available information is attended to and processed. Selective attention to threat is when individuals have an attentional bias to threatening stimuli in the environment. This process is explained by biased competition models which state individuals have a limited-capacity processing system that can only process a certain amount of information in the environment. This then creates competition for attention between information (Buehlmann & Deco, 2008; Mathews & Mackintosh, 1998; Mogg & Bradley, 1998; Williams, Watts, MacLeod & Mathews, 1997).

Hence, if mindfulness can improve executive attentional control (via the executive attentional control network) and allocation of resources, then it can be hypothesised mindfulness could improve stimulus over-selectivity and attentional bias to emotional stimuli, such as SAT, via this mechanism. This theory is further supported by Posner et al. (2006)'s argument that tasks involving conflict between stimulus dimensions competing for control of resources (such as the over-selectivity task and

emotional Stroop) cause different neural networks to compete for control of output. The executive control network then regulates activity in these other brain networks. Hence, if executive control can be improved by mindfulness, over-selectivity and SAT could be reduced.

Mechanisms and brain injury

However, the systematic review conducted in this portfolio highlighted that there is a lack of research exploring mechanisms of change in mindfulness-interventions within an ABI population. Furthermore, there is variation in mindfulness-based interventions investigated, including type, length and intensity. Based on the emerging literature on mechanisms within a neurologically healthy population, it could be hypothesised that if mindfulness improves executive attentional control and activation of the PFC and ACC, then it may be particularly helpful for those with EF deficits (Holzel et al., 2011). This, in turn, could improve emotional regulation.

On the other hand, it may be that mechanisms of change are disrupted or are different for this population, due to acquired cognitive deficits. Mindfulness exercises require a certain level of cognitive ability to learn and develop. During a focused attention exercise, like the mindfulness of breath and body scan used in this study, the alerting network is involved to sustain attention on the task. When the mind wanders, detection of attentional disengagement is provided by the executive network (executive attentional control). Then the orienting and executive networks are both needed to return to the object of focus (Malinowski, 2013). It may also be that learning mindfulness for the first time requires greater PFC activity and EF (Tang & Posner, 2009). This could have implications on the ability of mindfulness to evoke change and the mechanism of which this works for those with ABI. It may also depend on specific deficits and the severity of these.

The mixed findings in the systematic review could be a result of the variation in ABI aetiology and severity recruited and variation of mindfulness-interventions, as they could have had an impact on mechanisms of change. However, this hypothesis needs to be explored further.

Selective attention to threat following brain injury

Attentional bias to threatening over neutral stimuli in the environment (SAT) is a well-known causal and maintenance factor in emotional disorders, particularly anxiety (Bar-Haim et al., 2007; Epp, Dobson, Dozois & Frewen, 2012; Phaf & Kan, 2007). Further to this, heightened anxiety then lowers the threshold for perceiving information as threatening, causing increased SAT (Cisler & Koster, 2010). This is an area that has been extensively investigated in the emotional disorders literature, but much less explored in an ABI population.

Gracey, Longworth and Psaila (2015) argue that individuals following TBI experience greater SAT as they are more likely to appraise situations as threatening due to an acquired threat to self-identity post-injury, as well as acquired deficits in attentional control and EF. Stimuli associated with physical threat or negative social evaluation have been found to be perceived as particularly salient for those with ABI (Riley, Brennan & Powell, 2004), potentially increasing anxiety via increased perception of threat. Additionally, Williams, Suchy and Rau (2009) found that neurologically-healthy individuals with inferior EF are vulnerable to enhanced stress exposure. This suggests that acquired attentional and EF deficits due to neurological damage following ABI could cause and maintain emotional difficulties by increasing emotion-processing biases, such as SAT.

Both groups displayed some degree of SAT at baseline, as mean reaction times to threatening words on the emotional Stroop was slower compared to neutral.

However, exploratory analysis was conducted to see if the difference between reaction times to threatening and neutral words was significant at baseline across the whole sample. Although the difference between RTs for neutral and threatening words was in the correct direction on the emotional Stroop to imply the sample were displaying SAT at baseline, this difference was not statistically significant and had a very small effect size. This implies that the sample was experiencing minimal SAT at T1.

It is well documented in the literature that those with more severe clinical anxiety and depression display more SAT and larger effect sizes on the emotional Stroop than those who just display trait symptoms (Epp et al., 2012; Phaf & Kan, 2007). In this study, even though selection criteria used aimed to recruit those with emotional adjustment difficulties post-ABI, 47.6% of the whole sample recruited fell within the normal range on HADS anxiety subscale, and 40.5% on the depression subscale. If SAT as a process is the same or similar in those with cognitive neurodisability, as those who are neurologically healthy, it can be hypothesised that this study's sample was not sufficiently depressed or anxious to display enough SAT at baseline to detect an effect of the intervention.

Exploratory analysis in the additional method chapter was conducted in order to investigate this theory further. Correlational analysis found non-significant but weak relationships between higher anxiety and depression (scores on HADS subscales) and greater SAT at baseline. Although these relationships were non-significant, the analysis was underpowered to find a result. Some statisticians argue that the direction and strength of relationship is more important than significance value for correlational analysis (Pallant, 2002). However, this result should be taken with caution.

In addition, although the emotional Stroop is an established paradigm to measure SAT, to the authors knowledge there is only one other paper that has used the task with an ABI population (Coates, 2007). It may be that those with cognitive

difficulties perform differently on the emotional Stroop compared to a neurologically healthy population, as it relies on other general cognitive and attentional processes to complete, including word-processing, processing speed and psycho-motor processing. Additionally, the traditional Stroop task is a validated measure of attentional control and EF and widely used in clinical practice to detect EF deficits (Delis, Kramer, Kaplan & Holdnack, 2004). It may be that EF difficulties were a possible confounder on the emotional Stroop.

Emotional Stroop

Strong evidence supporting biased competition models of attentional biases, like SAT, (Mathews & Mackintosh, 1998; Mogg & Bradley, 1998; Williams, et al., 1997) has been found using experimental paradigms, such as the dot probe and emotional Stroop. In their meta-analysis of 125 studies, Bar-Haim et al. (2007) showed the emotional Stroop was the most used paradigm to date and the task found the biggest effect size (d=0.45) compared to the dot probe (d=0.38), suggesting that the dot probe is less sensitive to detecting SAT. Hence, the emotional Stroop was chosen as the outcome measure for the current study due to the common difficulty of recruitment in ABI studies (Carroll, Cassidy, Holm, Kraus & Coronado, 2004) and power considerations.

However, there is some controversy in the literature regarding the use of the emotional Stroop to measure SAT, as the exact cognitive processes causing the effect found by the task is debated (Yiend, 2010). Biased competition models would argue that slower response to threatening stimuli in the task is due to emotional stimuli attracting disproportionately more processing resources due to the activation of specific knowledge structure representing personal threats (Mogg, Mathews & Weinman, 1989). Others have argued that the emotional Stroop measures cognitive avoidance and inference may occur due to an attempt to avoid processing emotional stimuli. Hence,

emotional material is less readily supressed or filtered which then causes attention to be consumed by the threatening stimuli, slowing colour-naming (Dawkins & Furnham, 1989). Another possibility is that emotional stimuli affect other cognitive processes, or cognition more generally, causing general processing disruptions (Yiend, 2010).

Due to a lack of significant findings in the current study, none of the proposed theories can be supported or contradicted in this instance. However, it is important to acknowledge the unanswered debate in the literature regarding the emotional Stroop, as it may be possible that other cognitive processes have interacted with performance on the task in this study, due to cognitive deficits following ABI. It could also mean that a different cognitive process, other than SAT, was being measured in this study for all or some participants.

Strengths and limitations of the thesis portfolio

Although no significant results were found in the empirical paper and hypotheses were not supported, there are both strengths and limitations of the project that need to be considered. The RCT design is a particular strength, as these designs are considered the most scientifically credible of clinical studies and level one evidence by the Oxford Centre for Evidence-based Medicine (Howick et al 2011; Jones, Gebski, Onslow & Packman, 2001). This study used an active control group, matching the intervention task on length and mode of delivery. However, even though random allocation significantly decreases risk of bias that might occur with allocation of subjects to treatment (Jones et al., 2001), it is worth noting that there may have been some systematic bias introduced as there was suggestion that the control group were displaying more stimulus over-selectivity than the mindfulness group at baseline.

The systematic review highlighted that there is a lack of understanding in the existing literature regarding the various mechanisms of change within mindfulness-

interventions. In addition, the Medical Research Council (MRC) stress the importance of identifying active ingredients and how they are exerting their effects in complex interventions with multiple components, like mindfulness-based interventions (MRC, 2008). Hence, another strength of the empirical study was the investigation of a specific mindfulness exercise on specific cognitive processes following ABI.

However, there are also some limitations of the current study that need to be considered. Every effort was made to recruit the required sample size. A great number of brain injury services were approached for recruitment, spanning East Anglia. In addition, the required sample size was a consideration when inclusion and exclusion criteria were created, for example the study recruited a variety of ABI. However, the study was underpowered and hence conclusions from statistical analyses should be taken with caution. This included tests for the main hypotheses, as well as baseline comparisons. It may be that the tests were underpowered to detect any difference on confounding variables at baseline and hence some systematic bias between groups may have been present. Additionally, not all data met parametric assumptions (normality) for tests employed.

Although recruiting a range of ABI aetiologies increased the study's sample size, it meant there was great variation in many sample characteristics, including time since injury and areas of the brain damage. This study aimed to investigate specific attentional deficits and it may be that recruiting such a wide range of ABI meant that not all of the sample displayed these at baseline. As discussed earlier in the chapter, there is a proposed link between attentional control and EF deficits and SAT. Those with TBI specifically have been found to display over-selectivity (McHugh & Wood, 2013).

This study was unable to determine how much over-selectivity the sample was displaying at baseline, as the over-selectivity paradigm does not have any norms and therefore, there is no 'cut off' score to demonstrate over-selectivity. Furthermore,

although an established paradigm in the emotional disorders literature, to the authors' knowledge, there is only one other study that has used the emotional Stroop with an ABI population (Coates, 2008). Although participants were able to understand and complete the task, other cognitive deficits may have affected, and confounded performance as discussed above.

In addition to this, the emotional Stroop was created by the author (K.V.), based on a literature review of the existing emotional disorders literature. Some have proposed that the emotional Stroop measures different underlying mechanisms according to a particular format of the task used (Kindt, Bierman & Brosschot, 1996). Additionally, it has been found that SAT is detectable when the content of the stimuli is congruent with the concerns associated with the emotional disorder (Bar-Haim et al., 2007). In previous studies which have designed a version of the emotional Stroop, participants have rated a list of proposed threatening words and the most threatening have been used in the task. The current study did not do this.

The chosen 10-minute mindfulness intervention exercise may have been insufficient to improve mindfulness in participants and bring about change on task performance. Some participants fed back that they found it difficult to follow the exercise, some said they found it too boring and repetitive. This may support evidence that suggests novice mindfulness practitioners use more mental effort and EF processing to engage in meditation (Tang & Posner, 2009). It may be that the task required too much cognitive demand and was too difficult for some. There were also participants in the control group who reported focusing on external stimuli in the room or outside the window, indicating they were not following task instructions and perhaps employing a type of focusing exercise. Data on previous mindfulness experience was not collected by this study.

Implications for future research and clinical practice

Results from this portfolio cannot lead to any recommendations to incorporate mindfulness-based interventions into current clinical practice to improve cognitive difficulties following acquired neurodisability. In addition, it has not been possible to determine any mechanisms of change in mindfulness-based interventions on cognition following acquired neurodisability, or ABI specifically. However, some important avenues for future research have been highlighted.

Due to the heterogenous nature of cognitive deficits in this population, it seems vital to gain a greater understanding of what aspect of mindfulness-based interventions work on which cognitive processes for whom. Therefore, more good-quality proof of principle studies are needed to fully be able to understand and determine the effect of mindfulness-based interventions on cognition following acquired neurodisability. These could further test hypotheses concerning the proposed mechanism of change on sustained and selective attention (Chiesa et al, 2011), and attentional control and EF (Teper et al., 2013), via improved resource allocation and conflict resolution processes (Malinowski, 2013). Future research is also needed to determine if these mechanisms of change also apply to different neurocognitive profiles within ABI with varying severities.

Future research needs to investigate the use of various mindfulness-exercises, as research suggests different aspects of mindfulness work to improve different attentional processes (Chiesa et al., 2011). Additionally, more research is needed to determine if length and expertise of mindfulness practice has an impact on which neural networks and mechanisms of change occur. It is also vital to investigate if certain cognitive deficits (e.g. severe EF difficulties) are a barrier to engagement and hence the impact of mindfulness interventions.

Conclusions from the empirical paper and acknowledged limitations of the study, suggest that more understanding of stimulus over-selectivity and attentional biases to emotional material (like SAT) is needed in an ABI population. It is uncertain whether these attentional biases are present in only those with specific neurocognitive profiles (e.g. those with EF deficits). It is also uncertain whether findings regarding SAT in neurologically healthy individuals apply to those in a brain injury population too, for example the influence of clinical anxiety and depression.

Further research into paradigms to outcome SAT, like the emotional Stroop and the over-selectivity task, is needed to validate the use of such tasks on this population. This could include obtaining standardised norms for the stimulus over-selectivity task, or a future study that uses a neurologically healthy control group for comparison. This would also help to determine how much of a difficulty over-selectivity is for those with ABI, or specifically TBI. Aspects of emotional Stoop design need to be refined and then validated on this population. These steps will allow for more reliable and valid exploration of potential interventions, such as mindfulness, to treat these potential cognitive difficulties following ABI.

Conclusion

Those with acquired neurodisability, including those with ABI, are often left with a range of cognitive difficulties that can have a significant impact on quality of life and leave individuals at increased risk of developing an emotional disorder (Bombardier et al., 2010; Chiaravalloti & DeLuca, 2008; Djikers, 2004). Despite the growing interest in the use of mindfulness-based interventions to improve these difficulties in this population, this portfolio found there is currently a significant lack of high-quality research which investigates its use on cognition in an acquired neurodisability population. Additionally, due to the heterogenous nature of ABI and the complexity of

such interventions, it is vital more research is undertaken into specific mechanisms of mindfulness-based interventions on specific cognitive processes and neural mechanisms on different neurocognitive profiles within ABI. The current thesis portfolio has also highlighted the need for more research to further understand specific attentional biases in this population, such as stimulus over-selectivity and SAT. Only by addressing these areas of future research can clinical recommendations regarding the use of mindfulness be made for cognitive deficits following acquired neurodisability.

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Appendix A

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Starting in 2010, all manuscripts published in *Neuropsychology* will include a structured abstract of up to **250 words**. The Abstract, presented in paragraph form, should be typed on a separate page (page 2 of the manuscript), and must include each of the following sections:

- **Objective:** A brief statement of the purpose of the study
- **Method:** A detailed summary of the participants as well as descriptions of the study design, measures, and procedures
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- **Conclusions:** A summary of the research and implications of the findings

After the abstract, please supply three to five keywords.

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When an accepted paper is published, these sentences will be boxed beneath the abstract for easy accessibility. All such descriptions will also be published as part of the Table of Contents, as well as on the journal's web page. This new policy is in keeping with efforts to increase dissemination and usage by larger and diverse audiences.

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Nonstandard abbreviations should be introduced by placing the abbreviation in parentheses after the first occurrence of the term being abbreviated in both the abstract and the text. The metric system should be followed for all volumes, lengths, weights, and so on. Temperatures should be expressed in degrees Celsius (centigrade). Units should conform to the International System of Units (SI; see the *Publication Manual*).

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Whenever appropriate, statistical analyses should include effect sizes and confidence intervals and figures should include error bars. Authors are strongly encouraged to read the APA guidelines for statistical methods and reporting, L. Wilkinson and the Task Force on Statistical Inference, 1999, "Statistical Methods in Psychology Journals: Guidelines and Explanations," *American Psychologist, 54*, 594–604 (PDF, 1171KB).

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Each table should be submitted with the manuscript file. Each should start on a separate page and must be numbered and labeled with an appropriate title. All tables must be self-explanatory.

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- **Authored Book:**
  Rogers, T. T., & McClelland, J. L. (2004). *Semantic cognition: A parallel distributed processing approach.*Cambridge, MA: MIT Press.

- **Chapter in an Edited Book:**
  Gill, M. J., & Sypher, B. D. (2009). Workplace incivility and organizational trust. In P. Lutgen-Sandvik & B. D. Sypher (Eds.), *Destructive organizational communication: Processes, consequences, and constructive ways of organizing* (pp. 53–73). New York, NY: Taylor & Francis.

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Other Information

- Appeals Process for Manuscript Submissions
- Preparing Auxiliary Files for Production
- Document Deposit Procedures for APA Journals

Appendix C

Rating tool used to assess quality of RCTs, between-within and between group designs.

Bias domain	Source of bias	Rating criteria/ points to discuss
Selection bias	Appropriate and representative sample	*Does the sample diagnostic method and inclusion and exclusion criteria ensure that the study's sample is representative of the neurodisability investigated?* Low risk of bias (2 points) = There is a full description of and appropriate method and criteria. Participants were recruited from a representative sample and were a good representative of the neurodisability investigated. Moderate risk of bias (1 point) = Recruitment sample or inclusion and exclusion criteria applied may limit the generalisability of results. Or the description of diagnostic method or criteria is not complete. High risk of bias (0 points) = Poor description of method and inclusion and exclusion criteria and inappropriate method and criteria.
	Appropriate screening of sample	*Does the study detail the screening process? Is this appropriate?* Low risk of bias = Full description of appropriate screening process. Numbers of participants screened, included and excluded are reported. There is a detailed description of the screening procedure (e.g. a person conducted the screening assessments). Moderate risk of bias = Brief description of numbers screened, included and excluded. Or

	some information on the process. Generally, some information missing. High risk of bias = Poor or no description of numbers screened, included and excluded.
Random sequence generation (randomisation to groups)	*Has the method used to generate the allocation sequence produced comparable groups? (In SR describe the method in sufficient detail when assessing bias). Is there selection bias due to inadequate generation of randomised sequence?* Low risk of bias = Subject assignment to groups is randomised and methodology is appropriate. Differences on key variables between groups are assessed at baseline and they are sufficiently alike at baseline. Otherwise, differences on 80-100% of these variables are controlled for in the analysis. Moderate risk of bias = Participants are randomised into groups, but there may be some flaws in methodology or insufficient detail about methodology is given in the paper. Differences on some key variables are assessed at baseline and are sufficiently alike or 60-79% of cofounders were controlled for in the analysis High risk of bias = Subjects are not randomised to groups or assignment is not adequately described. Or the randomisation method was not appropriate. No comparison between groups at baseline on key variable and/or less than 60% of cofounders are controlled for in the analysis.
Allocation concealment	*Does the method used conceal the allocation sequence so that intervention allocations could not have been foreseen before or during enrolment? Is there selection bias due to inadequate concealment of allocations before assignment?* Low risk of bias = participants were unaware of whether they were assigned to an experimental or control condition.

		Moderate risk of bias = participants were made as blind as possible to which condition they were assigned, but there may be some knowledge of the research question High risk of bias/ not addressed = participants were aware of the research question and/or whether they were allocated to a controlled or experimental condition. Or not sufficient detail in the paper to determine.
Performance bias	Blinding of participants and personnel	*What methods were used to blind trial participants and researchers from knowledge of which intervention a participant received? Was the intended blinding effective? Is there performance bias due to knowledge of the allocated interventions by participants and personnel during the study?* Low risk of bias = Personnel and participants were unaware of which intervention participants received. Moderate risk of bias = There was an attempt at blinding personnel and participants from which intervention participants received and blinding of condition to those scoring the study, but this was not completely effective. High risk of bias = Researchers and/or participants were aware of which intervention participants received. Or insufficient detail included in paper.
Detection bias	Blinding of outcome assessment	*Which measures were used to blind outcome assessment from knowledge of which intervention a participant received? Was the intended blinding effective? Is there any detection bias due to the knowledge of allocated interventions by outcome assessment?* Low risk of bias = Researchers scoring and analysing data were blind to treatment condition.

		Moderate risk of bias = There was an attempt to blind researchers scoring and analysing the results to treatment condition, but this was not completely effective. High risk of bias = Researchers scoring and analysing results were not blinded to group allocation. Or insufficient detail in paper.
	Reliable, valid and standardised outcome measures	*Are cognition outcome measures reliable, valid and standardised on relevant population?* Low risk of bias = Standardised outcome measure(s) used that have good psychometric properties in the specific neurodisability population involved in the study (both valid and reliable). Moderate risk of bias = Standardised outcome measure(s) have been used that have adequate psychometric properties but there is little or no evidence of reliability and validity in the relevant neurodisability population. High risk of bias = Poor validation of outcome measures or non-standardised measures used.
Attrition bias	Incomplete outcome data	*Does the study report: attrition, exclusions, numbers in each intervention group (compared to total randomised participants), reasons for attrition or exclusions and any re-inclusions in the analysis? Is there any attrition bias due to the amount, nature, or handling of incomplete data?* Low risk of bias = Appropriate inclusion/ exclusion criteria were applied and 70% or more of those eligible to participate did so. Approximately equal number of participants in each group. The paper states attrition rates for all groups from pre- to post-intervention and they are similar for each group (rates within 10% of each other and 20% of total participants). Reasons for drop-outs are given. Appropriate statistical analysis was used for

		missing data (e.g. ITT with baseline score carried forward in order to minimise bias). Moderate risk of bias = Adequate inclusion/ exclusion criteria. Between 60-69% of those eligible to participate in the study do so (or authors attempt to minimise bias by comparing those who took part to those who didn't on appropriate variables). Somewhat equal number of participants in each group. Attrition rate stated pre- to post-intervention and somewhat alike between groups (within 20% of each other and less than 30% of total participants). Reasons for drop-out rates may or may not be given. There may not be statistical management of missing data but proportion of participants excluded is reported and less than 20%. High risk of bias = High dropout rate in general (more than 40%) and/or uneven attrition. Reasons for drop-outs not given. Poor method used to deal with missing data and participants excluded is more than 20% or not reported at all. Not addressed = attrition rate not reported and there was no mention of missing data or participants who have been excluded.
Reporting bias	Selective reporting	*How selective was outcome reporting? Is there any reporting bias? Were appropriate statistical tests used (e.g. use of Bonferroni correction, longitudinal data analysis, adjustment for cofounders)? Were statistical analyses powered?* Low risk of bias = Analysis was appropriate to the design used. All outcome data was analysed and reported on. Moderate risk of bias = Analysis was appropriate to design, but not all outcomes are reported or some bias with regards to analysis used. High risk of bias = Analysis is not appropriate or there is a high level of reporting bias.

	Conclusions reported	*Are conclusions of the study justified by the sample, measures and data analysis?* Low risk of bias = All conclusions of the study justified. Moderate risk of bias = Some conclusions of the study justified. High risk of bias = Poor or no justification of conclusions from results as presented, or insufficient information to evaluate (e.g. sample or treatment insufficiently documented, data analysis does not support conclusions, or number of withdrawals or dropouts makes findings unsupportable).
Other bias	Fidelity of treatment groups	*Does the study demonstrate that the treatment being studied is the treatment being delivered?* Low risk of bias = Full adherence reporting for intervention with a standardised measure (must be quantitative and completed by an independent rater). And there is a full description of the therapist delivering the intervention and their training and they are suitably qualified. Moderate risk of bias = There is brief adherence reporting with a standardised measure or full adherence reporting with non-standardised measure. Or there is a suitably qualified therapist (or they have adequate supervision). High risk of bias = There is poor or no adherence reporting. There are underqualified therapists who have inadequate therapist supervision. Or no information given in paper.
	Confounding variables - suitability of control group	*Is the comparison group from the same population and time frame as experimental group?*

		Low risk of bias = Control group is from the same population and time frame Moderate risk of bias = Control group is from a moderately different population and/or time frame High risk of bias = Control group is from a significantly different population and/or time frame
	Study design	*Does the study design introduce any bias? Consider whether study is RCT, SCED, other. Criteria here is based on CEBM Levels of evidence, 2011, when asking "does this intervention help?"* Low risk of bias = RCT or randomised n-of-1 trials (SCED) Adequately covered = non-randomised controlled trial, quasi-experimental design, or a well-designed multiple subject design or well designed between-subjects design (i.e. groups are assessed at baseline on appropriate measures). Poorly covered = case-series, case-control studies; or poorly-designed multiple subject design
Global quality rating		*Based on Hocsis et al 2010, but considering SIGN50 guidelines (maximum score = 26).* 1 = exceptionally high risk of bias 0-3 2 = very high risk of bias 4-7 3 = high risk of bias 8-11 4 = moderately high risk of bias 12-14 5 = moderate risk of bias 15-18 6 = low risk of bias 19-22 7 = exceptionally low risk of bias 23-26

Appendix D

Inter-rater agreement data of three papers independently reviewed

The quality assessment process for all papers was conducted by one reviewer (K.V.). Three papers (Johansson et al., 2012; Johansson et al., 2015; and McMillan et al., 2002) were independently assessed by a second reviewer (a final year Trainee Clinical Psychologist). The two raters then met to discuss any disagreements, which were resolved consensually. Table 9 details the level of agreement between raters. There is also a summary of how disagreements were resolved, and the final rating agreed upon, below.

Agreed final ratings

Johansson et al. (2012)

Reporting bias

Moderate risk of bias was agreed upon for both selective reporting and conclusions made. This was due to the multiple use of statistical analyses, including using between-groups and within-groups analysis for the same concepts, without justification. There was also no correction for multiple analyses. Conclusions drawn were too strong based on the mixed results (e.g. claiming that MBSR improved attention and processing speed, but this was not found for all outcome measures and all statistical analyses).

Johansson et al. (2015)

Attrition bias

High risk of bias was agreed upon, as there was a large difference in attrition between groups (greater than 20%). Then participants with missing data were excluded from analysis, hence a high risk of bias was introduced.

Reporting bias

The conclusions Johansson et al. (2015) claim in the abstract and overall conclusion were deemed too strong based on their design, small sample size and other areas of moderate- high risk of bias. Therefore, it was agreed that moderate risk of bias was introduced when reporting their conclusions.

Other bias

Moderate risk of bias was introduced with regards to fidelity of treatment groups as, although the qualifications of the intervention facilitator are adequate and a detailed description of the intervention is given, there are no adherence measures.

McMillan et al. (2002)

Selection bias

High risk of bias was agreed upon for the screening of the sample as there is no detail regarding the numbers of people screened, included and excluded. The paper states that 145 participants were recruited but there is no detail on how they were screened. The primary author was emailed and they had no further information on this. High risk of bias was agreed upon for allocation concealment as there is no detail on whether participants were concealed to which condition they were allocated to.

Performance bias

It was agreed that there was high risk of bias with regards to blinding of participants and personnel, as there is not enough detail in the paper to ascertain whether participants were blind to condition and the personnel running the groups would have been aware of the study aims.

Detection bias

All assessors were blind to group membership, but the paper does not state whether those analysing results were also blind to this. Therefore, moderate risk of bias was agreed upon.

Reporting bias

This was deemed high risk of bias in relation to selective reporting, as McMillan et al. (2002) did not report what statistical analysis they used to analyse the data. Based on this high risk of bias, conclusions drawn were deemed too strong to be fully justified, hence moderate risk of bias with regards to the conclusions made was agreed upon.

Table 9.

Independent ratings from the two quality raters.

Author & date	Selection bias				Performance bias	Detection bias		Attrition bias	Reporting bias			Other bias		Global risk rating (out of 24)
	Nature of sample	Screening of sample	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Reliable, valid, outcome measures	Incomplete outcome data	Selective reporting	Conclusions reported	Fidelity of treatment groups	Suitability of control group	Study design	
Johansson et al., 2012	Low	Moderate	Low	High	High	High	Low	High	Moderate (Low)	Moderate (Low)	High	Low	Low	Moderately high risk - 13 points
Johansson et al., 2015	Low	Low	High	High	High	High	Low	High (Moderate)	Moderate	Moderate (Low)	Moderate (Low)	Low	Low	Moderately high risk - 13 points
McMillan et al., 2002	Low	High (Moderate)	Low	High (Moderate)	High (Moderate)	Moderate (Low)	Low	Moderate	High (Low)*	Moderate (Low)	Moderate	Low	Low	Moderately high risk - 14 points

Note. High risk of bias = 0 points; moderate risk of bias = 1 points; low risk of bias = 2 points

The independent ratings that differed are shown in brackets. These were then discussed and agreement on the final rating was made by the two raters.

*This is the only rating that had a difference greater than 1 point between raters. In discussions between raters, it was deemed high risk of bias as McMillan et al. (2002) did not report what statistical analysis they used to analyse the data.

Appendix E

Reasons for paper exclusion at detailed screening.

Author	Population (neurodisability)	Reason(s) for exclusion
Azulay, Smart, Mott & Cicerone (2013)	Mild TBI	No control group.
Bedard et al. (2003)	TBI	No outcome measure of cognition.
Bedard et al. (2005)	TBI	One year follow-up of Bedard et al. (2003) and therefore no outcome measure of cognition.
Bedard et al. (2008)	TBI	This was a published poster presentation. After contacting one of the authors, they explained results are published in Bedard et al. (2012).
Bedard et al. (2012)	TBI	No control group and only uses subjective measures of cognition (subscale of Mayo Portland Adaptability Inventory-4).
Bedard et al. (2014)	TBI	No outcome measure of cognition.
Canadé (2014)	ABI / neurological condition	No outcome measure of cognition.
Cole, et al. (2015)	Mild TBI (with comorbid PTSD)	No control group.
Dickinson, Friary & McCann (2016)	Stroke	Single case design that does not meet criteria for a well-designed SCED as outlined by Tate et al. (2013).
Haller, Bosma, Kapur, Zafonte & Langer (2017)	TBI	Design did not meet criteria. Authors looked at the relationship between mindfulness and recovery over time following TBI, rather than comparing results on cognitive measures following a mindfulness intervention compared to control group.
Hofer et al. (2014)	Stroke	No measures of cognition were used and no control group. They investigated the effects of a neuro-psychotherapy program

		that incorporated mindfulness, but this was not the primary intervention.
Johansson, Bjuhr & Rönnenbäck (2013)	Stroke and TBI	No control group.
Kristofersson (2012)	TBI (with comorbid substance misuse)	No control group used and only cognitive outcome was a self-report measure of impulsivity, the Barratt Impulsivity Scale.
Laures-Gore & Shisler Marshall (2016)	Stroke	A case report. Does not meet criteria for a well-designed SCED as outlined by Tate et al. (2013).
Merriman, Walker-Bircham, Easton & Maddicks (2015)	Stroke	No control group. This was a pilot study with four participants.
Mills & Allen (2000)	MS	A subjective measure of cognition was used only: Symptom Rating Questionnaire.
Moustgaard (2005)	Stroke	No control group and only subjective measures of cognition used: part of the Stroke Specific Quality of Life Scale.
Moustgaard, Bedard & Felteau (2007)	Stroke	Published version of Moustgaard (2005) thesis. No control group and only subjective measures of cognition used: part of the Stroke Specific Quality of Life Scale.
Ozen, Dubois, Gibbons, Short, Maxwell & Bedard (2016)	TBI	The paper aimed to determine the clinical significance of individual changes in depression symptoms following mindfulness-based interventions by examining three studies that had previously investigated this. Two were pilot studies and the third a RCT. No outcome measure of cognition included. The paper looks at the BDI-II.
Simpson, Mair & Mercer (2017)	MS	Only subjective measures of cognition are used. Subjective cognitive dysfunction was self-rated by participants using the Perceived Deficits Questionnaire (PDQ). This assesses attention, retrospective memory, prospective memory and planning.

Tan, Dienes, Jansari & Goh (2013)	Neurologically healthy population	Population does not meet criteria.

Appendix F

Reference list of excluded papers after detailed screening.

Azulay, J., Smart, C.M., Mott, T., & Cicerone, K.D. (2013). A pilot study examining the effect of Mindfulness-based Stress Reduction on symptoms of chronic mild traumatic brain injury/ postconcussive syndrome. *Journal of Head Trauma Rehabilitation, 28*(4), 323-331.

Bedard, M., Felteau, M., Gibbons, C., Klein, R., Mazmanian, D., Fedyk, K., & Mack, G. (2005). A Mindfulness-Based Intervention to Improve Quality of Life Among Individuals Who Sustained Traumatic Brain Injuries: One-Year Follow-Up. *Journal of Cognitive Rehabilitation, 23*(1), 8-13.

Bedard, M., Felteau, M., Marshall, S., Cullen, N., Gibbons, C., Dubois, S., Maxwell, H., Weaver, B., Rees, L., Gainer, R., & Mazmanian, D. (2014). Mindfulness-based cognitive therapy reduces depression symptoms in people who have a traumatic brain injury: Results from a randomized controlled trial. *Journal of Head Trauma Rehabilitation, 29*(4), 13-22.

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Appendix G

Confirmation of Research Ethics Committee approval

NHS SCOTLAND
Research Ethics Service

East of Scotland Research Ethics Service (EoSRES)

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

TAyside medical Science Centre
Residency Block Level 3
George Pirie Way
Ninewells Hospital and Medical School
Dundee DD1 9SY

Miss Katrina Vicentijevic
Trainee Clinical Psychologist
University of East Anglia
Faculty of Medicine and Health Sciences
University of East Anglia
Norwich
NR4 7TJ

Date: 30 May 2017
Your Ref:
Our Ref: LR/AG17/ES/0046
Enquiries to: Arlene Grubb
Direct Line: 01382 383848
Email: [redacted]

Dear Miss Vicentijevic

Study title: **The effect of mindfulness on stimulus over-selectivity and selective attention to threat following traumatic brain injury**
REC reference: **17/ES/0046**
IRAS project ID: **213205**

Thank you for your letter of 23 May 2017, responding to the Committee's request for further information on the above research and submitting revised documentation.

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

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Confirmation of ethical opinion

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

Conditions of the favourable opinion

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

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host

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organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

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

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise). Guidance on applying for NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

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

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

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

Registration of Clinical Trials

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

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

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

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

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

Ethical review of research sites

NHS sites

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

Non-NHS sites

I am pleased to confirm that the favourable opinion applies to the following research site(s), subject to site management permission being obtained prior to the start of the study at the site (see under 'Conditions of the favourable opinion below').

Research site	Principal Investigator / Local Collaborator
Grafton Manor	Miss Katrina Vicentijevic
Burton Park	Miss Katrina Vicentijevic
Elm Park	Miss Katrina Vicentijevic
Fen House, Brain Injury Rehabilitation Trust (BIRT)	Miss Katrina Vicentijevic
Headway Cambridgeshire	Miss Katrina Vicentijevic
Headway Norfolk and Waveney	Miss Katrina Vicentijevic
St Andrew's Northampton	Miss Katrina Vicentijevic
Headway Essex	Miss Katrina Vicentijevic
Livability, Icanho	Miss Katrina Vicentijevic

Approved documents

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

Document	Version	Date
Covering letter on headed paper [Addressed REC feedback]	1	23 May 2017
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance and Indemnity letter]		15 March 2017
GP/consultant information sheets or letters [GP letter]	1	16 November 2016
GP/consultant information sheets or letters [GP letter]	1	23 May 2017
IRAS Application Form [IRAS_Form_07042017]		07 April 2017
IRAS Application Form XML file [IRAS_Form_07042017]		07 April 2017
IRAS Checklist XML [Checklist_07042017]		07 April 2017
IRAS Checklist XML [Checklist_25052017]		25 May 2017
Other [Consent form for researcher to contact participant]	3	16 November 2016
Other [Feedback on research proposal]		07 July 2016
Other [Assessment feedback and how it was addressed]	1	16 November 2016
Other [Emotional Stroop words]	1	16 November 2016
Other [Intervention exercises]	2	16 November 2016
Other [HRA schedule of events]		
Other [HRA statement of activities]		
Other [Consent form for researcher to contact participant]	4	23 May 2017
Other [HRA schedule of events]	2	23 May 2017
Other [HRA statement of activities]	2	23 May 2017
Other [Research project proposal]	4	23 May 2017
Other [Mindfulness information sheet]	1	23 May 2017
Other [Clinician recruitment handout]	2	23 May 2017
Participant consent form [Participant consent form]	3	16 November 2016
Participant consent form [Participant consent form]	4	23 May 2017
Participant information sheet (PIS) [Participant Information Sheet]	3	16 November 2016

Participant information sheet (PIS) [Participant Information Sheet]	4	23 May 2017
Research protocol or project proposal [Research project proposal]	3	16 November 2016
Response to Request for Further Information		23 May 2017
Summary CV for Chief Investigator (CI) [CI research CV]		05 August 2016
Summary CV for student [Student CV]		05 August 2016
Summary CV for supervisor (student research) [Supervisor CV]		08 August 2016
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Sequence of events]	1	16 November 2016
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Sequence of events]	2	23 May 2017
Validated questionnaire [HADS questionnaire]	1	16 November 2016
Validated questionnaire [The Five Facet Mindfulness Questionnaire]	1	16 November 2016

Statement of compliance

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

After ethical review

Reporting requirements

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

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

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

User Feedback

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

HRA Training

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

17/ES/0046	Please quote this number on all correspondence

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

Yours sincerely

Arlene Grubb
Assistant Co-ordinator

Email: eosres.tayside@nhs.net

Enclosures: "After ethical review – guidance for researchers" [SL-AR2]

Copy to: Mrs Tracy Moulton
Mrs Vivienne Shaw, Cambridgeshire Community Services NHS Trust

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Appendix H

Confirmation of Health Research Authority Approval

NHS
Health Research Authority

Miss Katrina Vicentijevic
Trainee Clinical Psychologist
University of East Anglia
Faculty of Medicine and Health Sciences
University of East Anglia
Norwich
NR4 7TJ

Email: hra.approval@nhs.net

31 May 2017

Dear Miss Vicentijevic

Letter of HRA Approval

Study title:	**The effect of mindfulness on stimulus over-selectivity and selective attention to threat following traumatic brain injury**
IRAS project ID:	**213205**
REC reference:	**17/ES/0046**
Sponsor	**University of East Anglia**

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

Participation of NHS Organisations in England

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

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

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

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

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

Appendices

The HRA Approval letter contains the following appendices:

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

After HRA Approval

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

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

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

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

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

Scope

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

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

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

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application

procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/.

HRA Training

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

Your IRAS project ID is **213205**. Please quote this on all correspondence.

Yours sincerely

Isobel Lyle | Senior Assessor
Health Research Authority
Room 002, TEDCO Business Centre, Rolling Mill Rd, Jarrow NE32 3DT
Hra.approval@nhs.net or Isobel.lyle@nhs.net
T: 0207 972 2496
www.hra.nhs.uk

Copy to: *Mrs Tracy Moulton, Sponsor contact, University of East Anglia*
Mrs Vivienne Shaw, R&D contact, Cambridgeshire Community Services NHS Trust

Appendix A - List of Documents

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

Document	Version	Date
Covering letter on headed paper [Addressed REC feedback]	1	23 May 2017
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance and Indemnity letter]		15 March 2017
GP/consultant information sheets or letters [GP letter]	1	23 May 2017
GP/consultant information sheets or letters [GP letter]	1	16 November 2016
IRAS Application Form [IRAS_Form_07042017]		07 April 2017
Other [Clinician recruitment handout]	2	23 May 2017
Other [Consent form for researcher to contact participant]	3	16 November 2016
Other [Feedback on research proposal]		07 July 2016
Other [Assessment feedback and how it was addressed]	1	16 November 2016
Other [Emotional Stroop words]	1	16 November 2016
Other [Intervention exercises]	2	16 November 2016
Other [Statement of Activities HRA Assessed 28 April 2017]	2.0	07 April 2017
Other [Schedule of Events HRA assessed 28 April 2017]	2.0	07 April 2017
Other [Consent form for researcher to contact participant]	4	23 May 2017
Other [HRA schedule of events]	2	23 May 2017
Other [HRA statement of activities]	2	23 May 2017
Other [Research project proposal]	4	23 May 2017
Other [Mindfulness information sheet]	1	23 May 2017
Participant consent form [Participant consent form]	3	16 November 2016
Participant consent form [Participant consent form]	4	23 May 2017
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Participant information sheet (PIS) [Participant Information Sheet]	3	16 November 2016
Research protocol or project proposal [Research project proposal]	3	16 November 2016
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Summary CV for student [Student CV]		05 August 2016
Summary CV for supervisor (student research) [Supervisor CV]		08 August 2016
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Sequence of events]	2	23 May 2017
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Sequence of events]	1	16 November 2016
Validated questionnaire [HADS questionnaire]	1	16 November 2016
Validated questionnaire [The Five Facet Mindfulness Questionnaire]	1	16 November 2016
213205 17-ES-0046 Favourable Opinion 30-5-2017		30 May 2017

IRAS project ID	213205

Appendix B - Summary of HRA Assessment

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

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

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

Name: Tracy Molton
Email: researchsponsor@uea.ac.uk

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards?	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	No comments
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	A statement of Activities has been provided as an Agreement between the Sponsor and participating NHS organisation. The Sponsor is not requesting and does not expect any other site agreement.
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the

Section	HRA Assessment Criteria	Compliant with Standards?	Comments
			activities expected of them for this research study
4.3	Financial arrangements assessed	Yes	No application for funding is being made and no funding is being provided to participating NHS organisations
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	No comments
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.
There is one site 'type' for this study and participating NHS organisations are being asked to support the study by acting as a Participant Identification Centres. There may also be a requirement to use NHS premises to meet with participants depending on their choice of location. The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. If Chief Investigators, sponsors or Principal Investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the Chief Investigator, sponsor or Principal Investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.
Participating NHS organisations in England **will be expected to formally confirm their capacity and capability** to host this research. • The sponsor should ensure that participating NHS organisations are provided with a copy of this letter and all relevant study documentation, and work jointly with NHS organisations to arrange capacity and capability whilst the HRA assessment is ongoing. • Further detail on how capacity and capability will be confirmed by participating NHS organisations, following issue of the Letter of HRA Approval, is provided in the *Participating NHS Organisations* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections of this appendix. • The Assessing, Arranging, and Confirming document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

Principal Investigator Suitability

This confirms whether the sponsor's position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England, and the minimum expectations for education, training and experience that PIs should meet (where applicable).
This is an educational study and the student is the CI with appropriate academic supervision. The central study team will undertake all research activities and there is no need for a Local Collaborator or a PI at each site. (source: Statement of Activities V2.0) GCP training is not a generic training expectation, in line with the HRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken.
For research team members not substantively employed by the organisation in which the research is taking place and administering questionnaires or surveys, a Letter of Access based on standard DBS checks and occupational health clearance would be appropriate.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England in study set-up.
The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.

Appendix I

Local R&D confirmations of capacity and capability and letters of access

Dear Sponsor Representative / Chief Investigator

RE: 2017GC09. IRAS 213205. Confirmation of Capacity and Capability at Norfolk Community Health and Care NHS Trust

Full Study Title: The effect of mindfulness on cognition and emotion following Traumatic Brain Injury

This email confirms that Norfolk Community Health and Care NHS Trust has the capacity and capability to deliver the above referenced study. Please find attached our agreed Statement of Activities as confirmation.

We agree to start this study on a date to be agreed when you as sponsor give the green light to begin.
If you have any queries, please do not hesitate to contact the R&D
Office snccg.RandDoffice@nhs.net.

Kind regards

Clare Symms
Research Management and Finance Lead, Norfolk & Suffolk Primary and Community Care Research Office on behalf of Norfolk Community Health and Care (NCH&C)

Cc: Lesley Maloney, Research Manager, NCH&C

Hi Katrina

Thank you forwarding the HRA Approval and study documentation. Have you also shared with Lesley?

In the case of NCH&C, a letter of access would not be required as there are existing arrangements in place between UEA and NCH&C to cover trainee clinical psychologists undertaking placements / research.

I'll now get in touch with Lesley to check on the assessment of capacity and capability needs, as confirmation by the site is required.

Best wishes
Helen

Helen Sutherland
Research & Development Officer

Norfolk & Suffolk Primary & Community Care Research Office
Hosted by South Norfolk CCG
Lakeside 400, Old Chapel Way, Broadland Business Park, Thorpe St Andrew, Norwich, NR7 0WG
Switchboard - 01603 257000
Direct Dial - 01603 257083
Fax - 01603 257292

E-mail: helen.sutherland6@nhs.net
Team email: snccg.RandDoffice@nhs.net
Website: http://nspccro.nihr.ac.uk

Please note my working hours are Tues-Fri 09.15-15.15.

The Norfolk & Suffolk Primary & Community Care Research Office, hosted by South Norfolk CCG, undertakes research management, design and delivery services for Primary and Community Care across Norfolk & Suffolk.

Before printing, think about the environment

RE: IRAS 213205 Confirmation of Capacity and Capability at Northamptonshire Healthcare NHS Foundation Trust.

Full Study Title: The effect of mindfulness on stimulus over-selectivity and selective attention to threat following traumatic brain injury

This email confirms that Northamptonshire Healthcare NHS Foundation Trust has the capacity and capability to deliver the above referenced study in accordance with the Statement of Activity & Schedule of Events and Protocol provided. The research must be conducted in line with the Protocol and fulfil any contractual obligations agreed. If you identify any issues during the course of your research that are likely to affect these obligations you must contact the R&I Office as soon as possible.

Please note that you may need to wait to start recruitment until your Sponsor issues a Green Light to commence. You must liaise with your Sponsor to confirm agreement that you may begin recruitment activity. If your sponsor is not copied into this email please ensure you forward for their records.

If you wish to discuss further, please do not hesitate to contact me

regards

Sue

Sue Palmer Hill, RGN, MSc
Head of Innovation Research and Clinical Effectiveness
Medical Directorate
Northamptonshire Healthcare NHS Foundation Trust
Berrywood Hospital
Northampton
NN5 6UD

sue.palmer-hill@nhft.nhs.uk
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Northamptonshire Healthcare NHS
NHS Foundation Trust

Medical Director: Dr Alex O'Neill-Kerr
Head of R&I: Sue Palmer-Hill

Research & Innovations Service
Berrywood Hospital
Berrywood Drive
Duston
Northampton, NN5 6UD

Tel: 01604 685527
Web: www.nhft.nhs.uk
Email:R&I@nhft.nhs.uk

Katrina Vicentijevic
Trainee Clinical Psychologist
Department of Cultural Psychology
Facility of Medicine & Health Sciences
University of East Anglia
Norwich
NR4 7TJ

IRAS Ref: 213205

REC Ref: 17/ES/0046

End Date: 30/09/2018

Approval date: 08/06/2017

Dear Katrina

Re: The effect of mindfulness on stimulus over-selectivity & selective attention to threat following traumatic brain injury

This letter confirms your right of access to conduct research through Northamptonshire Research & Innovations Service (Northamptonshire R&I Service) for the purpose and on the terms and conditions set out below.

This right of access commences on **June 8th 2017** and ends on **September 30th 2018**, unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this NHS organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving permission to conduct the project.

The information supplied about your role in research at Northamptonshire R&I Service has been reviewed and you do not require an honorary research contract with this NHS organisation. We are satisfied that such pre-engagement checks as we consider necessary have been carried out.

The documents reviewed for this letter of access assurance were:

Title	Version	Date
Signed CV	**N/A**	**05/08/2016**
Letter of Confirmation	**N/A**	**19/04/2018**
NHS to NHS Proforma	**N/A**	**30/09/2018**

You are considered to be a legal visitor to Northamptonshire R&I Service premises. You are not entitled to any form of payment or access to other benefits provided by this NHS organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee; Nor does this grant permission for you or your research team to access any patient data at practice level. The responsibility for this rests entirely with the practice, as the data controller for all patients registered with that practice.

While undertaking research through Northamptonshire R&I Service, you will remain accountable to your employer, **Cambridge & Peterborough NHS Foundation Trust**, but you are required to follow the reasonable instructions of **Sue Palmer-Hill** in this NHS organisation or those given on her behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with Northamptonshire R&I Service policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with Northamptonshire R&I Service in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on NHS premises. You must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other contract holder and you must act appropriately, responsibly and professionally at all times.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf) and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that this NHS organisation accepts no responsibility for damage to or loss of personal property.

We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence. As from 26 July 2010, your HEI employer may initiate your Independent Safeguarding Authority (IISA) registration (where applicable), and thereafter, will continue to monitor your ISA registration status via the on-line ISA service. Should you cease to be ISA-registered, this letter of access is immediately terminated. Your employer will immediately withdraw you from undertaking this or any other regulated activity. You MUST stop undertaking any regulated activity.

Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

Northamptonshire R&I Service will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

If your current role or involvement in research changes, or any of the information provided in your Research Passport changes, you must inform your employer through their normal procedures. You must also inform your nominated manager in this NHS organisation.

Yours sincerely

Sue Palmer-Hill
Head of Research and Innovation

Email thread:

Hi Katrina,

The agreement email from Andrew should act as a trigger that you are able to start at CCS. Our office does not cover CPFT so you will need to liaise with Katie Keating-Fedders regarding CPFT participation.

Best wishes
Alex

Alexander Phillips, Research Management & Governance Support Officer, NHS Cambridgeshire and Peterborough CCG, Lockton House, Clarendon Road, Cambridge, CB2 8FH, Tel: 01223 725469

Alexander.Phillips3@nhs.net

[www.crn.nihr.ac.uk/eastern]**www.crn.nihr.ac.uk/eastern**
https://sites.google.com/a/nihr.ac.uk/camstrad/

Primary and Community Care RMG Centre providing services on behalf of NHS Bedfordshire, Cambridgeshire Community Services, NHS Peterborough, and NHS Cambridgeshire

This message may contain confidential and privileged information. If you are not the intended recipient please accept our apologies. Please do not disclose, copy, or distribute information in this e-mail or take any action in reliance on its contents. To do so is strictly prohibited and may be unlawful. Please inform us that this message has gone astray before deleting it. Thank you for your co-operation

Katrina Vicentijevic (MED) <K.Vicentijevic@uea.ac.uk>

Wed 28/06/2017, 12:02

Hi Alex Do I need anything that officially says I am OK to start recruitment? Or anything that says officially that CPFT has the capacity and capability to act as a participant identification site? Thank you Katrina

PHILLIPS, Alexander (NHS CAMBRIDGESHIRE AND PETERBOROUGH CCG)

Wed 28/06/2017, 09:34

Hi Katrina,

Thanks for letting me know – wishing you the best on your study.

Best wishes
Alex

Alexander Phillips, Research Management & Governance Support Officer, NHS Cambridgeshire and Peterborough CCG, Lockton House, Clarendon Road, Cambridge, CB2 8FH, Tel: 01223 725469

Alexander.Phillips3@nhs.net

[www.crn.nihr.ac.uk/eastern]**www.crn.nihr.ac.uk/eastern**
https://sites.google.com/a/nihr.ac.uk/camstrad/

Primary and Community Care RMG Centre providing services on behalf of NHS Bedfordshire, Cambridgeshire Community Services, NHS Peterborough, and NHS Cambridgeshire

This message may contain confidential and privileged information. If you are not the intended recipient please accept our apologies. Please do not disclose, copy, or distribute information in this e-mail or take any action in reliance on its contents. To do so is strictly prohibited and may be unlawful. Please inform us that this message has gone astray before deleting it. Thank you for your co-operation

Thu 22/06/2017, 15:52

Hi Alex

The service lead has replied to my email and has approved CCS as a participant identification centre (please see below). You can see I sent him the SoA on 15th June.

If you need anything else then please let me know.

Thank you

Katrina

Cambridgeshire Community Services NHS
NHS Trust

1st June 2017

University of East Anglia
Department of clinical Psychology
Faculty of Medicine and Health Sciences
Norwich
NR4 7TJ

C/o RMG Office
NHS Cambridgeshire
Lockton House
Clarendon Road
Cambridge
Cambs
CB2 8FH

Dear Katrina,

Letter of access for research: Project specific- L01606- The effect of mindfulness on cognition and emotion following TBI

This letter confirms your right of access to conduct research through Cambridgeshire Community Services NHS Trust the purpose and on the terms and conditions set out below. This right of access commences on 01.06.17 and ends on 30.09.18 unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the HRA approval application to this NHS organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received a confirmation email from the relevant CCS NHST department.

The information supplied about your role in research at Cambridgeshire Community Services NHS Trust has been reviewed and you do not require an honorary research contract with this NHS organisation. We are satisfied that such pre-engagement checks as we consider necessary have been carried out.

You are considered to be a legal visitor to Cambridgeshire Community Services NHS Trust premises. You are not entitled to any form of payment or access to other benefits provided by this NHS organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through Cambridgeshire Community Services NHS Trust you will remain accountable to your employer, **University of East Anglia**, but you are required to follow the reasonable instructions of your CCS NHST nominated manager Andrew Bateman, Dr David Vickers, Medical Director, in this NHS organisation or those given on his behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with Cambridgeshire Community Services NHS Trust policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with Cambridgeshire Community Services NHS Trust in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on Cambridgeshire Community Services NHS Trust premises. You must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other contract holder and you must act appropriately, responsibly and professionally at all times.

If you have a physical or mental health condition or disability which may affect your research role and which might require special adjustments to your role, if you have not already done so you must notify your employer and your Trust manager prior to commencing your research role at the Trust.

You are required to ensure that all information regarding patients or staff remains **secure and strictly confidential at all times**. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf) and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that this NHS organisation accepts no responsibility for damage to or loss of personal property.

We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence.

You must not undertake regulated activity if you are barred from such work. If you are barred from working with adults or children this letter of access is immediately terminated. Your employer will immediately withdraw you from undertaking this or any other regulated activity and you **MUST** stop undertaking any regulated activity immediately.

Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

Cambridgeshire Community Services NHS Trust will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

If your current role or involvement in research changes, or any of the information provided in your Research Passport changes, you must inform your employer through their normal procedures. You must also inform your nominated manager in this NHS organisation.

Yours sincerely

Dr David Vickers
Medical Director
Cambridgeshire Community Services NHS Trust

cc: Vivienne Shaw CRN RMG Manager, RMG office, Lockton House, Clarendon Road Cambridge CB2 8FH

Cambridgeshire and Peterborough NHS
NHS Foundation Trust

Understanding mental health, understanding people
Research and Development Department

18/7/17

R&D Ref: M00821

Charlie Dorer
Clinical Manager Neuro Rehabilitation
Elizabeth House, Fulbourn Hospital,
Cambridge CB21 5EF

Joint Research Office
Box 277
Addenbrooke's Hospital
Hills Road
Cambridge
CB2 0QQ

Direct Dial: 01223 596371 ext 6371
E-mail: jane.ceffa
www.cpft.nhs.uk

Dear Dr Dorer,

Re: 17/ES/0046 The effect of mindfulness on stimulus over-selectivity and selective attention to threat following traumatic brain injury

In accordance with the Department of Health's Research Governance Framework for Health and Social Care, all research projects taking place within the Trust must receive a favourable opinion from an ethics committee and approval from the Department of Research and Development (R&D) prior to commencement.

I am pleased to confirm that Cambridgeshire and Peterborough NHS Foundation Trust has reviewed the above study and agree to act as a **Participant Identification Centre (PIC)** referring potential participants to the relevant research teams based in the University of East Anglia

Please note that as a PIC the Trust does not provide indemnity for this study.

Sponsor: UEA

Funder: UEA

End date: 3/01/2018

Protocol: Version 4 dated 19/5/17

The project must follow the agreed protocol and be conducted in accordance with all Trust Policies and Procedures especially those relating to research and data management.

Please ensure that you are aware of your responsibilities in relation to The Data Protection Act 1998, NHS Confidentiality Code of Practice, NHS Caldicott Report and Caldicott Guardians, the Human Tissue Act 2004, Good Clinical Practice, the NHS Research Governance Framework for Health and Social Care, Second Edition April 2005 and any further legislation released during the time of this study.

Members of the research team must have appropriate substantive or honorary contracts with the Trust prior to the study commencing. Any additional researchers who join the study at a later stage must also hold a suitable contract.

If the project is a clinical trial under the European Union Clinical Trials Directive the following must also be complied with:

- the EU Directive on Clinical Trials (Directive 2001/20/EC) and UK's implementation of the Directive: The Medicines for Human Use (Clinical Trials) Regulations 2004;
- the EU Directive on Principles and Guidelines for Good Clinical Practice (EU Commission Directive 2005/28/EC); and UK's implementation of the Directive: The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006;

Amendments

Please ensure that you submit a copy of any amendments made to this study to the R&D Department.

Annual Report

It is obligatory that an annual report is submitted by the Chief Investigator to the research ethics committee, and we ask that a copy is sent to the R&D Department. The yearly period commences from the date of receiving a favourable opinion from the ethics committee.

Please refer to our website www.cpft.nhs.uk for all information relating to R&D including honorary contract forms, policies and procedures and data protection.

Should you require any further information please do not hesitate to contact us.

Yours sincerely

Stephen Kelleher
Senior R&D Manager
Cambridgeshire and Peterborough NHS Foundation Trust

Appendix J

The modified Williams and Penman (2011) mindfulness exercise script

Create a breathing space. Sit up straight in your chair, relax your shoulders, place your hands in your lap and your feet on the floor. Make sure you are comfortable. Perhaps closing the eyes if that's possible.

And beginning step one, by seeing what's going on in your mind and body right now. What thoughts are around? What feelings or emotions are here? Any feelings in the body?

You are not trying to change anything but be open to what is already here.

Then moving to step two, bringing the attention to the breath. Focus your attention on the sensations of the breath in the stomach, focus your attention on the changing physical sensations of the in-breath for its full length and the outbreath for its full length.

And if the mind wanders, simply notice where it went and gently bring it back to the breath.

And now step three, bring the focus of your attention around the breath to take in the whole body, as if the whole body were breathing now. Be aware of how you are sat, your facial expression, feelings on the surface of the skin and from right inside the body.

Now your attention is on all of the sensations in your body right now, just as they are. Be aware of the feelings in the body. Be aware of this moment now.

Appendix K

List of words used in the emotional Stroop

Negative Evaluation (and paired neutral words)		Physical Threat (and paired neutral words)	
STUPID	BARREL	INJURY	SILVER
MOCKED	BANNER	DISEASE	VERSION
FOOLISH	GRADUAL	LETHAL	MARROW
EMBARRASSED	TRANSFORMED	CANCER	SADDLE
FAILURE	BALANCE	PAIN	BANK
DISGRACED	WAREHOUSE	AMBULANCE	FLOWERING
PATHETIC	EXTERIOR	DEADLY	LADDER
INFERIOR	INVENTOR	ILLNESS	MUSTARD
WORTHLESS	CULTIVATE	EMERGENCY	FURNITURE
RIDICULED	PICTORAL	VIOLENCE	CREATION
INEPT	PURGE	DOCTOR	CATTLE
CRITICISED	INGREDIENT	COFFIN	ROCKET
INADEQUATE	LOCOMOTION	STROKE	STRING
ASHAMED	ORCHARD	FATAL	PERCH
HUMILIATED	MINIATURES	HOSPITAL	NUTSHELL
INCOMPETENT	MANUFACTURE	CORONARY	SNAPSHOT

Appendix L

Participant information sheet

Can managing attention a certain way help with attention and emotion difficulties after a brain injury?

University of East Anglia

Invitation and summary

My name is Katrina Vicentijevic and I am required to do a project as part of my university course. I would like to invite you to take part in the following study.

Before you decide if you want to take part, I need to be sure that you understand why I am doing the project and what you would need to do. So, I am giving you the information below. Please read it carefully and be sure to ask any questions you might have. You can also discuss it with your friends and family if you want to. I will do my best to explain the project to you. I will provide you with any more information you may ask for later.

This research study aims to answer the question: does the way people with a brain injury manage their attention help with attention and emotion difficulties? Participants in this study will be people who have a brain injury and have some difficulties with emotions.

What will happen?

The diagram on the next page shows you the order of events in the research study.

This is a diagram showing you the order of events, tasks and exercises in the study.

1. A member of your care team gives you this information sheet and asks if it is OK if the researcher contact you.

↓

2. The researcher will ring or email you. They will give you more information. You can ask them any questions you may have. Or you can get your clinician to ask the researcher any questions for you if you would rather.

↓

3. The researcher will arrange to meet you in person. You can choose this to be at your house or in a clinic room where you would normally see someone from your care team. If you want to take part, you will sign a consent form.

↓

4. You will then complete part 1 of the study - a mood questionnaire and a mindfulness questionnaire. You will also complete two tasks looking at attention and a task that will guess your reading ability before your brain injury.

↓

5. You can choose to carry on with part 2 in the same visit or stop here and book in another visit with the researcher.

↓

6. Part 2 of the study. You will complete an attention task and an emotion task on a computer. You will then do a 10-minute exercise – you will listen to a tape and be asked to focus your attention on your breath or let your mind wander. You will then complete the attention and emotion task on the computer again.

↓

7. This is the end of the study. You will be asked for some feedback on how you found the study and you can ask the researcher any questions you may have. You will also be asked if you want a copy of the study's findings. This will be posted to you at a later date.

More information on what will happen

The research will take place over 1 or 2 visits. The number of visits is your choice. You also have the choice of the research happening at your home or in a local clinic room, e.g. where you would normally see a member of your care team.

You are welcome to invite a friend or family member to the first session if you would like some support with asking the researcher questions or the consent process. But once the study tasks and questionnaires begin then the researcher requires that friends and family are not present, as this may affect your scores on tasks.

The whole study will take 2 hours to complete at most. You can take breaks between tasks. But you are unable to take a break during a task, as it may affect your scores on the tasks.

Some information about you and your brain injury will need to be collected for the study. This will be taken from one of your recent medical reports. The information that will be taken from the report is: your age, education background, your age when you had your brain injury, the severity of your brain injury, time since your injury and which brain areas are damaged.

What questionnaires and tasks will I be asked to do?

There are 2 parts to the study:

Part one:

Part 1 will take around 50-60 minutes in total. You can take a break after each task or questionnaire if you need one.

1) You will complete a questionnaire that looks at your mood. It will take about 10 minutes.

2) You will complete a questionnaire on how mindful you are about things. It also has questions about your attention. It will take about 15 minutes to do.

3) You will complete 2 tasks which will look at attention. This involves counting sounds. This will take around 15 minutes.

4) The final task will guess your reading ability before your brain injury. You will be asked to read 50 words out loud. This will take about 10 minutes.

Part two:

The second part will take around 60 minutes.

1) You will complete 2 tasks:

- Attention task. This has 2 parts:
    - Memory part – remembering where some shapes are in a square. This will take about 5 minutes.
    - Attention part – clicking symbols on a computer screen. This will take about 10 minutes.
- Emotion task – naming colours of words as quickly as you can. This will take about 10 minutes.

2) You will either do a 10-minute exercise that asks you to focus your attention on your breathing **or** a 10-minute exercise which asks you to let your mind wander on anything of your choice.

3) You will complete the same memory, attention and emotion task.

If you choose to do the whole study in 1 visit, but then decide it is too much and you want to split it into 2 then that is OK. You are able to do this at the half way point. You cannot do this once you have started “part 2” as it would affect results.

If you chose to do the study in 2 visits and then change your mind and would rather do it in 1, that is also OK.

Decision to take part

You can decide to take part in the research or not. Your choice will not affect your care or treatment in any way.

If you are interested in finding out more about the study, then a member of your care team will ask you if it’s OK if the researcher contact you by phone or email. You will need to sign a form to say this is OK. The researcher will then contact you. You can then get

more information and ask any questions. You can ask a member of your care team to ask the researcher any questions if you would rather.

If you would still like to take part after this, then the researcher will arrange to meet you in person. If you decide to take part, you will need to sign another form to consent to this at this meeting. You will then start part 1 of the study straight away.

When the researcher meets with you, they may tell you that you don't meet criteria for the study. This is unlikely to happen, but it is possible. This will mean you cannot take part.

If you do take part then your GP will be informed by letter. Your care team will also be told.

What are the possible benefits of taking part?

You will have the option to get a summary of the study's findings once all data is collected. This will be sent to you at an address of your choice. This could be up to 10 months after you have completed the research study. Records of the address will be destroyed once this has been posted.

Taking part in this study will not improve your attention or how you are feeling. But it could help to improve treatment for attention and emotion difficulties for you or others in the future.

What are the possible disadvantages?

You may find some of the tasks difficult. The emotion task involves reading words that have an emotional meaning. Risk of distress is low but could happen when reading some of the words. You will be able to talk to the researcher or a member of your care team about any distress you may feel. You are also able to withdraw from the study at any point up until data has been analysed. You do not need to give a reason.

Will my personal details remain confidential?

Only the researcher and their supervisor will have access to your personal details. Any personal information will be stored on a

password protected memory stick. This will be kept separate to data collected for the study. All data from the questionnaires and the tasks will be made anonymous using a code. Any paper documents of these will be kept anonymous and in a locked draw at the University of East Anglia. Study findings may be published but you will not be identified. All data will be destroyed after 10 years.

By agreeing to take part and signing the consent form, you are agreeing for the researcher to have the following details from a medical report:

- Your name, gender and age
- The severity and details of your brain injury
- How long ago your brain injury was
- How old you were when you had your brain injury

During the research study, if you do or say anything to indicate that yourself or others are a risk, or the mood questionnaire shows you have high levels of anxiety or depression, then the researcher will need to tell a member of your care team. You will be told if this needs to happen.

What happens with the study results?

The researcher aims to use results to write a published paper in an academic journal. This will also be submitted to UEA for part of their university course. Results will also be published online and presented at a conference. No identifiable information of participants will be used.

What if I change my mind?

You can withdraw from the study at any point up until data has been analysed. Anything that contains your information will be destroyed. You do not need to give a reason. This will not affect your care in any way. You can withdraw by contacting the researcher by email or telephone on the contact details below.

Who is doing the research?

The researcher is Katrina Vicentijevic, a Trainee Clinical Psychologist from the University of East Anglia. This research

project is part of their Clinical Psychology Doctorate course. The project is being supervised by Dr. Fergus Gracey, a Clinical Neuropsychologist and Senior Research Fellow at the University, and by Dr. Nao Kishita, a Senior Post-Doctoral Research Associate at the University.

If you would like to know more, contact Katrina Vicentijevic or Fergus Gracey on the details below.

Research team contact details

Katrina Vicentijevic
Department of Clinical Psychology
Faculty of Medicine and Health Sciences
University of East Anglia
NORWICH NR4 7TJ
Email: k.vicentijevic@uea.ac.uk & Telephone: (number inserted)

Dr. Fergus Gracey
Department of Clinical Psychology
Faculty of Medicine and Health Sciences
University of East Anglia
NORWICH NR4 7TJ
Email: f.gracey@uea.ac.uk & Telephone: 01603 592898

What if I have a concern or complaint?

If you believe that you have been harmed in any way by taking part in this study, then you have the right to make a complaint and seek any resulting compensation through the University of East Anglia. The university are acting as the research sponsor. Details about this are available from the researcher or their supervisor. You can also contact Professor Ken Laidlaw, Head of Department of the Clinical Psychology Doctoral Programme at UEA.

Professor Ken Laidlaw
Head of Department
Department of Clinical Psychology
Faculty of Medicine and Health Sciences
University of East Anglia
NORWICH NR4 7TJ
Email: k.laidlaw@uea.ac.uk & Telephone: 01603 593600

As a patient of the NHS, you also have the right to pursue a complaint through the usual NHS process. To do so, you can submit a written complaint to the Patient Liaison Manager, Complaints Office << insert address (dependent on which service participant is a client at) >> (Free phone ……). Note that the NHS has no legal liability for non-negligent harm. However, if you are harmed and this is due to someone's negligence, you may have grounds for a legal action against NHS << insert name of Health Board/ Trust>> but you may have to pay your legal costs.

Who has reviewed the study?

The East of Scotland Research Ethics Service REC1 has responsibility for scrutinising all proposals for research on humans in Tayside. It has examined the proposal and has not raised any objections from the point of view of research ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for inspection by monitors from the University of East Anglia and NHS <<insert name of Health Board/ Trust (dependent on which service participant is a client at)>>. Their role is to check that research is properly conducted and the interests of those taking part are protected.

What to do now

It is recommended you talk about all the information here with a family member or friend before making your decision.

If you would like to find out more about the study from the researcher, then let a member of your care team know and sign the consent to contact form. The researcher will then contact you on the contact details you provide. Or you can ask a member of your care team to ask the researcher any questions for you.

Thank you for taking the time to read this information and to consider taking part in this study.

Appendix M

Consent to contact form

Consent form for researcher to contact participant

Title of project: Can managing attention a certain way help with attention and emotion difficulties after a brain injury?

Name of researcher: Katrina Vicentijevic

	Please initial
I confirm that a member of my care team can pass on my contact details to the researcher.	☐
I confirm that they can pass on my telephone number	☐
I confirm that they can pass on my email address	☐
I confirm that I understand that the researcher will contact me on the contact details I provide to talk to me	☐
I would like a member of my clinical team to contact the researcher on my behalf	☐
I understand that this does not mean I have to take part in the study	☐

Name of participant	Date	Signature
Name of person taking consent	Date	Signature

A copy of this form will be stored in a locked draw at the University of East Anglia, a copy will go in your patient records and you will keep a copy yourself.

Appendix N

Consent to take part in research form

Participant consent form to take part in research

Title of project: Can managing attention a certain way help with attention and emotion difficulties after a brain injury?

Name of researcher: Katrina Vicentijevic **Please initial**

I confirm that I have read the participant information sheet dated..... (version.....) for the above study. I have been able to consider the information and ask questions that have been answered acceptably. ☐

I understand that my participation is voluntary and that I am free to withdraw at any time, before data is analysed. I can do so without giving any reason. I know that my medical care or legal rights will not be affected. ☐

I understand that the researcher will have access to a recent medical report of mine during the study. I give permission for the researcher to have access to this. I know they will collect the following information: ☐

- My name, gender and age
- The severity and details of my brain injury
- How long ago my brain injury was
- How old I was when I had my brain injury

I understand that information about me will be kept anonymous. I understand that this may need to be broken if the researcher thinks I am at risk to myself or others, or if the study shows I have high levels of anxiety or depression. I understand that this information may be shared with my care team and GP. I understand that the researcher would discuss this with me before doing so. ☐

I understand that the researcher will let my GP know by letter that I am taking part in this study. My care team will also be told. ☐

I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

A copy of this form will be stored in a locked draw at the University of East Anglia, a copy will go in your patient records and you will keep a copy yourself.

Appendix O

Information given to participants on mindfulness

Mindfulness Resources

Mindfulness is one way of managing your attention. This research study is looking into whether mindfulness can help people with a brain injury
with attention and emotion difficulties. Mindfulness involves paying attention to what is happening in the here and now, in a non-judgemental way.

Mindfulness has been found to help people with their attention and emotion problems. But it is unclear if it can also help those with a brain injury. Future research is needed to explore this.

If you would like to find out more about mindfulness then here are some resources you can look at:

NHS website which introduces mindfulness:

http://www.nhs.uk/conditions/stress-anxiety-depression/pages/mindfulness.aspx

The NHS website recommends another website for more information. There are also details of recommended online courses and mindfulness teachers on:

http://bemindful.co.uk/

This website only lists teachers who follow the Good Practice Guidelines. These were developed by the UK Network of Mindfulness-based Teacher Training organisations.

The ‘bemindful’ website also recommends the following book for mindfulness beginners:

Mindfulness: A practical guide to finding peace in a frantic world – by Mark Williams and Danny Penman (2011). This also includes a CD of guided meditations.