

**A Comparison of the Effect of Relaxation and Focused Attention on Implicit Memory in
People with Acquired Brain Injury**

By

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**A Thesis Submitted to the University of Birmingham for the Partial Fulfilment of Degree of
Doctor of Clinical Psychology**

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Overview

This thesis is submitted in partial fulfilment of the requirements for the degree of Doctor of Clinical Psychology (Clin.Psy.D).

Volume I: Research Component

Volume I consists of three papers; a systematic literature review, empirical research paper, and public domain briefing. The systematic review concluded there is emerging evidence demonstrating that mindfulness can improve certain memory functions, but further, high quality research studies are required in order to make these findings more valid and reliable. The research paper presents a study exploring the relationship between relaxation and implicit memory in individuals with acquired brain injury. The results suggest that relaxation enhances implicit memory, particularly for priming effects, and may have clinical implications for individuals with acquired brain injuries. The public dissemination document provides an accessible overview of the literature review and empirical paper.

Volume II: Clinical Component

Volume II consists of five clinical practice reports (CPR's); CPR I presents a Cognitive-Behavioural and Psychodynamic formulation of a 31-year-old male convicted with arson. CPR II presents a service evaluation on the support offered to families and carers in a medium secure unit. CPR III presents a case study of a 13-year-old female experiencing stress and anxiety. CPR IV presents a single-case experimental design assessing the effectiveness of a Cognitive-Behavioural intervention for an 85-year-old female with agoraphobia. CPR V presents an abstract for a presentation delivered on a behavioural intervention for an 8-year-old male displaying behaviour that challenges.

Dedication

This thesis is dedicated to Penny, Ernie, and Wilbur. Thank you for giving my life so much meaning.

Acknowledgements

I would like to express huge gratitude to my academic supervisor, Dr Gerry Riley. Firstly, for providing me with a project I felt truly passionate about, then for his wisdom, clarity of thought, patience, and good humour throughout this process. Your support has been invaluable. Thanks also to Dr Barbara Hagger for her unwavering enthusiasm, pragmatism, and warmth. I miss our many interesting conversations, and the copious amounts of caffeine we had on our journeys together. Huge thanks to all of the people who participated in the study, and to those who facilitated their participation. Your hospitality and efforts were very much appreciated.

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Volume I

Chapter I: Literature Review

Do Mindfulness-Based Techniques Improve Memory?

Abstract

Mindfulness as an umbrella term for a range of practices has garnered a significant amount of attention in recent years, particularly with respect to the positive psychological effects it may be associated with. The current paper systematically reviews the evidence for the effects of mindfulness on measures of memory. Three databases were searched, and backward citation tracking was conducted. Nineteen randomised controlled trials providing valid measures of memory were included in the review. Overall, findings were mixed, with studies generally suggesting that mindfulness may improve some subtypes of memory including working memory. There is also some evidence that mindfulness may increase the susceptibility to recall of false memories. The quality of studies, evaluated using a risk of bias tool, was generally poor, possibly accounting for some of the inconsistencies in research findings. Issues in operationalising mindfulness may also have contributed to difficulties in comparing findings across studies. Therefore, the findings reviewed provide a primary analysis suggesting that mindfulness may enhance the use of some subtypes of memory. However, the available evidence is not generally of high quality, and should therefore be considered with caution. More rigorous randomised controlled trials are required to adequately evaluate whether mindfulness practices improve memory.

Introduction

Over the last 20 years or so, there has been considerable interest in mindfulness. Van Dam et al. (2018) conducted a search of original scientific content and media articles containing references to mindfulness between 1970 and 2015. From 1970 – 2000, there were approximately 8000 references for mindfulness. However, a search of the subsequent 15 years yielded a result including more than 25,000 references. This substantial increase in both academic literature and media references to mindfulness are clearly indicative of the surging interest in the subject of mindfulness.

Mindfulness is a broad construct with a variety of definitions (Gethin, 2011) and conceptualizations of how this should be practised (Zeidan, Gordon, Merchant & Goolkasian, 2010), as well as a diverse range of opinions on how helpful this is for a variety of psychological difficulties (Kabat-Zinn, 2005; Kreplin, Farias, & Brazil, 2018). The spectrum of opinions on the effectiveness of mindfulness amongst academics and the public are likely to be formed based on empirical evidence (Farias, 2019), and also the effective, but not necessarily balanced marketing of mindfulness techniques which some critics have labelled as the McDonaldizing of mindfulness (Hyland, 2017). Chiesa and Serretti (2009) note that despite the many claims relating to how beneficial mindfulness is for a range of issues, there is in fact a lack of good randomized controlled trials to actually substantiate this.

To try to bring some order to the field, there have been recent attempts at operationalising exactly what mindfulness is, and what it is not (Hayes & Shenk, 2004). Whilst not the only accepted definition, one of the most frequently referenced definitions of mindfulness is provided by Kabat-Zinn: ‘mindfulness means paying attention in a particular way; on purpose, in the present moment, and non-judgmentally’ (1994, p.4). Currently, there are a variety of

mindfulness-based techniques that are generally accepted as being included within Kabat-Zinn's definition, and come under the umbrella term of mindfulness. However, even this definition encompasses a very wide range of practices that vary on multiple dimensions. For example, there are no constraints in terms of time so mindfulness techniques can range from brief exercises such as mindful breathing which can last less than ten minutes (Burg & Michalak, 2011), to mindfulness retreats which may last a month (Jha, Krompinger, & Baime, 2007). As previous authors have suggested (Van Dam et al., 2018), the ambiguity surrounding mindfulness can result in practices that may practically share very little in common, yet are ascribed the same label of mindfulness. This can then result in distorted perceptions of what mindfulness techniques are, and which particular techniques are evidenced as being beneficial for particular psychological difficulties (Freeman & Freeman, 2015).

Regardless of which particular technique is being referenced, there have been many who have extolled the benefits of mindfulness for a range of psychological difficulties including depression, anxiety, and stress. The suggested benefits of mindfulness for some of these issues are supported by evidence from systematic review or meta-analyses (Khoury et al., 2013). However, there have been claims made about the effectiveness of mindfulness for addressing problems for which there has clearly been insufficient synthesis of the academic literature in order to make such assertions legitimate (Van Dam et al., 2018). One issue pertains to the proposed benefits of mindfulness for a range of cognitive abilities.

The issue of whether mindfulness facilitates improved cognition was reviewed by Chiesa, Calati, and Serretti (2011). Overall, the 23 studies reviewed by Chiesa, et al. (2011) indicated that mindfulness training is linked with significant enhancement of executive attention and selective attention. Furthermore, based on six studies reviewed, it was suggested that

mindfulness practices could enhance working memory capacity and some executive functions. However, the majority of studies that were reviewed suffered from a range of methodological issues with some also reporting negative associations between mindfulness and cognitive abilities. Accordingly, the authors conclude that the findings from their review should be interpreted with caution and recommend further high-quality studies in the future to investigate the relationship between mindfulness and cognition.

The review by Chiesa et al. (2011) was concerned with cognitive abilities more broadly and so there was a lack of a detailed focus on the impact of mindfulness on memory. Additionally, given the steady rise in academic literature on mindfulness, it is likely that there has been further research over the last eight years on the relationship between mindfulness and memory, that has not been subject to a systematic review. Therefore, the aim of the current paper is to systematically review evidence for the effects of mindfulness on memory and its various subtypes, and to provide a primary integration of the literature reviewed from a theoretical perspective. Contemporary issues in defining mindfulness and the current conceptualizations of memory are discussed, followed by a systematic review of the effects of mindfulness on various subtypes of memory.

Issues of Defining Mindfulness and its Variety of Forms

Many definitions of mindfulness exist. Classic definitions, some of which are still in use, are arguably more convoluted and inaccessible than contemporary definitions (Chiesa, 2013). Whilst no single definition exists, a common theme amongst contemporary definitions of mindfulness, particularly where applied to mental health issues, has been the focus on two discrete aspects of these practices; present moment awareness, and the adoption of a non-judgmental stance (Kabat-Zinn, 1994). At present, mindfulness can arguably be seen as a broad

construct that includes any practice or process which includes present-moment awareness and may also incorporate non-judgment.

Mindfulness practices can vary in a number of ways, in terms of the length of mindfulness practices (Mackenzie, Poulin, & Seidman-Carlson, 2006; Jain et al., 2007), the specific techniques involved (Lutz, Dunne, & Davidson, 2008), and the mode of communication, which may be via an in-phone app, through a mindfulness or 'expert' trainer, or audiotope for example (Bakosh, 2013; Mani, Kavanagh, Hides & Stoyanov, 2015). The particular reason for engaging in mindfulness can also vary and this might be expected to have some impact on the specific mindfulness practices that are chosen. For example, some mindfulness practices are specifically targeted at treating mental health issues in a traditional mental health setting (Kabat-Zinn, 1990), whilst others are set up as retreats that have a more spiritual dimension (Ostafin et al., 2006). This presents a major issue for research on the effects of mindfulness in terms of operationalising what mindfulness looks like in practice, even once issues relating to defining mindfulness have been addressed (Hayes & Shenk, 2004).

In an attempt to address the inherent issues in research focused on mindfulness due to the difficulties in defining this, and differentiating between the plethora of mindfulness practices, a framework for managing these has been proposed. Van Dam et al. (2018) outline key issues to be addressed by researchers focusing on mindfulness. The authors argue that the problems associated with mindfulness research fall under two categories; difficulties in defining mindfulness, and methodological issues for interpreting the results of mindfulness research.

With respect to defining mindfulness, Van Dam et al. (2018) suggest the semantic ambiguity of different aspects of mindfulness is a significant issue in that studies that differ in a number of ways may purport to be measuring essentially the same construct. For example, many

researchers fail to describe how they have arrived at the conclusion that an individual is a novice or expert in published research papers, despite this being of crucial importance to the findings of mindfulness research. For example, someone who has actually practiced a great deal of mindfulness but has not done this for a short time could be defined as a novice. The implication is that there may be very different effects from mindfulness for individuals who are deemed to be matched in terms of their experience based on how this is defined in mindfulness research, but who actually have very different levels of previous experience, which is likely to affect the validity of research findings.

With respect to methodological issues for mindfulness research, Van Dam et al. (2018), point out that the issues in operationalising mindfulness significantly hinder the reliability of findings from mindfulness research, and contribute to the replicability crisis that exists within the wider scientific community (Pashler & Harris, 2012). Van Dam et al. (2018) further focus on issues of measuring the effects of mindfulness, which has heavily relied on self-report, for which there are a lack of reliable and valid measures (Goldberg et al., 2016). Research focusing on the impacts of mindfulness on memory require an effective measure of changes in mindfulness states in order to be able to assert that any changes in memory following mindfulness are likely to be in response to this.

Given the wide-ranging issues that have beleaguered mindfulness research thus far, Van Dam et al. (2018) suggest a number of recommendations for future research. These include the effective replication of previous work using appropriately randomized designs with active control groups. To achieve this, it is suggested that authors provide clear details of measure of mindfulness, primary outcome, specific details of what mindfulness practices are used, and protocols for interventions. Creating active and proper control groups does pose a difficulty for

mindfulness research, however, this has been achieved in previous research, and ought to be the standard for future studies (Manicavasgar, Parker & Perich, 2011).

Classification of Different Types of Memory Processes

Problems in defining memory and its subtypes are akin to the issues discussed in relation to mindfulness (Kansteiner, 2002). Providing a detailed description of all models of memory previously proposed is outside the scope of this review. However, a summary of key subtypes of memory are discussed in a framework that underpins the conclusions drawn on the available findings from studies on mindfulness and memory.

Memory is not a single process, and a number of independent types of memory processes, controlled by separate regions of the brain have been identified using imaging such as fMRI (Reber, Gitelman, Parrish & Mesulam, 2003), and through experimental manipulation (Baird, Umbach, & Thompson, 2017). The relationship between different memory systems has been debated for many years, and conceptualizations of these have changed over time. One influential model of memory is the working memory model (Figure. 1) first proposed by Baddeley and Hitch (1974), and since updated to include additional processes such as the episodic buffer (Baddeley, 2000).

The working memory model brings together processes involved in sensory, short-term and long-term memory, and whilst the model does not explain all findings in memory research (Baddeley & Lieberman, 1980), there have been numerous studies over the last four decades that have demonstrated its usefulness in describing memory processes (Cowan, 2008, Baddeley, 2012; Nee et al., 2012).

The key aspects of working memory, according to the working memory model are the central executive, visuospatial sketchpad, phonological loop and episodic buffer. The central

executive is the most complex aspect of the working memory model. The original description of this assumed that the central executive was capable of storage, attentional focus, and decision-making processes (Baddeley & Hitch, 1974). Baddeley (2000) has described this as akin to a homunculus, with multiple capabilities, not available to the other two fluid systems that make-up the core processes involved in working memory.

The visuo-spatial sketch-pad, one of two so-called 'slave systems' to the central executive, operates through retaining visual and spatial information. The term 'sketchpad' refers to the necessity of active maintenance of visual-spatial imagery in the 'mind's-eye' (Hamamé et al., 2012). The phonological loop, as can be seen in Figure.1, is the other slave system within the working memory model and operates similarly to the visuo-spatial sketchpad in that this provides a short-term store but instead uses a subvocal rehearsal process rather than a visual-spatial one.

The episodic buffer was added to the working memory model as a system that stores information and is fed by the visual and verbal slave systems, as well as being linked to the central executive. The episodic buffer is proposed to act as a buffer in that this holds multidimensional information temporarily, such as visual and verbal information, and then combines this information into discrete chunks or episodes.

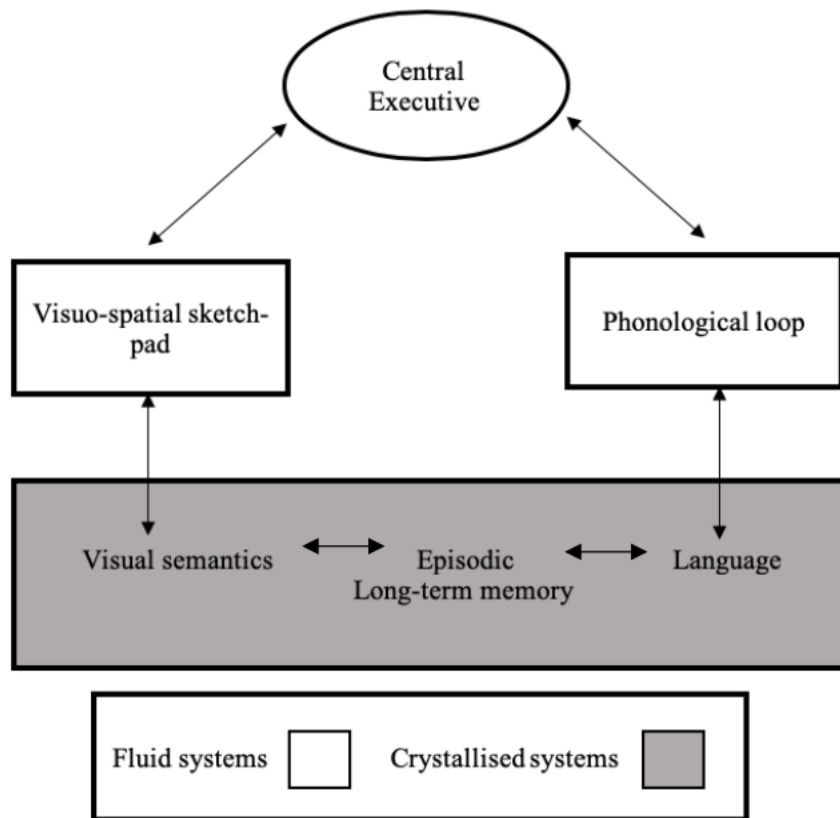


Figure 1. Contemporary Working Memory Model based on Baddeley (2000)

Another influential early model of memory is the multi-store model proposed by Atkinson and Shiffrin (1968). This provided three separate components to memory, namely, a sensory register, short-term store, and long-term store. A version of the multi-storage model is provided in Figure. 2. Short-term memory, long-term memory, implicit and explicit memory, as well as priming and procedural memory will be discussed as these are the types of memory most relevant to the studies reviewed for this paper.

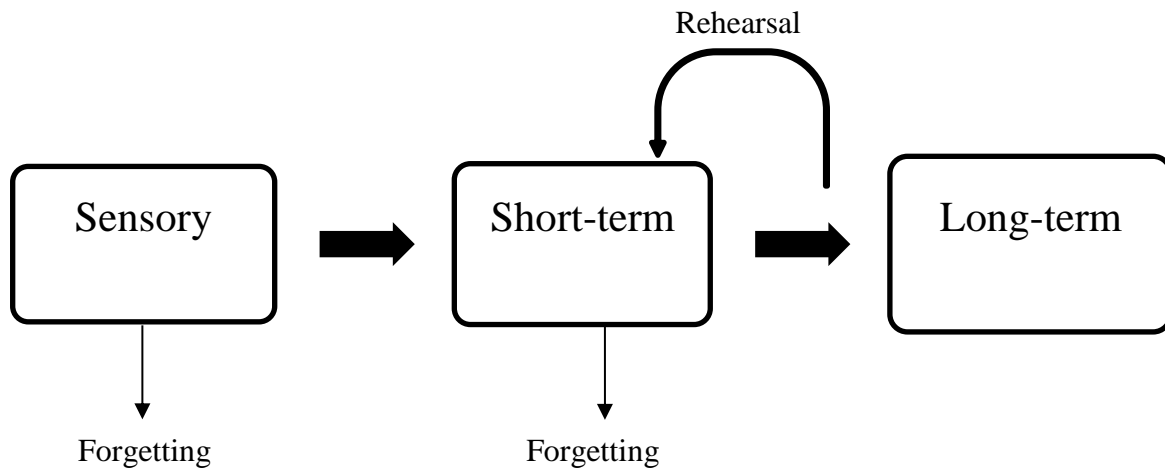


Figure 2. Multi-store Model based on Atkinson and Shiffrin (1968)

Peterson & Peterson (1959), were the first to propose the idea that short-term memory is limited in both the length and the amount of information it can hold. They conducted a study in which they asked participants to remember three-letter consonant syllables (e.g. CHJ), Participants were then asked to count backwards in threes from a random number provided (i.e. 500, 497, 494) until asked to stop, at which time the participant would try to recall the three-letter consonants.

Peterson and Peterson (1959) found the material was quickly forgotten, so that by 18 seconds there was virtually no correct recall of the target consonants. This study therefore provided some of the first evidence of short-term memory decay. Peterson and Peterons (1959) demonstrated that in short-term memory, particularly when preventing rehearsal, information is quickly decays and is forgotten. Conversely, one way to prevent the decay of information held in short-term memory is to rehearse this. Maintenance rehearsal is a process of repeating information with the goal of keeping it in memory (Craik & Lockhart, 1972). When engaging in

maintenance rehearsal in order to remember a specific piece of information (i.e. telephone number), this can then be transferred to long-term memory.

In the original multi-store model, long-term memory was described as the lasting retention of information and skills (Atkinson & Shiffrin, 1968). It was also suggested that this may have a virtually unlimited capacity and duration, although access to this information was constrained by the ability to recall it. A large number of studies have explored the duration and capacity of long-term memory, and have demonstrated that specific types of information, for example names, can be remembered for almost a lifetime (Bahrick, Bahrick & Wittlinger, 1975), and that vast amounts of information, including entire books can be committed to long-term memory (Ariffin et al., 2013).

Two broad ways of categorising long-term memories can be made by distinguishing between explicit and implicit memories. Explicit memory refers to the conscious and intentional recollection of previously learned information. An example of this is actively recalling the details of an emotionally charged event such as a wedding, or birth of a child (Tulving, 1972). Conversely, implicit memory has been defined in terms of the influence of past experience in the absence of any intention to recall that experience, and in many cases of any conscious recollection of this past experience (Ochsner, Chiu & Schacter, 1994). A typical example is remembering how to ride a bicycle without having to recall the sequence of motor skills required to perform this activity. Whilst some authors have argued that the explicit/implicit dichotomy is purely a theoretical abstraction (Preuss, 1995), there has been an extensive amount of research published supporting the argument for two distinct forms of long-term memory (Fleischman, Wilson, Gabrieli, Bienias & Bennett, 2004; Squire & Zola-Morgan, 2011).

Much of the evidence for implicit and explicit memory as being clearly distinct comes from case study research with individuals who have severe anterograde amnesia following an acquired brain injury (ABI). A particular sub-type of implicit memory, procedural memory, has often been explored in case studies of participants with amnesia. Procedural memory has been defined as ‘the memory system in charge of the encoding, storage, and retrieval of the procedures (rather than episodes) that underlie motor, visuospatial, or cognitive skills’ (Pitel, Eustache & Beaunieux, 2014, p.118).

Cases demonstrating intact procedural memory include the well-documented subject, H.M, an individual who was able to acquire motor skills for experimental tasks without any conscious recollection of learning trials having taken place (Corkin, 1968). More recent examples also exist such as S.Z, a gentleman who demonstrated significant improvements in his ability to learn how to play novel, unfamiliar songs on a saxophone, despite the inability to recognize these at the declarative level (Cavaco, Feinstein, van Twillert, & Tranel, 2012). The experimental research on amnesic subjects demonstrates that following an ABI, implicit memory function can be spared in the absence of the mechanisms required for explicit (conscious) memory.

Another well-studied sub-type of implicit memory is priming (Bock, 1986; Stoykov & Madhavan, 2015; Mahowald, James, Futrell & Gibson, 2016). Priming is a technique in which exposure to one stimulus influences a response to a subsequent stimulus, without conscious guidance or intention (Bargh & Chartrand, 2000). One common priming task is word-stem completion (Postle & Corkin, 1998). In this task, words are encoded in a pre-exposure stage and then word stems of primed and unprimed words are completed with the first word that comes to mind in a test stage. Evidence of priming is demonstrated by the increased production of primed

words (e.g., BLACK) over unprimed words (e.g., BLAND) to complete the word stem being presented (e.g., BLA__).

In summary, this overview of memory demonstrates that memory is a complex construct, with constituent parts and processes that may function in very different ways. Indeed, whilst memory has been discussed according to the theories, models, and research most pertinent to the current review, it is noteworthy that memory has been categorized in numerous other ways, such as distinctions made between explicit versus implicit memory (Graf & Schacter, 1985). The reader should consider the interconnections between different memory processes in the evaluation of the following results, particularly given that the majority of studies reviewed focus on the relationship between mindfulness and one particular facet of memory.

Statement of intent

The purpose of this systematic review is to answer the question ‘Do mindfulness-based techniques improve memory?’ In order to answer this question, research focused on exploring this relationship has been appraised in order to draw a conclusion on what the current evidence base suggests with respect to this.

Methods

Literature Search

A literature search was conducted using the PsycINFO, MEDLINE, and Google Scholar databases with references for the retrieved articles exported into Mendeley reference management software on 25th March 2019. The search terms used were ‘mindfulness’, or ‘mindful* or ‘MBSR’ and ‘memory’. MBSR is a frequently used acronym for mindfulness-based stress reduction. For Google Scholar, search terms were only applied to titles, as the only alternative strategy was to search anywhere in the paper, and the results in excess of 250,000

could not feasibly be screened by one author. The reference lists of the selected papers were also searched for further relevant papers not identified by the initial search. The search strategy is detailed in Table 1.

Table 1.

Search Terms used in the PsychINFO, MEDLINE, and Google Scholar

Electronic Databases

Cluster 1		Cluster 2
Mindfulness 'OR' Mindful* 'OR' MBSR	'AND'	Memory

Note. All terms exploded. 'AND'/'OR' are Boolean operators. Terms searched within all fields of PsychINFO and MEDLINE databases. * denotes truncation

Selection of Trials

Included reports had to: 1. Be defined as randomized controlled studies (RCT) based on Higgins and Green (2011). 2. Clearly describe the type of mindfulness practice used. 3. Include a control condition, either active (relaxation) or inactive (waiting list). 4. Make clear use of quantitative measures and appropriate statistical analysis. 5. Provide a statistical analysis of the relationship between mindfulness and memory. 6. Be peer-reviewed. 7. Be available in English.

Reasons for exclusion were: 1. Non-experimental reports. 2. Qualitative studies. 3. Case studies. 4. Systematic reviews or meta-analyses. 5. Studies with inadequate descriptions of mindfulness practices used. 6. Studies with no direct exploration of the relationship between mindfulness and memory. 7. Due to problems in accurately measuring dispositional mindfulness and the validity of manipulations aimed at affecting this, studies focused on dispositional

mindfulness were excluded from the current review. 8. Papers published before 2011 as a systematic review focusing on the effects of mindfulness on cognition was conducted by Chiesa et al. (2011).

Although the clear set of guidelines provided by Van Dam et al. (2018) suggest that eight-week mindfulness-based stress reduction interventions are the gold-standard, this was not factored into inclusion/exclusion criteria. Firstly, as this would have limited the scope of the current review to very few studies, and secondly, because it was deemed useful to include studies that reflected the broad use of techniques that are considered to constitute mindfulness practices. Whilst this may affect the reliability of conclusions drawn from the review, this hopefully increases its ecological validity in reflecting how mindfulness is typically practiced in reality.

Data Extraction

Data were extracted independently by the author from the original reports. In the event of any difficulties classifying study designs or whether there was a suitable description of mindfulness techniques, a second researcher (a senior academic) was consulted. The outcome of interest was the evaluation of the effects of any type of mindfulness-based activity on any specific type or subtype of memory (e.g. working memory) so long as this was clearly described, and a suitable quantitative measure was applied to examine this. Type of subjects included in each study, including clinical populations and student subjects, was also reported.

Results

Search Results

The search retrieved 815 papers, and 812 papers after removing duplicates. A total of 345 papers were excluded through screening of titles and keywords because there was no reference to mindfulness or mindfulness techniques (e.g. MBSR), and cognition, or memory. A further 169

were excluded through screening of abstracts where the focus of the study was clearly not exploring the relationship between mindfulness and memory. After initial screening of titles and abstracts, inclusion and exclusion criteria were applied to the remaining 297 papers. Following this, 280 papers were excluded and 17 were included in the present review (see Figure. 3).

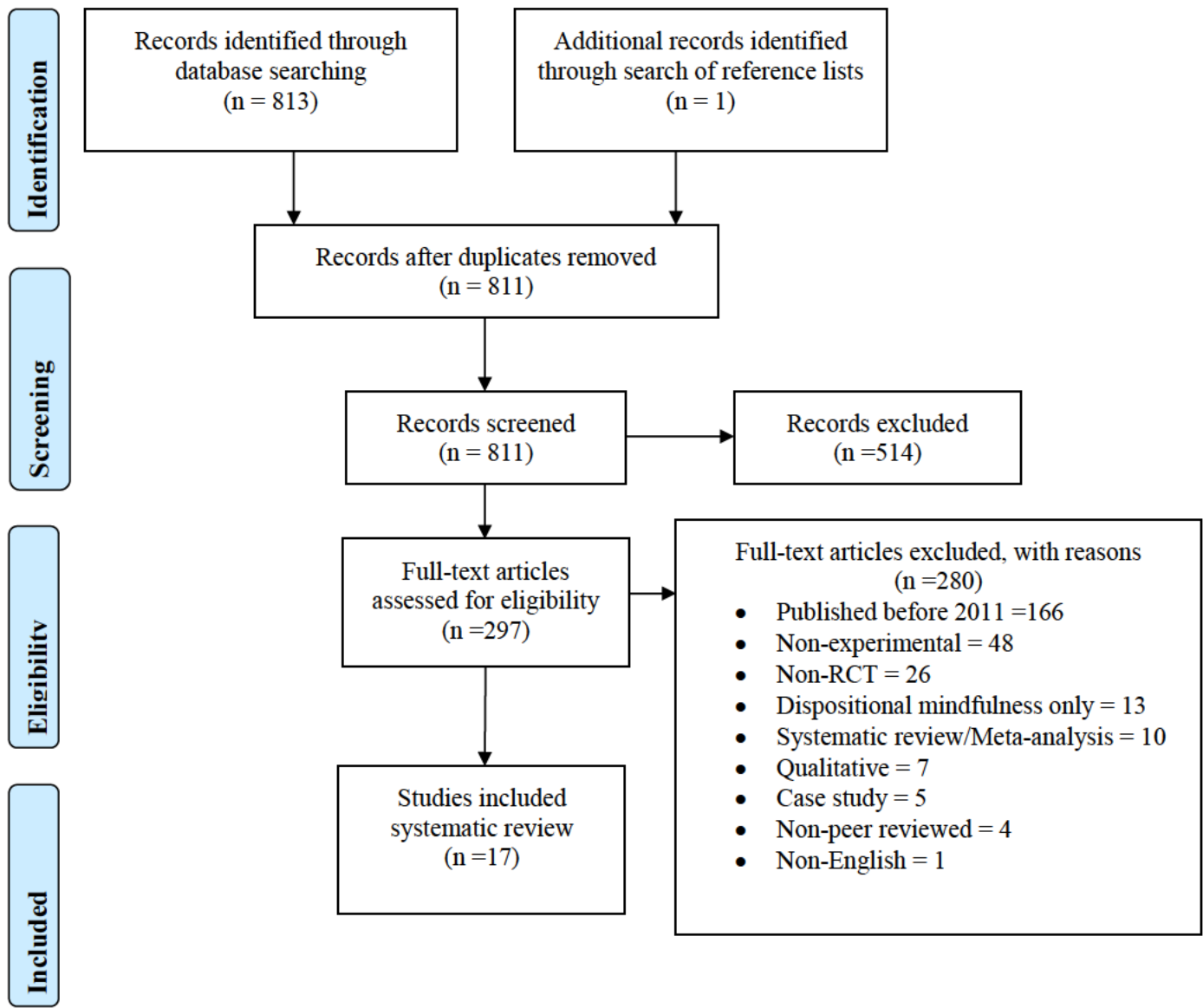


Figure 3. Flow Diagram of Review Process

Characteristics of Included Studies

Included studies comprised 19 randomized controlled trials (RCT). Of the 19 RCT's, six specified that all participants had little or no experience in mindfulness techniques, and one specified that participants could not have regularly engaged in mindfulness techniques in the six months preceding the study. Five studies focused on mindful meditation, two on mindfulness-based stress reduction, one on mindfulness-based cognitive therapy, one on the *mindful me* programme for students, with the remaining eight studies using other practices consistent with mindfulness training methods such as guided visualization, and audio cassette recordings of a mindfulness script. Six studies compared mindfulness techniques with a non-active control i.e. no mindfulness/waiting list, two with psychoeducation, one with treatment as usual, and the rest with active controls that were structurally equivalent to the mindfulness task. No definition of structurally equivalent control was provided by any of the studies reviewed, but this typically consisted of an activity that was similar to the experimental mindfulness task in duration, took place in a similar environment (i.e. university lab), and made use of similar materials (i.e. audio recording of excerpt from a book vs audio recording of mindfulness script). All studies avoided using a structurally equivalent task that encouraged responses associated with mindfulness such as paying attention to thoughts and physical sensations. Nine studies used undergraduate student samples, two older adults (one with participants who had mild cognitive impairment), three adults with mental health diagnoses, two secondary school aged participants, and one a representative adult sample. The characteristics of the included studies are detailed in Table 2, Table 3, and Table 4.

Table 2 provides a description of the study authors, design, participant type, sample size, mindfulness techniques, and control condition/s. This was deemed to be important and is in line

with recommendations by Van Dam et al. (2018). Table 2 also provides details on the standardised measure/s of memory used in each study, and a brief summary of the main findings.

Table 3 provides further detail on the experimental and control conditions. These details were considered important based on Van Dam et al's. (2018) recommendation that mindfulness studies use adequate control groups. Whilst no overall assessment can be made, each study can be looked at in turn and a judgement made about whether the control condition is a good match to the experimental condition.

Table 4 provides details on the particular measures of memory and how these are conducted. Those that are referred to as free recall by authors are not described in detail as these are all measured by comparing the amount of information recalled between conditions and are fairly self-explanatory.

Table 2.

Summary of Studies Reviewed

Author (date)	Study design	Type of participants	Number of participants	Mindfulness/control condition/s	Measure/s of memory	Summary of findings on relationship between mindfulness and memory
Alberts, Otgaar, & Kalagi (2017)	RCT	University students	28 28	Mindful meditation No mindfulness	Source monitoring test	No significant differences between mindfulness condition and control condition.
Alberts & Thewissen (2011)	RCT	Undergraduate students	20 20	Mindful training No mindfulness	California Verbal Learning Test (Delis et al., 1987).	Significant improvement for mindfulness group over psychoeducation group on target-correct response and time of response
Bachmann et al., (2018)	RCT	Attention deficit hyperactivity disorder	32 27	Mindful awareness practice Psychoeducation	N-back task	Significant improvement for mindfulness group over psychoeducation group on target-correct response and time of response
Brown, Goodman, Ryan, & Anālayo (2016) – Experiments 2 & 3	RCT	2. Undergraduate psychology students	44 49	Focused attention mindfulness Structurally equivalent control	Remember-know episodic memory performance task	Mindfulness produced significantly better recognition memory performance relative to control
	RCT	3. Undergraduate students	19 19 19	Audio cassette recording of mindfulness script Distraction control No-task control	Free recall of 372-word script	Mindfulness significantly increased accuracy of free recall
	RCT	Undergraduate students	23 23	Focused breathing mindfulness Audiobook of JRR Tolkien’s ‘the hobbit’	Logical Memory Subtest 1 (Wechsler Memory Scale; Wechsler, 1945).	Focused breathing mindfulness significantly enhanced recall on the memory task
Greenberg et	RCT	Healthy	50	Mindful meditation	Recent probes task	Mindfulness significantly protected

al., (2018)			29	Active control		against proactive interference
Johnson, Gur, David, & Currier (2015)	RCT	University students	41 25 26	Audiotaped mindfulness meditation Sham meditation Book listening	Symbol digit modalities test Computer-adaptive adjustable N-back task Forward/backward digit span	No evidence that brief mindfulness enhances working memory
Larouche, Hudon, & Goulet (2019)	RCT	Older adults with mild cognitive impairment	20 21	Mindfulness-based intervention Psychoeducation-based intervention	Free recall verbal episodic memory task	No significant difference between experimental and control conditions
Mallya, & Fiocco, (2016)	RCT	Older adults	52 28	Mindfulness-based stress reduction Reading and relaxation	California verbal learning test-long delay free recall Mini-mental state examination	No clinical meaningful differences observed between experimental and control groups
Mrazek, Franklin, Phillips, Baird, & Schooler (2013)	RCT	University students	26 22	Mindfulness class Nutrition class	Operation span task	Significant improvements in working memory for mindfulness condition
Qi, Zhang, Hanceroglu, Caggianiello, & Roberts, (2018)	RCT	School students aged 13-14	21 19	'Mindful me' program for students Social and emotional skills training programme	Cued recall – immediate and delayed	Mindfulness increased susceptibility to memory intrusions, and hindered both retention and retrieval
Quach, Mano & Alexander (2016)	RCT	Adolescents	54 65 53	Mindful meditation Hatha yoga Waiting list	Operation span task	Participants in the mindfulness meditation condition showed significant improvements in working memory, whereas those in the hatha yoga and waitlist control groups did not

Valls-Serrano, Caracuel, & Verdejo-Garcia, (2016).	RCT	Poly-substance users	18 18	Goal management training and mindfulness meditation Treatment as usual	Letter-number sequencing (Wechsler adult intelligence scale, WAIS-III; Wechsler, 1997).	The mindfulness condition significantly improved working memory compared to the treatment as usual condition.
Van Vugt, Hitchcock, Shahar, & Britton (2012).	RCT	Unipolar depression in partial or full remission	29 23	Mindfulness-based cognitive therapy Waiting list control	Free recall – word lists	Experimental group demonstrated significantly increased recall of positively valenced words
Watier, & Dubois, (2016)	RCT	Undergraduate psychology students	26 26 26	Mindfulness Attention Arithmetic	Emotional stroop task	Brief mindfulness significantly enhanced recognition memory
Wetherell et al., (2017)	RCT	Older adults aged 65+	47 56	Mindfulness based stress reduction Health education	Immediate and delayed paragraph and list recall	Significantly improved recall for mindfulness condition
Wilson, Mickes, Stolarz-Fantino, Evrard, & Fantino (2015) – Experiments 1 & 2	RCT	1.Undergraduate students	153	Guided focused breathing/mind wandering induction	Deese-Roediger-Mcdermott Paradigm	Mindfulness significantly increased the potential for false recall
	RCT	2.Undergraduate student	140	Mindfulness/mind-wandering	Deese-Roediger-Mcdermott Paradigm	Mindfulness significantly increased the potential for false recall

Table 3.

Description of Interventions in Experimental and Control Conditions

Author (date)	Mindfulness/Control Condition	Specific technique/s employed	Study duration for participants	Number and duration of meetings	Duration of mindfulness/control technique during testing	Prior meditation experience	Tests of memory assessed immediately following mindfulness?
Alberts, Otgaar, & Kalagi (2017)	Mindful meditation	Audio-tape instruction on paying attention to breathing and present moment	Not specified	Not specified	12-minutes	Not specified	No
	No mindfulness	None	Not specified	Not specified	Not specified	Not specified	No
Alberts & Thewissen (2011)	Mindful training	Audio-tape instruction on paying attention to breathing and present moment	Not specified	Not specified	12-minutes	Not specified	No
	No mindfulness	None	Not specified	Not specified	30 seconds	Not specified	
Bachmann et al., (2018)	Mindful awareness practice	Mindful awareness practices, daily seated meditation, homework	8 weeks	8 weekly meetings of 2.5 hours	None during testing	None	No
	Psychoeducation	Information on causes, symptoms and	8 weeks	8 weekly sessions (duration not	None during testing	None	No

		treatment of ADHD		specified)			
Brown, Goodman, Ryan, & Anālayo (2016) – Experiments 2 & 3	Experiment 2 Focused attention mindfulness	Audiotaped instructions to focus on receptive attention and awareness of physical sensations.	Not specified	Not specified	9-minutes 40-seconds	Not specified	Yes
	Structurally equivalent control	Audiotaped instructions to focus on important aspects of life and future.	Not specified	Not specified	9 minutes 40-seconds	Not specified	Yes
	Experiment 3 Mindfulness script	Audiotaped instructions to focus on receptive attention and awareness of physical sensations.	Not specified	Not specified	9-minutes 40-seconds	Not specified	No
	Distraction control	Identical to mindfulness script except for addition of white noise throughout.	Not specified	Not specified	9-minutes 40-seconds	Not specified	No
	No-task control	Wearing headphones and wait without engaging in other activities.	Not specified	Not specified	9-minutes 40-seconds	Not specified	No

Eisenbeck, Luciano, Valdivia-Salas, (2018)	Focused breathing mindfulness	Awareness of body, sensations of breathing, posture of acceptance and curiosity	1 day	1 meeting of 50 minutes	13-minutes 11-seconds	No prior experience	Not specified
Greenberg et al., (2018)	Audiobook of JRR Tolkien's 'the hobbit'		1 day	1 meeting of 50 minutes	13-minutes 11-seconds	No prior experience	Not specified
	Mindful meditation	Focused-attention meditation, and open monitoring	8 weeks	4 weekly, 1-hour long training sessions plus 30 minutes home practice 5 times per week	None during testing	No more than 3 previous meditation classes	No
	No mindfulness	Creative writing		4 weekly, 1-hour long training sessions plus 30minutes home practice 5 times per week	None during testing	No more than 3 previous meditation classes	No

Johnson, Gur, David, & Currier (2015)	Mindfulness meditation	Common mindfulness techniques focused on breathing and acceptance	90 minutes	90 minutes	25-minutes 52-seconds	No prior experience	Not specified
	Sham meditation	A less detailed meditation script without emphasis on breathing and acceptance	90 minutes	90 minutes	25-minutes 52-seconds	No prior experience	Not specified
	Book listening	Audiobook of JRR Tolkien's 'the hobbit'	90 minutes	90 minutes	25-minutes 52-seconds	No prior experience	Not specified
Larouche, Hudon, & Goulet (2019)	Mindfulness-based intervention	Common mindfulness strategies but using more concrete concepts, continuous verbal guidance, and facilitating active participation	Approximately 7 months	8-weekly sessions of 2.5-hours	None during testing	Not specified	No
	Psychoeducation-based intervention	Based on popular book on healthy aging	Approximately 7 months	8-weekly sessions of 2.5 hours	Not during testing	Not specified	No

Mallya, & Fiocco, (2016)	Mindfulness-based stress reduction	Common mindfulness but shortened and elimination of full-day retreat	10-12 weeks	8-weekly sessions of 2.5-hours	None during testing	No regular or active participation in mindfulness	No
	Reading and relaxation	Short stories in book club format and progressive muscle relaxation	10-12 weeks	8-weekly sessions of 2.5 hours	None during testing	No regular or active participation mindfulness	No
Mrazek, Franklin, Phillips, Baird, & Schooler (2013)	Mindfulness class	Physical posture and focused attention	Not specified	45-minutes, 4 times per week for 2 weeks plus 10 minutes per day outside of class	None during testing	Not specified	No
	Nutrition class	Nutrition science and applied healthy eating strategies	Not specified	45-minutes, 4 times per week for 2 weeks plus 10 minutes per day outside of class	None during testing	Not specified	No
Qi, Zhang, Hanceroglu, Caggianiello, & Roberts, (2018)	Mindful me program for students	Meditation practices, deep breathing, body scans	8 weeks	30-minutes, once-per week for 7 weeks	30 minutes	Not specified	Yes
	Social and emotional skills training programme	Emotional processes, interpersonal skills, cognitive regulation	8 weeks	30-minutes once-per-week for 7 weeks	30 minutes	Not specified	Yes

Quach, Mano & Alexander (2016)	Mindful meditation	Breathing, being in the body, awareness, silent and loving kindness	4 weeks	45 minutes, twice weekly for 4 weeks plus daily meditation of 15-30 minutes	None during testing	Not specified	No
	Hatha yoga	Breathing techniques, yoga poses, discussion	4 weeks	45 minutes, twice weekly for 4 weeks plus daily yoga of 15-30 minutes	None during testing	Not specified	No
	Waiting list	None	4 weeks	None	None during testing	Not specified	No
Valls-Serrano, Caracuel, & Verdejo-Garcia, (2016).	Goal management training and mindfulness meditation	Theory and practice required to implement goal-directed behaviour	8 weeks	8 sessions of goal management training for 120 minutes per week. 8 sessions of mindfulness of 45 minutes per week	None during testing	Not specified	No
Van Vugt, Hitchcock, Shahar, & Britton (2012).	Treatment as usual	Not specified	8 weeks	Not specified	None during testing	Not specified	No
	Mindfulness-based cognitive therapy	Psycho-education and non-judgemental present moment awareness	8 weeks	45-minutes per day, 6-days per week	None during testing	No regular meditation	No
	Waiting list control	None	8 weeks	Not specified	None during testing	No regular meditation	No

Watier, & Dubois, (2016)	Mindfulness	Mindful breathing and awareness	Not specified	Not specified	10 minutes	No prior experience	Yes
	Attention	Divided and selected attention	Not specified	Not specified	10 minutes	No prior experience	Yes
	Arithmetic	Arithmetic questions	Not specified	Not specified	10 minutes	No prior experience	Yes
Wetherell et al., (2017)	Mindfulness based stress reduction	Meditation and light yoga	Not specified	8 sessions	None during testing	No regular engagement in mindfulness	No
	Health education	Understanding common conditions, healthy eating, managing medication, and communicating with health professionals	Not specified	8 sessions	None during testing	No regular engagement in mindfulness	No
Wilson, Mickes, Stolarz-Fantino, Evrard, & Fantino (2015) – Experiments 1 & 2	Experiment 1	Focused attention and breathing	Not specified	Not specified	15 minutes	Not specified	Yes
	Guided focused breathing	Non-guided focus on thoughts	Not specified	Not specified	15 minutes	Not specified	Yes
	Mind wandering induction	Focused attention and breathing	Not specified	Not specified	15 minutes	Not specified	Yes
	Experiment 2 Mindfulness	Non-guided focus on thoughts	Not specified	Not specified	15 minutes	Not specified	Yes
	Mind-wandering						

Table 4.

Description of Measures of Memory

Measure	Description
Source monitoring test	Participants indicate what they see in an original event. Some items are misinformation items and some control items. There are also irrelevant filler items. For misinformation items, participants can choose between original information (true memory), misinformation (false memory), and new information (foil item).
California Verbal Learning Test (Delis, et al., 1987).	The experimenter reads a list of words out loud, at fixed intervals a number of learning trials (list A). After each trial, the participant is asked to recall as many words as they can in any order (i.e., free recall). The CVLT has a recognition task, where the experimenter presents the participant with a word list, and the participant must indicate whether it is a target word or a distractor.
One-back task	The participant is presented with a sequence of stimuli, and the task requires them to state when the current stimulus matches the one from a pre-specified number of steps earlier in the sequence.
Remember-know memory performance task	The R-K task is designed to dissociate the recognition of objects previously observed relative to felt familiarity of the object and to mere guessing.
Logical Memory Subtest 1 (Wechsler Memory Scale; Wechsler, 1945).	The participant is read two short stories and is asked to provide immediate and delayed recall of the stories.
Recent probes task	Participants are given a small number of items to remember over a short time period, followed by a recognition probe.
Symbol digit modalities test	The SDMT involves a simple task of substitution. Using a reference key, the participant has 90 seconds to pair specific numbers with given geometric figures. Responses can be written or given orally, and administration time is approximately five minutes.
Mini-mental state examination	This is a 30-point questionnaire that is used extensively in clinical and research settings to measure cognitive impairment.
Operation span task	Participants try to remember sequentially presented words in their correct order while simultaneously solving simple math equations.
Letter-number sequencing (Wechsler adult intelligence scale,	Participants receive 3 training tasks and the number of tasks are extended from 21 to 30 by introducing 6 tasks involving only one letter and number and by extending the number of three-letter tasks to 9 instead of 3.

WAIS-III; Wechsler, 1997).	The participant is given a random sequence of letter then number and must then provide the letters in alphabetical order followed by the number.
Emotional Stroop task	Emotional Stroop test works by examining the response time of the participant to name colors of words presented to them. Words presented are either positively or negatively valenced, or neutral
Deese-Roediger-Mcdermott Paradigm	The procedure typically involves the oral presentation of a list of related words (e.g. bed, rest, awake, tired, dream, wake, snooze, blanket, doze, slumber, snore, nap, peace, yawn, drowsy) and then requires the subject to remember as many words from the list as possible.

Review of Methodological Quality

A Cochrane risk-of-bias tool for randomized controlled trials, referred to as the RoB2, was used to evaluate the risk of bias for each study included in the review (Higgins et al., 2016). The RoB2 assesses risk of bias across five key domains, each of which is assessed through answering a number of questions in relation to the particular study being assessed. For each question, there is the option of responding with *yes* (Y), *probably yes* (PY), *no* (N), *probably no* (PN), or *not enough information* (NI). For some questions there is also the option to respond with *not applicable* (NA) where a response on a previous question makes the subsequent question largely redundant. A response of *yes* is weighted exactly the same as a response of *probably yes*, and a response of *no*, is weighted exactly the same as *probably no*, but the reviewer is expected to make a judgement as to whether they can conclusively say *yes* or *no*, or would prefer to be cautious and state *probably yes* or *probably no* where they may be some slight uncertainties. Whether a response of *yes* or *no* indicates a higher or lower risk of bias depends on the particular question being responded to.

In order to summarise scores on the RoB2, the highest assessment of risk of bias for any question within each domain is taken to represent the overall risk of bias. For example, a domain with five questions will still have a high risk of bias overall if the response to four of the questions indicates a low risk of bias, and only one indicates a high risk of bias. There is also an overall risk of bias assessment based on the overall assessment on each of the five domains. The same principle of

taking the highest assessment of risk of bias is used when forming a judgement on this. The results from the RoB2 for each study are summarised in Table 5.

Table 5.

Summary Scores from the ROB-2 Assessment of Bias

Study	Domain 1: Risk of bias arising from the randomization process	Domain 2: Risk of bias due to deviations from the intended	Domain 3: Missing outcome data	Domain 4: Risk of bias in measurement of the outcome	Domain 5: Risk of bias in selection of the reported result	Overall risk of bias
Alberts, Otgaar, & Kalagi (2017)	H	H	L	H	L	H
Alberts & Thewissen (2011)	H	SC	L	H	H	H
Bachmann et al (2018)	L	H	H	H	H	H
Brown et al (2016) – Experiment 2	H	H	H	H	SC	H
Brown et al(2016) – Experiment 3	H	H	H	H	SC	H
Eisenbeck, Luciano, Valdivia-Salas (2018)	H	H	H	H	SC	H
Greenberg et al (2018)	L	H	H	H	SC	H
Johnson et al (2015)	L	H	L	SC	SC	H
Larouche, Hudon, & Goulet (2019)	H	H	L	L	L	H
Mallya, & Fiocco (2016)	H	H	H	H	SC	H
Mrzcek et al (2013)	H	H	H	H	SC	H
Qi et al (2018)	H	H	H	L	SC	H
Quach, Mano & Alexander (2016)	H	H	H	H	SC	H
Valls-Serrano, Caracuel, & Verdejo-Garcia (2016)	H	H	L	H	SC	H
Van Vugt et al (2012)	H	H	SC	H	SC	H
Wattier, & Dubois (2016)	H	H	H	H	SC	H
Wetherell et al (2017)	L	H	L	L	L	H
Wilson et al (2015) – Experiment - 1	H	H	H	H	SC	H
Wilson et al (2015) – Experiments - 2	H	H	H	H	SC	H

Note. H = High, SC = Some concerns, L = Low

All studies reviewed were assessed as having a high risk of bias overall. As discussed, the overall assessment of bias is based on the highest assessment of risk of bias across any of the five domains, and each study had at least one domain assessed as having a high risk of bias (see Appendix A). The conclusion drawn from this is that all studies were deemed to be of low quality overall, although within particular aspects of the risk of bias assessment, some studies demonstrated a low risk of bias on some domains and were therefore of relative high quality compared to other studies.

Effects of mindfulness on working memory

The effect of mindfulness on working memory was investigated in six studies. Four studies investigated the effects of mindfulness meditation, but the studies varied in how mindfulness meditation was carried out. For example, participants in the study by Quach et al. (2016) engaged in mindfulness meditation twice per week for four weeks, whereas the participants in Valls-Serrano et al. (2016) engaged in one session of mindfulness meditation per week for eight weeks. The remaining two studies employed different mindfulness techniques. These were mindful awareness (Bachmann et al., 2018), and focused attention mindfulness (Mrazek et al., 2013).

The measures of working memory also varied, but all were standardised and validated methods that have been employed in numerous other studies. Two studies used the automated operation span task (Mrazek et al, 2013; Quach et al., 2016), two studies used variations of the n-back task, specifically the one-back test (Bachmann et al, 2018) and the two-back task (Johnson et al, 2015), one used the recent probes test (Greenberg et al, 2018), and the final study used the letter number sequencing task from the Weschler Adult Intelligence Scale.

For five of the six studies, mindfulness was found to significantly improve working memory. This suggests that working memory is generally improved by mindfulness practices and more specifically, given the duration of the mindfulness practices used within the studies (Table 3), that more extensive practice in mindfulness is likely to improve working memory. This does not mean that brief mindfulness exercises may not be effective in improving working memory, but none of the studies included in the review used brief mindfulness so no conclusions can be drawn on this.

One study did not find a statistically significant effect of mindfulness on working memory (Johnson et al., 2015). If there were a high degree of similarity between the other studies, it may have been possible to have identified methodological reasons for why not significant effect was found. However, the study by Johnson et al. (2015) is does not appear to differ markedly from other studies in terms of the sample, methods, or any other feature of the research.

Despite the relatively strong evidence suggesting mindfulness improves working memory, this finding should be interpreted with caution, as the risk of bias was high for all studies, and so it is possible that the results were affected by the influence of biases.

The complexities in defining different types of memory and how these are measured creates difficulty in accurately and succinctly summarizing the findings of studies in relation to the impact of particular types of mindfulness on specific types of memory. For instance, a study purporting to measure working memory, could feasibly be measuring long-term memory also depending on the particular methods and measures employed. Therefore, the reporting of results is based on the influence of mindfulness on the specific type of memory studies were intending to measure only.

Effects of mindfulness on short-term memory

Seven studies explored the effect of mindfulness on short-term memory. Two studies used focused attention mindfulness (Brown et al., 2016), two used mindfulness-based stress reduction (Mallya & Fiocco, 2016; Wetherell et al., 2017). two used focused-breathing mindfulness (Eisenbeck et al., 2018; Watier, & Dubois, 2016), one used a range of common mindfulness techniques (Larouche et al., 2019).

The measures of memory were a remember-know task (Brown et al., 2016), a free-recall memory task (Larouche et al., 2019), the California Verbal Learning Test (Mallya & Fiocco), two used the logical memory subtest from the Weschler Memory Scale (Eisenbeck et al., 2018), or a slight variation of this (Wetherell et al., 2017), and the emotional stroop task. The free-recall memory task is not standardised but the description of this task suggests this is an appropriate measure of short-term memory, and this has been used in at least one previous study (Moulin et al., 2004).

Two studies by Brown et al. (2016) found statistically significant effects in both experiments two ($p < 0.01$) and three ($p < 0.005$), as did Eisenbeck et al. (2018) and Wetherell et al. (2017) who's results were both significant at the $p < 0.01$ and $p < 0.05$ alpha respectively. Larouche et al.

(2019), found no significant effect ($p = 0.522$), as was the case in the Mallya and Fiocco (2016) study ($p < 0.08$) and the Watier and Dubois (2016) study ($p = 0.18$). No clear conclusions can be drawn from the results of the seven studies on whether mindfulness practices improve short-term memory due to a lack of reliable findings and methodological limitations such as poor standardisation across mindfulness techniques.

With respect to issues of bias, the fact that two of the studies to find statistically significant effects were conducted by the same authors is an issue in that any significant results arising from bias in one study are likely to have affected the other study in a similar fashion, particularly given the almost identical methodologies used. However, these were not the only studies to have found statistically significant effects.

Effects of mindfulness on false memory

Four studies explored the effect of mindfulness on false memory. One study used mindfulness meditation (Alberts et al., 2017), one study used a 'Mindful Me' programme designed for school-aged students (Qi et al, 2018), and two studies used mindfulness techniques based on guided breathing (Wilson et al., 2015). The methods of assessing false memory included the source monitoring test (Alberts et al., 2017), delayed free recall (Qi et al, 2018), and the Deese-Roediger-Mcdermott Paradigm (Wilson et al., 2015), which is a standardised recall task.

One study found no significant ($p = 0.25$) differences between the mindfulness and control condition with respect to the amount of false information recalled (Alberts et al., 2017), with the remaining three studies finding a moderately significant effect of mindfulness in increasing false memory.

As with episodic memory, two studies were undertaken by the same authors exploring the effects of mindfulness on false memory. Therefore, any influence on the findings arising from bias in one study by Wilson et al. (2015), is likely to have a similar effect on the other study.

Whilst the results must be interpreted with caution, the results suggest that mindfulness may increase false memory susceptibility.

Effects of mindfulness on emotional memory

Three studies explored the effect of mindfulness on emotional memory. The mindfulness techniques used included mindfulness-based cognitive therapy (Van Vugt et al., 2012), and mindful breathing techniques (Alberts & Thewissen, 2011; Watier & Dubois, 2016). All three studies used variations of a similar method in which words which are emotionally charged in one way or another (i.e. negative, neutral, positive) and processed during a learning trial, followed by a recall task. The relative difference in recall of positive and negative words is taken to reflect the processing of those words based on how they are valenced emotionally. There was no significant effect of mindfulness on most aspects of emotional memory for the studies. One significant effect was found for a reduced likelihood of recall for negatively valenced words following the use of a mindfulness technique (Alberts & Thewissen, 2011).

Based on their findings, Alberts and Thewissen, (2011) suggest that mindfulness may favourably alter perception to more emotionally positive stimuli. However, given that this was only found in one study, this is not a reliable finding, and so this is too strong a conclusion to draw until these findings are replicated by future studies. The fact that there was generally no significant difference between the mindfulness and control conditions suggest that mindfulness may not affect emotional memory at all.

Discussion

The purpose of this systematic review is to answer the question ‘Do mindfulness-based techniques improve memory?’ In order to answer this question, research focused on exploring this relationship has been appraised in order to draw a conclusion on what the current evidence base suggests with respect to this.

Working memory was one of most frequently researched types of memory in the review. Whilst mindfulness is an ill-defined concept, the majority of definitions implicate a focus on attention as part of mindfulness practices (Kabat-Zinn, 1994, p.4). Given the substantial overlap between the construct of attention and working memory (Baddeley, 2000), it is perhaps no surprise that mindfulness potentially enhances working memory. Overall, findings from reviewed studies suggest that mindfulness techniques may have the potential to enhance working memory (Mrazek et al, 2013; Quach et al., 2016; Valls-Serrano et al., 2016; Bachmann et al, 2018; Greenberg et al, 2018). Based on the frequency and duration of mindfulness practices in most of the reviewed studies, it is possible that regular mindfulness practice may be necessary to enhancing working memory capacity. However, there is not a sufficient number of comparable studies on brief mindfulness to draw conclusions on the efficacy of these approaches in enhancing working memory.

Finally, one study found mindfulness did not significantly improve working memory (Johnson et al., 2015), suggesting that whilst mindfulness can enhance working memory, this conclusion should be treated with some caution because the quality review suggested the studies had a high risk of bias and there is also one study that failed to observe a significant effect.

The findings from reviewed papers on the effect of mindfulness on types of memory other than working memory were not as clear in the conclusions that could be drawn from these. There were seven studies focused on the impact of mindfulness on short-term memory (Brown et al., 2016; Eisenbeck, et al., 2018; Larouche, et al., 2019; Mallya & Fiocco, 2016; Watier, & Dubois, 2016; Wetherell et al., 2017). Whilst all studies used valid mindfulness techniques and measures of short-term memory, four studies found mindfulness significantly improved episodic memory (Brown et al., 2016; Eisenbeck, et al., 2018; Wetherell et al., 2017), and three studies found there was no significant improvement (Larouche et al., 2019; Mallya & Fiocco, 2016; Watier & Dubois, 2016).

A key issue is that two studies that found a significant main effect were conducted by the same authors. These were also two studies with appraised as being at a high risk of bias across different areas of research based on the RoB2 tool, and it is likely that the issues affecting one of the studies would also have a similar negative affect on the other study. However, the remaining studies that found no significant effect were also deemed to have a high risk of bias, therefore there is no reason to privilege the findings from one study over another in evaluating whether mindfulness enhances short-term memory.

With respect to differences between studies that may offer an explanation of the differences observed in the studies, there is a potentially significant difference in the characteristics of participants. Brown et al. (2016) used undergraduate psychology students in their sample, whereas Mallya and Fiocco (2016), and Larouche et al. (2019) used a sample of older adults. It is possible that due to the general cognitive decline that is experienced in older adulthood (Deary et al., 2009) older participants may have found it more difficult to learn and generalise mindfulness techniques (Kinugawa et al., 2013; Nyberg, 2017).

Four studies explored the relationship between mindfulness and false memory. Overall, the results from the studies suggest that mindfulness may increase the susceptibility to recall false memory. Arguably, under most circumstances enhancing false memory is likely to be an undesirable effect based on the literature that demonstrates the problems this amplifies, such as inaccuracies in eyewitness testimony (Loftus, 2003; Wang et al., 2018). One study found no significant effect (Alberts et al., 2017), and the remaining three studies found that mindfulness increased false memory with varying levels of significance. Currently, there is some evidence suggesting mindfulness may have an impact on false memory, but one cannot be confident about this because it is based on a relatively small number of studies, their methodological quality is relatively poor, and one study failed to observe an impact.

Three studies explored the effect of mindfulness on emotional memory. Overall, there was no good evidence that mindfulness affects emotional memory. There was one significant finding on the impact that mindfulness has in reducing recall of negatively valenced words (Alberts & Thewissen, 2011). The authors suggest that the positive effect mindfulness can have on mood may account for the finding that there is a reduced likelihood of recalling words with negative associations. However, this would seem to be a strong conclusion to draw from limited findings. In conclusion, there is no good support for the claim that mindfulness affects emotional memory.

Implications

Although the findings are preliminary, and a greater amount of evidence needs to be generated before clearer conclusions can be made, the studies suggest that there may be potential benefits in using mindfulness to improve memory performance in some circumstances. Firstly, the findings that are suggestive of mindfulness enhancing working memory when performing certain tasks may have benefits for the general population with respect to some everyday tasks such as when performing mental arithmetic. (Bellinger, DeCaro & Ralston, 2015).

There is also some evidence that mindfulness may enhance short-term memory, which may also be of use with respect to tasks that require a piece of information to be committed to memory, such as telephone numbers. However, as with working memory, further evidential support is required before these benefits can be properly substantiated.

The finding that mindfulness enhances false memory potentially has implications for eyewitness testimony. Numerous inaccuracies are created by a range of factors in eyewitness testimony (Loftus, 2003), and it is possible that mindfulness could act to enhance these and reduce the reliability of eyewitness testimony further.

Limitations of current research

There was a high risk of bias across all studies (Table 5), which brings into question the validity of the results on the effects of mindfulness on memory, irrespective of which type of mindfulness technique or subset of memory was being investigated.

Three studies compared mindfulness to a waiting list/ no intervention control condition, which cannot account for any of the non-specific effects of mindfulness. Therefore, it is not possible to determine to what extent a different, but structurally similar intervention could lead outcomes similar to mindfulness. This was an issue identified by Chiesa et al. (2011) in their review, and whilst this is less of an issue for studies in the current review, this can clearly still be an issue in current research exploring the relationship between mindfulness and memory.

The heterogeneity in mindfulness techniques employed is a cause for concern. It makes it difficult to compare the results of different studies, and this may have been a major factor in some of the inconsistency found across studies. It is therefore difficult to appreciate the reliability across study findings affecting the ability to draw clear conclusions.

Other issues that have been identified as specifically affecting mindfulness research (Van Dam et al., 2018) concern the semantic ambiguity of mindfulness. The majority of studies did not specify whether participants had prior experience of mindfulness. This causes difficulty in interpreting the results of such studies with respect to who the findings are most applicable to, and also what influence previous experience of mindfulness has when factored as a covariate in studies exploring the effect of mindfulness on memory.

Whilst this is a difficult issue to address in mindfulness research, Van Dam et al. (2018) also suggest that studies ought to operationalise what is meant by mindfulness in their study, as well as providing a breakdown of what activities make up the particular mindfulness techniques, they make use of. None of the studies provided a working definition of mindfulness that the authors used for their particular study. However, the majority provided a number of definitions and all studies provided details of the particular exercise that made up the mindfulness techniques they were using.

Another strength across most studies was the statement of a clear hypothesis that typically suggested mindfulness would enhance memory. There was one exception with Qi et al (2018), although this may be justifiable given that the authors suggest that the findings from previous research are inconsistent and do not point in any particular direction. Therefore, it is difficult to hypothesis whether mindfulness is likely to enhance or reduce false-memory susceptibility.

As with most research, university students were over-represented, being used as the sample in ten of the 19 studies. The benefits of mindfulness for this population are important to consider; however, this lack of a representative sample limits the extent to which the findings can be said to be applicable to other populations. Furthermore, individuals such as older adults or those with acquired brain injuries, clearly differ cognitively from young and healthy populations, further limiting how helpful the findings from the reviewed literature are for those populations that arguably could benefit from this the most.

Considerations for future research

Some fundamental aspects of studies exploring the relationship between mindfulness and memory need to be address in future. For example, the majority of studies do not currently provide sufficient detail on the previous experience of participants in the use of mindfulness techniques. In addition to this, future studies need to ensure that adequate, and structurally equivalent control conditions are designed that provide a better ability to draw conclusions on the effects that are specific to mindfulness techniques. Although all studies reviewed used randomisation, for the majority of studies this was not adequately described in order to be able to firmly conclude that effective randomisation had occurred, as was the case in those studies that used block sequences with external statisticians (Wetherall et al., 2017).

Studies need to operate with a clear theoretical understanding of what aspect of mindfulness they are interested in (i.e. non-judgemental stance, breathing, awareness), what aspect of memory they are interested in (i.e. working memory), and why they would expect that aspect of mindfulness

to have an impact on that aspect of memory. These details are often not discussed adequately, and so it is left to the reader to interpret how the findings can be applied. More consideration needs to be given to the particular mindfulness techniques used. Whilst only a few studies specified using brief mindfulness exercises in the current review, future studies need to determine whether the mindfulness practices they use are sufficient to elicit the effect they are trying to identify. Alongside this, there needs to be a consideration of the real-world applicability of the methods used in mindfulness research, if the findings are to have any positive implications for individuals. It is not sufficient to demonstrate that mindfulness techniques might have an impact on a memory exercise in an experimental setting immediately after an exercise. Equally, if following an eight-week intensive mindfulness programme, improvement in memory are statistically significant, but not particularly substantial in terms of day-to-day benefits for an individual, it is possibly unlikely that they will feel it is worth investing in mindfulness techniques that demand a relatively large time commitment.

As a limited number of studies focused on older adult populations, and those with mild cognitive impairment, it is unclear how mindfulness may benefit these populations. Based on the studies available, it would appear that the benefits of mindfulness are not present for older adults, which may be due to the age-related cognitive decline (Gopie, Craik, & Hasher, 2010). However, further research is needed to better understand the potential benefits of mindfulness on memory for the populations who suffer from the greatest memory difficulties.

Overall conclusions

Chiesa et al. (2011) reviewed the evidence for whether mindfulness improved cognition, including specific studies focused on memory. They concluded that there was some limited evidence that mindfulness could enhance some types of memory such as working memory, but that all findings, whichever direction these pointed in, needed to be interpreted cautiously. The reason for this was because of wide-ranging methodological limitations in the studies reviewed which

affected the validity and reliability of their findings. This included some studies having an inadequate control group such as a waiting list control, which does not allow for a comparison of aspects of mindfulness as beneficial. In such cases, the main effect being measured could be caused by the fact that those participants in the experimental condition knew they were receiving some form of intervention, and equally those in a waiting list condition anticipating that cognition will not improve based on not receiving an intervention.

In addition to this, Chiesa et al. (2011) reference the poorly standardised mindfulness practices across studies which results in the inability to effectively compare findings across studies and to make generalisations. These issues were the subject of a paper by Van Dam et al. (2018), and suggestions were made as to how to address these issues. Given that a significant amount of time has passed since the review by Chiesa et al. (2011), and the upward trend in the publication of mindfulness research, the current review aimed to understand if there was any clearer evidence on the relationship between mindfulness and memory.

In conclusion, the results of the current systematic review provide some preliminary support for the suggestion that mindfulness could provide benefits in terms of enhancing working memory, short-term memory, and false-memory susceptibility. However, further higher quality studies focusing on the effects of mindfulness on various subsets of memory are needed to replicate available findings, and to address discrepancies in current findings.

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Chapter II: Empirical Paper

**A Comparison of the Effect of Relaxation and Focused Attention on Implicit Memory in
People with Acquired Brain Injury**

Abstract

Introduction. There are established links between relaxation and involuntary memories, and between involuntary memories and priming, posing the question of whether relaxation may also facilitate priming. The current study aimed to answer this question, as knowing how to facilitate intact systems such as priming in acquired brain injury, may improve memory rehabilitation methods by enabling people to make greater use of relatively intact systems to compensate for their difficulties. **Method.** Thirty-four participants with acquired brain injuries and varying degrees of memory impairment completed two priming tasks (stem completion and perceptual identification) with both primed and unprimed word lists, and under relaxation and focused attention conditions. **Results.** On the perceptual identification task, priming effects were significantly larger in the relaxation condition. Although they were also larger on the stem completion task, this difference was not significant. However, when individual responsiveness to relaxation techniques was taken into account through heart rate, the difference was significant for the stem completion task also. **Discussion.** Findings suggest a period of relaxation after learning may help in memory rehabilitation. Limitations of the study and considerations for further research are discussed.

Keywords: acquired brain injury, implicit memory, priming, perceptual identification, stem completion, relaxation

Introduction

Brain Injury and Memory

It is a well-established finding that acquired brain injuries (ABI) are associated with severe and long-term impairments of memory (Vakil, 2005; Dunning, Westgate, & Adlam, 2016).

However, not all types of memory are affected to the same degree, and implicit memory tends to remain relatively intact following brain injury (Graf & Schacter, 1985). Implicit memory has been defined as ‘memory for procedures or skills that is long-lasting and does not require conscious recollection or intentional retrieval’ (Rovee-Collier, Hayne, & Colombo, 2001, p.2).

Much of the evidence demonstrating the intactness of implicit memory following ABI comes from amnesiac patients. Procedural memory (memory of how to do things) is one subset of implicit memory that has been demonstrated as being intact in individuals with amnesia (Rovee-Collier et al., 2001). For example, Cavaco, Feinstein, van Twillert, and Tranel (2012) reported on a case study referred to as S.Z, an amateur saxophonist with severe anterograde amnesia following damage to his temporal lobes as a result of encephalitis. The authors tested S.Z.’s ability to learn and play 11 songs previously unknown to him through sight-reading, following three months of practice occurring bi-weekly. Recordings of S.Z.’s performance on the 11 practised songs, and five control (non-practised) songs were evaluated by a professional saxophonist who was unaware of which songs were practised, or acted as controls. S.Z. demonstrated significant improvement in his ability to read and play new music that he had been practising, despite the total inability to recognize any of the songs at a declarative level. The results from the study of S.Z.’s ability to learn new music clearly demonstrate that implicit procedural learning processes can remain intact following ABI, and when explicit learning processes are severely damaged.

Another type of implicit memory is priming, an effect in which exposure to a stimulus influences a response to a later stimulus without conscious awareness of this (Hsu & Schutt, 2012). Again, there is substantial evidence that this remains relatively intact after ABI (Rovee-

Collier et al., 2001). For example, Yeates and Enrile (2005) examined implicit and explicit (declarative) memory in a sample of 22 children with congenital brain injuries, 28 with ABI, and a control group of 29, with ages ranging from 8 to 15. Participants completed a fragmented picture identification task to assess perceptual priming, as well as a semantic decision-making task to assess conceptual priming. Each task also assessed explicit recall and recognition. All three groups showed roughly equivalent levels of perceptual and semantic priming, suggesting the groups with brain injury had relatively intact implicit memory. However, both brain injury groups demonstrated significantly poorer explicit memory compared to the control group. This study therefore adds further weight to the argument that implicit memory remains intact following brain injury, whereas explicit memory is often impaired.

Theoretical Divisions

On the basis of studies of amnesia, a distinction between procedural (knowing how) and declarative memory (knowing that) has been posited (Cohen & Squire, 1980; Tulving, 1985). Procedural memory has traditionally been viewed as a more primitive form of memory, largely governed by behavioural conditioning principles, whose contents are inaccessible to consciousness; as opposed to declarative memory whose contents are necessarily available to consciousness because they involve the internal representation of things that are not perceptually present. However, this division ran into difficulty in accounting for priming studies, in which declarative memories could potentially influence behaviour without conscious awareness.

Another framework that distinguished between implicit and explicit memory attempted to account for this (Graf & Schacter, 1985). Explicit memory was held to involve conscious recollection of previous experiences, whereas implicit memory involves the influence of previous experiences on current responses in the absence of any conscious recollection. However, this framework also ran into difficulty because of the evidence that participants often realise that the primed material presented at retrieval has been presented previously, and therefore the effect did not

occur in the absence of any conscious recollection (Schacter, Bowers, & Booker, 1989). To address this, implicit memory was subsequently defined as memory in which there is no conscious recollection of the material, or there is no intention to retrieve the material (Schacter, Chiu, & Ochsner, 1993). This confounding of the two characteristics in one definition seems unhelpful (Reber, 2013).

A preferable approach may be to place the emphasis on intentionality rather than consciousness in distinguishing different memory systems. Jacoby (1991) proposes a process framework that differentiates controlled and automatic processes, rather than using explicit and implicit memory to denote the dissociations between types of memory. Controlled processes are associated with intention and effort and can therefore be described as intentional memory when referring to controlled memory processes; within the explicit-implicit distinction, this is the equivalent of explicit memory. Conversely, automatic processes are those that occur passively without intention or effort and may or may not be accompanied by conscious awareness. Another feature of automatic processes is that they do not make the kinds of demands on the central processor controlling mental processes that intentional processes do.

The unique conceptual difference offered by Jacoby's process-driven framework is that unintentional memory covers both the traditional form of implicit memory (retrieval that occurs in the absence of conscious recollection) and the occurrence of non-intentional memory that one is also conscious of (labelled 'involuntary memory'). The latter form of memory is commonly triggered by environmental cues that are easily identifiable approximately 80% of the time (Ball & Little, 2006; Mace, 2004, 2006), and includes both episodic autobiographical memories (Berntsen, 2010) and semantic memories (Mandler, 1994).

Involuntary Memory

Experimental investigations with laboratory procedures have begun to investigate the variables that may lead to unintentional autobiographical memories. Mazzoni, Vannucci, and Batool (2014)

compared pictorial cues and corresponding verbal cues to assess their relative effectiveness in eliciting unintentional autobiographical memories in 40 participants. In the first experiment, pictorial cues and their associated verbal labels were relatively complex (e.g., armed bank robbery) and in the second experiment they were relatively simple (e.g., horse). In both experiments, participants took part in a vigilance task in which they were presented with frequent non-target and infrequent target visual stimuli (see Schlagman & Kvavilashvili, 2008). Pictorial or verbal cues were shown on both target and non-target stimuli, but participants were told that these were irrelevant to the task. Participants were then instructed to interrupt the task when they became aware of task-unrelated mental contents and to report them to researchers. In both experiments, significantly more involuntary memories were elicited in the verbal cue condition. However, memories following pictorial cues were reported to be much more vivid. The results from the study demonstrate that environmental cues can elicit unintentional memory retrieval, and that the form a cue takes can affect the frequency and vividness of these memories.

Implications for Rehabilitation

The work on intact implicit memory in amnesia led Baddeley and Wilson (1984) to suggest that errors should be avoided when people with acquired memory impairments are trying to learn something new. They argued that the recognition and elimination of errors during learning is dependent on explicit memory; those with impaired explicit memories will therefore struggle to recognise and eliminate errors but will learn them alongside the correct responses; and the competition between correct and incorrect learning will reduce the effectiveness of learning. This gave rise to errorless learning, which focuses on teaching methods that eliminate errors and which has been widely researched and implemented in rehabilitation settings (Kessels & Haslam, 2018). This conclusion about avoiding errors during learning is, perhaps, not the most obvious implication to draw from the evidence of intact memory systems. We should also be trying to find ways of

facilitating the use of these systems in people with memory impairments as a way of compensating for the impairments in their explicit memory (Riley & Venn, 2015).

It has been argued that involuntary memories arise from similar processes that underlie priming. Priming has been explained in terms of a reactivation and spreading activation model (Bower, 1996): Long-term representations of memory are activated when a person perceives them again; this activation spreads out to associated representations (e.g. to different examples of the same general category – e.g. seeing the word ‘apple’ will result in some activation of the representations of other fruit words); this activation and spreading activation remains for a non-trivial amount of time; and when in this activated state it is more likely to get selected amongst alternatives when some associated cue is presented in the priming test.

A similar account has been given of involuntary memory (Mandler, 1994; Kvavilashvili & Mandler, 2004; Mace, 2005). Autobiographical or semantic memories have long term representations in memory. Sometimes environmental or internal cues associated with those memories occur (e.g. a smell might occur that is associated with some particular incident in childhood). Through the process of activation and spreading activation, the representation can be activated to a sufficient level that it intrudes into consciousness (e.g. the smell is enough to trigger off the childhood memory that it is associated with).

There is evidence that involuntary memories are more likely to occur when a person is relaxed, and less likely to occur when they are focusing their attention on something. In a study in which participants kept a diary record of the occurrence of involuntary autobiographical memories, Berntsen (1998) found that such memories were far more likely to occur in situations when attentional demands were minimal (e.g. doing routine household chores, relaxing or doing nothing) or when the situation was failing to engage or maintain the person’s attention (e.g. when they found the activity boring). Kvavilashvili and Mandler (2004) reported similar findings for involuntary semantic memories, as well as autobiographical memories. In an experimental study, Giambra

(1995) found that the occurrence of task-unrelated images and thoughts during an ongoing laboratory vigilance task decreased as the frequency of the to-be-detected targets increased. Mandler (1994) provided an explanation of this in terms of the notion that associated environmental or internal cues excite the representations of these memories through the process of spreading activation, and suggested that spreading activation is suppressed when attention is engaged so that representations of the memories are less likely to reach the threshold required for conscious awareness (Mandler, 1994; Kvavilashvili & Mandler, 2004).

The links between relaxation and involuntary memories, and between involuntary memories and priming, raises the question of whether relaxation can facilitate priming as well. This was the aim of the present study. The practical value of this is that knowing how to facilitate intact systems such as priming may improve memory rehabilitation methods by enabling people to make greater use of relatively intact systems to compensate for their difficulties with explicit memory (Riley & Venn, 2015).

Method

Ethical Approval

The study was given ethical approval by the University of Birmingham Ethics Committee (Appendix B).

Overview

Each participant took part in three sessions. In the first, they were shown a range of different relaxation techniques. In the second and third, they took part in the two experimental conditions (relaxation and focused attention). In both sessions, participants were first exposed to two word lists; then they either relaxed using the technique they identified as most relaxing for them (relaxation condition), or took part in a challenging selective attention task (focused attention condition). Following this, they completed two priming tasks (stem completion and perceptual identification) that involved the pre-exposed (primed) lists coupled with unexposed lists (unprimed).

Participants

Participants were recruited from three branches of a charity providing day services for adults with ABI's in the community. They were recruited using two methods. Potential participants were initially provided with information about the study by support staff in the form of an invitation-to-participate letter (Appendix C), alongside a verbal explanation. The potential participant was then asked to consider whether they would be interested in participating in the study. If they were interested in finding out more about the research, they were required to sign a consent-to-contact form (Appendix D), giving the researcher permission to contact them. The researcher then arranged a meeting with the individual during operational hours at the service, where the study was explained in more detail and the individual was provided with the participant information sheet (Appendix E). Potential participants were given 24 hours to consider whether they wished to participate before being contacted again, and if they were still interested in participating in the research, a further meeting was arranged to obtain signed consent (Appendix F). The alternative method of recruitment was identical with the only exception being that instead of using the invitation-to-participate letter, a five-minute talk about the research was given by the researcher and people who expressed an interest were then given the consent-to-contact forms.

The criteria by which participants were included in the study were as follows. Participants were required to be fluent English language speakers (English did not have to be their first language) and over the age of 18. Participants had to be capable of giving informed consent. Informed consent was determined by participants being able to answer three questions: (1) How many times will we meet up after today? (2) Can you give me one example of the kind of task I will ask you to do if you take part? (3) Can you tell me one potential benefit and potential risk of participating in the study?

Participants had to have some form of ABI but not within the last 6 months prior to their participation in the study, and participants were also required to have some degree of memory

impairment, which was determined by asking participants about this and cross-referencing this with their records held by the service if this was not clear. To avoid any potential confounds, the intention was to exclude any participants with fluctuating or worsening cognitive status, or who would be unable to engage in the experimental tasks. Based on exclusion criteria, six participants were excluded from the study.

GPower analysis determined that for a two-factor repeated measures ANOVA, with the two factor being the relaxed versus focused attention conditions and primed versus unprimed, with the alpha set at 0.05 and power at 0.80, a sample size of 16 would be required to detect a large main effect ($f=0.4$), and a sample size of 34 would be required to detect a moderate effect ($f=.25$). Therefore, the aim was to recruit a sample of at least 34 participants.

Forty participants were recruited of whom 34 completed the study. Of the six who did not complete the study, four withdrew part way through the study stating that they were no longer interested in participating in the study. The remaining two participants were excluded from the study due to evidence that they could not provide informed consent or complete the tasks required as part of the study.

Design

A repeated measures design was used, with all participants receiving training in relaxation techniques and taking part in both conditions (relaxation vs focused attention). It was anticipated that performance might be affected by list content (i.e. despite matching them from the normative data, the word stems in one list may be more likely to be completed by the target words in the unprimed condition than the word stems in another list); and by session order (e.g. the novelty of the situation may lead to better performance in the first session). Counterbalancing was therefore used to ensure that each word list appeared an equal number of times in the two conditions (relaxation vs. attention); appeared an equal number of times as a primed and an unprimed list; and appeared an equal number of times in the first session and the second session. Counterbalancing was also

required to ensure that each condition (relaxation vs. attention) appeared an equal number of times in the first and second sessions. Eight allocations were required to ensure these criteria were met. These are shown in Table 1. There was no counterbalancing of how the lists were paired in each session: Each word list was always paired with the same equivalent word list. This was because it was not expected that the combination of lists would have any impact on performance.

Table 1.

Allocation, Condition, and Order of Experimental Procedures

Allocation	Condition and order	Stem Completion lists		Perceptual Identification lists	
1	1st Relaxation	A - primed	B – unprimed	E - primed	F – unprimed
	2nd Attention	C - primed	D - unprimed	G - primed	H - unprimed
2	1st Attention	A - primed	B – unprimed	E - primed	F – unprimed
	2nd Relaxation	C - primed	D - unprimed	G - primed	H - unprimed
3	1st Relaxation	A - unprimed	B – primed	E - unprimed	F – primed
	2nd Attention	C - unprimed	D - primed	G - unprimed	H - primed
4	1st Attention	A - unprimed	B – primed	E - unprimed	F – primed
	2nd Relaxation	C - unprimed	D - primed	G - unprimed	H - primed
5	1st Relaxation	C - primed	D – unprimed	G - primed	H– unprimed
	2nd Attention	A - primed	B - unprimed	E - primed	F - unprimed
6	1st Attention	C - primed	D – unprimed	G - primed	H – unprimed
	2nd Relaxation	A - primed	B - unprimed	E - primed	F - unprimed
7	1st Relaxation	C - unprimed	D – primed	G - unprimed	H – primed
	2nd Attention	A - unprimed	B - primed	E - unprimed	F- primed
8	1st Attention	C - unprimed	D – primed	G - unprimed	H – primed
	2nd Relaxation	A - unprimed	B - primed	E - unprimed	F - primed

The first participant was randomly allocated to one of the eight allocations; the next participant was randomly allocated to one of the remaining seven; and so on until all eight allocations had been used up. A new list of eight identical allocations was then drawn up, and the next participant was randomly allocated to one of the eight allocations. Allocation then proceeded as for the first set of eight allocations.

Materials**Word lists.**

Eight word lists were compiled (Tables 2 and 3). To compile the word lists, the normative data provided by Migo, Roper, Montaldi and Mayes (2010) was used. Using a UK sample of 80 participants, Migo et al., (2010) asked participants to complete a series of three-letter word stems (e.g. pir____) with the first word that came to mind. For each word that was given in response, they provided data about the frequency with which that word was given by the sample (e.g. how often 'pir____' was completed with the word 'pirate'). For each word they also provided information, gathered from other sources, about age of acquisition, concreteness, printed familiarity, imageability, number of syllables, common part of speech, and frequency of the occurrence of the words in the British language. All words selected for the present study were required to meet a minimum requirement for printed familiarity of at least 400 occurrences per million. This was to avoid the selection of rare or unusual words which the participants may have been unfamiliar with (since stems are unlikely to be completed by participants with words that they are unfamiliar with, and they are unlikely to identify unfamiliar words on the stem completion task). To further ensure that the words would be ones with which the participants were familiar, where there was an option, concrete nouns and verbs (which scored high on imageability) in the data provided by Migo et al., (2010) were selected in preference to abstract words. All words in the list were 5, 6 or 7 letters long. The length of the word was again likely to be associated with its familiarity and concreteness, and words that had too many letters were likely to have required longer exposure times in the perceptual identification task.

For the stem completion task, the primary aim in compiling the lists was to ensure that they were reasonably well matched in terms of the base rate of completing the stem with the target word in the normative data. Ensuring a reasonable match facilitates attribution of differences in performance on the lists to priming or condition effects. In order to complete the matching, the four lists used for the stem completion task were separated into two pairs (list A and list B; and list C and list D). For each word in list A, a word for list B was selected that was within 0.28% of the sample

spontaneous completion rate for the A-list word. The same matching process was used in compiling lists C and D. The lists, together with the base-rate completion of the word stem with the target word, are provided in Table 2.

Table 2.

Word Lists A, B, C, and D Familiarity and Base-rate Completion

Word List			Word List		
A	FAM	FRE	B	FAM	FRE
chain	513	0.00	paste	504	0.00
leather	571	0.00	pickle	562	0.00
volcano	461	0.00	carrot	539	0.00
boulder	495	2.50	seller	459	2.56
squint	528	2.63	epistle	536	2.7
monkey	531	2.63	bandage	546	2.63
scooter	468	2.70	stove	525	2.70
feast	457	3.13	uniform	484	3.13
harbour	512	3.33	coral	425	3.33
garlic	509	4.55	birch	518	4.55

Word List			Word List		
C	FAM	FRE	D	FAM	FRE
blade	517	0.00	pearl	508	0.00
plank	483	0.00	steak	558	0
shark	516	0.00	shield	464	0
truck	620	0.00	larch	406	0
tremor	401	0.00	latch	432	0
tribe	503	2.13	delta	359	2.44
trolley	449	2.22	swell	443	2.5
balloon	520	2.78	gloom	475	2.5
breeze	511	2.86	filth	532	2.78
arrow	490	4.76	fatigue	499	4.76

Note. FAM = printed familiarity, FRE = frequency (base-rate completion)

For the perceptual identification task, it was less apparent what factors might influence the ease with which the words could be identified other than familiarity. It was assumed that the length of the word would also affect performance. In compiling the lists, the four were again separated into two pairs (lists E and F, and lists G and H). Each word in list was matched with another in the

corresponding list that was within +/- 117 of the printed familiarity figure (out of a possible 700) provided by Migo et al., and that had the same number of letters. The lists are provided in Table 3.

Table 3.

Word Lists E, F, G, and H with Familiarity

Word List E	FAM	Word List F	FAM	Word List G	FAM	Word List H	FAM
scarlet	428	admiral	436	deposit	532	dresser	526
circuit	442	cockpit	481	reflex	515	bronze	398
statue	444	marble	436	medal	494	frown	502
casket	466	salute	479	fleece	410	pulpit	415
spinach	452	mineral	454	residue	401	duchess	416
parade	468	recital	468	chisel	469	beaver	470
assault	470	grizzly	471	tornado	484	antique	484
asphalt	488	whisker	489	stumble	536	sparrow	523
throat	548	blouse	562	gravel	502	locker	538
closet	540	poster	545	chute	437	shore	443

Note. FAM = printed familiarity

Equipment.

E-Prime software was used to display the word lists as part of the pre-exposure procedure, for the stems in the stem-completion task, and words for the perceptual identification task.

An encrypted university laptop was used to display word lists for the experimental tasks, to play soothing music, and to play the selective attention task video.

An Apple Watch Series 3 was used to monitor heart rate as a measure of relaxation. Recent research has shown the Apple Watch heart rate monitor measures beats per minute (BPM) with an accuracy of 99.9%, and precision of 5.9% (El-Amrawy & Nounou, 2015).

Methods for inducing relaxation or heightened attention.

Prior to engaging in any experimental sessions, participants were taken through a range of different relaxation techniques as a group; specifically, guided imagery, progressive muscle relaxation, mindful breathing and relaxing music (Appendix G). The relaxation techniques were

retrieved from the Massachusetts Department of Mental Health via the following website:

http://www.traumacenter.org/resources/pdf_files/relaxation_exercises.pdf, with the exception of soothing music which was available on YouTube via the following link:

<https://www.youtube.com/watch?v=1ZYbU82GIz4>

Each relaxation technique was read out loud by the researcher and lasted between three and four minutes long so that these were fairly matched to the focused attention task.

The focused attention exercise was a three minute, 21-second-long video of a selective attention task also available on YouTube via the following link:

<https://www.youtube.com/watch?v=XkaeiGl68Zo>. The video displayed three separate tasks for participants to attend to, with written instructions for each. The first task asked participants to count the number of kick-ups performed with a football, the second asked participants to follow where a ball was hid under three cups whilst the order of these were rearranged, and the final tasks required participants to count the number of skips executed correctly with a skipping rope.

Measures.

The dependent variable for the stem completion task was the number of words given on the test that corresponded to the words on the lists. For the perceptual identification task, it was the number of words correctly identified.

To provide information about the cognitive impairments of the sample, participants were required to complete a test of memory and a test of executive function. The measure of severity of memory impairment was provided by the standardised scores from Logical Memory I and II subtests of the Wechsler Memory Scale - Third Edition (WMS-III; Wechsler, 1997). This test requires the immediate and delayed recall of two short stories and provides an immediate recall score, and a retention score based on the amount of information on the two stories retained over a 25-35-minute period.

The measure of executive functioning was provided by scaled score from the Tower Test from the Delis Kaplan Executive Functioning System (DKEFS; Delis, Kaplan & Kramer, 2001). This test was chosen because it assesses a fairly wide range of executive function skills, including rule learning, spatial planning, and inhibition, and because participants generally appear to engage well when completing the task.

Other measures used to provide a description of the participants included the Test of Pre-Morbid Functioning – UK Version (Wechsler, 2011) and European Brain Injury Questionnaire (Teasdale et al, 1997). The former provided an estimate from reading performance of each participant's pre-morbid IQ. The EBIQ is a 66-item, self-report measure using a 3-point Likert scale to assess the cognitive, emotional and social difficulties experienced by people with brain injury. The 34-item core version of this measure detailed in the Teasdale et al (1997) paper was used as this provided an adequate measure for the current research, and reduced the burden on participants, which was an important consideration given the difficulties in relation to attention and fatigue that are commonly associated with ABI (Park & Ingles, 2001; Wilkinson et al., 2018).

A demographic questionnaire was developed by the researcher (Appendix H), in part to assess suitability of participants against inclusion criteria, but also to determine the representativeness of the sample.

An Apple Watch was used to measure heart rate before and after each of the four relaxation techniques that were completed as part of the pre-experimental relaxation session. Heart rate was recorded again before and after the relaxation or focused attention condition for each participant in order to evaluate relaxation during the experimental tasks. A state of relaxation is associated with reduced heart rate (van Dixhoorn & White, 2005), and focused attention is associated with an increased heart rate (Kennedy & Scholey, 2000; Luque-Casado, Perales, Cárdenas & Sanabria, 2016). The final measure used as part of the research alongside the physiological measure of arousal was the Smith Relaxation Evaluation Scale (SRES; Smith, 2001). The SRES is a brief four-item

self-report evaluation measure of relaxation techniques on a scale of one to ten. The SRES was used to complement data from the Apple Watch and was completed immediately after each relaxation technique in the relaxation sessions. The aim was that the data from the SRES would support participants to appreciate which technique worked most effectively for them in inducing a state of relaxation

Procedures

Session 1: Selection of a method of relaxation.

There is a range of relaxation methods available and people differ in how relaxing they find them (Manzoni, Pagnini, Castelnuovo, & Molinari, 2008; McCallie, Blum, & Hood, 2006; Pelletier, 2004). To try to ensure that all participants would be relaxed by the method used in the experimental sessions, different methods were demonstrated to the participants in a prior session and measures were taken of how relaxing each method was for each particular participant, so that the most relaxing method could be used for that individual in the experimental session. This prior session also enabled the participants to become familiar with the method used in the experimental session with the expectation that they would find it easier to relax using a method they were already familiar with. This prior relaxation session was done in groups of six to ten participants. Participants tried four methods; specifically, guided imagery, progressive muscle relaxation, mindful breathing and relaxing music (see Appendix G). Which technique most effectively created a state of relaxation for each participant was then assessed using the SRES (Smith, 2001) and an Apple Watch in order to obtain qualitative and quantitative measures of relaxation respectively. Each participant was then told which method had achieved the highest reduction in heart rate and which method achieved the highest score on the SRES. Participants then made a decision about which method they wanted to use in the experimental sessions.

Session 2: First experimental session.

A full list of instructions provided to participants during the experiment can be found in Appendix I. In the first experimental session, participants were shown two lists of 10 words each (one acting as the primed list for the subsequent stem completion task, and one acting as the primed list for perceptual identification task). The words were presented one at a time on a computer screen, by means of the E-Prime programme. Words from the primed and unprimed lists for each condition were mixed randomly on E-Prime before being used with participants, and the result of this randomizing of lists was then presented in the same order for all participants. To ensure that they attended to the words, participants were asked to say the word out loud, and to state the third letter of the word and whether or not it contained the letter 'e'.

Following the priming procedure, the participant would get into either a relaxed state using the specific technique selected during the first session or a state of focused attention using the selective attention video, depending on what they had been allocated for that session. The relaxation or the focused attention task took between three and four minutes. Heart rate was measured before, and following this task using an Apple Watch to ascertain whether there was a difference between the conditions in terms of the participant's arousal levels.

Following this, the participant completed two tests of implicit memory – a stem-completion task and a perceptual identification task. For each test of implicit memory, half of the words came from one of the two lists shown earlier in the priming task (primed list), and half came from a list not previously shown to the participant (unprimed list). This provided ten primed words and ten unprimed words for each task, and these were randomly combined. Each random combination was kept the same for each participant using the same combination of word lists.

On the stem completion task, participants were shown a three-letter word stem followed by three underscores representing missing letters (e.g. BLA___) and asked to complete it with the first word that came to mind. All words stems were presented with three underscores and participants were informed that the gap did not represent the number of missing letters, only the space where

missing letters would go. Once the participant had provided a word or had indicated that they could not think of one, the next word was shown. On the perceptual identification task, the participant was shown a series of words, one at a time, on a computer screen for 0.045 seconds and asked to identify the word. The time the word was displayed for in the task was determined by a pilot study involving four participants using a separate set of words to the ones used in the actual study. In the pilot, various times were trialled. At 0.045 seconds, approximately half of all words were correctly identified by participants suggesting that there was the opportunity to identify some, but not all of the words, which would enable a comparison of correct responses on the primed and unprimed lists.

Session 3: Second experimental session.

In the second experimental session conducted one week later, the participant completed the session in the relaxed or focused attention condition, depending on which condition they were allocated in the first session.

Completion of assessments.

Participants were free to choose when to complete the assessments required as part of the study. The majority of participants chose to do this after the first experimental session, however some chose to do this in the second session, or across both conditions due to their time constraints. The order in which participants completed the assessments was not consistent between participants as it was not anticipated that this would have any bearing on the outcome of the experimental tasks because completion of these tasks always preceded completion of other measures. Once participants had completed all experimental tasks and assessments they were provided with a debrief and the opportunity to discuss the research (Appendix J).

Results

Description of Sample

Results from the demographic questionnaire with the exclusion of occupation are summarised in Table 4. The average age of participants was 50.8, with a range from 30 – 66.

The highest standard of qualification achieved by each participant was coded using the Office of Qualifications and Examinations Regulations standards (Ofqual, 2015). The levels are based on the standards of knowledge, skill and competence needed for each qualification, with higher numbers representing qualifications requiring more knowledge, skills, and competence (Appendix K).

Traumatic brain injury was the most common cause of injury (38.2%), followed by stroke (35.2%), tumour (11.7%), infection (5.8%), surgery (5.8%), and hypoxia (2.9%).

The shortest period of time since injury prior to participating in the study was 2.1 years, and the longest period of time since injury prior to participating in the study was 35.5 years. When the participant was unable to give an accurate time since injury, confirmation was provided by staff that the participant had been attending the service for at least six months (and thus met the inclusion criteria).

Table 4.

Participant Demographic Information Excluding Occupation

Participant Number	Current age M=50.81 SD= 10.66	Gender F=female (39%) M=Male (61%)	Highest Educational Qualification* (Level)	Cause of Injury	Time Since Injury M= 12.91 SD = 8.65
1	63	F	Postgraduate diploma (7)	Traumatic brain injury	27.3
2	37	M	DipHE (5)	Tumour	17.3
3	59	M	A level (3)	Stroke	Unknown
4	55	M	Degree in computer science (6)	Stroke	12.10
5	57	M	HND (5)	Tumour	15.2
6	25	M	Msci Mechanical engineering (7)	Traumatic brain injury	6.3
7	53	F	B.A German (6)	Infection	28.6
8	59	M	None (Entry)	Stroke	17.9
9	57	F	O level (2)	Traumatic brain injury	Unknown
10	62	M	O level (2)	Surgery	7.9
11	55	F	O level (2)	Traumatic brain injury	6.3
12	30	M	None (Entry)	Traumatic	13.3

				brain injury	
13	48	M	CSE 1 (1/2)	Stroke	13.9
14	52	F	O level (2)	Stroke	Unknown
15	53	M	CSE (1/2)	Stroke	2.3
16	47	M	None (Entry)	Stroke	3.9
17	53	M	None (Entry)	Traumatic	Unknown
				brain injury	
18	52	M	None (Entry)	Surgery	35.5
19	53	F	O level (2)	Traumatic	12.3
				brain injury	
20	36	F	BSc (6)	Infection	2.1
21	47	M	GCSE (2)	Traumatic	24.3
				brain injury	
22	66	M	A Level (3)	Traumatic	19.3
				brain injury	
23	63	M	CSE (1/2)	Traumatic	Unknown
				brain injury	
24	42	F	A Level (3)	Traumatic	6.4
				brain injury	
25	57	F	None (Entry)	Stroke	6.5
26	44	F	NVQ (4)	Stroke	Unknown
27	54	F	A Level (3)	Stroke	19.6
28	24	F	None (Entry)	Tumour	4.0
29	57	M	City and Guilds (4)	Traumatic	19.3
				brain injury	
30	63	M	BA Classical Music (6)	Stroke	5.2
31	59	F	None (entry)	Hypoxia	10.3
32	49	M	Teaching Certificate (5)	Stroke	4.3
33	46	M	BTEC (3)	Tumour	12.3
34	31	M	GCSE (2)	Traumatic	7.9
				brain injury	

Items three and four from the demographic questionnaire asked participants about their employment status before and after their brain injury. Responses were coded using the Labour Force Survey (ONS, 2009). Results from items three and four are summarised in Table 5.

It can be seen from Table 6 that all participants were in some form of employment prior to acquiring their brain injuries. However, out of 34 participants, only one was in (part-time) employment following their brain injury. Three participants described themselves as retired, two as house husbands, and one as a volunteer. These are classed as 'unemployed' by the Labour Force Survey (ONS, 2009).

Table 5.

Summary of Occupation Before and After Injury

Occupation Code	Frequency Pre-injury	Frequency Post-injury
Managers and senior officials	1	0
Professional occupations	2	0
Associate prof. and technical occupations	8	0
Administrative and secretarial occupations	4	0
Skilled trades occupations	4	0
Personal service occupations	7	0
Sales and customer service occupations	3	1
Road Transport Operatives	3	0
Elementary occupations	2	0
Unemployed	0	33
Total	34	34

Table 6 provides summary results for the neuropsychological tests and EBIQ completed by each participant. Comparative scores are provided at the bottom of the table. The population norms for the TOPF and the WMS are taken from their respective manuals. Carlozzi, Grech, and Tulsky (2013) provided data about the WMS performance of a sample of 65 individuals classified as having a 'severe traumatic brain injury'. For the EBIQ, average scores are provided from the Teasdale et al. (1997) paper based on a sample of 905 people with a brain injury and 203 people without a brain injury. The EBIQ is a three-point Likert scale with scores of one for 'not at all', two for 'a little', and three for 'a lot' in relation to how much or often individuals experience a particular difficulty in the previous month. A total averaged score is provided which indicates the level of difficulty experienced by an individual, with a minimum score of one, and a maximum score of three. Comparison with the other brain injury samples indicates that the sample in this study had relatively severe memory impairment, and a relatively high level of functional problems.

Overall, whilst slightly lower than scores for the normative data set, the average scores on the TOPF were in the typical range that would be expected. Some participants' scores were significantly lower than others, and whilst for some this possibly reflected their premorbid IQ, this appears more likely a reflection of the cognitive difficulties associated with their ABI's, based on their pre-morbid occupational status. For example, participant three had a score of three on the TOPF which provides an estimated IQ of 51. It is unlikely that an individual with an IQ of 51 would be able to attain A-levels, which was participant three's highest level of educational qualification achieved. The removal of scores for participants 3, 10, 20, 24, and 36, which appear dubious when accounting for the pre-morbid employment, gives a mean of 98.90 and standard deviation of 11.84. This arguably provides a score that is likely to be more reflective of the pre-morbid IQ for participants in the study.

Scores on the D-KEFS suggested that overall participants were likely to exhibit difficulties associated with damage to executive functions such as planning. There were some exceptions, with a small number of participants performing better on the test than the age-equivalent norms.

Table. 6

Summary Results for the Neuropsychological Tests and EBIQ Completed by each Participant along with Normative Data

Participant number	TOPF score (estimated FSIQ)	WMS Logical memory 1 scaled score	WMS Logical memory 2 scaled score	D-KEFS scaled score	EBIQ score
1	67 (121)	5	6	4	1.08
2	57 (107)	3	2	3	1.85
3	3 (51)	1	1	6	1.14
4	55 (105)	5	5	4	1.41
5	34 (94)	2	4	5	1.7
6	54 (104)	4	6	4	2.26
7	49 (101)	3	4	1	1.91
8	29 (91)	5	9	5	1.79
9	13 (74)	4	6	3	1.61
10	38 (95)	7	4	1	2.14
11	56 (106)	4	6	8	2.76
12	18 (81)	1	1	1	2.26
13	23 (86)	1	1	8	2.76
14	50 (101)	2	4	7	2.29

15	29 (91)	1	3	10	2.05
16	23 (86)	1	1	3	2.73
17	7 (62)	1	1	6	2
18	18 (81)	5	5	2	1.82
19	20 (83)	6	6	4	2.76
20	47 (99)	5	6	11	1.85
21	16 (78)	1	1	1	1.58
22	49 (101)	8	9	9	2.26
23	67 (121)	4	7	10	2.11
24	36 (94)	2	3	13	2.29
25	21 (85)	3	4	5	2.14
26	55 (105)	4	5	10	2.7
27	64 (116)	2	4	13	2.11
28	59 (109)	2	1	13	2.02
29	20 (83)	1	2	13	1.32
30	64 (116)	2	5	10	2.08
31	9 (66)	1	1	11	1.76
32	35 (94)	3	4	8	2
33	49 (101)	4	7	9	1.73
34	61 (111)	5	6	10	1.41
Participant Mean and SD	Mean = 38.08 (94.08) SD = 19.55 (16.45)	Mean = 3.12 SD = 1.91 Range = 1-8	Mean = 4.11 SD = 2.34 Range = 1-9	Mean = 6.79 SD = 3.88	Mean = 1.99 SD = 0.44 Range = 1.08-2.76
ABI sample for comparison	*	M= 8.03** SD= 3.52	M = 7.32** SD = 3.82		M=1.68*** SD=0.36
General Population	M=100 SD = 15	M = 10 SD = 3	M = 10 SD = 3	M = 10 SD = 3	M=1.45*** SD=0.30

*No available data

** Data from Carlozzi et al. (2013)

*** Data from Teasdale et al., (1997)

Analyses

The sequence of steps involved in the data analysis is described in Table 7. The alpha level for all analyses was set at .05.

Table 7.

Sequence of Data Analysis

Steps	Analysis conducted
Step 1	

Analysis of effectiveness of different relaxation techniques during initial session to select technique	Paired t-test comparing pre and post heart rate data, and descriptive data for SRS
Step 2 Analysis of effectiveness of relaxation vs. attentional condition in relaxing participants	Two-way repeated measure ANOVA of the heart rate data during the two experimental sessions, with the two factors being experimental condition (relaxation vs. attention) and time (before vs. after experimental condition)
Step 3a: Analysis of whether relaxation led to increased priming on the stem completion task compared to focused attention	Two-way repeated measures ANOVA of stem completion data with the two factors being condition (relaxation vs. attention) and priming (primed vs. unprimed)
Step 3b As for step 3a, but using data from perceptual identification	
Step 4: Step 3a and 3b repeated, but taking into account individual differences in responsiveness to the relaxation techniques based on heart rate	Two-way repeated measures ANCOVA, with pre and post difference in heart rate as a covariate

Checking whether data met assumptions of analysis.

Variables were examined for their proximity to the normal distribution and outliers based on methods recommended by Tabachnick, Fidell, and Ullman (2007). A score was considered as an outlier if it was more than 3.29 standard deviations from the mean; and skew and kurtosis was considered as significant if the skewness (or kurtosis) statistic divided by its standard error was greater than 3.29. For the relaxation session before and after HR and SRES scores, there was one extreme value for participant 7 on the post-heart rate score for the soothing music technique.

However, the score was not adjusted because adjusting it made no real difference to the outcome of the analysis. Distributions did not depart significantly from normal.

Secondly, for the relaxation scores based on heart rate within the experimental sessions, there was some moderate skew and kurtosis on the post-attention heart rate score and participant 33 was identified as an outlier on this variable. However, the scores were left unadjusted as again this made little difference to the outcome of the analysis.

Finally, for the scores on the perceptual identification and stem completion tasks, there were no outliers and no significant departures from the normal distribution on the perceptual identification test. There were no outliers on the stem completion test, but there was skewing and kurtosis on the unprimed relaxation and unprimed attention score. This was due to floor effects and a limited range of scores. Because of the limited range of scores, it was not possible to transform the distributions to make them closer to the normal distribution. Therefore, the outcome of the analysis involving these scores needs to be treated with some caution because of this.

Repeated measures ANOVAs also require that the assumption of sphericity is met. The outcome of Mauchley's test of sphericity was checked on the SPSS output files for the analyses, and the assumption was met in all cases.

Relaxation effects in the pre-experimental session (Step 1).

Six participants chose to use a relaxation technique which was not indicated as the most relaxing for them based on the heart rate measure i.e. they opted for a technique that had not reduced their heart rate as much as a different technique. However, where this was the case, participants typically chose the technique they found most relaxing subjectively, based on the scores they gave their chosen technique on the SRES. Participant heart rate scores from directly before and after the relaxation condition are summarised in Table 8.

Table 8.

Choice of Relaxation Technique, Pre-relaxation, and Post-relaxation Heart Rate Readings during the Relaxation Condition including Descriptive Statistics

Participant number	Relaxation technique	SRES score for chosen technique M=22.02 SD=8.04	Pre-relaxation heart rate (BPM) M=77.64 SD=7.04	Post-relaxation heart rate (BPM) M=72.38 SD=7.29	Difference between pre and post heart rate scores M=5.26 SD=6.67
1	GI	26	81	74	7
2	GI	30	79	63	16
3	SM	3	75	74	1
4	MB	23	86	72	14
5	GI	19	75	76	-1
6	GI	14	69	67	2
7	SM	22	73	70	3
8	PMR	16	79	65	14
9	MB	27	74	77	-3
10	GI	30	74	67	7
11	SM	12	80	77	3
12	GI	18	86	80	6
13	SM	21	75	63	12
14	MB	21	70	68	2
15	GI	27	73	79	-6
16	GI	15	72	75	-3
17	GI	12	81	68	13
18	GI	15	75	69	6
19	GI	30	73	72	1
20	GI	24	91	85	6
21	GI	3	85	80	5
22	SM	30	76	68	8
23	GI	30	65	58	7
24	MB	18	77	77	0
25	PMR	27	76	64	12
26	SM	30	83	81	2
27	SM	30	92	65	27
28	SM	30	99	95	4
29	SM	30	74	71	3
30	PMR	12	76	68	8
31	SM	30	78	73	5
32	GI	30	72	75	-3
33	MB	25	72	68	4
34	MB	19	74	77	-3

GI = Guided imagery; SM = Soothing music; PMR = Progressive muscle relaxation; MB = Mindful breathing

In order to evaluate the effectiveness of each relaxation technique in inducing a state of relaxation during the pre-experimental session, a paired samples t-test was conducted on the before and after HR data. The results from this are in Table 9.

Table 9.

Descriptive Statistics and Significance of Relaxation Effect for each Relaxation Technique using HR Data

Relaxation technique	Mean	SD	Sig. (2-tailed)
Progressive muscle relaxation	1.00	10.4	.581
Mindful breathing	.941	13.04	.677
Guided visualization	5.23	9.79	.004
Soothing music	6.94	11.26	.001

It can be seen from Table 9 that the relaxation effects for progressive muscle relaxation and mindful breathing were not significant, and guided visualization and soothing music appeared to be more effective. This is consistent with the participants' choices detailed in Table 8, with the most popular choices being guided visualization (44%) and soothing music (29%) and the least popular being mindful breathing (18%) and progressive muscle relaxation (9%)

Effectiveness of relaxation technique during the experimental session (Step 2).

A two-way repeated measures ANOVA of the HR data during the two experimental sessions was carried out, with the two factors being experimental condition (relaxation vs. attention) and time (before vs. after experimental condition). The aim of this was to establish whether the experimental manipulations were effective in producing a more relaxed state during the relaxation condition compared to the focused attention condition. The results are summarised in Table 10. The mean HR before the experimental condition was 78.08 for relaxation and 76.88 for the attention condition; for after the condition the mean was 72.69 for relaxation and 79.73 for attention (Figure

1). The significant interaction effect indicates that the relaxation manipulation was, indeed, more effective than the attention manipulation in reducing heart rate (and therefore presumably in relaxing the participants).

Table 10.

ANOVA for Pre and Post Heart Rate Readings in the Experimental Sessions

	F	sig
<u>Main effects</u>		
Condition (relaxation vs. attention)	17.15	<.001
Time (before vs. after)	2.54	.124
<u>Interaction effect</u>		
Condition-x-time	32.70	<.001

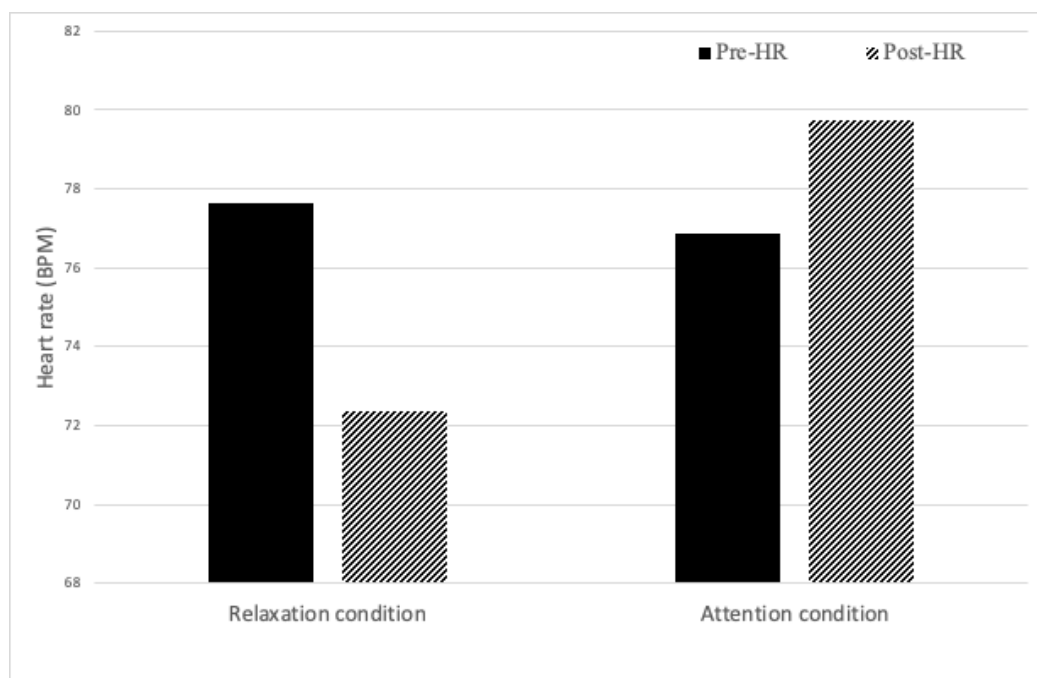


Figure 1. Relaxation Versus Focused Attention Pre and Post Heart Rate.

Evaluating the impact of relaxation on priming (Steps 3a and 3b).

To test the main hypothesis (that relaxation will facilitate priming) a two-way repeated measures ANOVA of stem completion data was carried out with the two factors being condition (relaxation vs. attention) and priming (primed vs. unprimed). The same analysis was also carried out for the perceptual identification data. The results for the analysis of the stem completion task and perceptual identification task are summarised in Table 11.

Table 11.

Summary of ANOVA for the Stem Completion and Perceptual Identification Data

	F	sig
Stem Completion		
Main effects:		
Condition (relaxation vs. attention)	.081	.778
Priming (primed vs. non-primed)	47.46	<.001
Interaction effect:		
Condition-x-priming	2.57	.119
Perceptual identification		
Main effects:		
Condition (relaxation vs. attention)	3.88	.057
Priming (primed vs. non-primed)	39.32	<.001
Interaction effect:		
Condition-x-priming	5.09	.031

A highly significant priming effect was observed for both the stem completion and perceptual identification tasks. This was important because, without a large priming effect, the study's hypothesis could not be tested. However, it should be noted that, for some participants, the stem completion task was subject to floor effects and the perceptual identification to ceiling effects, and this increased the probability of Type 2 errors (i.e. accepting the null hypothesis when the alternative was true).

The main hypothesis (that relaxation would increase the priming effect) was tested by means of the interaction effect. For the stem completion task, the mean for the primed items in the relaxation condition was 2.38 and the mean for the unprimed items was .441; for the attention condition the means were 2.06 and .647 respectively (Figure 2). Although as expected the priming effect (i.e. primed minus unprimed score) was larger in the relaxation condition, the interaction effect was not significant.

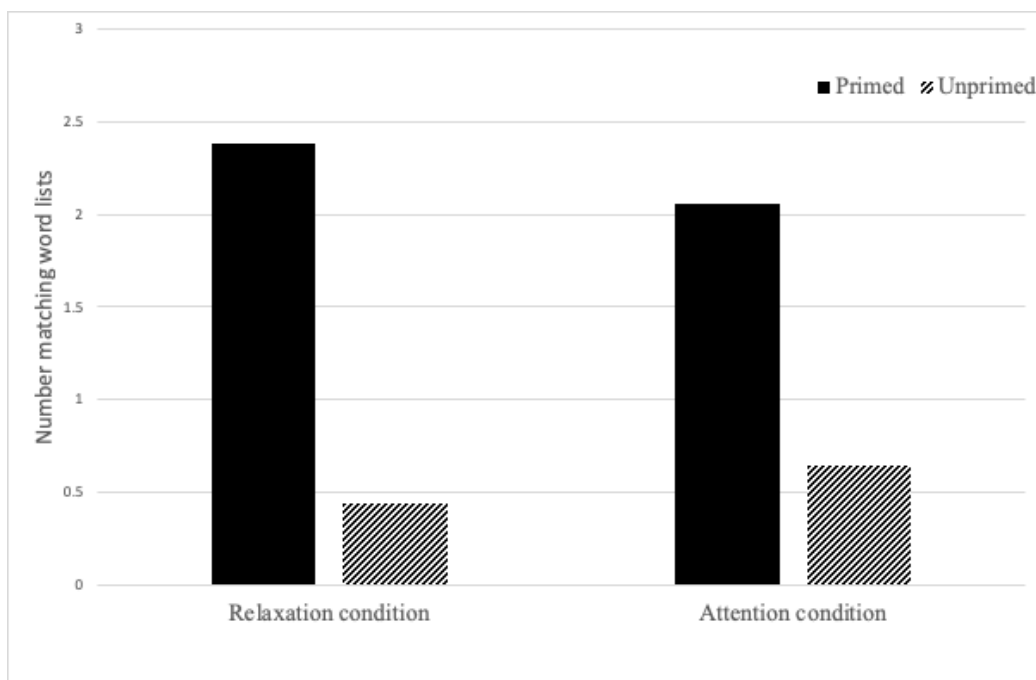


Figure 2. Mean Number of Items Correctly Recalled on the Stem Completion Task

For the perceptual identification task, the mean for the primed items in the relaxation condition was 5.18 and the mean for the unprimed items was 3.32; for the attention condition the means were 4.12 and 3.11 respectively (Figure 3). The significant interaction effect (Table 12) indicates that the priming effect was significantly larger in the relaxation condition, supporting the main hypothesis of the study.

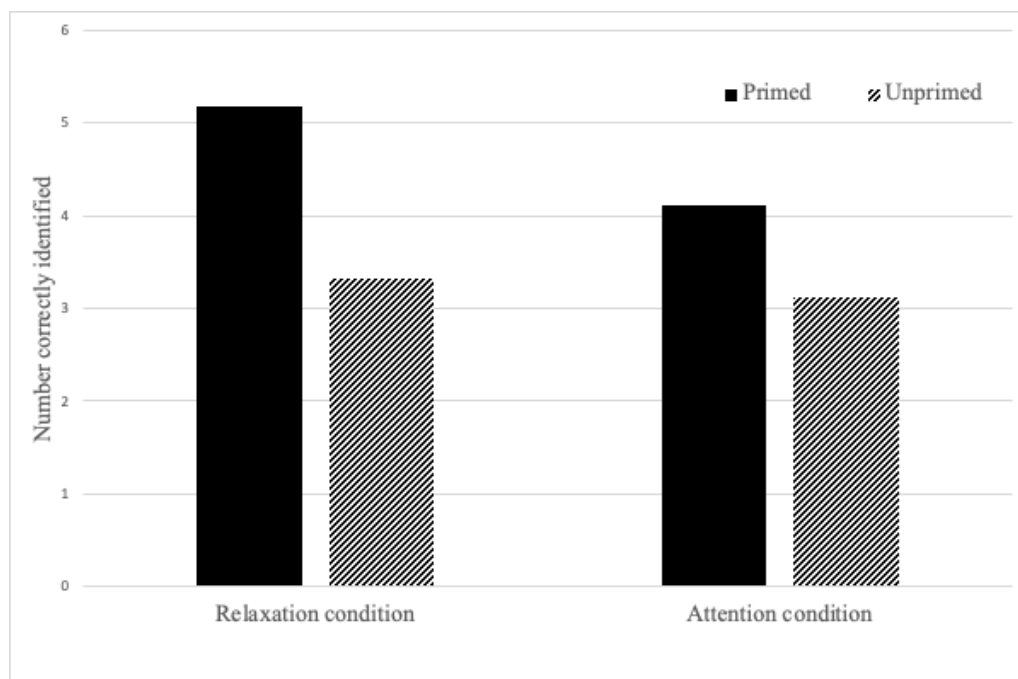


Figure 3. Mean Number of Items Correctly Recalled on the Perceptual Identification Task

Analysis with responsiveness to relaxation as a covariate (Step 4).

The final step of the analysis was conducted to test whether relaxation resulted in a significant priming effect when taking account of individual differences in responsiveness to the relaxation technique. The justification for this analysis came from the observation that some participants' heart rates did not reduce following the relaxation technique (see Table 9). If the technique did not make the person more relaxed, then the hypothesised effect of relaxation would not occur. Thus, the absence of a relaxation effect for some participants increases the probability of Type 2 errors, and it was important to test the hypothesis when controlling for this lack of effect.

An ANCOVA was carried out on the stem completion data with the two repeated factors being condition (relaxation vs. attention) and priming (primed vs. unprimed), and with the heart rate difference (pre-condition HR minus post-condition HR) as a covariate. The same analysis was also carried out for the perceptual identification data. The results from the analysis are represented in Table 12. The interaction effects for both the stem completion and the perceptual identification data were significant, supporting the hypothesis that relaxation would enhance the priming effect.

Table 12.

Summary of ANCOVA for the Stem Completion and Perceptual Identification Data, with HR

Difference as the Covariate

	F	sig
Stem Completion		
Main effects:		
Condition (relaxation vs. attention)	.060	.807
Priming (primed vs. non-primed)	29.75	<.001
Interaction effect:		
Condition-x-priming	4.27	.037
Perceptual identification		
Main effects:		
Condition (relaxation vs. attention)	4.63	.039
Priming (primed vs. non-primed)	39.54	<.001
Interaction effect:		
Condition-x-priming	7.04	.012

Discussion

Summary of Results

The aim of the study was to evaluate whether relaxation can increase priming effects. The initial analysis provided some support for this idea in that the priming effect was significantly larger in the relaxation condition compared to the attention condition for the perceptual identification task. However, although the priming effect in the relaxation condition was also larger in the stem completion task, this difference was not significant. However, when heart rate change was added to the analysis as a covariate, the priming effect was significant for both the stem completion and perceptual identification tasks. Additional analyses showed that there were significant priming effects on both tasks. Also, in general the relaxation techniques significantly reduced heart rate compared to the attention task, but not all participants appeared to be particularly relaxed by the techniques.

Association between Relaxation and Priming

Why did relaxation lead to increased priming effects? In the studies of the link between relaxation and involuntary memories described in the introduction (Berntsen, 1998; Giambra, 1995; Kvavilashvili & Mandler, 2004), the involuntary memories are typically long-established ones that are activated by some internal or external cue. A classic example is the account by the French novelist Proust of the memories of childhood triggered by eating a particular kind of cake (Draaisma, 2006). Here the effect of relaxation is presumably at the retrieval phase of the memory process: Relaxation makes established memories more accessible for retrieval. A similar account might be given for the findings of the present study: The effects of the relaxation (or attention-demanding task) persist to the priming task, and the state of relaxation makes the representations that were activated during the initial acquisition phase more accessible for retrieval.

Another possibility is that relaxation facilitated consolidation processes, whereas the attention condition interfered with consolidation. In studies of explicit memory, it has long been known that learning two things in succession results in poorer learning than just learning one thing. For example, in studies of retroactive interference, studying word list A and then word list B results in poorer subsequent recall for list A than if just list A is learnt followed by an interval of no learning (Lechner et al., 1999). However, it does not have to be two learning tasks that create interference in this way. Any kind of mental activity involving concentration can interfere with prior learning and this is known as nonspecific retroactive interference (Wixted, 2004). For example, in the study by Dewar et al. (2007), participants learnt a word list and then during an 8-minute interval, different groups did a range of attention-engaging activities (such as listening to a radio recording or solving mathematical problems) and were compared to a group that did nothing in the interval. All the five attention groups did worse on subsequent recall than the group that did nothing in the interval. An account of this nonspecific retroactive interference has been given in terms of the second task interfering with the consolidation of the first task (Dewar et al., 2007 and 2012; Craig et al., 2016).

Something similar may have been happening in the present study: The attentional task may have interfered with the consolidation of the studied material, whereas relaxation did not.

Similar to the findings of the present study, several studies in explicit memory have also found that a period of relaxation immediately after the acquisition phase can result in better learning than a period in which the learner engages in an attention-demanding task (Brokaw et al, 2016; Craig et al., 2015 and 2016; Dewar et al., 2012; Martini et al., 2019). Relaxation in these studies has usually taken the form of the participants being placed in a quiet darkened room and being instructed to close their eyes, while the attention-demanding task has involved such activities as watching movies or completing neuropsychological tests. Similar studies, again involving the explicit recall of material, have also involved people with acquired memory impairments and found a benefit for the relaxation condition (Cowan et al., 2004 and 2005; Dewar et al., 2009 and 2012B).

Limitations of the Study

There were a number of limitations to the study. One of the most significant in terms of implications for the study was the large individual variability in terms of responses to relaxation and priming. For example, the large variation in ability to detect words on the perceptual identification task, meant some participants showed ceiling effects and some floor effects, which in turn would have decreased the effect size. Similarly, variability was also seen in the stem completion task, with some participants showing floor effects (i.e. no priming), again decreasing effect size. This may have been related to the possibility that, judging by the large discrepancy between the estimated pre-injury IQ and pre-injury status for some participants, the brain injury may have caused some reading difficulties for these participants. Reading difficulties may have then caused low levels of performance on the stem completion and perceptual identification tasks.

Variable effectiveness of the relaxation procedure during the experimental sessions and the prior relaxation sessions was also observed. Based on the analysis, it was clear that a priming effect was only likely to happen if the participant successfully relaxed during the experimental session. It

is possible that more effective relaxation could have been achieved by using other methods that have improved the ability of participants to relax including lighting (Minguillon, Lopez-Gordo, Renedo-Criado, Sanchez-Carrion, & Pelayo, 2017), touch (Fakouri & Jones, 1987; Harris & Richards, 2010), and virtual reality (Stetz et al., 2011).

Another key limitation of the study is that priming effects for word lists are not an ecologically valid task; that is, there is no direct real-world equivalent of this task that makes improved efficacy on this task adaptive. Providing evidence of the benefits of relaxation for learning material of practical relevance to the participants (e.g. a sequence of directions) would have been useful. However, at this initial stage of investigating the impact of relaxation, word lists were preferable because they provided better experimental control.

The study compared relaxation techniques (relaxation condition) with an attentionally-demanding task (focused attention condition). It would be useful to compare both relaxation and focused attention with a condition in which the participant was not given any specific instructions about what to do. This would provide a sound basis for stating whether it was having to concentrate that led to the significant differences in priming effects in the two conditions, or whether relaxation effects are additive – i.e. whether relaxation is better than just leaving the participant to do nothing.

Clinical and Research Implications

The context of the present study was errorless learning that was based on the observation of impaired explicit memory and relatively intact implicit memory in ABI and that tries to improve learning in ABI by avoiding errors, the recognition of which is held to be dependent on impaired explicit memory (Baddeley & Wilson, 1984). It has been suggested that memory rehabilitation may benefit from trying to find more direct ways of facilitating the use of implicit memory (Riley & Venn, 2015). The present study suggests that relaxation after learning something (or while retrieving it – depending on the explanation of the current findings) can facilitate implicit memory

for that material. Relaxation has the additional benefit that it has also been shown to benefit explicit memory as well (Cowan et al., 2004 and 2005; Dewar et al., 2009 and 2012B).

Further work is needed to establish whether the impact of relaxation for people with acquired memory impairments applies at the consolidation or at the retrieval phase, or both. Further work is also required to establish whether relaxation adds an additional benefit over learners doing nothing when engaging in recall of previously learned material. Finally, it would also be helpful to establish whether relaxation can be used in everyday environments to enhance memory for ecologically relevant material in individuals with ABI.

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Chapter III – Public Domain Briefing

**A Comparison of the Effect of Relaxation and Focused Attention on Implicit Memory in
People with Acquired Brain Injury**

This document provides an accessible summary of Volume I of this thesis, including the systematic literature review and the research study.

Literature Review

Do Mindfulness-Based Techniques Improve Memory?

Introduction

Mindfulness is an umbrella term used for a range of practices that are reported to be beneficial in a number of ways, such as for the management of mental health issues. There is no consensus on how mindfulness is defined, or what practices can legitimately be seen to count as mindfulness. This has resulted in very different mindfulness practices being studied by researchers, creating difficulty in how comparable the findings from studies of mindfulness. Previous research has suggested that mindfulness may help improve memory. Therefore, the current paper reviewed the evidence for the effects of mindfulness on measures of memory.

Method

Three online databases were searched. Nineteen studies, providing valid measures of memory were included in the review. The studies were reviewed using a standard template which helps to understand if the studies were conducted in a way that means their results were more or less likely to be valid.

Results

Overall, findings were mixed, with studies generally suggesting that mindfulness may improve some types of memory including working memory which is used for lots of everyday activities such as when remembering the steps of how to cook a recipe. There is also some evidence that mindfulness increases false memories which is when an individual thinks they remember something that did not actually happen.

Discussion

The quality of studies was generally poor. Issues in defining mindfulness in a consistent manner may have contributed to difficulties in comparing findings across studies. Therefore, the findings reviewed provide an initial indication that mindfulness may enhance the use of some types of memory. However, the available evidence is not generally of high quality, and should therefore be considered with caution. More rigorous randomised controlled trials are required to adequately evaluate whether mindfulness practices improve memory.

Empirical Paper

A Comparison of the Effect of Relaxation and Focused Attention on Implicit Memory in People with Acquired Brain Injury

Introduction

Previous research has shown there is a link between relaxation and memories that individuals do not try to recall (such as remembering a party that one previously attended in a seemingly random fashion), and between these types of memories and priming (something that increases the chance of you remembering something like seeing an individual from the party that was attended), posing the question of whether relaxation may also facilitate priming. The study aimed to answer this question, as knowing how to increase priming for people with brain injuries may improve attempts to support them with their memory difficulties.

Method

Thirty-four participants with brain injuries and varying degrees of memory impairment completed two tasks (stem completion and perceptual identification) under a relaxation (e.g. soothing music) and focused attention (e.g. watch a video and focus on what is going on) conditions.

Results

On a task where participants see words flash up on the screen very quickly, significantly more words were identified when participants were relaxed, than when they had been watching the

focused attention video. This was not the case for the other task, the stem completion task, where participants get given a part of a word and they have to complete this. However, when the individual response to relaxation was taken into account, the result for the stem completion was also significant. In other words, individuals who did not relax as much during the relaxation task, did not perform as well on the tasks than those individuals who did respond well to the relaxation task.

Discussion

Findings suggest a period of relaxation after learning may help in memory rehabilitation.

Appendix A

Revised Cochrane risk-of-bias tool for randomized trials (RoB 2.0)

TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the ROB2 Development Group
Version of 9 October 2018

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.



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Study details

Reference

Alberts, H. J., Otgaar, H., & Kalagi, J. (2017). Minding the source: The impact of mindfulness on source monitoring. *Legal and Criminological Psychology*, 22(2), 302-313.

Study design

- Individually-randomized parallel-group trial
- Cluster-randomized parallel-group trial
- Individually randomized cross-over (or other matched) trial

Specify which outcome is being assessed for risk of bias

Effect of mindfulness on source monitoring

Specify the numerical result being assessed. In case of multiple

ANOVA with condition as independent variable and number

alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

of correct source attributions as dependent variable ($p = 0.03$)

Is the review team's aim for this result...?

- to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

Which of the following sources were obtained to help inform the risk-of-bias assessment? (tick as many as apply)

- Journal article(s) with results of the trial
- Trial protocol
- Statistical analysis plan (SAP)
- Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- "Grey literature" (e.g. unpublished thesis)
- Conference abstract(s) about the trial
- Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- Research ethics application
- Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- Personal communication with trialist
- Personal communication with the sponsor

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Description	Response options
1.1 Was the allocation sequence random?	Only brief reference to random assignment and this is not sufficient for	PN

1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	determining that proper randomization occurred. No reference to this so whilst the chances are that answer to this is No, this has been assigned NI as there is insufficient information to determine this and it makes no difference to the overall risk of bias based on the previous question.	NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	No significant differences in mood but there could be other significant differences between participants that were not analyzed i.e. age and impact on retention and recall	NI
Risk-of-bias judgement		High

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Description	Response options
2.1. Were participants aware of their assigned intervention during the trial?	There is not information to suggest that they weren't aware and it is likely that participants are aware unless they have been specific attempts to make this less likely.	PY
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	As proper randomization did not occur and there is nothing to suggest otherwise, the judgement has been made that the interventions were delivered by researchers who would have known which condition was which.	Y
2.3. <u>If Y/PY/NI to 2.1 or 2.2:</u> Were there deviations from the intended intervention that arose because of the experimental context?	No information to determine this. There is no reason to believe there were deviations but there is also no reason to believe that there wasn't.	NI
2.4. <u>If Y/PY to 2.3:</u> Were these deviations from intended intervention balanced between groups?	Cannot say	NA

2.5 If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome?	Cannot say	NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	The analysis appears appropriate.	Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA
Risk-of-bias judgement		High

Domain 3: Missing outcome data

Signalling questions	Description	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	There was no reference to data being missing although this is not guaranteed	PY
3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data?		NA
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NA
3.4 If Y/PY/NI to 3.3: Do the proportions of missing outcome data differ between intervention groups?		NA

3.5 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA
Risk-of-bias judgement		Low

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Description	Response options
4.1 Was the method of measuring the outcome inappropriate?	Appears appropriate given the detail provided.	N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups ?	Unlikely as the way this is described suggests this was standardised.	N
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants ?	Almost certainly yes as previously noted.	Y
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	It's possible that consciously or subconsciously there could have been manipulations that affected the outcome.	Y
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	If participants knew anything about mindfulness and believed that their recall would be better then it is possible that this could have had an effect on performance during recall.	NI
Risk-of-bias judgement		High

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Description	Response options
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5.1 Was the trial analysed in accordance with a pre-specified plan that was finalized before unblinded outcome data were available for analysis ?		Y
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?		N
5.3 ... multiple analyses of the data?		N
Risk-of-bias judgement		Low

Overall risk of bias

Risk-of-bias judgement		High
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Revised Cochrane risk-of-bias tool for randomized trials (RoB 2.0)

TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
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Study details

Reference

Alberts, H. J., & Thewissen, R. (2011). The effect of a brief mindfulness intervention on memory for positively and negatively valenced stimuli. *Mindfulness*, 2(2), 73-77.

Study design

- Individually-randomized parallel-group trial
- Cluster-randomized parallel-group trial
- Individually randomized cross-over (or other matched) trial

Specify which outcome is being assessed for risk of bias

Impact of mindfulness on memory for positively and negatively valenced stimuli

Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

Recall on the verbal learning test ($F(1, 36) = 0.42, p=.52$).

Is the review team's aim for this result...?

- to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

Which of the following sources were obtained to help inform the risk-of-bias assessment? (tick as many as apply)

- Journal article(s) with results of the trial
- Trial protocol
- Statistical analysis plan (SAP)
- Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- "Grey literature" (e.g. unpublished thesis)
- Conference abstract(s) about the trial
- Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- Research ethics application
- Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- Personal communication with trialist

Personal communication with the sponsor

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Description	Response options
1.1 Was the allocation sequence random?	No, there is insufficient information to determine this, there is simply a reference to randomization	PN
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	From the description provided it seems this was the case.	PY
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	Mood was assessed and a good argument is provided for why this might be important. There were no significant differences but there could have been other important factors not considered.	NI
Risk-of-bias judgement		High

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Description	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Participants were intentionally misinformed about the purpose of the study.	PN
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	Not enough information to determine this from the text	NI
2.3. <u>If Y/PY/NI to 2.1 or 2.2:</u> Were there deviations from the intended intervention that arose because of the experimental context?	The experimenter used a protocol throughout the entire research study.	PN

2.4. If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups?		NA
2.5 If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome?		NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Yes the analysis was appropriate	Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA
Risk-of-bias judgement		Some concerns

Domain 3: Missing outcome data

Signalling questions	Description	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	Two participants were excluded as they realized the purpose of the study. However, the authors specifically state that they ran the analysis with their data and it made not difference in the pattern of the results.	<u>PY</u>
3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data?		NA
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NA

3.4 If Y/PY/NI to 3.3: Do the proportions of missing outcome data differ between intervention groups?		NA
3.5 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA
Risk-of-bias judgement		Low

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Description	Response options
4.1 Was the method of measuring the outcome inappropriate?	No, the valence of recall is a good fit with the purpose of the study and so there does not seem to be any issue with this. This has also been used on previous research.	<u>PN</u>
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups ?	Not likely given that the procedures were standardised. The only difference should have been the condition that participants were assigned to.	<u>PN</u>
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants ?	Yes they were almost certainly aware.	PY
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	There was a protocol used although that does not prevent there from being issues relating to bias from the experimenter.	PY
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NI
Risk-of-bias judgement		High

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Description	Response options
5.1 Was the trial analysed in accordance with a pre-specified plan that was finalized before unblinded outcome data were available for analysis ?	A protocol was used for the experimental procedures but none are described for the analysis.	N
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?		PN
5.3 ... multiple analyses of the data?		PN
Risk-of-bias judgement		High

Overall risk of bias

Risk-of-bias judgement		High
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Revised Cochrane risk-of-bias tool for randomized trials (RoB 2.0)

TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the ROB2 Development Group
Version of 9 October 2018

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.



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Study details

Reference

Bachmann, K., Lam, A. P., Sörös, P., Kanat, M., Hoxhaj, E., Matthies, S., ... & Philipsen, A. (2018). Effects of mindfulness and psychoeducation on working memory in adult ADHD: a randomised, controlled fMRI study. *Behaviour research and therapy*, 106, 47-56.

Study design

- Individually-randomized parallel-group trial
- Cluster-randomized parallel-group trial
- Individually randomized cross-over (or other matched) trial

Specify which outcome is being assessed for risk of bias	Effect of mindfulness on working memory
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<p>Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.</p>	<p>Overall true memory (No statistically significant differences between the groups were observed, $F(1, 54) = 1.38, p = .25, g^2 = .03$ (Mmindfulness = 5.50, SD = 1.40; Mcontrol = 5.07, SD = 1.33).</p> <p>False memory $F(1, 54) = 0.08, p = .78, g^2 < .001$ (Mmindfulness = 1.36, SD = 0.95; Mcontrol = 1.43, SD = 0.96)</p>
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Is the review team’s aim for this result...?

- to assess the effect of *assignment to intervention* (the ‘intention-to-treat’ effect)
- to assess the effect of *adhering to intervention* (the ‘per-protocol’ effect)

Which of the following sources were obtained to help inform the risk-of-bias assessment? (tick as many as apply)

- Journal article(s) with results of the trial

- Trial protocol
- Statistical analysis plan (SAP)
- Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- “Grey literature” (e.g. unpublished thesis)
- Conference abstract(s) about the trial
- Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- Research ethics application
- Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- Personal communication with trialist
- Personal communication with the sponsor

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Description	Response options
1.1 Was the allocation sequence random?	No detailed description provided. Assigned PN a per protocol.	PN
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	No information to determine this	NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	No information to determine this.	NI
Risk-of-bias judgement		High

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Description	Response options
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2.1. Were participants aware of their assigned intervention during the trial?	There is not information to suggest that they weren't aware and it is likely that participants are aware unless they have been specific attempts to make this less likely.	PY
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	As proper randomization did not occur and there is nothing to suggest otherwise, the judgement has been made that the interventions were delivered by researchers who would have known which condition was which.	Y
2.3. <u>If Y/PY/NI to 2.1 or 2.2:</u> Were there deviations from the intended intervention that arose because of the experimental context?		NI
2.4. <u>If Y/PY to 2.3:</u> Were these deviations from intended intervention balanced between groups?		NA
2.5 <u>If N/PN/NI to 2.4:</u> Were these deviations likely to have affected the outcome?		NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	The analysis appears appropriate	Y
2.7 <u>If N/PN/NI to 2.6:</u> Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA
Risk-of-bias judgement		High

Domain 3: Missing outcome data

Signalling questions	Description	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	Yes data for all participants was available.	PY
3.2 <u>If N/PN/NI to 3.1</u>: Is there evidence that result was not biased by missing outcome data?		NA
3.3 <u>If N/PN to 3.2</u>: Could missingness in the outcome depend on its true value?		NA
3.4 <u>If Y/PY/NI to 3.3</u>: Do the proportions of missing outcome data differ between intervention groups?		NA
3.5 <u>If Y/PY/NI to 3.3</u>: Is it likely that missingness in the outcome depended on its true value?		NA
Risk-of-bias judgement		Low

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Description	Response options
4.1 Was the method of measuring the outcome inappropriate?	No the method of measuring the outcome was described adequately and makes sense.	N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups ?	Not likely given the procedures were standardised and the only difference should have been in assigned condition.	N

4.3 <u>If N/PN/NI to 4.1 and 4.2:</u> Were outcome assessors aware of the intervention received by study participants ?	Based on the description provided, they almost certainly were aware.	Y
4.4 <u>If Y/PY/NI to 4.3:</u> Could assessment of the outcome have been influenced by knowledge of intervention received?	Yes, the potential risk of bias from knowledge of which intervention had been received was possible.	Y
4.5 <u>If Y/PY/NI to 4.4:</u> Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NI
Risk-of-bias judgement		High

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Description	Response options
5.1 Was the trial analysed in accordance with a pre-specified plan that was finalized before unblinded outcome data were available for analysis ?	There is a pre-specified plan for the analysis that is followed.	Y
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?		N
5.3 ... multiple analyses of the data?		N
Risk-of-bias judgement		Low

Overall risk of bias

Risk-of-bias judgement	High
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Revised Cochrane risk-of-bias tool for randomized trials (RoB 2.0)

TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the ROB2 Development Group
Version of 9 October 2018

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.



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Study details

Reference

Brown, K. W., Goodman, R. J., Ryan, R. M., & Anālayo, B. (2016). Mindfulness enhances episodic memory performance: evidence from a multimethod investigation. *PloS one*, *11*(4), e0153309.
Experiment 1

Study design

- Individually-randomized parallel-group trial
- Cluster-randomized parallel-group trial
- Individually randomized cross-over (or other matched) trial

Specify which outcome is being assessed for risk of bias

Impact of mindfulness on episodic memory

Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

remember responses, $t(141) = 4.50$, $p < .001$, $\eta_p^2 = .13$.

Is the review team's aim for this result...?

- to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

Which of the following sources were obtained to help inform the risk-of-bias assessment? (tick as many as apply)

- Journal article(s) with results of the trial
- Trial protocol
- Statistical analysis plan (SAP)
- Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- "Grey literature" (e.g. unpublished thesis)
- Conference abstract(s) about the trial
- Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- Research ethics application
- Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- Personal communication with trialist
- Personal communication with the sponsor

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Description	Response options
1.1 Was the allocation sequence random?	Inadequately described therefore it is likely that this was not truly randomised	PN

1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	based on the ROB2 guidelines. There is not enough information to determine this but the absence of information suggests this is not likely. However, on balance it seems fairer to assign this NI as the issue pertains more to a lack of adequate information	NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	There was not enough information to determine this.	NI
Risk-of-bias judgement		High

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Description	Response options
2.1. Were participants aware of their assigned intervention during the trial?	A structurally equivalent task was provided as the control condition which mirrored the some aspects of the mindfulness condition. However, there is not enough detail to state whether participants were made aware of their condition at some point during the study. The experimenters were likely to be the individuals delivering the intervention given that they have not stated otherwise.	NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		PY
2.3. <u>If Y/PY/NI to 2.1 or 2.2:</u> Were there deviations from the intended intervention that arose because of the experimental context?	No indicators of this	<u>N</u>
2.4. <u>If Y/PY to 2.3:</u> Were these deviations from intended intervention balanced between groups?		NA

2.5 If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome?		NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Mixed-model ANOVA	<u>Y</u>
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA
Risk-of-bias judgement		High

Domain 3: Missing outcome data

Signalling questions	Description	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?		N
3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data?		N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NI
3.4 If Y/PY/NI to 3.3: Do the proportions of missing outcome data differ between intervention groups?		NI

3.5 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NI
Risk-of-bias judgement		High

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Description	Response options
4.1 Was the method of measuring the outcome inappropriate?	Remember-know discrepancy between conditions as a measure of episodic memory	<u>Y</u>
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups ?		<u>PN</u>
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants ?	There is insufficient information to determine this but it is likely given that no alternative has been stated	PY
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	It seems unlikely as recall should have been judged objectively against the learning task. However, it is possible so there is not enough information to determine this	<u>NI</u>
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	As above, cannot tell for certain, but it seems as though the answer would be probably not	<u>PN</u>
Risk-of-bias judgement		High

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Description	Response options
5.1 Was the trial analysed in accordance with a pre-specified plan that was finalized before unblinded outcome data were available for analysis ?	There was no pre-specified plan that could be considered against the actual analysis	NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	There is no indication of this, and the analysis is a good match with the objectives of the experiment	<u>N</u>
5.3 ... multiple analyses of the data?	As above	<u>PN</u>
Risk-of-bias judgement		Some concerns

Overall risk of bias

Risk-of-bias judgement		High
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Revised Cochrane risk-of-bias tool for randomized trials (RoB 2.0)

TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the ROB2 Development Group
Version of 9 October 2018

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.



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Study details

Reference

Brown, K. W., Goodman, R. J., Ryan, R. M., & Anālayo, B. (2016). Mindfulness enhances episodic memory performance: evidence from a multimethod investigation. *PloS one*, *11*(4), e0153309.
Experiment 2

Study design

- Individually-randomized parallel-group trial
- Cluster-randomized parallel-group trial
- Individually randomized cross-over (or other matched) trial

Specify which outcome is being assessed for risk of bias

Impact of mindfulness on episodic memory

Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

remember responses $p < .001$

Is the review team's aim for this result...?

- to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

Which of the following sources were obtained to help inform the risk-of-bias assessment? (tick as many as apply)

- Journal article(s) with results of the trial
- Trial protocol
- Statistical analysis plan (SAP)
- Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- "Grey literature" (e.g. unpublished thesis)
- Conference abstract(s) about the trial
- Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- Research ethics application
- Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- Personal communication with trialist
- Personal communication with the sponsor

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Description	Response options
1.1 Was the allocation sequence random?	Inadequately described therefore it is likely that this was not truly randomised	PN

1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	based on the ROB2 guidelines. There is not enough information to determine this but the absence of information suggests this is not likely. However, on balance it seems fairer to assign this NI as the issue pertains more to a lack of adequate information	NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	There was not enough information to determine this.	NI
Risk-of-bias judgement		High

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Description	Response options
2.1. Were participants aware of their assigned intervention during the trial?	A structurally equivalent task was provided as the control condition which mirrored the some aspects of the mindfulness condition. However, there is not enough detail to state whether participants were made aware of their condition at some point during the study. The experimenters were likely to be the individuals delivering the intervention given that they have not stated otherwise.	NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		PY
2.3. <u>If Y/PY/NI to 2.1 or 2.2:</u> Were there deviations from the intended intervention that arose because of the experimental context?	No indicators of this	<u>N</u>
2.4. <u>If Y/PY to 2.3:</u> Were these deviations from intended intervention balanced between groups?		NA

2.5 If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome?		NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Mixed-model ANOVA	<u>Y</u>
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA
Risk-of-bias judgement		High

Domain 3: Missing outcome data

Signalling questions	Description	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?		N
3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data?		N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NI
3.4 If Y/PY/NI to 3.3: Do the proportions of missing outcome data differ between intervention groups?		NI

3.5 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NI
Risk-of-bias judgement		High

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Description	Response options
4.1 Was the method of measuring the outcome inappropriate?	Remember-know discrepancy between conditions as a measure of episodic memory	<u>Y</u>
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups ?		<u>PN</u>
4.3 <u>If N/PN/NI to 4.1 and 4.2:</u> Were outcome assessors aware of the intervention received by study participants ?	There is insufficient information to determine this but it is likely given that no alternative has been stated	PY
4.4 <u>If Y/PY/NI to 4.3:</u> Could assessment of the outcome have been influenced by knowledge of intervention received?	It seems unlikely as recall should have been judged objectively against the learning task. However, it is possible so there is not enough information to determine this	<u>NI</u>
4.5 <u>If Y/PY/NI to 4.4:</u> Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	As above, cannot tell for certain, but it seems as though the answer would be probably not	<u>PN</u>
Risk-of-bias judgement		High

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Description	Response options
5.1 Was the trial analysed in accordance with a pre-specified plan that was finalized before unblinded outcome data were available for analysis ?	There was no pre-specified plan that could be considered against the actual analysis	NI

Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	There is no indication of this, and the analysis is a good match with the objectives of the experiment	<u>N</u>
5.3 ... multiple analyses of the data?	As above	<u>PN</u>
Risk-of-bias judgement		Some concerns

Overall risk of bias

Risk-of-bias judgement		High
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Revised Cochrane risk-of-bias tool for randomized trials (RoB 2.0)

TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the ROB2 Development Group
Version of 9 October 2018

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.



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Study details

Reference

Eisenbeck, N., Luciano, C., & Valdivia-Salas, S. (2018). Effects of a Focused Breathing Mindfulness Exercise on Attention, Memory, and Mood: The Importance of Task Characteristics. *Behaviour Change*, 35(1), 54-70.

Study design

- Individually-randomized parallel-group trial
- Cluster-randomized parallel-group trial
- Individually randomized cross-over (or other matched) trial

Specify which outcome is being assessed for risk of bias

Effect of focused breathing mindfulness on memory

Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

The condition \times time ANOVA conducted on thematic unit score revealed a trend towards a significant interaction effect, $F(1, 39) = 4.10, p = .050, \eta^2 = .095$. No other effects were significant, $p > .05$. This suggests that the participants did not perform better at posttest than at pretest. None of the conditions showed significant pre-post changes on the thematic unit score, $p > .05$.

Is the review team's aim for this result...?

- to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

Which of the following sources were obtained to help inform the risk-of-bias assessment? (tick as many as apply)

- Journal article(s) with results of the trial
- Trial protocol
- Statistical analysis plan (SAP)
- Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- "Grey literature" (e.g. unpublished thesis)
- Conference abstract(s) about the trial
- Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- Research ethics application
- Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- Personal communication with trialist
- Personal communication with the sponsor

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Description	Response options
1.1 Was the allocation sequence random?	Lack of detail regarding randomisation, suggesting full randomisation has not occurred.	PN
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		PN
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	No details provided on this	NI
Risk-of-bias judgement		High

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Description	Response options
2.1. Were participants aware of their assigned intervention during the trial?	No details provided	NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	It is likely that researchers were aware of condition as they did not specify being blinded to condition	PY
2.3. <u>If Y/PY/NI to 2.1 or 2.2:</u> Were there deviations from the intended intervention that arose because of the experimental context?	None reported but this was not made explicit	NI

2.4. If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups?	As above	NI
2.5 If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome?	As above	NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?		NI
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NI
Risk-of-bias judgement		High

Domain 3: Missing outcome data

Signalling questions	Description	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	Not presented in paper – no supplementary documents could be found	N
3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data?	None reported	N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	Not clear	NI

3.4 If Y/PY/NI to 3.3: Do the proportions of missing outcome data differ between intervention groups?	Not clear	NI
3.5 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?	Not clear	NI
Risk-of-bias judgement		High

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Description	Response options
4.1 Was the method of measuring the outcome inappropriate?	A well-established and validated measure of working memory was used. The authors did not specify that they were measuring working memory until the results and discussion sections.	<u>N</u>
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups ?	It is possible but assuming that the guidelines accompanying the measure were following there would more likely be a consistent interpretation of participant responses.	<u>PN</u>
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants ?	It does not specify otherwise, and therefore assessors were likely to be the researchers who would have also administered the procedures for the experimental and control conditions.	PY
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		PY
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NI
Risk-of-bias judgement		High

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Description	Response options
5.1 Was the trial analysed in accordance with a pre-specified plan that was finalized before unblinded outcome data were available for analysis ?	No information to suggest whether there was or not	NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	The data from the outcome measure is what is analysed so there would not have been various results to have chosen from	<u>PN</u>
5.3 ... multiple analyses of the data?	As above	<u>PN</u>
Risk-of-bias judgement		Low

Overall risk of bias

Risk-of-bias judgement		High
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Revised Cochrane risk-of-bias tool for randomized trials (RoB 2.0)

TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the ROB2 Development Group
Version of 9 October 2018

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.



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Study details

Reference

Greenberg, J., Romero, V. L., Elkin-Frankston, S., Bezdek, M. A., Schumacher, E. H., & Lazar, S. W. (2018). Reduced interference in working memory following mindfulness training is associated with increases in hippocampal volume. *Brain imaging and behavior*, 1-11.

Study design

- Individually-randomized parallel-group trial
- Cluster-randomized parallel-group trial
- Individually randomized cross-over (or other matched) trial

Specify which outcome is being assessed for risk of bias

Impact if mindfulness on working memory

Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

Post-intervention compared to the active control group while controlling for baseline proactive interference error rates (F(1,51) = 4.37, p = .04, $\eta^2=0.08$;

Is the review team's aim for this result...?

- to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

Which of the following sources were obtained to help inform the risk-of-bias assessment? (tick as many as apply)

- Journal article(s) with results of the trial
- Trial protocol
- Statistical analysis plan (SAP)
- Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- "Grey literature" (e.g. unpublished thesis)
- Conference abstract(s) about the trial
- Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- Research ethics application
- Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- Personal communication with trialist
- Personal communication with the sponsor

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Description	Response options
1.1 Was the allocation sequence random?	Clearly simple randomisation has occurred based on descriptions within text and the flowchart provided	PY
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	There is not enough information on baseline differences to appreciate whether there may be an issue with the randomisation process	NI
Risk-of-bias judgement		Low

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Description	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Possible but it is not clear whether participants were aware if there were in the experimental or control condition	NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		PY
2.3. <u>If Y/PY/NI to 2.1 or 2.2:</u> Were there deviations from the intended intervention that arose because of the experimental context?		NI

2.4. If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups?		NA
2.5 If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome?		NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?		<u>PY</u>
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA
Risk-of-bias judgement		High

]

Domain 3: Missing outcome data

Signalling questions	Description	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	It is not clear if this was the case or not	<u>PN</u>
3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data?		NI
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NI

3.4 If Y/PY/NI to 3.3: Do the proportions of missing outcome data differ between intervention groups?		NI
3.5 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NI
Risk-of-bias judgement		High

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Description	Response options
4.1 Was the method of measuring the outcome inappropriate?		<u>N</u>
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups ?		<u>PN</u>
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants ?		NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		NI
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NI
Risk-of-bias judgement		Some concerns

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Description	Response options
5.1 Was the trial analysed in accordance with a pre-specified plan that was finalized before unblinded outcome data were available for analysis ?		PN
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?		NI
5.3 ... multiple analyses of the data?		NI
Risk-of-bias judgement		High

Overall risk of bias

Risk-of-bias judgement		High
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Revised Cochrane risk-of-bias tool for randomized trials (RoB 2.0)

TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the ROB2 Development Group
Version of 9 October 2018

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.



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Study details

Reference

Johnson, S., Gur, R. M., David, Z., & Currier, E. (2015). One-session mindfulness meditation: a randomized controlled study of effects on cognition and mood. *Mindfulness*, 6(1), 88-98.

Study design

- Individually-randomized parallel-group trial
- Cluster-randomized parallel-group trial
- Individually randomized cross-over (or other matched) trial

Specify which outcome is being assessed for risk of bias

Impact of one-session of mindfulness on working memory

Specify the numerical result being assessed. In case of multiple

Univariate analyses were run for the each of the cognitive

alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

measures. There were no significant differences on any of the measures between groups, trails A, $F(2, 89) = 2.6, p = 0.086,$

Is the review team's aim for this result...?

- to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

Which of the following sources were obtained to help inform the risk-of-bias assessment? (tick as many as apply)

- Journal article(s) with results of the trial
- Trial protocol
- Statistical analysis plan (SAP)
- Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- "Grey literature" (e.g. unpublished thesis)
- Conference abstract(s) about the trial
- Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- Research ethics application
- Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- Personal communication with trialist
- Personal communication with the sponsor

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Description	Response options
1.1 Was the allocation sequence random?	Computer-generated randomisation just before allocation	<u>Y</u>
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		<u>Y</u>
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	No differences on age, gender, or ethnic composition	<u>PN</u>
Risk-of-bias judgement		Low

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Description	Response options
2.1. Were participants aware of their assigned intervention during the trial?	All participants were informed that they were partaking in mindfulness research, however, it is possible that those in the book control condition had some sense that they were not in an active condition, although no participants had prior experience with mindfulness. Whilst the lead researchers may not have been aware, the RA had to know in order to assign the correct condition i.e. mindfulness/sham meditation/book	<u>PN</u>
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		<u>PY</u>
2.3. <u>If Y/PY/NI to 2.1 or 2.2:</u> Were there deviations from the intended intervention that arose because of the experimental context?	None were specified	<u>PN</u>

2.4. If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups?		NA
2.5 If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome?		NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Univariate analysis	<u>Y</u>
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA
Risk-of-bias judgement		High

Domain 3: Missing outcome data

Signalling questions	Description	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	As participants turned up and immediately completed the experimental tasks, those that did not turn up were allocated as participants	<u>PY</u>
3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data?		NA
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NA

3.4 If Y/PY/NI to 3.3: Do the proportions of missing outcome data differ between intervention groups?		NA
3.5 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA
Risk-of-bias judgement		Low

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Description	Response options
4.1 Was the method of measuring the outcome inappropriate?	Commonly used standardised assessments of working memory and immediate digit span were used.	<u>N</u>
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups ?	Not likely due to standardised assessment being used.	<u>PN</u>
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants ?	A research assistant complete the experimental aspects of the study, but it is not clear if they were the outcome assessor or not	NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	It was unlikely that participants could have known which intervention they had received, and it is unlikely that knowing this would have made a significant difference to performance on standardised tests	<u>PN</u>
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA
Risk-of-bias judgement		Some concerns

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Description	Response options
5.1 Was the trial analysed in accordance with a pre-specified plan that was finalized before unblinded outcome data were available for analysis ?	There is no specified plan outlined	NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	Outcomes from all measures were reported	<u>PN</u>
5.3 ... multiple analyses of the data?	Difficult to say although this seems unlikely given the results were not significant across all measures of memory	PN
Risk-of-bias judgement		Some concerns

Overall risk of bias

Risk-of-bias judgement		High
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Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)

TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the RoB2 Development Group
Version of 15 March 2018

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.



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Study details

Reference

Larouche, E., Hudon, C., & Goulet, S. (2019). Mindfulness mechanisms and psychological effects for aMCI patients: A comparison with psychoeducation. *Complementary therapies in clinical practice*, 34, 93-104.

Study design

- Individually-randomized parallel-group trial
- Cluster-randomized parallel-group trial

- Individually randomized cross-over (or other matched) trial

Specify which outcome is being assessed for risk of bias

Impact of mindfulness on episodic memory

Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

$R^2 = 0.14$, $F(3,37) = 2.06$, $p = .122$. The inclusion of the moderator did not lead to a significant increase in explained variance, $R^2_{inc} = 0.005$, $F(1,37) = 0.19$, $p = .660$. The effect did not reach statistical significance for the MBI condition, $\beta = -0.15$, $t(40) = -1.55$, $p = .129$, nor for the PBI condition, $\beta = -0.22$, $t(40) = -1.88$, $p = .069$. No effect was found for any condition, similarly to the correlation analyses.

Is the review team's aim for this result...?

- to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

Which of the following sources were obtained to help inform the risk-of-bias assessment? (tick as many as apply)

- Journal article(s) with results of the trial
- Trial protocol
- Statistical analysis plan (SAP)
- Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- "Grey literature" (e.g. unpublished thesis)
- Conference abstract(s) about the trial
- Regulatory document (e.g. Clinical Study Report, Drug Approval Package)

<input type="checkbox"/>	Research ethics application
<input type="checkbox"/>	Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
<input type="checkbox"/>	Personal communication with trialist
<input type="checkbox"/>	Personal communication with the sponsor

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	Procedures were not clear and the ROB2 guidelines suggest that reference to randomisation is not sufficient	<u>PN</u>
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	This is clearly detailed in the procedures	<u>Y</u>
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	This was analysed and there were no significant differences between groups	<u>N</u>
Risk-of-bias judgement		High

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Yes, they were blinded for the baseline evaluation only	<u>Y</u>

2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	Intervention facilitators were no blinded	Y
2.3. <u>If Y/PY/NI to 2.1 or 2.2:</u> Were there deviations from the intended intervention that arose because of the experimental context?	There were none stated and there would be no apparent reason for why this would be the case	PN
2.4. <u>If Y/PY to 2.3:</u> Were these deviations from intended intervention balanced between groups?		NA
2.5 <u>If N/PN/NI to 2.4:</u> Were these deviations likely to have affected the outcome?		NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Yes this is clearly described	<u>Y</u>
2.7 <u>If N/PN/NI to 2.6:</u> Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		<u>PN</u>
Risk-of-bias judgement		High

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	Yes, there was an intent-to-treat analysis which accounted for those participants who withdrew from the study before the post-test or follow-up	<u>Y</u>

3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	Yes as above	<u>Y</u>
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NA
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA
Risk-of-bias judgement		Low

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	The analysis is detailed and confusing at times but appears appropriate	<u>PN</u>
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	Not likely given that this was measured objectively	<u>PN</u>
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	The evaluators were blinded to participant assignment	<u>N</u>
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		NA

4.5 <u>If Y/PY/NI to 4.4:</u> Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA
Risk-of-bias judgement		Low

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	There is reference to how this data was going to be analysed i.e. intent-to-treat before data were available for analysis	<u>Y</u>
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	All outcomes are reported	<u>PN</u>
5.3 ... multiple analyses of the data?	As above, and many of the outcomes including those for memory were insignificant	<u>PN</u>
Risk-of-bias judgement		Low

Overall risk of bias

Risk-of-bias judgement		High
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Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)

TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the RoB2 Development Group
Version of 15 March 2019

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.



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Study details**Reference**

Mallya, S., & Fiocco, A. J. (2016). Effects of mindfulness training on cognition and well-being in healthy older adults. *Mindfulness*, 7(2), 453-465.

Study design

- Individually-randomized parallel-group trial
 Cluster-randomized parallel-group trial
 Individually randomized cross-over (or other matched) trial

Specify which outcome is being assessed for risk of bias

Impact of mindfulness on verbal memory

Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR

2x2 ANCOVA
MMSE = .82

= 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

CVLT – 0.21

Is the review team’s aim for this result...?

- to assess the effect of *assignment to intervention* (the ‘intention-to-treat’ effect)
- to assess the effect of *adhering to intervention* (the ‘per-protocol’ effect)

Which of the following sources were obtained to help inform the risk-of-bias assessment? (tick as many as apply)

- X Journal article(s) with results of the trial
- Trial protocol
- Statistical analysis plan (SAP)
- Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- “Grey literature” (e.g. unpublished thesis)
- Conference abstract(s) about the trial
- Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- Research ethics application
- Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- Personal communication with trialist
- Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in **red** are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	A randomizer allocated participants and in cases where this was not possible due to participants ability to commit they were allocated to the condition they could attend. They were not aware of which condition they were allocated to.	<u>Y</u>
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		<u>Y</u>
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	There was a significant difference in baseline mood based on GDS with	PY
Risk-of-bias judgement		High

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	After first treatment	Y
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	It is not clearly described so the assumption is that those delivering the intervention were aware of the participant assigned intervention	PY

2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context?	The authors state that the MBSR programme they used encourages deviations from the script to accommodate for client needs. The authors state they feel confident this does not compromise fidelity, however it is not clear how they were confident of this as this simply could have been used to legitimise any observer-expectancy effects	PY
2.4. If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups?	It is not entirely clear but there is not reference to the control condition having the same degree of flexibility with respect to how the intervention is delivered. A facilitator feedback questionnaire was used in both groups due to different facilitators being used which aimed to ensure there were no significant differences in how these were perceived.	PN
2.5 If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome?	There are no references to specific deviations	NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	2x2 ANCOVA	Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	ITT analysis was conducted	N
Risk-of-bias judgement		High

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of adhering to intervention*)

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	Yes ITT analysis conducted with all those participants who were randomised but then dropped out	Y

3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	No data is provided to evidence that the result was not biased by missing outcome data	N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	There were a number of participants who discontinued the intervention or were lost to follow-up and it is possible that low mood, and given the link with this to memory, those with more severe memory impairments could have been less likely to complete the experiment	Y
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?	There is not enough detail regarding the individuals who dropped out of the study to draw firm conclusions on this.	NI
Risk-of-bias judgement		High

Domain 4: Risk of bias in measurement of th outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	Standardised measures that are reliable and valid were used. MMSE is not very specific to memory but the alternative measure is.	N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	It seems unlikely given the standardised assessments being used but equally there could have been some influence from the outcome assessors who were not blinded to the condition the participant had been allocated to.	NI
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	There was nothing specifying that outcome assessors were not aware of the intervention received by participants so it can be assumed that this did know given that they were not blinded to this at earlier stages of the study	PY

4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		NA
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA
Risk-of-bias judgement		High

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	Not based on the information contained within the journal article and there were no supplementary materials available that may have contained this. The ITT analysis was mentioned prior to analysis in the reporting of the study, and was conducted which would seem unlikely unless this had been a pre-planned part of the analysis	NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	The analysis appears to be a reporting of all of the results from all assessments, and given that these are not significant, there does not appear to be any cherry picking of reported results	<u>N</u>
5.3 ... multiple analyses of the data?		<u>N</u>

Risk-of-bias judgement		Some concerns
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Overall risk of bias

Risk-of-bias judgement		High
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Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)

TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the RoB2 Development Group
Version of 15 March 2019

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.



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Study details

Reference	Mrazek, M. D., Franklin, M. S., Phillips, D. T., Baird, B., & Schooler, J. W. (2013). Mindfulness training improves working memory capacity and GRE performance while reducing mind wandering. <i>Psychological science</i> , 24(5), 776-781.
Study design	
<input checked="" type="checkbox"/> Individually-randomized parallel-group trial <input type="checkbox"/> Cluster-randomized parallel-group trial <input type="checkbox"/> Individually randomized cross-over (or other matched) trial	
Specify which outcome is being assessed for risk of bias	Impact of mindfulness on working memory
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	main effect of session only for WMC, $F(1, 46) = 17.102$, $p < .001$ (all other p s $> .05$).
Is the review team's aim for this result...?	
<input type="checkbox"/> to assess the effect of <i>assignment to intervention</i> (the 'intention-to-treat' effect) <input checked="" type="checkbox"/> to assess the effect of <i>adhering to intervention</i> (the 'per-protocol' effect)	
Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)	
<input checked="" type="checkbox"/> Journal article(s) with results of the trial <input type="checkbox"/> Trial protocol <input type="checkbox"/> Statistical analysis plan (SAP) <input type="checkbox"/> Non-commercial trial registry record (e.g. ClinicalTrials.gov record) <input type="checkbox"/> Company-owned trial registry record (e.g. GSK Clinical Study Register record)	

<input type="checkbox"/>	“Grey literature” (e.g. unpublished thesis)
<input type="checkbox"/>	Conference abstract(s) about the trial
<input type="checkbox"/>	Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
<input type="checkbox"/>	Research ethics application
<input type="checkbox"/>	Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
<input type="checkbox"/>	Personal communication with trialist
<input type="checkbox"/>	Personal communication with the sponsor

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	As per the ROB2 guidelines, stating that participants are randomised does not provide a sufficient description of the process and it is likely the process may not have been truly random.	PN
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	Lack of sufficient detail provided on this, but on the basis of the description of the study it is likely participants knew which condition they were allocated to.	PN
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	Not described in adequate detail.	NI
Risk-of-bias judgement		High

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
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2.1. Were participants aware of their assigned intervention during the trial?	It does not state otherwise, and it is hard to imagine not being aware of the condition they were assigned to due to the clear differences between nutrition programmes and mindfulness. There were also informed both interventions were likely to be equally effective. They certainly were as they were experts in their fields	PY
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y
2.3. <u>If Y/PY/NI to 2.1 or 2.2:</u> Were there deviations from the intended intervention that arose because of the experimental context?	There is not information to suggest that there were any deviations to the intervention due to the experimental context but this is not made explicit	NI
2.4. <u>If Y/PY to 2.3:</u> Were these deviations from intended intervention balanced between groups?		NA
2.5 <u>If N/PN/NI to 2.4:</u> Were these deviations likely to have affected the outcome?		NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	None provided	N
2.7 <u>If N/PN/NI to 2.6:</u> Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	The assessments they completed were standardised and based on the fact that they had not had regular mindfulness practice previously, it is less likely that there would have been issues regarding participants understanding which condition was theoretically more likely to enhance memory	PN
Risk-of-bias judgement		High

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of adhering to intervention*)

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
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3.1 Were data for this outcome available for all, or nearly all, participants randomized?	Not enough information to determine. Quite possible because it would seem all participants completed the study. It is unusual for there to be no attrition however, so it is possible that only those that completed study are being reported.	NI
3.2 <u>If N/PN/NI to 3.1:</u> Is there evidence that the result was not biased by missing outcome data?	None provided	N
3.3 <u>If N/PN to 3.2:</u> Could missingness in the outcome depend on its true value?	It does not seem likely that there would be any relationship between missing data and the outcomes of interest	<u>PN</u>
3.4 <u>If Y/PY/NI to 3.3:</u> Is it likely that missingness in the outcome depended on its true value?	As above. It seems unlikely that participants dropping out of the study would have any specific bearing on working memory performance.	<u>PN</u>
Risk-of-bias judgement		High

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	The OSPAN is a validated and reliable measure of working memory	<u>N</u>
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	The OSPAN was used following standard procedures	<u>PN</u>
4.3 <u>If N/PN/NI to 4.1 and 4.2:</u> Were outcome assessors aware of the intervention received by study participants?	There is no reference to blinding for outcome assessors, so they were probably aware of participant condition	PY

4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	All participants were given the impression that the comparison of two equally viable programs for improving cognitive performance were being provided, reducing likelihood of placebo and other biasing effects	PN
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	As above the OSPAN is a standardised instrument and was completed in a standardised manner. Almost all task instructions were delivered via computer to reduce experimenter expectancy effects	PN
Risk-of-bias judgement		High

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	There is insufficient information to determine this. It is likely that the ethics application for example contained details of this but this was not available.	NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	The outcomes reported are what would be expected based on the aims of the study. However, the reference to insignificant effects reports 'all other $ps > 0.5$ '	PN
5.3 ... multiple analyses of the data?	The analysis using ANOVA is appropriate and would not appear to be chosen on the basis of this producing a more favourable effect	PN
Risk-of-bias judgement		Some concerns

Overall risk of bias

Risk-of-bias judgement		High
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Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)

TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the RoB2 Development Group
Version of 15 March 2019

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.



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Study details

Reference

Qi, H., Zhang, H. H., Hanceroglu, L., Caggianiello, J., & Roberts, K. P. (2018). The influence of mindfulness on young adolescents' eyewitness memory and suggestibility. *Applied Cognitive Psychology*, 32(6), 823-829.

Study design

- Individually-randomized parallel-group trial
 Cluster-randomized parallel-group trial
 Individually randomized cross-over (or other matched) trial

Specify which outcome is being assessed for risk of bias

Impact of mindfulness on delayed recall

Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

Correct hits during immediate recall -M = 6.76; SD = 0.83; control: M = 6.90; SD = 0.72), t(39) = .57, p = 0.573, Cohen's d = 0.18, 95% CI [-0.35, 0.63],

Correct hits during delayed recall t(38) = 2.11, p = 0.041, Cohen's d = 0.68, 95% CI [0.05, 2.36]. Students in the control group (M = 13.16, SD = 1.54)

Is the review team's aim for this result...?

to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)

- to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

Which of the following sources were obtained to help inform the risk-of-bias assessment? (tick as many as apply)

- X Journal article(s) with results of the trial
- Trial protocol
- Statistical analysis plan (SAP)
- Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- “Grey literature” (e.g. unpublished thesis)
- Conference abstract(s) about the trial
- Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- Research ethics application
- Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- Personal communication with trialist
- Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in **red** are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	The allocation sequence was reportedly random; however no specific detail is provided on this, therefore the randomisation process was unlikely to be adequate.	PN
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	No specific reference is made to this so it cannot be assumed that participants were not aware of the condition they were allocated to. Furthermore the mindfulness condition would have been likely to have made specific reference to mindfulness.	PN
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	There are insufficient details to clearly state whether there were issues with in the differences between groups	NI
Risk-of-bias judgement		High

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Probably yes see 1.2	PY
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	Yes because it was the same two research assistants delivering the programmes for seven weeks	Y
2.3. <u>If Y/PY/NI to 2.1 or 2.2:</u> Were there deviations from the intended intervention that arose because of the experimental context?	Not specified so cannot conclude	NI
2.4. <u>If Y/PY to 2.3:</u> Were these deviations from intended intervention balanced between groups?		NA
2.5 <u>If N/PN/NI to 2.4:</u> Were these deviations likely to have affected the outcome?		NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	None mentioned	N
2.7 <u>If N/PN/NI to 2.6:</u> Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	Too difficult to determine as it is possible that this would unconsciously effect the correct recall, however there is not necessarily the specific evidence to demonstrate this was likely to occur	NI
Risk-of-bias judgement		High

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
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3.1 Were data for this outcome available for all, or nearly all, participants randomized?	It would seem that there most likely was but this is not explicitly addressed so this cannot be determined effectively	NI
3.2 <u>If N/PN/NI to 3.1:</u> Is there evidence that the result was not biased by missing outcome data?	No there is no reference to this	N
3.3 <u>If N/PN to 3.2:</u> Could missingness in the outcome depend on its true value?		<u>NI</u>
3.4 <u>If Y/PY/NI to 3.3:</u> Is it likely that missingness in the outcome depended on its true value?		NI
Risk-of-bias judgement		High

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	Yes an appropriate analysis was conducted	N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	A research assistant unfamiliar with allocation of individuals conducted the outcome assessment	<u>PN</u>
4.3 <u>If N/PN/NI to 4.1 and 4.2:</u> Were outcome assessors aware of the intervention received by study participants?	As above	<u>N</u>

4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		NA
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA
Risk-of-bias judgement		Low

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	It is not clear as only the journal article was retrieved and this does not specify a pre-planned analysis	<u>NI</u>
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	Results for all outcomes were analysed	<u>PN</u>
5.3 ... multiple analyses of the data?	There is no evidence that the analysis presented were chosen due to these being more favourable	<u>PN</u>

Risk-of-bias judgement		Some concerns
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Overall risk of bias

Risk-of-bias judgement		High
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Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)

TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the RoB2 Development Group
Version of 15 March 2019

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Study details**Reference**

Quach, D., Mano, K. E. J., & Alexander, K. (2016). A randomized controlled trial examining the effect of mindfulness meditation on working memory capacity in adolescents. *Journal of Adolescent Health, 58*(5), 489-496.

Study design

- Individually-randomized parallel-group trial
- Cluster-randomized parallel-group trial
- Individually randomized cross-over (or other matched) trial

Specify which outcome is being assessed for risk of bias

Impact of mindfulness on working memory

Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

WMC, $F(1,50) \frac{1}{4} 15.71$, $p < .001$, $h^2_p \frac{1}{4} .24$, whereas participants in the hatha yoga and waitlist control groups did not [hatha yoga: $F(1,59) \frac{1}{4} 3.85$, $p \frac{1}{4} .11$, $h^2_p \frac{1}{4} .04$, waitlist: $F(1, 51) \frac{1}{4} .50$, $p \frac{1}{4} .46$, $h^2_p \frac{1}{4} .01$;

Is the review team's aim for this result...?

- to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

Which of the following sources were obtained to help inform the risk-of-bias assessment? (tick as many as apply)

- Journal article(s) with results of the trial
- Trial protocol
- Statistical analysis plan (SAP)
- Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- "Grey literature" (e.g. unpublished thesis)
- Conference abstract(s) about the trial
- Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- Research ethics application
- Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- Personal communication with trialist
- Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in **red** are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	There is only reference to randomisation which is insufficient for determining if this was conducted effectively.	PN
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	There was no reference to this so it is unlikely that participants were blinded to this. It is also hard to imagine that this would have been possible given that there was a waitlist control who would have been aware they were not receiving an intervention initially	PN
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	ANOVA conducted and results suggested no significant differences between the three groups	<u>N</u>
Risk-of-bias judgement		High

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Most likely. See 1.2	PY
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	Almost certainly as they were trained instructors in the specific interventions	Y

2.3. <u>If Y/PY/NI to 2.1 or 2.2:</u> Were there deviations from the intended intervention that arose because of the experimental context?	None specified in the text. It is possible that there were modifications but none were made explicit.	NI
2.4. <u>If Y/PY to 2.3:</u> Were these deviations from intended intervention balanced between groups?		NA
2.5 <u>If N/PN/NI to 2.4:</u> Were these deviations likely to have affected the outcome?		NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	There was no specific analysis of the effect of assignment, so it seems unlikely	N
2.7 <u>If N/PN/NI to 2.6:</u> Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	It seems unlikely due to the methods used to assess working memory but it is possible that those participants with no active condition anticipated worse performance	<u>PN</u>
Risk-of-bias judgement		High

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	Those participants randomised but later excluded from the study were not included within the analysis and outcome data were not available for them	N
3.2 <u>If N/PN/NI to 3.1:</u> Is there evidence that the result was not biased by missing outcome data?	There is no specific reference to this	N

3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	It seems unlikely as the issues referenced were sickness, suspension from school etc., which would be likely to have little bearing on working memory.	<u>PN</u>
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA
Risk-of-bias judgement		High

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	The A-OSPAN is a common and valid measure of working memory	<u>N</u>
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	Unlikely assuming that the test was administered in a standardised format	<u>PN</u>
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	It would appear that they were as there is not reference to them being blinded to participant condition	Y
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	It could have but it is difficult to determine whether this was likely as a standardised assessment was used, although outcome assessors could have influenced participants responses unconsciously for example	PY

4.5 <u>If Y/PY/NI to 4.4:</u> Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	It's not clear based on the description of the outcome assessment	NI
Risk-of-bias judgement		High

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	As with the majority of studies, there was no pre-specified analysis but may have been in the ethical application	<u>NI</u>
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	The analysis is significant but not highly so and also seems entirely appropriate in terms of being in line with the aims of the study.	<u>PN</u>
5.3 ... multiple analyses of the data?	As above	<u>PN</u>
Risk-of-bias judgement		Some concerns

Overall risk of bias

Risk-of-bias judgement		High
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Domain 1: Risk of bias arising from the randomization process

Signalling questions	Description	Response options
1.1 Was the allocation sequence random?	A relatively good level of detail is provided on the randomisation process	<u>PY</u>
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	Participants were only informed which condition they were allocated to at the beginning of their first 'class'.	<u>Y</u>
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	A good level of detail is provided regarding demographics which are relatively well matched in terms of ethnicity, gender, years in university etc.	<u>PN</u>
Risk-of-bias judgement		Low

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Description	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Participants were informed of which intervention they were receiving, probably as this would be difficult or near impossible to avoid with the creative writing and mindfulness conditions being qualitatively different.	Y
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	There is no reference to blinding so the assumption is that experimenters knew which condition each participant was in.	PY
2.3. <u>If Y/PY/NI to 2.1 or 2.2:</u> Were there deviations from the intended intervention that arose because of the experimental context?	There is no explicit reference to this so it's not possible to determine whether there were deviations from the intended intervention	NI
2.4. <u>If Y/PY to 2.3:</u> Were these deviations from intended intervention balanced between groups?		NA
2.5 <u>If N/PN/NI to 2.4:</u> Were these deviations likely to have affected the outcome?		NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	ANCOVA appears to be an appropriate method of analysis	Y
2.7 <u>If N/PN/NI to 2.6:</u> Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA
Risk-of-bias judgement		High

Domain 3: Missing outcome data

Signalling questions	Description	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	There were some participants lost to follow-up, and where there were gaps in analysis simulated values were formed. No additional details on how this was performed.	N
3.2 <u>If N/PN/NI to 3.1</u>: Is there evidence that result was not biased by missing outcome data?	Explanations are provided as to why data is missing for some participants i.e. 2 responses excluded due to technical error	PY
3.3 <u>If N/PN to 3.2</u>: Could missingness in the outcome depend on its true value?		N
3.4 <u>If Y/PY/NI to 3.3</u>: Do the proportions of missing outcome data differ between intervention groups?		NA
3.5 <u>If Y/PY/NI to 3.3</u>: Is it likely that missingness in the outcome depended on its true value?		NA
Risk-of-bias judgement		High

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Description	Response options
4.1 Was the method of measuring the outcome inappropriate?	Recent probes task is a common measure of working memory	N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups ?	Responses were measured as objectively correct or incorrect and were therefore less likely to vary between groups. They were also administered in a standardised format i.e. target set of six letters for two seconds.	<u>PN</u>
4.3 <u>If N/PN/NI to 4.1 and 4.2:</u> Were outcome assessors aware of the intervention received by study participants ?	There is no information to suggest that they weren't so it can be assumed that the assessors knew about the intervention allocated to each individual	PY
4.4 <u>If Y/PY/NI to 4.3:</u> Could assessment of the outcome have been influenced by knowledge of intervention received?	As described the assessment was standardised in a manner that would reduce the any influence by assessors	<u>PN</u>
4.5 <u>If Y/PY/NI to 4.4:</u> Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA
Risk-of-bias judgement		High

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Description	Response options
5.1 Was the trial analysed in accordance with a pre-specified plan that was finalized before unblinded outcome data were available for analysis ?		NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	The description of the study aims and protocol fit with the analysis	<u>PN</u>
5.3 ... multiple analyses of the data?		<u>PN</u>
Risk-of-bias judgement		Some concerns

Overall risk of bias

Risk-of-bias judgement	High
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Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)

TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the RoB2 Development Group
Version of 15 March 2019

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.



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Study details**Reference**

Valls-Serrano, C., Caracuel, A., & Verdejo-Garcia, A. (2016). Goal management training and mindfulness meditation improve executive functions and transfer to ecological tasks of daily life in polysubstance users enrolled in therapeutic community treatment. *Drug and alcohol dependence*, 165, 9-14.

Study design

- Individually-randomized parallel-group trial
- Cluster-randomized parallel-group trial
- Individually randomized cross-over (or other matched) trial

Specify which outcome is being assessed for risk of bias

Impact of mindfulness meditation on working memory

Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR

GMT+MM group, $F(1,15)=9.099$, $p=0.009$), but not in the

= 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

TAU only group, $F(1,15) = 0.789$, $p = 0.388$.

Is the review team's aim for this result...?

- to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

Which of the following sources were obtained to help inform the risk-of-bias assessment? (tick as many as apply)

- Journal article(s) with results of the trial
- Trial protocol
- Statistical analysis plan (SAP)
- Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- "Grey literature" (e.g. unpublished thesis)
- Conference abstract(s) about the trial
- Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- Research ethics application
- Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- Personal communication with trialist
- Personal communication with the sponsor

Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in **red** are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	The randomisation was performed using a set of procedures including the use of an independent researcher who was not involved in the study in any significant capacity.	<u>Y</u>
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	There is insufficient information to conclude this although it seems likely that the treatment as usual group would be aware of the intervention, they were receiving	PN
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	No, there was adequate description and there were no apparent differences	<u>PN</u>
Risk-of-bias judgement		High

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Most likely as once they were allocated they would have known if there were receiving a novel or standard form of treatment.	PY
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	No specified so it is likely that they were	PY

2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context?	Nothing specified so cannot determine this	NI
2.4. If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups?		NA
2.5 If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome?		NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?		N
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	There is reference to a an incomplete data set that would appear to be included in the analysis	<u>PN</u>
Risk-of-bias judgement		High

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of adhering to intervention*)

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	See 2.7	<u>PY</u>

3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		NA
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NA
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA
Risk-of-bias judgement		Low

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?		N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	Not likely but possible due to sources of bias such as experimenter expectancy effect	NI
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	As discussed previously, it is likely that outcome assessors were aware of assignment	PY
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	Those participants assigned to treatment as usual may have anticipated poorer performance.	PY

4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	There is insufficient information to conclude whether this was likely or not	NI
Risk-of-bias judgement		High

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	Insufficient information to determine this based on article alone.	NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	Analysis seems appropriate and results are reported for every assessment conducted	<u>PN</u>
5.3 ... multiple analyses of the data?	Cannot be certain but the analysis does not appear to have been chosen on the basis of likelihood in providing a more favourable result.	<u>PN</u>
Risk-of-bias judgement		Some concerns

Overall risk of bias

Risk-of-bias judgement		High
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Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)

TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the RoB2 Development Group
Version of 15 March 2019

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.



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Study details

Reference

Van Vugt, M. K., Hitchcock, P., Shahar, B., & Britton, W. (2012). The effects of mindfulness-based cognitive therapy on affective memory recall dynamics in depression: a mechanistic model of rumination. *Frontiers in human neuroscience*, 6, 257.

Study design

- Individually-randomized parallel-group trial
- Cluster-randomized parallel-group trial
- Individually randomized cross-over (or other matched) trial

Specify which outcome is being assessed for risk of bias

Effect of mindfulness on recall of positively valanced words

Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

$p < 0.001$

Is the review team's aim for this result...?

- to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

Which of the following sources were obtained to help inform the risk-of-bias assessment? (tick as many as apply)

- Journal article(s) with results of the trial
- Trial protocol
- Statistical analysis plan (SAP)
- Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- "Grey literature" (e.g. unpublished thesis)
- Conference abstract(s) about the trial
- Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- Research ethics application
- Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- Personal communication with trialist
- Personal communication with the sponsor

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	Block randomisation was specified as the method used to randomise participants to their condition.	PY

1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	It is not possible to say as there is no information to suggest whether this was the case or not.	NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	There is inadequate information to determine this	NI
Risk-of-bias judgement		High

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Most likely given that one was an active mindfulness condition and the other was waitlist control.	PY
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	The study states that the people delivering interventions were blinded to condition	N
2.3. <u>If Y/PY/NI to 2.1 or 2.2:</u> Were there deviations from the intended intervention that arose because of the experimental context?	Not specified	NI
2.4. <u>If Y/PY to 2.3:</u> Were these deviations from intended intervention balanced between groups?		NA

2.5 If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome?		NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	There was no analysis of effect of assignment of intervention	N
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	It seems probably that this was not likely but there is still a chance that there were significant differences between the groups.	NI
Risk-of-bias judgement		High

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	It is not clear if data for the participants who dropped out were included in the analysis	NI
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	No specific evidence that the result was not biased by the absence of missing data	NI
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NA
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA

Risk-of-bias judgement		Some concerns
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Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	Free recall appears to be appropriate although may be more vulnerable to bias than other standardised test which would be delivered in a consistent manner	<u>PN</u>
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	There is a possibility that this would have been biased by experimenter expectancy effects etc	PY
4.3 <u>If N/PN/NI to 4.1 and 4.2:</u> Were outcome assessors aware of the intervention received by study participants?		NA
4.4 <u>If Y/PY/NI to 4.3:</u> Could assessment of the outcome have been influenced by knowledge of intervention received?		NA
4.5 <u>If Y/PY/NI to 4.4:</u> Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA
Risk-of-bias judgement		High

Domain 5: Risk of bias in selectio of the reported result

Signalling questions	Comments	Response options
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5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	None provided but this could have been made explicit within a ethics application etc.	_____ NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	Results from all measurements and assessments were reported	PN
5.3 ... multiple analyses of the data?	There were multiple assessments of data but all were reported	PN
Risk-of-bias judgement		Some concerns

Overall risk of bias

Risk-of-bias judgement		High
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Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)

TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the RoB2 Development Group
Version of 15 March 2019

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.



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Study details

Reference

Watier, N., & Dubois, M. (2016). The effects of a brief mindfulness exercise on executive attention and recognition memory. *Mindfulness*, 7(3), 745-753.

Study design

- Individually-randomized parallel-group trial
- Cluster-randomized parallel-group trial
- Individually randomized cross-over (or other matched) trial

Specify which outcome is being assessed for risk of bias	Effect of mindfulness on recognition memory
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	F(1,65) = 48.99, p < 0.001, $\eta^2_p = 0.43$,
Is the review team's aim for this result...?	
<input type="checkbox"/> to assess the effect of <i>assignment to intervention</i> (the 'intention-to-treat' effect)	
<input checked="" type="checkbox"/> to assess the effect of <i>adhering to intervention</i> (the 'per-protocol' effect)	
Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)	
<input checked="" type="checkbox"/> Journal article(s) with results of the trial	
<input type="checkbox"/> Trial protocol	
<input type="checkbox"/> Statistical analysis plan (SAP)	
<input type="checkbox"/> Non-commercial trial registry record (e.g. ClinicalTrials.gov record)	
<input type="checkbox"/> Company-owned trial registry record (e.g. GSK Clinical Study Register record)	
<input type="checkbox"/> "Grey literature" (e.g. unpublished thesis)	
<input type="checkbox"/> Conference abstract(s) about the trial	
<input type="checkbox"/> Regulatory document (e.g. Clinical Study Report, Drug Approval Package)	
<input type="checkbox"/> Research ethics application	
<input type="checkbox"/> Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)	
<input type="checkbox"/> Personal communication with trialist	
<input type="checkbox"/> Personal communication with the sponsor	

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
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1.1 Was the allocation sequence random?	Not sufficiently detailed in order to say that randomisation actually occurred.	PN
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	Unclear as no detail is provided	NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	Not clear as differences between groups are not described adequately	NI
Risk-of-bias judgement		High

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Most likely as there is no discussion of them having been blinded to this and there are clear differences between mindfulness and mental arithmetic	PY
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	Almost certainly as experimenters were in a separate room to the participants	Y
2.3. <u>If Y/PY/NI to 2.1 or 2.2:</u> Were there deviations from the intended intervention that arose because of the experimental context?	None described	NI

2.4. If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups?		NI
2.5 If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome?		NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	No reference to this	N
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	Insufficient information to state as it was not clear how each participant might perform at mental arithmetic for example.	NI
Risk-of-bias judgement		High

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	Eight participants were excluded due to being outliers.	N
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	There is a possibility that the results were biased by removing eight outliers although the sample of 78 makes this less likely. No evidence is provided to demonstrate the results weren't biased.	N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	Not clear	NI

3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?	Not clear	NI
Risk-of-bias judgement		High

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	Stroop test is validated method for measuring recognition memory	PY
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	As above	PN
4.3 <u>If N/PN/NI to 4.1 and 4.2:</u> Were outcome assessors aware of the intervention received by study participants?	Most likely as there is nothing to suggest they weren't so this was most likely the researchers	PY
4.4 <u>If Y/PY/NI to 4.3:</u> Could assessment of the outcome have been influenced by knowledge of intervention received?	More of an implicit test so less likely but could have been unconsciously biased	NI
4.5 <u>If Y/PY/NI to 4.4:</u> Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	Insufficient information to determine	NI
Risk-of-bias judgement		High

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	Insufficient information to be able to tell	NI

Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	The process of analysis seems appropriate and it would not appear likely that the result reported was selected from multiple measures based on the assessments detailed within the article	<u>PN</u>
5.3 ... multiple analyses of the data?	As above	<u>N</u>
Risk-of-bias judgement		Some concerns

Overall risk of bias

Risk-of-bias judgement		High
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Revised Cochrane risk-of-bias tool for randomized trials (RoB 2.0)

TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the ROB2 Development Group
Version of 9 October 2018

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.



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Study details

Reference

M Watier, N., & Dubois, M. (2016). The effects of a brief mindfulness exercise on executive attention and recognition memory. *Mindfulness*, 7(3), 745-753.

Study design

- Individually-randomized parallel-group trial
- Cluster-randomized parallel-group trial
- Individually randomized cross-over (or other matched) trial

Specify which outcome is being assessed for risk of bias

Impact of MBSR on immediate and delayed memory

Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

Immediate list recall p = 0.46
 Immediate story recall p = 0.36
 Delayed list recall p = .107
 Delayed story recall p = .210
 Cognitive composite p = .627

Is the review team's aim for this result...?

- to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

Which of the following sources were obtained to help inform the risk-of-bias assessment? (tick as many as apply)

- Journal article(s) with results of the trial
- Trial protocol
- Statistical analysis plan (SAP)
- Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- "Grey literature" (e.g. unpublished thesis)
- Conference abstract(s) about the trial
- Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- Research ethics application
- Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- Personal communication with trialist
- Personal communication with the sponsor

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Description	Response options
1.1 Was the allocation sequence random?	Yes randomisation occurred using block sequencing and was conducted by a the study statistician who had not contact with participants or raters.	<u>Y</u>
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	Yes detailed within study	<u>Y</u>
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	No significant differences between groups and this is detailed across cognitive domains being measures although there were some significant demographic differences such as ethnicity. Whilst these may effect the representativeness of the sample, this probably does not represent a problem with the randomisation as the findings are likely to be valid based on the cognitive profiles of participants	<u>PN</u>
Risk-of-bias judgement		Low

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Description	Response options
2.1. Were participants aware of their assigned intervention during the trial?	It was likely to be difficult to prevent participants from being aware of whether they were in a MBSR or Health education.	Y
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	Yes these were trained professionals who would have understood which intervention the participant was in, although they may not have known which condition was the control or experimental condition	Y
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context?	Adaptations were made to the intervention but these were planned and did not deviate because of the experimental context	<u>N</u>

2.4. If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups?		NA
2.5 If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome?		NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	None is referenced	NI
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		<u>PN</u>
Risk-of-bias judgement		High

Domain 3: Missing outcome data

Signalling questions	Description	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	Yes, this is detailed throughout such as participants who had missing values for a particular part of the analysis	<u>PY</u>
3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data?	Yes a missingness test was conducted using MCAR and was found to be insignificant	Y
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NA

3.4 If Y/PY/NI to 3.3: Do the proportions of missing outcome data differ between intervention groups?		NA
3.5 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?	Not likely based on analysis	<u>PN</u>
Risk-of-bias judgement		Low

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Description	Response options
4.1 Was the method of measuring the outcome inappropriate?	Not likely, composite memory scores were created that were insignificant between conditions. The individual tests were standardised and valid measures of memory	<u>PN</u>
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups ?	Highly unlikely, no significant differences between groups and test administrators and analysis conducted independently and blinded.	<u>N</u>
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants ?	No as above	<u>N</u>
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		NA
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	It is possible but unlikely that an unconscious bias would significantly have affected the result	<u>PN</u>
Risk-of-bias judgement		Low

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Description	Response options
5.1 Was the trial analysed in accordance with a pre-specified plan that was finalized before unblinded outcome data were available for analysis ?		NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	Multiple results were reported, some of which were favourable to the study aims and others that were not	<u>N</u>
5.3 ... multiple analyses of the data?		<u>N</u>
Risk-of-bias judgement		Low

Overall risk of bias

Risk-of-bias judgement		High
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Revised Cochrane risk-of-bias tool for randomized trials (RoB 2.0)

TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the ROB2 Development Group
Version of 9 October 2018

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.



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Study details

Reference

Wilson, B. M., Mickes, L., Stolarz-Fantino, S., Evrard, M., & Fantino, E. (2015). Increased false-memory susceptibility after mindfulness meditation. *Psychological Science*, 26(10), 1567-1573.

Study design

- Individually-randomized parallel-group trial
- Cluster-randomized parallel-group trial
- Individually randomized cross-over (or other matched) trial

Specify which outcome is being assessed for risk of bias

Impact of mindfulness on false memory

Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR

Difference in false memory between mindfulness and mind wandering condition p = .250

= 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

Is the review team's aim for this result...?

- to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

Which of the following sources were obtained to help inform the risk-of-bias assessment? (tick as many as apply)

- Journal article(s) with results of the trial
- Trial protocol
- Statistical analysis plan (SAP)
- Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- "Grey literature" (e.g. unpublished thesis)
- Conference abstract(s) about the trial
- Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- Research ethics application
- Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- Personal communication with trialist
- Personal communication with the sponsor

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Description	Response options
1.1 Was the allocation sequence random?	Only reference to randomisation so unlikely and does not meet the standard set by the ROB2 for randomisation.	PN
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	Yes because they assigned randomly and immediately after being enrolled based on the description provided in the journal article	PY
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	Poorly described so cannot determine. Baseline differences in false-memory susceptibility were insignificant.	NI
Risk-of-bias judgement		High

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Description	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Most likely as one was mind wandering and the other was mindfulness	PY /
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	Yes	Y
2.3. <u>If Y/PY/NI to 2.1 or 2.2:</u> Were there deviations from the intended intervention that arose because of the experimental context?	Not described adequately	NI

2.4. If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups?	Not described adequately	NI
2.5 If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome?		NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?		N
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NI
Risk-of-bias judgement		High

Domain 3: Missing outcome data

Signalling questions	Description	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?		<u>PY</u>
3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data?		N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		<u>PN</u>

3.4 If Y/PY/NI to 3.3: Do the proportions of missing outcome data differ between intervention groups?		<u>PN</u>
3.5 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NI
Risk-of-bias judgement		High

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Description	Response options
4.1 Was the method of measuring the outcome inappropriate?		<u>N</u>
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups ?		<u>PN</u>
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants ?		Y I
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		<u>PN</u>
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NI
Risk-of-bias judgement		High

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Description	Response options
5.1 Was the trial analysed in accordance with a pre-specified plan that was finalized before unblinded outcome data were available for analysis ?		NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?		<u>N</u>
5.3 ... multiple analyses of the data?		<u>N</u>
Risk-of-bias judgement		Some concerns

Overall risk of bias

Risk-of-bias judgement		High
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Revised Cochrane risk-of-bias tool for randomized trials (RoB 2.0)

TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the ROB2 Development Group
Version of 9 October 2018

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.



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Study details

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Specify which outcome is being assessed for risk of bias

Impact of mindfulness on false memory

Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

Difference in false memory between mindfulness and mind wandering condition $p = .250$

Is the review team's aim for this result...?

- to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

Which of the following sources were obtained to help inform the risk-of-bias assessment? (tick as many as apply)

- Journal article(s) with results of the trial
- Trial protocol
- Statistical analysis plan (SAP)
- Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
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Risk-of-bias judgement		High

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Description	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Most likely as one was mind wandering and the other was mindfulness	PY /
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2.4. If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups?	Not described adequately	NI
2.5 If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome?		NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?		N
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NI
Risk-of-bias judgement		High

Domain 3: Missing outcome data

Signalling questions	Description	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?		<u>PY</u>
3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data?		N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		<u>PN</u>

3.4 If Y/PY/NI to 3.3: Do the proportions of missing outcome data differ between intervention groups?		<u>PN</u>
3.5 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NI
Risk-of-bias judgement		High

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Description	Response options
4.1 Was the method of measuring the outcome inappropriate?		<u>N</u>
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups ?		<u>PN</u>
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants ?		Y I
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		<u>PN</u>
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NI
Risk-of-bias judgement		High

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Description	Response options
5.1 Was the trial analysed in accordance with a pre-specified plan that was finalized before unblinded outcome data were available for analysis ?		NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?		<u>N</u>
5.3 ... multiple analyses of the data?		<u>N</u>
Risk-of-bias judgement		Some concerns

Overall risk of bias

Risk-of-bias judgement		High
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Appendix B

Dear [REDACTED] and Mr [REDACTED]

Re: “Comparing the effect of relaxation and focused attention on implicit recall in acquired brain injury”
Application for Ethical Review ERN_17-1612

Thank you for your application for ethical review for the above project, which was reviewed by the Science, Technology, Engineering and Mathematics Ethical Review Committee.

On behalf of the Committee, I confirm that this study now has full ethical approval.

I would like to remind you that any substantive changes to the nature of the study as described in the Application for Ethical Review, and/or any adverse events occurring during the study should be promptly brought to the Committee’s attention by the Principal Investigator and may necessitate further ethical review.

Please also ensure that the relevant requirements within the University’s Code of Practice for Research and the information and guidance provided on the University’s ethics webpages (available at <https://intranet.birmingham.ac.uk/finance/accounting/Research-Support-Group/Research-Ethics/Links-and-Resources.aspx>) are adhered to and referred to in any future applications for ethical review. It is now a requirement on the revised application form (<https://intranet.birmingham.ac.uk/finance/accounting/Research-Support-Group/Research-Ethics/Ethical-Review-Forms.aspx>) to confirm that this guidance has been consulted and is understood, and that it has been taken into account when completing your application for ethical review.

Please be aware that whilst Health and Safety (H&S) issues may be considered during the ethical review process, you are still required to follow the University’s guidance on H&S and to ensure that H&S risk assessments have been carried out as appropriate. For further information about this, please contact your School H&S representative or the University’s H&S Unit at healthandsafety@contacts.bham.ac.uk.


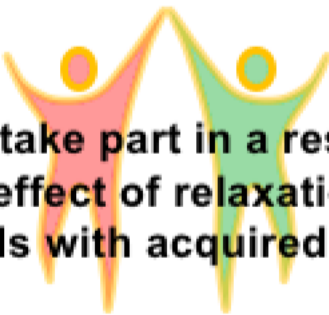
Kind regards

[REDACTED]
Research Ethics Officer
Research Support Group

[REDACTED]

Appendix C

Comparing the effect of relaxation and focused attention on implicit recall in acquired brain injury. Invitation to participate. Version 1. 25 November 2017

**UNIVERSITY OF
BIRMINGHAM**

**Invitation to take part in a research study
exploring the effect of relaxation on learning
in individuals with acquired brain injury**

We would like to invite you to take part in a research study being carried out by researchers at the University of Birmingham.

This research study is being carried out as part of a Clinical Psychology Doctorate course at the University of Birmingham. The study has been approved by the Universities Research Ethics Committee.

The purpose of the research study is to identify the benefits of learning strategies for people with acquired brain injury when they relaxed.

- ❖ Participation includes two 25-minute relaxation training sessions, and a further two 30-minute sessions which will test your recall of words under different conditions.
- ❖ You will also be required to meet to conduct some assessments.
- ❖ Your participation and personal information will be treated with the utmost confidentiality.
- ❖ Choosing not to take part in this research will not disadvantage you in any way.

For more information about why this research is being done and what it would involve for you, please contact:

<p>Arthur Pearce Principal Researcher Trainee Clinical Psychologist University of Birmingham [REDACTED] AXP651@bham.ac.uk</p>	<p>Dr Gerry Riley Chief Investigator Senior Academic Tutor University of Birmingham [REDACTED] AXP651@bham.ac.uk g.a.riley@bham.ac.uk</p>
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Appendix D

Participant Identification Number:.....

CONSENT TO CONTACT FORM

CONSENT TO CONTACT FOR RESEARCH PURPOSES

Title of Project: *Comparing the effect of relaxation and focused attention on implicit recall in acquired brain injury*

Researcher: Arthur Pearce (Trainee Clinical Psychologist)

Supervisor: Gerard Riley (University of Birmingham)

You are being invited to give consent for Arthur Pearce to contact you about taking part in the above study.

Are you willing to allow Arthur Pearce to contact you further about the study (Circle one).

YES NO

If yes, you will be contacted at a later date. Please include your contact information below.

Telephone: _____

Email: _____

Please sign here: _____

Date: _____

Appendix E

PARTICIPANT INFORMATION SHEET

Title of Project: *Comparing the effect of relaxation and focused attention on implicit recall in acquired brain injury*

Researcher: Arthur Pearce (Trainee Clinical Psychologist)

Supervisor: Gerard Riley (University of Birmingham)

Hello, my name is Arthur Pearce and I am from the University of Birmingham. I would like to invite you to take part in some research I am doing at Headway. This research is being undertaken as part of a doctoral thesis, and will be exploring the effect that relaxation techniques have on memory in individuals with acquired brain injury. Before you decide to take part, please take the time to read the rest of this information sheet. If you have any questions after reading this information sheet, please feel free to speak with a member of staff or contact me directly using the contact details at the end of this sheet.

What is the purpose of the research?

There are two kinds of memory – one where you deliberately try to remember something (e.g. someone's phone number when you are giving them a call) and one where the memory comes to you without you trying (e.g. hearing the rumble of your neighbour's bin reminds you that you need to take the bins out for collection). The aim of the research is to see whether the second type of memory works better when you are in a relaxed state. Some memory rehabilitation techniques try to help you make more use of the second type of memory because it is usually less damaged by brain injury. We are hoping that this research will help us improve these techniques.

Why have I been invited to take part?

You are invited to participate in this study as the focus is on people with acquired brain injury who have memory problems. The following individuals are invited to take part in the study:

- You are at least 18 years of age
- You have an acquired brain injury (e.g. a stroke or a head injury) that happened at least 6 months ago
- Your brain injury caused some problems with your memory that you still have
- You are sufficiently fluent in English to understand this participant information leaflet and the instructions given in the study
- Any cognitive problems you experience are stable
- You are capable of giving informed consent

What will happen to me if I agree to take part?

We will have four meetings altogether. All the meetings will take place at the Headway centre you attend.

At the first two meetings, I will show you some different relaxation techniques. The aim is to find one that best suits you and that helps you feel most relaxed. Your ability to relax will be assessed using a wristwatch that will monitor your heart rate and a questionnaire. Each of these first two meetings should take no more than 25 minutes. They will be carried out in a small group of about 6 people, although we could arrange to do this individually if you prefer.

The third and fourth meetings will follow the same pattern. You will be asked to provide some simple information about a series of words that you will see on a computer screen (e.g. you will be asked to say what the third letter of the word is). You will then either relax, using the technique that worked best for you, or you will watch a short video of a basketball game and count the number of times the players pass the ball. After this, you will complete two tasks. In one task, you will be asked to say the first word that comes into your head when you are shown the first three letters (e.g. BLA____). In the second task, you will be shown words for a very brief moment and you have to say whether you saw what the word said or not.

The third and fourth meetings will be exactly the same except that, in one you will relax, but in the other you will watch the basketball video. At the end of these meetings, I will also ask you to complete two questionnaires about yourself and your brain injury; a memory test involving a short story; a problem-solving puzzle; and a short reading test. These meetings should take no longer than 40 minutes each.

Do I have to take part?

Absolutely not. Please do not take part if you are not happy or unsure about any aspect of the study. No one will put any pressure on you to take part if you do not want to. Nothing will happen to you if you decide not to take part.

What will happen if I do not want to carry on with the study?

You have the right to withdraw from the study at any time, up until your participation in the experiment comes to an end. After this period you will not be able to withdraw from the study as your data will be included in the write-up of the research. If you decide you no longer wish to carry on with the study, you can let the researcher know directly, or ask a member of staff to do this for you.

Nothing will happen to you if you decide to withdraw. You will be free to continue accessing Headway as you were prior to being involved in the study.

If you wish to stop taking part in the study I will immediately destroy any information you have given me.

What are the possible disadvantages of taking part in this study?

Whilst it is not the intention of this study, it is possible that you might find aspects of the study stressful.

You have the right to withdraw at any time up until your participation in the experiment comes to an end, and you will be reminded of this if you appear stressed at any point during the study.

If you do not respond to the relaxation techniques you are exposed to early on in the study i.e. there are no changes in your heart rate, or you do not feel the techniques are helping you to feel relaxed, you will not be invited to continue with the rest of the study.

What are the possible benefits of taking part in this study?

You will learn some relaxation techniques that may help you in managing stress. I will give you some materials to take away with you that will enable you to carry on using these techniques in your everyday life.

How will my information be protected?

All the information that is collected about you during the study will be kept strictly confidential. Paper copies of the consent forms will be kept in a locked cabinet at the University of Birmingham. All electronic data will be kept on a password protected computer. The only individuals who will be able to access this information will be me and my research supervisor, although in exceptional circumstances the data may need to be shown to someone authorised by the University of Birmingham to conduct a research audit.

None of your personal information will be included in the write-up of the research. Your data will be collected and stored in line with the Data Protection Act (1998). Your data will be held at the University of Birmingham for ten years before being destroyed.

I will only disclose personal information about you without your consent if you mention something that suggests you might harm yourself or someone else.

What will happen to the results of the research study?

The research will be completed in September 2019. Once finished, the study will be written up as a University thesis. The results may also be published in a scientific journal or presented at a scientific conference. A summary of the results will also be sent to the Headway centre that you attend and you will be offered a copy. The researcher may also give a talk about the results to the Headway centre. However, at no time will any personal information be included in these write-ups or presentations.

Will there be any expenses or payments?

There will be no payments or expenses paid for taking part in this study. However, there should not be any personal costs to participants.

What should I do if I am unhappy with any aspect of the research?

If you would like to speak with someone independent of the research, please contact Biza Kroese (Senior lecturer and consultant clinical psychologist) at the University of Birmingham on:

Telephone: [REDACTED]

Email: k.l.shapiro@bham.ac.uk

What happens if I have any further questions?

If you would like to discuss any aspect of this research, please speak to a member of staff at Headway, or contact the researcher directly using the contact details below. I will respond to any queries or questions you have as soon as possible.

The lead researcher can be contacted via the following:

Telephone: [REDACTED]

Email: axp651@student.bham.ac.uk

Post: Arthur Pearce, Birmingham University, Psychology Department, Hills Building, Edgbaston Park Rd, Birmingham B15 2TT

Thank you for taking the time to read this and I hope you consider taking part in this research.

If you have any concerns about your memory after reading this or after taking part in the study, please speak to a member of staff at Headway who will try to arrange suitable support. Alternatively, you can read the information leaflet on memory problems after brain injury produced by Headway which is available from the staff or from <https://www.headway.org.uk/media/3996/memory-problems-after-brain-injury-e-booklet.pdf>

Appendix F

CONSENT FORM

Participant Identification Number:.....

CONSENT TO PARTICIPATE

Title of Project: Comparing the effect of relaxation and focused attention on implicit recall in acquired brain injury

Researcher: Arthur Pearce (Trainee Clinical Psychologist)

Supervisor: Gerard Riley (University of Birmingham)

Please initial box

1. I confirm that I have understood the information sheet dated (version 1) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that I have the right to withdraw from the study at any time until my participation in the experimental comes to an end.
3. I understand that the data collected during this study may need to be shown to persons authorised by the University of Birmingham to conduct research audit.
4. I agree to take part in the above study.

.....
Name of participant

.....
Date

.....
Signature

.....
Name of researcher

.....
Date

.....
Signature

Appendix G

Guided Imagery

Imagine going to a place, real or invented, where you feel safe, peaceful and calm. You want to take the time to develop the imagery so you fully experience this place with all your senses.

Start out with a simple check-in of your emotional state, your thoughts, and what you are feeling in your body. Just notice what's happening, without judgment or expectation. Let your breath deepen, and locate a spot in your body where you are starting to feel an opening, a lightness, or a loosening. Allow that to expand with every in-breath and every out-breath, imagining it gradually filling up your entire body. Imagine this relaxing energy moving through your body in waves, reaching every part of you.

Sea Shore

Imagine you are at the sea shore on a beautiful day. It's the perfect time of day, and the perfect time of year for you to be there. Recall the feeling you get in your body when you are at the beach, or what it was like when you were there as a child. Let yourself explore that feeling.

Imagine the warmth of the sun on the top of your head and your shoulders. Allow this image to develop. Perhaps there's a pleasant breeze, which you feel on your face and arms. Imagine the refreshing, salty breeze off the water, and breathe. Maybe you can even taste the salt spray.

Look up and down the beach and notice the expanse of sand, the color and texture of it, the way it sparkles in the sunlight. Imagine that you are standing in the dry, soft, sand, and feel it beneath your feet and between your toes. Imagine taking a few steps, and feeling what it's like to walk in deep, warm, soft sand. Move closer to the water and walk in the cool, firm sand. Feel it take on the shape of your feet as you walk. Look behind you and see your footprints. Notice the waves gently rolling in and lapping the shore, gradually smoothing those footprints out, rhythmically washing them away as the waves roll back out.

Look at the edge of the water and notice the color. Notice that color meeting the sand, and the waves gently lapping on the shore, rolling in, breaking softly, and going back out, over and over, endlessly. Hear the, deep, calming, rhythmic sound of the waves breaking on the beach. Look out to the horizon, and notice the waves as far back as you can see, rolling toward the shore, breaking, glittering in the sunlight. Notice the dancing light moving rhythmically across the whole surface of the water. Notice the place where the surf meets the sky, and see where the colors come together. Notice the light. Let yourself feel the expanse of the sky, and imagine breathing that in, filling yourself with that feeling of spaciousness, brightness and light.

If you like, you might imagine going into the water, and feeling gently carried on the waves, safe in the protected cove, warmed by the sun. Just rolling gently on the surf, carried safely on the buoyant waves.

When you come out of the water, find the clean, dry, soft towel you have placed there. Imagine lying down on the towel, feeling the warm sand beneath mold itself to your body. Notice how the warm, firm surface supports your whole body, and allow yourself to relax deeply into it, letting the warmth and comfort fill your body and mind.

When you have finished your guided meditation, take a few minutes to sit quietly, noticing what you are experiencing in your body, what your thoughts and emotions are like.

Other ideas for guided meditation: walking through a meadow, floating in the clouds, snorkeling in a coral reef, sitting by a fire in a cozy cabin, being in lovely, comfortable room, or in bed on a rainy day.

Progressive Muscle Relaxation

This exercise involves systematically tensing and relaxing different muscle groups. This is a good relaxation exercise for those who have trouble concentrating, or experience racing thoughts or other mental distractions. You may leave your eyes open or close them, as you prefer. Experiment with how much you tense your target muscles: some find tensing tightly is most helpful, while others use "threshold tensing," just tightening enough to barely sense the tension.

Start out by taking a few deep breaths into the abdomen. Just notice the breath.

Do a simple check-in of your emotional state, your thoughts, and what you are feeling in your body. Just notice what is happening, without judgment or expectation.

Make a fist with your right hand, and tense the muscles in your right forearm, allowing the rest of the arm to remain relaxed.

Study the sensations of tension.

Compare the tensed muscles to the relaxed ones in the opposite arm, and in the rest of the body.

When you're ready, take a deep breath in, and, as you exhale, slowly, gradually release all of the tension, until every last bit has left the tensed muscles. You may imagine it's like a fire hose that was rigid and becomes more flexible as the water drains out, or a any image that works for you.

Spend a few moments studying and appreciating the sensations in the muscles once they are relaxed.

Repeat this with your left fist and forearm.

Raise your right shoulder, pin your right upper arm to the side of your body, and tense the muscles in the right upper arm and shoulder.

Study the sensations of tension.

Compare the tensed muscles to the relaxed ones in the opposite arm, and in the rest of the body.

When you're ready, take a deep breath in, and, as you exhale, slowly, gradually release all of the tension, until every last bit has left the tensed muscles. Find an image that captures this gradual release of tension for you: the sun melting ice, butter melting, releasing pressure with a valve, et cetera.

Spend a few moments studying and appreciating the sensations in the muscles once they are relaxed.

Repeat this with your left upper arm and shoulder.

With your leg extended, bend your right foot up at an angle, so the muscles of your right calf, shin, ankle and foot are tensed. Allow the rest of the leg to remain relaxed.

Study the sensations of tension.

Compare the tensed muscles to the relaxed ones in the rest of the leg, and in the rest of the body.

When you're ready, take a deep breath in, and, as you exhale, slowly, gradually release all of the tension, until every last bit has left the tensed muscles. You may imagine it's like a fire hose that was rigid and becomes more flexible as the water drains out.

Spend a few moments studying and appreciating the sensations in the muscles once they are relaxed.

Repeat this with your left foot and lower leg.

Tense the muscles in the right buttock and thigh, allowing the remaining muscles in the right leg to remain as relaxed as possible.

Study the sensations of tension.

Compare the tensed muscles to the relaxed ones in the opposite buttock and thigh, and in the rest of the body.

When you're ready, take a deep breath in, and, as you exhale, slowly, gradually release all of the tension, until every last bit has left the tensed muscles.

Spend a few moments studying and appreciating the sensations in the muscles once they are relaxed.

Repeat this on the left side.

Suck in your abdominal muscles, and simultaneously push the small of your back against the chair or floor. Study the sensations of tension.

Compare the tensed muscles to the relaxed ones in the rest of your body.

When you're ready, take a deep breath in, and, as you exhale, slowly, gradually release all of the tension, until every last bit has left the tensed muscles.

Spend a few moments studying and appreciating the sensations in the muscles once they are relaxed.

Let your head fall forward, or, alternatively, press your head backward against a wall, to tense the muscles in the back of your neck.

Study the sensations of tension.

Compare the tensed muscles to the relaxed ones in the rest of your body.

When you're ready, take a deep breath in, and, as you exhale, slowly, gradually release all of the tension, until every last bit has left the tensed muscles.

Spend a few moments studying and appreciating the sensations in the muscles once they are relaxed.

Push your tongue against your upper palette, purse your lips, squint your eyes, tighten your jaw and scrunch up your face.

Study the sensations of tension.

Compare the tensed muscles to the relaxed ones in the rest of your body.

When you're ready, take a deep breath in, and, as you exhale, slowly, gradually release all of the tension, until every last bit has left the tensed muscles.

Spend a few moments studying and appreciating the sensations in the muscles once they are relaxed.

Take a few slow, deep breaths, and allow yourself to be aware of the sensations throughout your body. If there is any part that remains tense, repeat the exercise there until the tension is gone. Just allow the relaxation to move through your body in waves, allowing yourself to relax more, and more, and more deeply as you continue to take slow, deep breaths. If you like the seashore, you may want to think of gentle waves lapping at the sand, gradually washing away physical, and emotional, and mental tension, smoothing ... soothing ...relaxing.

When you are done with the relaxation exercise, allow yourself a few minutes to reorient before getting up. Just enjoy the sensations of relaxation throughout your body. You may notice sensations you have never been aware of before.

Appendix H

DEMOGRAPHIC QUESTIONNAIRE

Participant Information Questionnaire (to be administered to all participants)

1. What is your date of birth?
2. What is your highest educational qualification received?
3. If any, what was your occupation prior to your injury?
4. If any, what is your current occupation?
5. What type of brain injury did you sustain?
6. On what date did you sustain your brain injury?

Appendix I

Experimental Instructions – Irrespective of Assigned Condition

1. Liaise with Headway and individual participants to find a mutually agreed date and time to complete conditions 1 and 2. Use the table below to record this. There must be a week gap exactly between conditions 1 & 2 to ensure consistency between participants in relation to any residual effects from the 1st condition they participated in.
2. Assign which condition a participant does first randomly.

Allocation	Condition and order	Stem Completion lists		Perceptual Identification lists	
1	1st Relaxation	A - primed	B – unprimed	E - primed	F – unprimed
	2nd Attention	C - primed	D - unprimed	G - primed	H - unprimed
2	1st Attention	A - primed	B – unprimed	E - primed	F – unprimed
	2nd Relaxation	C - primed	D - unprimed	G - primed	H - unprimed
3	1st Relaxation	A - unprimed	B – primed	E - unprimed	F – primed
	2nd Attention	C - unprimed	D - primed	G - unprimed	H - primed
4	1st Attention	A - unprimed	B – primed	E - unprimed	F – primed
	2nd Relaxation	C - unprimed	D - primed	G - unprimed	H - primed
5	1st Relaxation	C - primed	D – unprimed	G - primed	H– unprimed
	2nd Attention	A - primed	B - unprimed	E - primed	F - unprimed
6	1st Attention	C - primed	D – unprimed	G - primed	H – unprimed
	2nd Relaxation	A - primed	B - unprimed	E - primed	F - unprimed
7	1st Relaxation	C - unprimed	D – primed	G - unprimed	H – primed
	2nd Attention	A - unprimed	B - primed	E - unprimed	F- primed
8	1st Attention	C - unprimed	D – primed	G - unprimed	H – primed
	2nd Relaxation	A - unprimed	B - primed	E - unprimed	F - primed

Participant Identification Number	Allocation (1-8)	Condition 1: Date and Time	Condition 2: Date and Time
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3. Open and run the E-Prime programme for the study condition that the participant is in (total of 8 programmes). Enter the subject number associated with their participant identification number for each participant for the session.
4. Pre-exposure to two of the eight word lists (1 x recall - stem completion. 1 x recall – perceptual identification task). Present the words one at a time using E-Prime. The lists need to be mixed-up in a set order and presented to each participant in the same manner. To make sure participants attend fully to each word and process them visually and semantically ask participants to do the following:

“For this part of the study, you will see a word on the screen. All you need to do is to say the word, tell me the third letter of the word, and say whether or not the word contains the letter ‘e’. For example, the third letter of the word "potato" is T and it does not contain the letter ‘e’.”

“When you have done this, and are ready, I will click on the mouse for the next word to appear. We will start with some practice trials first. I will show how to do the first one and then you have a try doing the next three before we make a start.”

If the participant does not understand the instruction you should repeat this using the same example of a potato. Check the participants understanding of the task by asking them how they would respond to seeing the word ‘potato’ if this were to appear on the screen. Please refer to word list document for categories.

5. Start the practice trails (total of three to ensure they have got this). First use potato example and will talk them through this as above, the next trial will give them the letter but they will complete the next three trials independently. Give correction or further instruction if they do not do this task correctly; and keep giving them new practice words until they get it correct. If the person is unable to complete the task, you would have to withdraw them from the study.
6. Instruct the participant using the activity relevant to the condition they are assigned to:

Relaxed state (condition 1)

Ask the participant *“Are you happy for us to do the relaxation technique that worked most effectively for you in the practice sessions. Before we do this I would like you to wear the Apple Watch so I can take a recording before and after doing this, is that okay?”*

You should have identified which was most effective in the relaxation trials, and this is the one you will be doing with the participant.

The relaxation scripts can be found here:

www.traumacenter.org/resources/pdf_files/relaxation_exercises.pdf

Record the current reading from the heart rate monitor in the form in step 5 of relaxation training sessions. Then complete the relaxation technique using the script. Take a further reading following the completion of the relaxation technique.

Focused attention (condition 2)

1. Tell the participant: *“I am going to show you a video now and would like you to focus on what is going on in this. The video has no audio but you will see instructions at different points telling you what to look out for. I will pause the video between tasks to tell you what you need to do at each stage. Do you have any questions before we begin?”*
2. The following video will be embedded in E-prime so will automatically begin when you click the mouse. (ensure this is set to have no audio):

<https://www.youtube.com/watch?v=XkaeiG168Zo>

Stem-completion and Perceptual Identification Task

1. Open and run the relevant E-Prime programme. Make sure, when prompted, that you enter the subject number for the data file that matches the participant's number on the allocation sheet. Say to the participant:

“You will now see some words that will be flashed up on the screen very quickly. Your task is to try to identify the word. Please say out loud whatever word comes into your head, even if you are not completely sure what you have seen. Don’t worry about getting it right. It doesn’t matter if you get it right or not – we are more interested in the first word that comes into your head. Don’t worry if you can’t see anything – sometimes the word will be flashed up very quickly and won’t be that easy to see. If this happens, just tell me that you didn’t see anything and we will move on to the next item. A row of XXXXs will appear on the screen first at the exact spot where the word will appear - so you need to look at the XXXXs when they appear.

First there are some practice words to try. I will click the mouse for the next word when you have given me your answer to which word you think has just flashed up on the screen.”

Once the perceptual identification task has been completed. Tell the participant:

“In the next task, I’ll show you the first few letters of a word. All you have to do is say a word that starts with those letters. Please say out loud the first word that comes into your head. There are no right or wrong answers. We are only interested in the first word that comes into your head. Just say whatever comes into your head. If no word comes to mind, just tell me and we will move on to the next item.

First there are some practice words to try. I will click on the mouse when you are ready for the next word.”

2. Thank the participant and give them the opportunity to ask any questions they may have about the study.
3. Make sure that you save the data file from the identification stage of the study onto your memory stick.

Experimental Instructions – Chief Investigator –Stage 3

1. Second experimental session – as for first session, with exception that participant completes in other condition.

Appendix J

DEBRIEF

The aim of the research is to identify whether a certain type of memory (implicit memory) works better when you are in a relaxed state. Some learning strategies try to help you make more use of implicit memory because it is usually less damaged by brain injury. We are hoping that this research will help us improve the effectiveness of these techniques.

How was this tested?

The two tasks you did at the end of the session (trying to identify words that were flashed up on the screen very quickly, and saying the first word that came to mind when you were shown the first few letters) are both tests of implicit memory. In one of the sessions, you used the relaxation techniques to get you relaxed, and in the other session you had to concentrate hard to count the number of ball passes in the video. What I am interested in is whether people do better on the two implicit memory tasks after they relaxed compared to after they concentrated hard.

Hypotheses and main questions:

We expect to find that people did better on the implicit memory tasks (identifying words flashed up quickly and saying the first word that comes to mind when shown the first few letters) after the relaxation compared to after concentrating hard on the basketball video.

Why is this important to study?

We want to find out if being relaxed helps people remember better after a brain injury. If it does, this could make a difference to how people are helped to learn and remember things.

What if I want to know more?

If you are interested in learning more about the problems people with acquired brain injury experience in relation to memory, you may want to consult:

<https://www.headway.org.uk/media/3996/memory-problems-after-brain-injury-e-booklet.pdf>

Thank you again for your participation.

Appendix K

RQF level	Level criteria	Example qualifications ^[1]	Equivalent FHEQ qualifications ^[2]
Level 8	<p>Holder develops original practical, conceptual or technological understanding to create ways forward in contexts that lack definition and where there are many complex, interacting factors. Holder critically analyses, interprets and evaluates complex information, concepts and theories to produce new knowledge and theories. Holder understands and reconceptualises the wider contexts in which the field of knowledge or work is located. Holder extends a field of knowledge or work by contributing original knowledge and thinking. Holder exercises critical understanding of different theoretical and methodological perspectives and how they affect the field of knowledge or work.</p> <p>AND/OR Holder can use advanced and specialised skills and techniques to conceptualise and address problematic situations that involve many complex, interacting factors. Holder can formulate and use appropriate methodologies and approaches. Holder can initiate, design and undertake research, development or strategic activities that extend or produce significant change in the field of work or study. Holder can critically evaluate actions, methods and results and their short- and long-term implications for the field of work or knowledge and its wider context.</p>	<ul style="list-style-type: none"> • Level 8 Award • Level 8 Certificate • Level 8 Diploma 	<ul style="list-style-type: none"> • PhD/DPhil • Professional doctorates
Level 7	<p>Holder reformulates and uses practical, conceptual or technological knowledge and understanding of a subject or field of work to create ways forward in contexts where there are many interacting factors. Holder critically analyses, interprets and evaluates</p>	<ul style="list-style-type: none"> • Level 7 Award • Level 7 Certificate • Level 7 Diploma • Level 7 NVQ 	<ul style="list-style-type: none"> • Master's degree • Integrated master's degree • Primary qualifications (first degrees) in medicine, dentistry and veterinary science • PGCE

	<p>complex information, concepts and theories to produce modified conceptions. Holder understands the wider contexts in which the area of study or work is located. Holder understands current developments in the area of study or work. Holder understands different theoretical and methodological perspectives and how they affect the area of study or work.</p> <p>AND/OR Holder can use specialised skills to conceptualise and address problematic situations that involve many interacting factors. Holder can determine and use appropriate methodologies and approaches. Holder can design and undertake research, development or strategic activities to inform or produce change in the area of work or study. Holder can critically evaluate actions, methods and results and their short- and long-term implications.</p>		<ul style="list-style-type: none"> • PGDip • PGCert
Level 6	<p>Holder has advanced practical, conceptual or technological knowledge and understanding of a subject or field of work to create ways forward in contexts where there are many interacting factors. Holder understands different perspectives, approaches or schools of thought and the theories that underpin them. Holder can critically analyse, interpret and evaluate complex information, concepts and ideas.</p> <p>AND/OR Holder can determine, refine, adapt and use appropriate methods and advanced cognitive and practical skills to address problems that have limited definition and involve many interacting factors. Holder can use and, where appropriate, design relevant research and development to inform actions. Holder can evaluate actions, methods and results and their implications.</p>	<ul style="list-style-type: none"> • Level 6 Award • Level 6 Certificate • Level 6 Diploma • Level 6 NVQ • Degree Apprenticeship 	<ul style="list-style-type: none"> • Bachelor's degree • Graduate Certificate • Graduate Diploma • Professional Graduate Certificate in Education
Level 5	<p>Holder has practical, theoretical or technological knowledge and understanding of a subject or field of work to find ways forward in broadly defined,</p>	<ul style="list-style-type: none"> • Higher National Diploma • Level 5 Award • Level 5 Certificate 	<ul style="list-style-type: none"> • Foundation degree • Diploma of Higher Education • Higher National Diploma (awarded by a degree-

	<p>complex contexts. Holder can analyse, interpret and evaluate relevant information, concepts and ideas. Holder is aware of the nature and scope of the area of study or work. Holder understands different perspectives, approaches or schools of thought and the reasoning behind them.</p> <p>AND/OR Holder can determine, adapt and use appropriate methods, cognitive and practical skills to address broadly defined, complex problems. Holder can use relevant research or development to inform actions. Holder can evaluate actions, methods and results.</p>	<ul style="list-style-type: none"> • Level 5 Diploma • Level 5 NVQ • Level 5 Higher Apprenticeship 	<p>awarding body)</p>
<p>Level 4</p>	<p>Holder has practical, theoretical or technical knowledge and understanding of a subject or field of work to address problems that are well defined but complex and non-routine. Holder can analyse, interpret and evaluate relevant information and ideas. Holder is aware of the nature of approximate scope of the area of study or work. Holder has an informed awareness of different perspectives or approaches within the area of study or work.</p> <p>AND/OR Holder can identify, adapt and use appropriate cognitive and practical skills to inform actions and address problems that are complex and non-routine while normally fairly well-defined. Holder can review the effectiveness and appropriateness of methods, actions and results.</p>	<ul style="list-style-type: none"> • Higher National Certificate • Level 4 Award • Level 4 Certificate • Level 4 Diploma • Level 4 NVQ • Level 4 Higher Apprenticeship 	<ul style="list-style-type: none"> • Certificate of Higher Education • Higher National Certificate (awarded by a degree-awarding body)
<p>Level 3</p>	<p>Holder has factual, procedural and theoretical knowledge and understanding of a subject or field of work to complete tasks and address problems that while well-defined, may be complex and non-routine. Holder can interpret and evaluate relevant information and ideas. Holder is aware of the nature of the area of study or work. Holder is aware of different perspectives or approaches within the area of study or work.</p> <p>AND/OR Holder can identify, select and use appropriate</p>	<ul style="list-style-type: none"> • A Level • Access to Higher Education Diploma • AS Level • Applied General • International Baccalaureate Diploma • T Level • Level 3 Award • Level 3 Certificate • Level 3 Diploma • Level 3 NVQ • Level 3 ESOL 	

	<p>cognitive and practical skills, methods and procedures to address problems that while well-defined, may be complex and non-routine. Holder can use appropriate investigation to inform actions. Holder can review how effective methods and actions have been.</p>	<ul style="list-style-type: none"> • Level 3 National Certificate • Level 3 National Diploma • Music grades 6, 7 and 8 • Advanced Apprenticeship • Welsh Bacc Advanced^[7] 	
Level 2	<p>Has knowledge and understanding of facts, procedures and ideas in an area of study or field of work to complete well-defined tasks and address straightforward problems. Holder can interpret relevant information and ideas. Holder is aware of a range of information that is relevant to the area of study or work.</p> <p>AND/OR Holder can select and use relevant cognitive and practical skills to complete well-defined, generally routine tasks and address straightforward problems. Holder can identify how effective actions have been. Holder can identify, gather and use relevant information to inform actions.</p>	<ul style="list-style-type: none"> • GCSE grades A*–C • Reformed GCSE grades 4–9^[8] • CSE grade 1 • Level 2 Award • Level 2 Certificate • Level 2 Diploma • Level 2 NVQ • Level 2 ESOL • Level 2 Essential Skills • Level 2 Functional Skills • Level 2 National Certificate • Level 2 National Diploma • Music grades 4 and 5 • Welsh Bacc National^[7] • Intermediate Apprenticeship 	
Level 1	<p>Holder has basic factual knowledge of a subject and/or knowledge of facts, procedures and ideas to complete well-defined routine tasks and address simple problems; and is aware of aspects of information relevant to the area of study or work. AND/OR Holder can use basic cognitive and practical skills to complete well-defined routine tasks and procedures. Holder can identify whether actions have been effective. Holder can select and use relevant information.</p>	<ul style="list-style-type: none"> • First Certificate • GCSE grades D–G • Reformed GCSE grades 1–3^[8] • Level 1 Award • Level 1 Certificate • Level 1 Diploma • Level 1 NVQ • Level 2 ESOL • Level 2 Essential Skills • Level 2 Functional Skills • Music grades 1, 2 and 3 • Welsh Bacc Foundation^[7] 	
Entry	<p>Entry Level 3 Holder has basic knowledge and understanding</p>	<ul style="list-style-type: none"> • Entry Level Award 	

<p><u>Level</u></p>	<p>to carry out structured tasks and activities in familiar contexts; and knows and understands the steps needed to complete structured tasks and activities in familiar contexts.</p> <p>AND/OR Holder can carry out structured tasks and activities in familiar contexts. Holder can be aware of the consequences of actions for self and others.</p>	<ul style="list-style-type: none"> • Entry Level Certificate • Entry Level Diploma • Entry Level ESOL • Entry Level Essential Skills • Entry Level Functional Skills • Skills for Life 	
<p>Entry Level 2 Holder has basic knowledge or understanding of a subject and/or can carry out simple, familiar tasks; and knows the steps needed to complete simple activities.</p> <p>AND/OR Holder can carry out simple, familiar tasks and activities. Follow instructions or use rehearsed steps to complete tasks and activities.</p>			