EVALUATING THE EFFECTIVENESS OF COMPENSATORY INTERVENTIONS IN ADULTS WITH ACQUIRED BRAIN INJURY: A SYSTEMATIC REVIEW AND META-ANALYSIS OF MEMORY AND EVERYDAY IMPACT OUTCOMES

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Abstract

Adults with acquired brain injury (ABI) often experience memory impairments that are persistent and difficult to treat. Although evidence has shown that rehabilitation programs may improve cognitive performance in persons with ABI, there is an opportunity to look more closely at the benefits provided by specific interventions. We conducted a systematic review and meta-analysis to evaluate whether compensation-based memory programs improve memory or everyday impact outcomes in adults with ABI. The review was limited to published, English-language controlled trials that evaluated compensatory memory interventions for adults (18+) with ABI using at least one memory or everyday impact outcome. The final search was conducted in April 2021 using PsychINFO, Medline, EMBASE, the Cochrane Review database, Google Scholar, and the reference lists of relevant articles. Of 2817 identified articles, 22 controlled trials met inclusion criteria, of which 12 provided sufficient data to include in the meta-analyses. A risk of bias assessment using the Effective Public Health Practice Project tool identified common problems with recruitment and masking procedures. Results from the meta-analyses indicate that compared to controls, these interventions produce positive effects on outcomes of immediate verbal recall (g = 0.43, 95% CI [0.134, 0.723]), participant-reported memory (g = 0.28, 95% CI [0.131, 0.468]), and strategy use (g = 0.39, 95% CI [0.057, 0.727]), and that these improvements are maintained at follow-up. Future research focusing on specific subsets of ABI populations and a broader range of participant-reported outcomes is needed. This review was pre-registered in the PROSPERO database for systematic reviews (Registration number: CRD42020197592).

Dedication

I would like to dedicate this thesis to my lovely mother and late father, who have always provided me with the support and strength I needed to persevere.

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Introduction

Acquired Brain Injury

Acquired brain injury (ABI) is one of the leading causes of disability worldwide and can have a profound and lasting impact on everyday life (Chan et al., 2013; Tate, 1997). Acquired brain injury has been defined as damage to the brain that occurs after birth and is not related to a congenital or neurodegenerative disorder. Causes of ABI can be either traumatic (e.g., car accident) or nontraumatic (e.g., stroke, infection) and can range in severity from mild or moderate to severe (Chan et al., 2013; Mahan et al., 2017). Impairments that occur postinjury can vary depending on a number of injury- and patient-specific variables (Rabinowitz & Levin, 2014), and thus individual neuropsychological presentations can be diverse. Impairments often occur across multiple domains, and can include deficits related to attention, memory, visuospatial function, executive function, or language (Cicerone et al., 2000; Fernández López & Antolí, 2020; Sohlberg & Mateer, 2001).

Despite the heterogeneity among presentations, persons with ABI often experience some common neuropsychological sequelae, with memory, attention, and executive functioning impairments among the most frequently reported (Evans et al., 2003; Tate, 1997; Whyte et al., 2011). Although memory is just one of many domains affected, it is often one of the first impairments to be reported post injury and one of the last functions to be restored in the recovery process (Barman et al., 2016). Within the domain of memory, individuals with ABI often report difficulties with prospective memory (e.g., remembering to take medications) and episodic memory (e.g., learning and retaining new information; Mahan et al., 2017; Russel et al., 2010). These memory impairments are long-lasting and difficult to treat, and have been associated with decreased independence, social engagement, and overall quality of life (das Nair et al., 2015;

Olsson et al., 2006; Sherer & Sander, 2014; Spreij et al., 2014; Vakil et al., 2019). Considering the debilitating nature of memory impairments and their high frequency following ABI, there is an urgent need to identify effective memory rehabilitation programs for this population.

Cognitive Rehabilitation

Cognitive rehabilitation interventions have been developed to improve memory functioning in persons with ABI. Although the memory rehabilitation literature for this population is diverse, it can generally be categorized into two broad approaches: restorative and compensatory. Current restoration-based memory interventions often involve computer-assisted training that focuses on practice and repetition of specific memory skills (e.g., list learning) with the goal of restoring or recovering lost memory function (Sherer & Sander, 2014; Spriej et al., 2014). These interventions are generally founded on the belief that training the basic cognitive processes that support memory, such as attention or executive functions such as working memory, will lead to improvements in everyday memory performance (Gehring et al., 2011; Hering et al., 2014). Although some studies have demonstrated that restorative interventions may improve scores on laboratory-based measures of cognitive performance, such as verbal fluency (e.g., De Luca et al., 2014) and working memory (e.g., Akerlund et al., 2013; Westerberg et al., 2007), evidence suggests that they do not produce lasting memory improvement and do not transfer to untrained tasks (Evans et al., 2003; Velikonja, et al., 2014).

In contrast to restoration-based interventions, compensatory approaches involve teaching internal or external memory strategies (e.g., mnemonics, memory notebooks) that support memory function and help individuals compensate for their existing memory impairments (Sherer & Sander, 2014; Velikonja, et al., 2014). Evidence has shown that compensatory strategies can improve memory and everyday functioning post-ABI (Sherer & Sander, 2014; for

reviews, see O'Neil-Pirozzi et al., 2016; Sohlberg et al., 2007). However, currently no review has provided a quantitative summary of the effectiveness of compensatory interventions.

As evidence accumulates, there is an opportunity to synthesize and quantify the effectiveness of compensatory interventions with respect to memory and everyday impact. Wilson (2010) noted that the goal of rehabilitation should be to reduce the everyday impact of cognitive impairment and enhance overall well-being rather than focus on improving scores on cognitive tests. In line with this, there has been an increasing focus in several areas of intervention research on the utilization of participant-reported outcomes, such as self-reported memory or other measures of everyday impact (e.g., measures of overall well-being, such as mood, quality of life, or community participation), to assess intervention benefit (Chandler et al., 2016; Chouliara & Lincoln, 2016; Hudes et al., 2019; Price-Haywood et al., 2018; Salinas et al., 2016; Valentijn et al., 2005). Furthermore, it has been suggested that these types of measures may complement assessments of objective memory performance by providing a more complete picture of everyday functioning (Chouliara & Lincoln, 2016; Sherer & Sander, 2014). Thus, it is important to consider a broad range of outcomes when evaluating the impact of interventions.

To date, there have been several well-conducted systematic reviews on the effectiveness of cognitive rehabilitation post-brain injury. Many of these reviews have provided qualitative summaries of the impact of interventions on broad categories of cognitive function, such as attention, language, or memory (e.g., Cicerone et al., 2000, 2011, 2019; O'Neil-Pirozzi, et al., 2016; Sohlberg et al., 2007). Two meta-analyses have quantitatively examined the effectiveness of cognitive rehabilitation on memory function (Elliot et al., 2014; Rohling et al., 2009) and other cognitive domains (Rohling et al., 2009), with both studies utilizing broad inclusion criteria and reporting inconsistent findings. As the cognitive rehabilitation literature grows, there is an

opportunity to look more closely at specific approaches to memory rehabilitation, such as compensation-based training, to determine the benefit of such programs.

The Current Review

Considering the evidence that suggests compensation-based techniques may be more effective than restorative approaches at improving everyday functioning, the current study entails a systematic review and meta-analysis of compensatory memory rehabilitation interventions for adults with ABI. Furthermore, as current research has emphasized the importance of utilizing a broad range of outcomes to assess real-world impact, this review will provide a quantitative summary of specific outcomes, including participant-reported and objective memory in addition to other measures of everyday impact.

Methods

Study Selection

The current study was pre-registered in the PROSPERO database for systematic reviews prior to beginning the study selection process (Registration number: CRD42020197592). Details of the protocol can be accessed at www.crd.york.ac.uk/PROSPERO.

We limited this review to published, English-language controlled trials that evaluated compensation-based memory interventions for adults (18+) with ABI. Interventions had to include the use of external and/or internal memory strategies and report at least one measure of memory functioning or everyday impact (e.g., mood, quality of life, community integration). Multimodal interventions were included if they did not involve pharmacological treatment or focus predominantly on targeting basic cognitive processes (e.g., processing speed or working memory training). Interventions were required to have either a no-treatment or active control group, and studies comparing two different interventions (e.g., an electronic memory aid vs. a

memory diary) were excluded unless an eligible control group was also used. For studies that included more than one eligible compensatory intervention, the data from each group were combined to form a single group for analysis. In these cases (n = 1), the means and standard deviations for the groups were combined using the formula provided in the Cochrane Handbook for Systematic Reviews and Interventions (Higgins, Li & Deeks, 2021). When multiple published studies used the same sample, only the original study was included in the review.

For the study selection process, two reviewers independently assessed the eligibility of each study, and any discrepancies were discussed to reach consensus. Interrater reliability for the selection process was calculated using Cohen's kappa and percentage agreement.

Search Strategy

A systematic literature search was be performed using PsychINFO, Medline, EMBASE, and the Cochrane Review database. The following key search terms were used across the databases: "compensatory memory training" or "compensation-based memory training" "memory compensation" or "memory training" or "memory aid*" or "memory strateg*" or "memory intervention*" or "memory program*" or "memory skill*" or "memory treatment*" or "mnemonic training" or "mnemonic strateg*" or "memory rehabilitat*" or "cognitive training" or "cognitive rehabilitat*" or "cognitive intervention" or "memory retraining" or "brain train*" or "compensatory strateg*" or "memory remediation" AND "acquired brain injur*" or "abi" or "brain injur*" or "head injur*" or "traumatic brain injur*" or "tbi" or "stroke" or "head trauma" or "cva" or "cerebrovascular accident*" or "post-stroke" or "post stroke" or "poststroke" AND "adult*" or "older adult*" or "middle aged" or "young adult*" (See Appendix A for sample of search strategy). Limits were applied when available to restrict the searches to relevant inclusion criteria (e.g., adult samples, published in English).

The initial search was also supplemented with a search of Google Scholar, as well as a manual search from references lists of included papers and previous systematic reviews. The original search included all articles published up to September 2020. The search was rerun in April 2021 following the initial analysis to identify any newly published articles and no new studies met criteria for inclusion.

Risk of Bias Assessment

The methodological quality of the included studies was assessed using the Effective Public Health Practice Project (EPHPP) tool. This tool was developed and validated for assessing the quality of quantitative studies and has demonstrated both content and construct validity (Thomas et al., 2004). In addition, the EPHPP tool has shown acceptable inter-rater reliability and test-retest reliability (Thomas et al., 2004). The tool assesses study quality in the following areas: selection bias, study design, confounders, masking, data collection methods, withdrawals and drop-outs, intervention integrity, and analysis. All studies were assigned a rating (i.e., strong, moderate, or weak) for each area as well as a global rating of overall quality based on criteria outlined in the EPHPP scoring dictionary. Ratings for each study were assigned independently by two investigators, and any discrepancies were discussed to reach consensus.

Data Extraction and Analysis

Data from the selected studies were collected independently by two investigators using a standardized extraction form. Relevant data were extracted from each study, including participant (e.g., age, sex, severity of brain injury) and intervention characteristics (e.g., description of intervention, type of memory strategy taught, duration), sample size, and information relevant to study quality (e.g., masking, data collection methods, recruitment).

Where reported, relevant summary statistics (e.g., means, standard deviations, statistical test results) for all memory and everyday impact outcomes were extracted, and study authors were contacted for any missing data.

To prepare the data for analysis, all outcome measures were categorized into conceptually distinct groupings by two independent investigators using a document that included a description of each measure and the scales reported. No information regarding the identification or findings of the included studies was provided.

A meta-analysis was conducted using Comprehensive Meta-Analysis software (Borenstein et al., 2003), and studies that reported sufficient data were included. Random effects models were used to generate effect size estimates for each outcome of interest, as they are better suited to situations where heterogeneity may exist between studies (DerSimonian & Kacker, 2007; DerSimonian & Laird, 1986). Hedges g was used as the summary effect size for each outcome because it is a slightly more conservative measure of effect size that corrects for positive bias (Lakens, 2013). There was an insufficient number of studies to perform the planned subgroup analyses (i.e., mild vs. moderate to severe injury, active vs. wait-list control, type of compensatory training, or study design). Two sensitivity analyses were conducted to determine whether the decision to include studies with a high risk of bias or those consisting of mixed etiology brain injury populations influenced the results. The results of the sensitivity analyses are described below.

There were several cases where studies reported data for multiple measures of closely related outcomes (n = 15). To avoid the statistical issue of assigning more weight to those studies, a single measure was selected or generated for each outcome. In five of the cases where multiple outcomes were reported, a single measure was chosen for inclusion in the meta-

analysis. This was decided based on theoretical grounds, which were applied to each case in the following order: (a) selecting the measure that was most closely related to the target construct, (b) selecting the measure that was most similar to the measures reported by other studies in the analysis, or (c) selecting the most comprehensive measure (e.g., choosing the measure that reported the total score rather than a single trial). In the remaining 10 cases where there were no clear theoretical grounds to guide selection and the measures captured closely related constructs, the outcomes were averaged together to calculate a single effect size for analysis.

Results

Included Studies

The search identified 2817 studies, with 1685 studies remaining after duplicates were removed. Figure 1 summarizes the study selection process using the PRISMA flow diagram (Moher, Liberati, Tetzlaff, Altman, & the PRISMA Group, 2009). Two reviewers screened the studies based on title and abstract and identified 89 articles eligible for further examination. The full texts of those studies were subsequently assessed based on study inclusion criteria, resulting in a total of 22 studies included in the final review (See Table 1 for characteristics of these studies). Inter-rater reliability of the screening process was substantial for both the title and abstract ($k = 0.61$) and full-text screening stages ($k = 0.65$). Percentage agreement for each stage was 95% and 88%, respectively. The most common reason for exclusion was research design, with 22 out of the 89 full text articles screened being excluded because they did not include a control group. Out of the final 22 studies included in the review, 12 were included in the meta-analysis across various outcomes, and 10 studies were not included in the meta-analysis due to insufficient data.

Figure 1

PRISMA Flow Diagram of the Study Selection Process

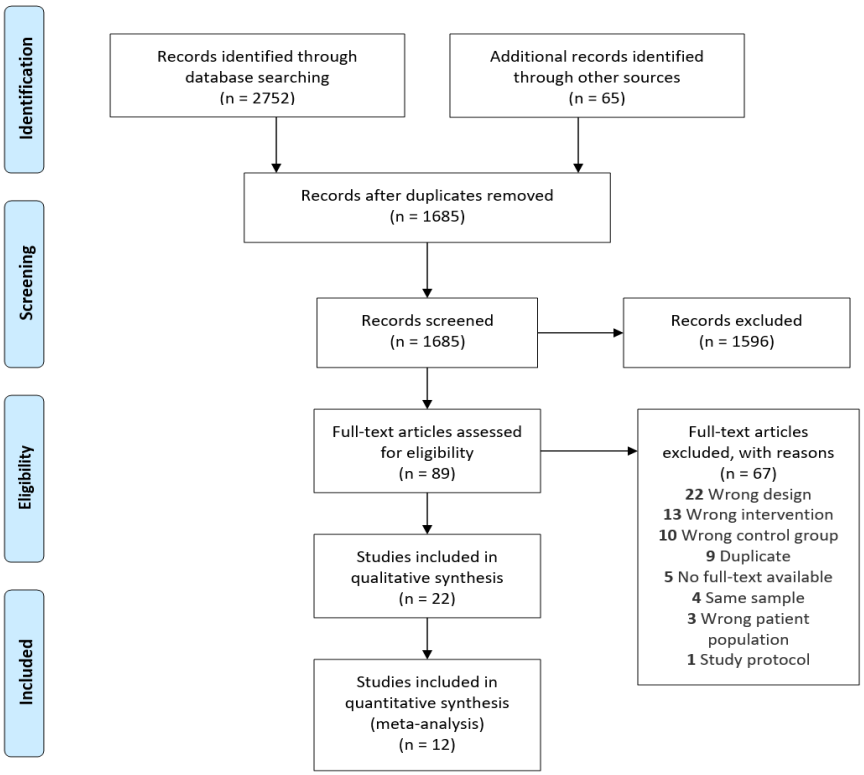


Table 1

Intervention Characteristics and Results of Included Studies

Study	Intervention	Sample	Age (*M*)	N	Outcomes of interest	Results
Aben et al. (2013)	Combination of memory strategies, goal setting, and psychoeducation on influence of beliefs, anxiety, and memory-related worries.	Stroke	58	153	RBMT – delayed recall RAVLT – delayed recall Metamemory in Adulthood Questionnaire – Self-Efficacy Center for Epidemiologic Studies Depression Scale European Quality of Life – Utility Score European Quality of Life – VAS Score European Quality of Life – Psychological European Quality of Life – Social	*ns* *ns* sig *ns* *ns* *ns* *ns* *ns*
Berg, Koning-Haanstra, & Deelman (1991)	Instruction in memory strategies aimed at improving memory function and their application in everyday life.	Closed-head injury	36	28	15 Words Test Face-Name Learning Test Shopping Lists Test	sig sig sig

Table 1 *(continued)*

Study	Intervention	Sample	Age (*M*)	N	Outcomes of interest	Results
Bergquist et al. (2009)	Focused on developing calendar skills and strategies to address difficulties with memory.	TBI	48	18	NFI – Memory Compensation Techniques Questionnaire NFI – Depression Community Integration Questionnaire	*ns* *ns* *ns* *ns*
Chiaravalotti et al. (2016)	Focused on teaching imagery and context to facilitate learning and taught how to generalize strategies to real-world memory tasks.	TBI	39	69	Memory Assessment Scales, Prose Memory CVLT – learning slope RBMT – Object Chicago Multidimensional Depression Inventory State-Trait Anxiety Inventory	sig *ns* sig *ns* *ns*
das Nair et al. (2019)	Intervention consisted of teaching compensation strategies, attention training, and external memory aids.	TBI	45	328	RBMT EMQ-Patient EMQ-Relative General Health Questionnaire	*ns* *ns* *ns* *ns*
Doornhein & De Haan (1998)	Taught mnemonic strategies and external aids with instruction on how to apply them to individual situations.	Stroke	52	12	Name-Face Paired Associated Memory Test Oxford Recurring faces Test 15 Words Test The Memory Questionnaire	sig *ns* *ns* *ns*
Fish et al. (2008)	Provided training in the use of Neuropage, a paging service that sends pre-set reminder messages.	Stroke	47	36	Goal Attainment – Memory	sig
Freeman et al. (1992)	Taught memory techniques such as note-taking in a memory notebook and the use of imagery.	Closed-head injury	43	12	Paragraph Retention Task	sig
Hildebrandt et al. (2006)	Consisted of teaching internal and external strategies to increase memory performance, included instruction on how to adapt them to different situations.	Mixed (TBI, stroke, SAB, and "other")	59	38	CVLT – short-term free recall CVLT – short-term cued recall CVLT – trial 1-5, List B RBMT – First name RBMT – Last name RBMT – Object RBMT - Appointment Map Learning Test Text Reproduction	*ns* *ns* sig* *ns* *ns* *ns* *ns* *ns* sig
Jennett & Lincoln (1991)	Intervention of internal and external memory strategies.	Mixed (stroke and closed-head injury)	52	25	RBMT Subjective Memory Questionnaire Memory Aids Questionnaire	*ns* *ns* sig

Table 1 *(continued)*

Study	Intervention	Sample	Age (*M*)	N	Outcomes of interest	Results
Lesniak (2018)	Combination of memory strategies, psychoeducation, and coping strategies.	Mixed (TBI, stroke, and encephalitis)	42	63	Pattern Recognition Memory Test – delayed nonverbal recognition	*ns*
					Pattern Recognition Memory Test – immediate nonverbal recall	*ns*
					RBMT	*ns*
Milders, Deelman, & Berg (1998)	Focused on teaching internal memory strategies for learning and retrieving names.	Closed-head injury	36	26	Name Learning Test	*ns*
					Name-Occupation-Town	sig
					RAVLT	*ns*
					Famous Faces Test	sig
Miller & Radford (2014)	Consisted of memory strategy training, psychoeducation, and stress management	Stroke	51	40	RAVLT – total learning	*ns*
					RAVLT – delayed recall	*ns*
					RPA-ProMem	*ns*
					CAPM-Self	*ns*
					CAPM-Other	*ns*
O'Neil-Pirozzi et al. (2010)	Combination of memory strategies and psychoeducation.	TBI	47	94	HVLT-R – delayed recall	sig
					RBMT	sig
Potvin et al. (2011)	Consisted of training in visual imagery and psychoeducation on prospective memory function.	TBI	33	30	Sullivan Logical Memory – delayed verbal recall	*ns*
					Sullivan Logical Memory – immediate verbal recall	*ns*
					RAVLT – delayed verbal recall	*ns*
					RAVLT – immediate verbal recall	*ns*
					BVMT – immediate nonverbal recall	*ns*
					BVMT – delayed nonverbal recall	*ns*
					CAPM-Self	sig
					CAPM-Other	sig
					TEMP	sig
					Beck Anxiety Inventory	*ns*
					Beck Depression Inventory	sig
Raskin et al. (2019)	Consisted of PM training using visual imagery strategies.	TBI	42	20	Memory for Intentions Test	*sig*
Ryan & Ruff (1988)	Taught participants to use memory strategies, external memory aids, and provided psychoeducation.	Closed-head injury	33	20	BVRT – immediate nonverbal recall	*ns*
					Rey-Osterrieth Complex Figure Test – delayed nonverbal recall	*ns*
					Taylor Complex Figure Test – delayed nonverbal recall	*ns*
					Selective Reminding Test – verbal recall	*ns*
					Ruff-Light Trail Learning Test – delayed nonverbal recall	*ns*
					WMS-LM – delayed verbal recall	*ns*
					WMS-LM – immediate verbal recall	*ns*
Schmitter-Edgecombe et al. (1995)	Instruction on memory strategies for names, the use of a memory notebook, and psychoeducation.	Closed-head injury	28	8	WMS – recall score	*ns*
					RBMT	*ns*
					EMQ – Retrospective Memory	*ns*
					EMQ – Observed Memory	sig
					Symptom Checklist-90	*ns*

Table 1 *(continued)*

Study	Intervention	Patient sample	Age (*M)*	N	Outcomes of interest	Results
Shum et al. (2011)	Training in external memory strategies to compensate for prospective memory deficits and self-awareness training to improve insight into PM problems.	TBI	28	22	CAPM Cambridge Prospective Memory Test Sydney Psychosocial Reintegration Scale	*ns* sig *ns*
Storzbach et al. (2017)	Consisted of teaching a variety of internal and external cognitive strategies.	TBI	35	119	HVLT-R – Retention T Score HVLT-R – Total Recall T Score Prospective-Retrospective Memory Questionnaire Memory Compensation Questionnaire Portland Cognitive Strategies Scale Beck Depression Inventory Satisfaction with Life Questionnaire	*ns* sig sig *ns* sig *ns* *ns*
Thickpenny-Davis & Barker-Collo (2007)	Sessions involved instruction in internal and external memory strategies and psychoeducation.	Mixed (TBI and stroke)	33	14	Visual Paired Associates – Delayed Visual Paired Associates – Immediate WMS-LM – delayed verbal recall WMS-LM – immediate verbal recall CVLT – short delay free recall CVLT – short delay cued recall CVLT – long delay cued recall CVLT – long delay free recall Memory Knowledge Quiz Memory Aids – Self Memory Aids – Other Memory in Everyday Life – Self Memory in Everyday Life – Other	*ns* *ns* sig *ns* *ns* *ns* *ns* sig sig *ns* sig *ns* *ns*
Withiel et al. (2019)	A combination of internal and external memory strategies, psychoeducation, nutritional information, and stress management.	Stroke	60	43	RAVLT – delayed verbal recall RAVLT – immediate verbal recall BVMT – immediate nonverbal recall BVMT – delayed nonverbal recall RPAProMem EMQ CAPM – Self CAPM – Other Strategy Use – Internal Strategy Use – External Goal Attainment – Memory	*ns* *ns* *ns* *ns* sig sig *ns* *ns* sig *ns* sig

Note. Significant (sig) results indicate that the authors reported a positive intervention effect for the memory training group. * = significant only for Trial 4. RBMT = Rivermead Behavioural Memory Test; *ns* = not significant; *sig* = significant; RAVLT = Rey Auditory Verbal Learning Test; TBI = traumatic brain injury; WhoQoL = World Health Organization Quality of Life; NFI = Neurobehavioural Functioning Inventory; CVLT = California Verbal Learning Test; EMQ = Everyday Memory Questionnaire; SAB = subarachnoid bleeding; RPA-ProMem = Royal Prince Alfred Prospective Memory Test; CAPM = Comprehensive Assessment of Prospective Memory; HVLT-R = Hopkins Verbal Learning Test-Revised; BVMT = Brief Visuospatial Memory Test; TEMP = Test Ecologique de Memoire Prospective; BVRT = Benton Visual Retention Test; WMS-LM = Wechsler Memory Scale - Logical Memory

Study Characteristics

Participant characteristics. There were 1,218 participants across the 22 controlled trials included in this review. Altogether, there were 620 participants allocated to the compensatory memory rehabilitation group, with the number of participants assigned to the intervention varying across studies (median = 17; minimum = 4, Schmitter-Edgecombe & Fahy, 1995; maximum = 171, das Nair et al., 2019). All participants were adults with ABI, ranging in age from 19 (Berg, Koning-Haanstra, & Deelman, 1991) to 86 (Jennett & Lincoln, 1991). The majority of participants were male, ranging from 50% (Bergquist et al., 2009) to 95% (Storzbach et al., 2017) of the sample.

The type and severity of brain injury also varied across trials. Thirteen out of the 22 trials looked at participants with traumatic brain injury (TBI; Berg et al., 1991; Bergquist et al., 2009; Chiaravalloti et al., 2016; das Nair et al., 2016; Freeman et al., 1992; Milders, Deelman & Berg, 1998; O'Neil-Pirozzi et al., 2010; Potvin et al., 2011; Raskin et al., 2019; Ryan & Ruff, 1998; Schmitter-Edgecombe et al., 1995; Shum et al., 2011; Storzbach et al., 2017), five included participants with a history of stroke (Aben et al., 2013; Doornhein & De Haan, 1998; Fish et al., 2008; Miller & Radford, 2014; Withiel et al., 2019), and the remaining four studies utilized a mixed population with ABI. Furthermore, 10 out of 22 studies recruited participants with moderate-severe injury (Berg et al., 1991; Bergquist et al., 2009; Chiaravalloti et al., 2016; Milders, Deelman & Berg, 1998; Potvin et al., 2011; Raskin et al., 2019; Ryan & Ruff, 1998; Schmitter-Edgecombe et al., 1995; Shum et al., 2011; Thickpenny-Davis & Barker-Collo, 2007), one recruited only participants with mild severity (Storzbach et al., 2017), four included participants with brain injury of all severities (das Nair et al., 2019; Hildebrandt et al., 2006;

Jennett & Lincoln, 1991; O'Neil-Pirozzi et al., 2010), and the remaining seven studies did not specify the severity of injury.

Time post-injury of individual participants ranged considerably across studies, from 2.5 months (Jennett & Lincoln., 1991) to 564 months (Miller & Radford, 2014). Recruitment methods differed between studies, with most using multiple recruitment strategies. Most studies recruited participants from rehabilitation clinics, local brain injury support groups, clinician referrals, public advertisements, and various brain injury associations.

Intervention characteristics. Consistent with the inclusion criteria for this review, all 22 studies included interventions that involved teaching internal and external memory strategies. These included strategies such as visualization (Berg et al., 2009; Chiaravaollti et al., 2016; Freeman et al., 1992; Jennett & Lincoln, 1991; Lesniak et al., 2018; O'Neil-Pirozzi et al., 2010; Potvin et al., 2011; Raskin et al., 2019; Ryan & Ruff, 1988; Storzbach et al., 2017), association (Berg et al., 2009; Doornhein & De Haan, 1998; Hildebrandt et al., 2006; O'Neil-Pirozzi et al., 2010; Milders et al., 1998; Withiel et al., 2019), rehearsal/repetition (Berg et al., 2009; Ryan & Ruff, 1988; Withiel et al., 2019), electronic aids (Fish et al., 2008), and memory calendars/notebooks (Bergquist et al., 2009; Freeman et al., 1992; Thickpenny-Davis & Barker-Collo, 2007; Schmitter-Edgecombe et al., 1995; Storzbach et al., 2017).

Twelve of the 22 studies were multimodal interventions that included supportive elements in addition to memory strategy training, such as goal setting (Aben et al., 2013; Schmitter-Edgecombe et al., 1995; Storzbach et al., 2017), psychoeducation (Aben et al., 2013; Lesniak et al., 2018; Miller & Radford, 2014; O'Neil-Pirozzi et al., 2010; Potvin et al., 2011; Ryan & Ruff, 1988; Schmitter-Edgecombe et al., 1995; Shum et al., 2011; Thickpenny-Davis & Barker-Collo, 2007; Withiel et al., 2019), nutritional information (Miller & Radford, 2014;

Withiel et al., 2019), and stress management techniques (Miller & Radford, 2014; Storzbach et al., 2017; Withiel et al., 2019). The remaining 10 studies provided memory skills training without any additional elements.

The delivery format and duration of the memory training programs varied across studies. Thirteen of the 22 studies delivered the training in a group format (Aben et al., 2013; das Nair et al., 2019; Freeman et al., 1992; Hildebrandt et al., 2006; Jennett & Lincoln, 1991; Lesniak et al., 2018; Miller & Radford, 2014; O'Neil-Pirozzi et al., 2010; Ryan & Ruff, 1998; Schmitter-Edgecombe et al., 1995; Storzbach et al., 2017; Thickpenny-Davis & Barker-Collo, 2007; Withiel et al., 2019), eight studies provided one-on-one training (Berg et al., 1991; Bergquist et al., 2009; Chiaravalloti et al., 2016; Doornhein & De Haan, 1998; Fish et al., 2008; Milders et al., 1998; Potvin et al., 2011; Shum et al., 2011), and one study did not specify the intervention format.

The number of hours spent in the training programs ($M = 21$) ranged from 8 hours (Thickpenny-Davis & Barker-Collo, 2007) to 132 hours (Ryan & Ruff, 1998). All but one study (Bergquist et al., 2009) used an in-person format for the training. All studies reported results from an immediate postintervention assessment, and 12 studies reported some data from at least one delayed follow-up assessment. Time to first follow-up ranged from one month (O'Neil-Pirozzi et al., 2010; Thickpenny-Davis & Barker-Collo, 2007) to one year (das Nair et al., 2019; Raskin et al., 2019).

Control characteristics. Consistent with the inclusion criteria, all 22 studies included in the review utilized some form of comparison group. Ten studies used a waitlist or similar form of no-contact control condition, 10 studies used an active control, and two studies described their control as "usual care". In the 10 studies that deployed an active control condition, the groups

consisted of minimal social support (Aben et al., 2013; Bergquist et al., 1991; Ryan & Ruff, 1988; Schmitter-Edgecombe et al., 1995), a brief educational session (Potvin et al., 2011), or some form of pseudo training (e.g., drill and practice exercises or reading stories and answering content questions), that was not expected to influence performance (Chiaravalloti et al., 2016; Doornhein & De Haan, 1998; Hildebrandt et al., 2006; Raskin et al., 2019; Shum et al., 2011). Participants in the two studies with a usual care control group were not receiving any formal rehabilitation services, however, they continued to receive their usual clinical care, which included services such as regular medical or psychotherapeutic visits (Storzbach et al., 2017), employment services, self-help groups, or support from specialist charities (das Nair et al., 2019).

Risk of Bias Assessment.

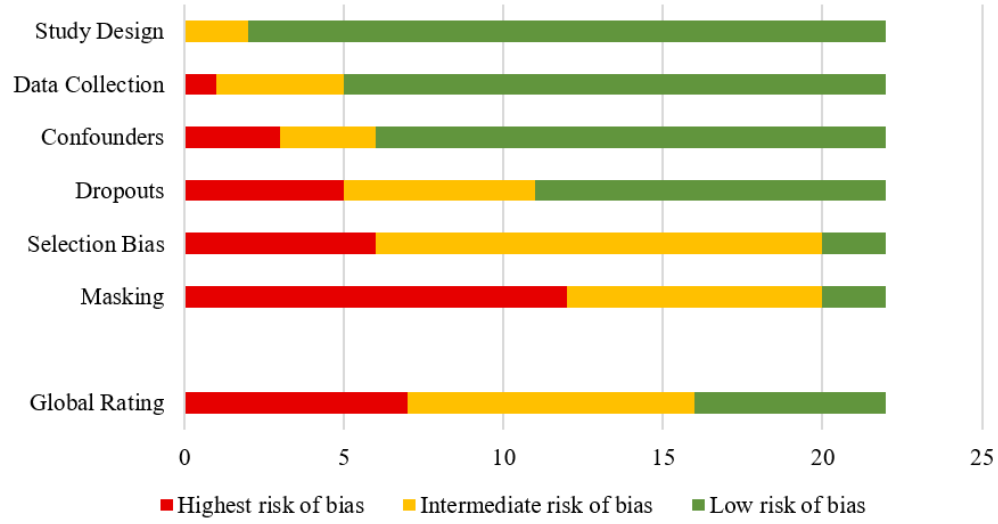
Results of the risk of bias assessment are summarized in Figure 2. Overall, most studies received a global methodological quality rating of moderate or strong, with 27% (n = 6) receiving a strong score (indicating a low risk of bias), 41% receiving a moderate score (n = 9), and 32% receiving a weak score (n = 7).

The areas that most commonly contributed to an increased risk of bias were problems with masking procedures, selection bias, and withdrawals and drop-outs. Only 2 out of the 22 studies reported using a double-masked design, and eight studies were single-masked designs in which only one of the following occurred: (a) outcome assessors were unaware of group assignment, or (b) the nature of the research question was concealed from the participants. The remaining 12 studies did not report using any masking procedures. Problems with selection bias were observed in 20 out of 22 studies, which resulted from having lower than a 79% participation rate and/or relying on a convenience sample of self- and/or clinic-referred

participants, rather than intentional random sampling from a defined target population. Withdrawals and drop-outs were rated moderate to high in 50% of the studies (n = 11), with studies either reporting an attrition rate of greater than 20%, or not reporting any data on withdrawals and drop-outs (see Appendix B for the EPHPP scoring dictionary).

Figure 2

Risk of Bias Assessment Summary for Each Study Component Using the EPHPP Tool



Summary of Findings and Meta-Analytic Results

Objective memory outcomes. Overall, 20 out of 22 studies used an objective measure of memory to evaluate intervention effectiveness. Objective memory outcomes were grouped into the following categories: immediate verbal recall, delayed verbal recall, immediate nonverbal recall, delayed nonverbal recall, delayed verbal recognition, immediate nonverbal recognition, delayed nonverbal recognition, associative memory, prospective memory, and general memory (see Table 2 for a list of all measures in each outcome category). Due to an insufficient number of studies for several of the groupings, a meta-analysis was not conducted for delayed verbal recognition, immediate nonverbal recognition, and delayed nonverbal recognition.

Table 2

Memory and Everyday Impact Outcomes by Category

Construct	Measure
Immediate verbal recall	RAVLT immediate recall score, CVLT – Learning slope T1-5, CVLT – total immediate recall score, Weschler Memory Scale Logical Memory Subtest – immediate recall score, HVLT – Total recall T score, Text Reproduction Test, Paragraph Retention Task, 15 Words Test
Delayed verbal recall	RBMT – delayed recall score, RBMT – First name, RBMT – Last name, RAVLT – delayed recall score, SLM – delayed recall score, Weschler Memory Scale Logical Memory Subtest – delayed recall score, HVLT – delayed recall score, HVLT – Retention T score, CVLT – short delay free recall, CVLT – short delay cued recall, CVLT – long delay free recall, CVLT – long delay cued recall, Memory Assessment Scales, Prose Memory – delayed recall score
Immediate nonverbal recall	BVRT – immediate recall score, BVMT – immediate free recall score, Pattern Recognition Memory Test – immediate recall score, Map Learning Test
Delayed nonverbal recall	Rey-Osterrieth Complex Figure Test, Taylor Complex Figure Test, Ruff-Light Trail Learning Test, BVMT – delayed free recall
Delayed verbal recognition	CVLT – delayed recognition score
Immediate nonverbal recognition	Oxford Recurring Faces Test
Delayed nonverbal recognition	Pattern Recognition Memory Test – delayed recognition
Associative memory	Visual Paired Associates, Name-Face Paired Associated Memory Test, Name Learning Test, Name-Occupation-Town Test
Prospective memory	Cambridge Prospective Memory Test, Royal Prince Alfred Prospective Memory Test, Test Ecologique de Memoire Prospective, RBMT – Object, RBMT – Appointment
General memory	RBMT – total score
Participant-reported memory	Metamemory in Adulthood – Self Efficacy, Everyday Memory Questionnaire – Self, The Memory Questionnaire, Subjective Memory Questionnaire, Prospective-Retrospective Memory Questionnaire, NFI – Memory, CAPM – Self, Memory in Everyday Life and Use of Aids and Strategies Questionnaire – Everyday Memory Self
Informant-reported memory	Everyday Memory Questionnaire – Relative, Memory in Everyday Life and Use of Aids and Strategies Questionnaire – Everyday Memory Other, CAPM – Relative
Memory strategy-use	Memory in Everyday Life and Use of Aids and Strategies Questionnaire – Memory Aids, Strategies in Everyday Life Questionnaire, Memory Compensation Questionnaire, Portland Cognitive Strategies Scale, Memory Aids Questionnaire
Mental health	Chicago Multi-Dimensional Depression Inventory, State-Trait Anxiety Inventory, Beck Anxiety Inventory, Beck Depression Inventory, Symptom Checklist-90, Center for Epidemiologic Studies Depression Scale, NFI – Depression, General Health Questionnaire
Quality of life	Satisfaction with Life Questionnaire, EuroQoL WhoQoL
Community integration	Community Integration Questionnaire, Sydney Psychosocial Reintegration Scale

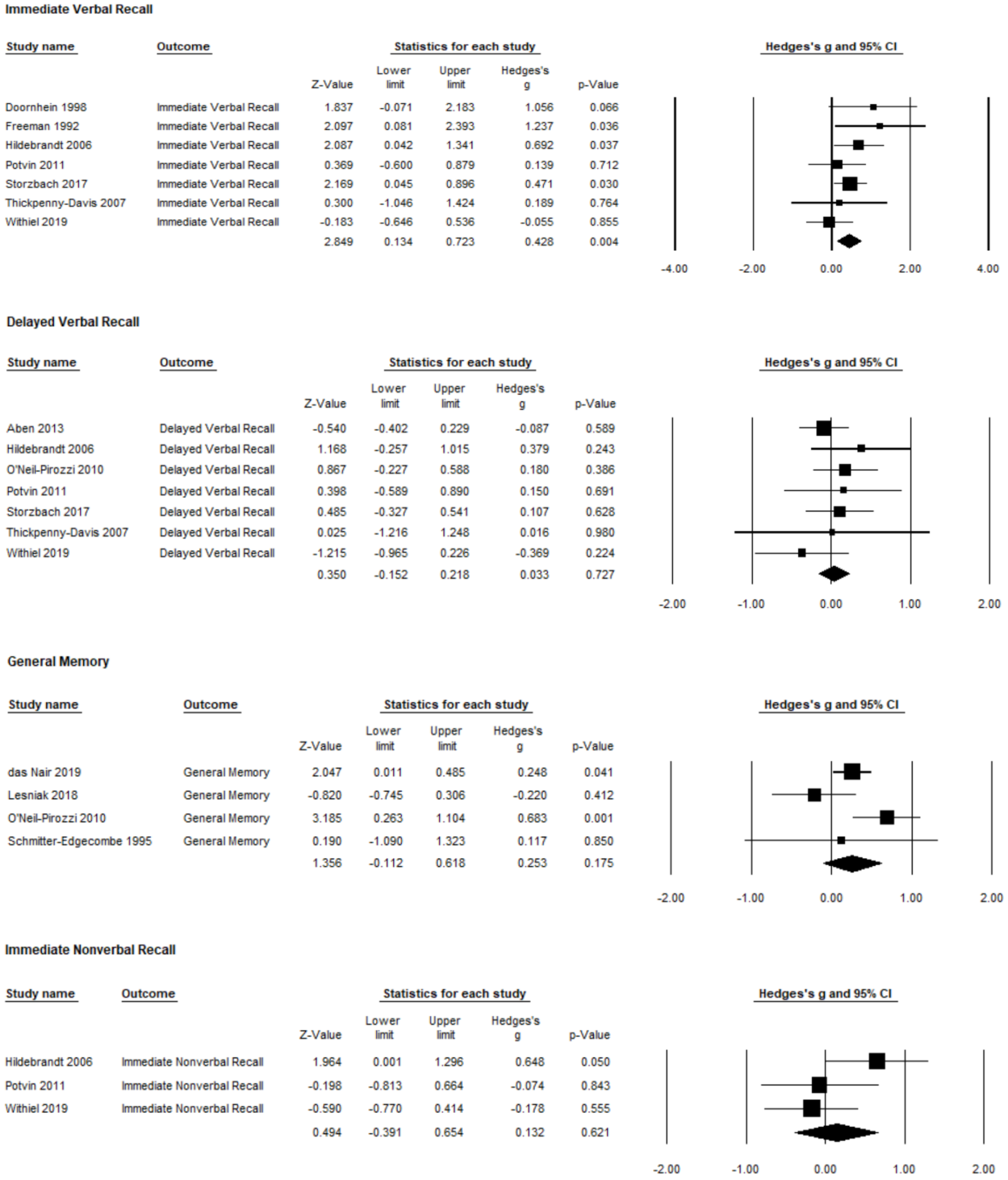
Note. RBMT = Rivermead Behavioural Memory Test; RAVLT = Rey Auditory Verbal Learning Test; SLM = Sullivan Logical Memory; HVLT = Hopkins Verbal Learning Test; CVLT = California Verbal Learning Test; BVRT = Benton Visual Retention Test; BVMT = Brief Visuospatial Memory Test; NFI = Neurobehavioural Functioning Inventory; CAPM = Comprehensive Assessment of Prospective Memory; EuroQoL = European Quality of Life; WhoQoL = World Health Organization Quality of Life.

As seen in Figure 3, 10 studies included a measure of immediate verbal recall; however, three were excluded from the meta-analysis due to missing data (Chiaravalotti et al., 2016; Miller & Radford, 2014; Ryan & Ruff, 1988). Results from the remaining seven studies with a combined sample size of 232 showed that compared to controls, compensatory memory training resulted in a small but significant improvement in participants' performance on measures of immediate verbal recall (g = 0.43, 95% CI [0.134, 0.723], Z = 2.85, p < .01). Meta-analyses of seven studies with a delayed verbal recall measure (g = 0.03, 95% CI [-0.152, 0.218], Z = 0.35, p = .727), three studies with an immediate nonverbal recall measure (g = 0.13, 95% CI [-0.391, 0.654], Z = 0.494, p = .621), four studies with a measure of general memory (g = 0.25, 95% CI [-0.112, 0.618], Z = 1.36, p = .175), two studies with a measure of prospective memory (g = 0.39, 95% CI [-0.236, 1.022], Z = 1.23, p = .22), two studies with a measure of delayed nonverbal recall (g = 0.13, 95% CI [-0.596, 0.330], Z = -0.57, p = .572), and two studies with a measure of associative memory (g = 0.14, 95% CI [-0.925, 1.211], Z = 0.26, p = .793) showed negligible to small effects that were not significant.

A sensitivity analysis was conducted to explore whether the decision to include studies of both stroke and TBI populations influenced the findings. Analyses were repeated for each outcome that had at least two studies remaining after all trials that included stroke patients were removed (general memory, delayed verbal recall, immediate verbal recall). The overall results remained similar across outcomes with the exception of general memory, which reached significance and showed a small effect of training (g = 0.39, 95% CI [0.063, 0.722], Z = 2.33, p < .05) when one study that included stroke patients was removed (Lesniak et al., 2018). Further, a sensitivity analysis of study quality for all objective memory outcomes showed that the overall results remained similar when studies with a high risk of bias were removed.

Figure 3

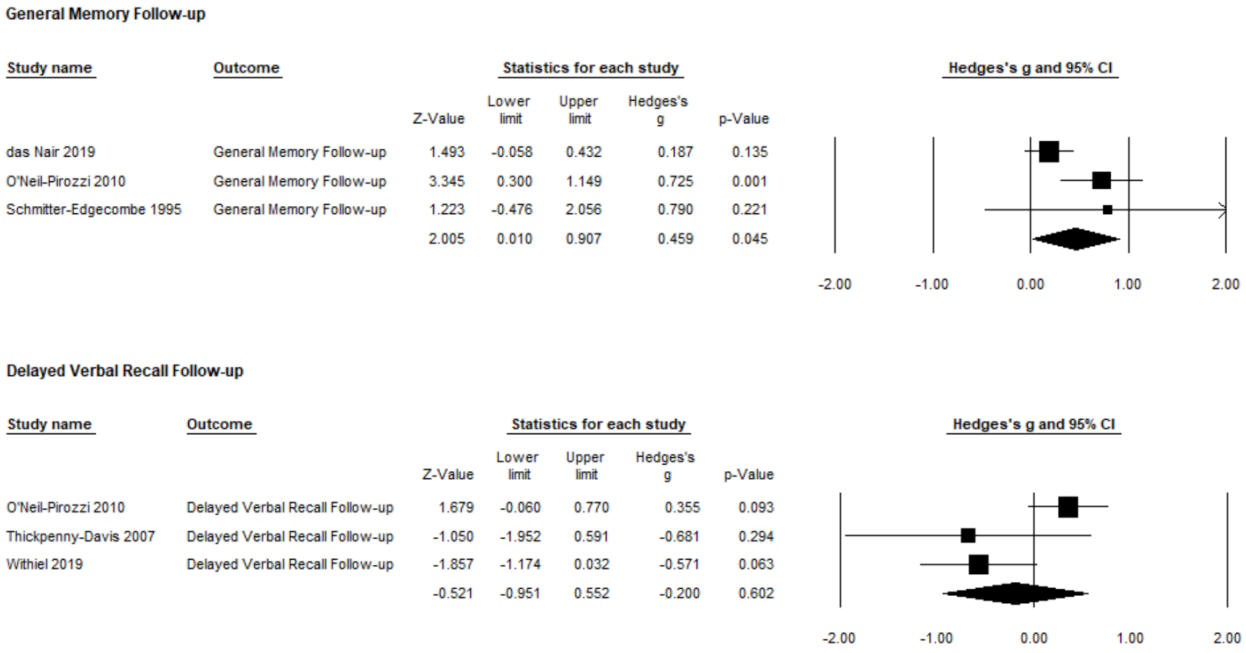
Meta-Analyses of Objective Memory Outcomes



As seen in Figure 4, meta-analyses of follow-up assessments were possible for two out of four objective memory outcomes (general memory and delayed verbal recall). Three studies with a combined sample size of 144 reported follow-up results for a measure of general memory. Results showed a small but significant improvement in general memory ability compared to controls at follow-up (g = 0.46, 95% CI [0.010, 0.907], Z = 2.00, p < .05), indicating that postintervention gains were maintained over time. A meta-analysis of three studies with a delayed verbal recall follow-up measure showed a small effect of training that was not significant (g = 0.2, 95% CI [-0.951, 0.552], Z = -0.521, p =.602).

Figure 4

Meta-Analyses of Follow-Up Assessments for Objective Memory Outcomes



Participant-reported memory outcomes. Eleven studies used at least one measure of participant-reported memory to evaluate intervention benefit. A meta-analysis was performed for

each of the following categories: participant-reported memory ability, informant-reported memory ability, and memory strategy use.

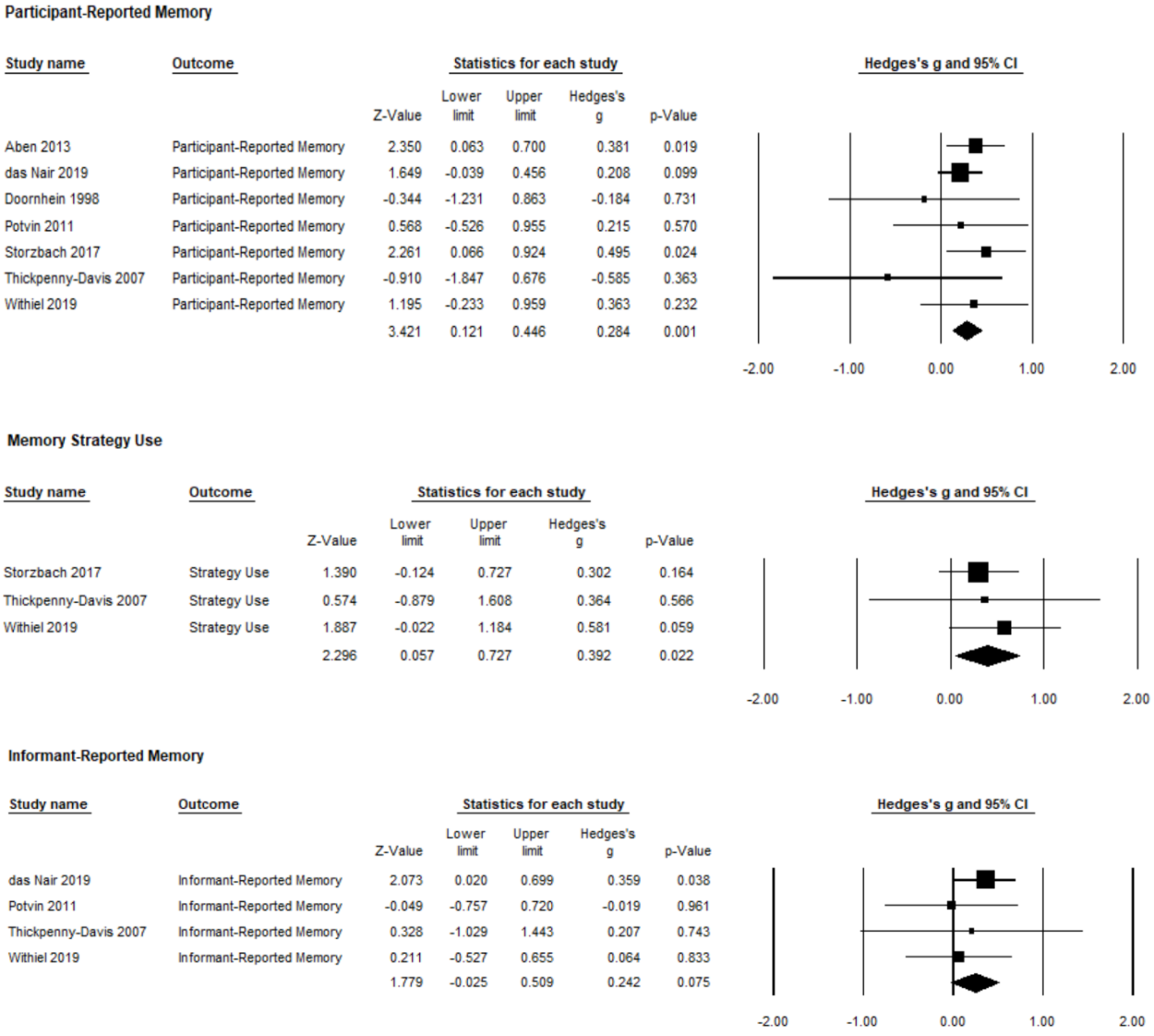
As seen in Figure 5, 11 studies used a measure of participant-reported memory ability, but four were excluded because of insufficient data (Bergquist et al., 2009; Jennett & Lincoln, 1991; Miller & Radford, 2014; Shum et al., 2011). Results from the remaining seven studies with a combined sample size of 585 showed that compared to controls, memory training resulted in a small but significant increase in participants' perceived memory ability post-intervention (g = 0.28, 95% CI [0.121, 0.446], Z = 3.42, p = .001). A sensitivity analysis of this effect excluding two studies with a high risk of bias revealed that the overall effect remained positive and statistically significant, with a slight increase in effect size (g = 0.47, 95% CI [0.131, 0.468], Z = 3.478, p = .001).

Strategy use was assessed in five studies. However, two were excluded due to missing data (Bergquist et al., 2009; Jennett & Lincoln, 1991). Meta-analysis results from the remaining three studies with a combined sample size of 139 showed a small but significant effect (g = 0.39, 95% CI [0.057, 0.727], Z = 2.29, p < .05), indicating an increase in strategy usage postintervention compared to controls.

Last, five studies included a measure of informant-reported memory ability, but one study was excluded from the meta-analysis due to missing data (Bergquist et al., 2009). Results from the remaining four studies with a combined sample size of 216 participants showed a small effect that did not reach significance (g = 0.24, 95% CI [-0.025, 0.509], Z = 1.78, p = .075). A sensitivity analysis of this effect excluding one study with a high risk of bias showed that although the overall effect remained similar, it showed a trend towards significance (g = 0.28, 95% CI [-0.005, 0.568], Z = 1.93, p = .054).

Figure 5

Meta-Analyses of Participant-Reported Memory Outcomes

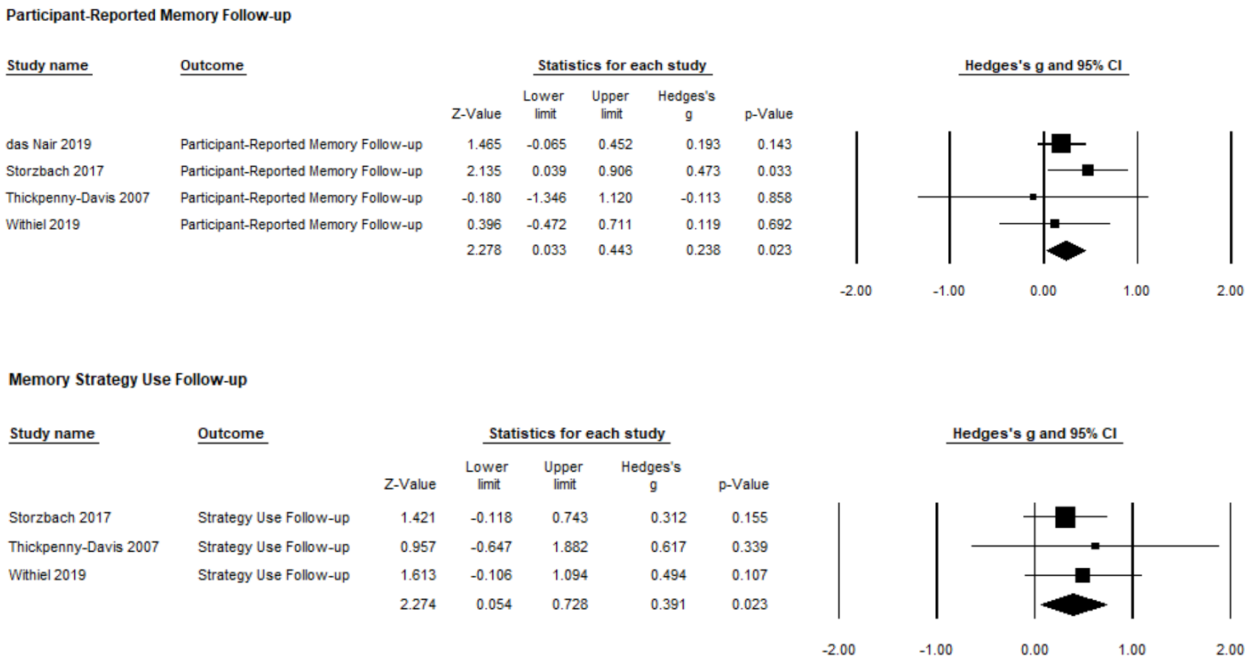


As seen in Figure 6, meta-analyses of follow-up assessments were conducted for all participant-reported memory outcomes. Four studies with a combined sample size of 368 reported follow-up results for a measure of participant-reported memory ability. Results revealed that improvements were maintained at follow-up, with memory training participants showing a small but significant increase in perceived memory ability compared to controls (g = 0.24, 95%

CI [0.033, 0.443], $Z = 2.28$, $p < .05$). Results from three studies with a follow-up assessment of strategy use also showed that results were maintained in the intervention group, with memory training resulting in a small but significant increase in reported strategy use compared to controls ($g = 0.39$, 95% CI [-0.054, 0.728], $Z = 2.27$, $p < .05$). Meta-analysis results from three studies reporting a follow-up assessment for informant-reported memory ability showed a negligible effect of memory training that was not significant ($g = 0.08$, 95% CI [-0.215, 0.373], $Z = 0.53$, $p = .598$).

Figure 6

Meta-Analyses of Follow-Up Assessments for Participant-Reported Memory Outcomes

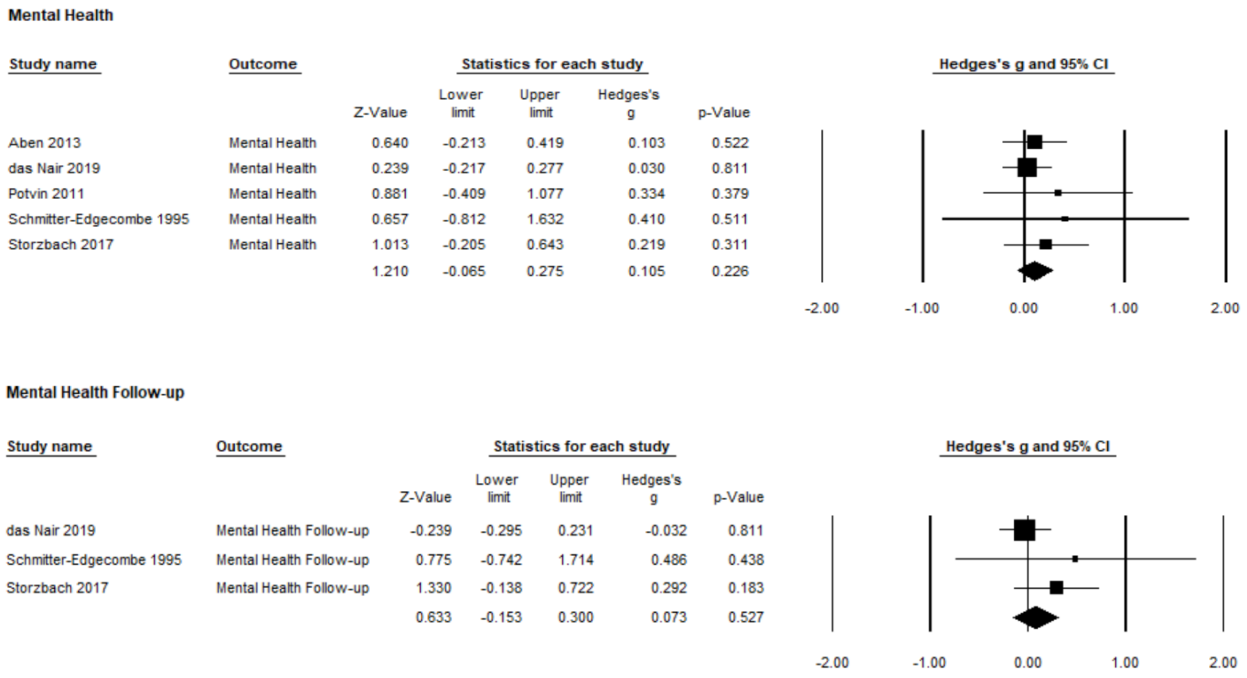


Everyday impact outcomes. Eight studies used at least one measure of everyday impact to evaluate the effectiveness of the memory training program. Outcomes were separated into three separate groups: mental health, quality of life, and community integration. Due to missing data, a meta-analysis was only possible for the mental health and quality of life categories.

As seen in Figure 7, seven studies included a mental health outcome; however, two studies were excluded from the meta-analysis due to missing data (Bergquist et al., 2009; Chiaravalloti et al., 2016). Results from the remaining five studies showed a negligible effect of memory training that was not significant (g = 0.11, 95% CI [-0.065, 0.275], Z = 1.210, p = .226). A sensitivity analysis of this effect excluding one study with a high risk of bias remained nonsignificant. A meta-analysis of follow-up assessments was conducted for three out of the five studies that reported data from a follow-up assessment. Results of this analysis was not significant (g = 0.07, 95% CI [-0.153, 0.300], Z = 0.63, p = .527), and revealed negligible effects of memory training on mental health outcomes.

Figure 7

Meta-Analyses of Mental Health Outcomes

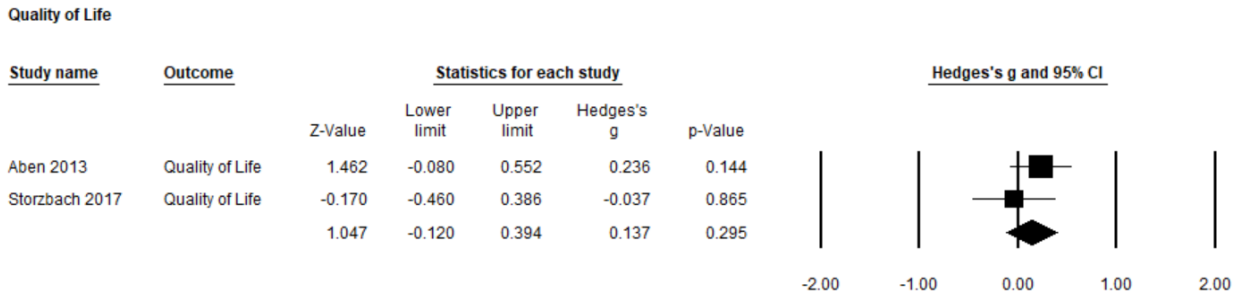


As seen in Figure 8, only two studies included a quality-of-life measure, and results from the meta-analysis showed negligible effects that were not significant (g = 0.14, 95% CI [-0.120,

0.394], $Z = 1.04$, $p = .295$). It was not possible to conduct a meta-analysis of follow-up findings because only one study reported this information. Only two studies used a measure of community integration to evaluate intervention effectiveness (Bergquist et al., 2009; Shum et al., 2011), and both studies reported that no significant effects were found. A meta-analysis was not conducted for this outcome because neither study reported immediate postintervention data.

Figure 8

Meta-Analysis of Quality-of-Life Outcomes.



Discussion

The present systematic review identified 22 controlled trials that evaluated the impact of compensatory memory interventions on at least one measure of memory or everyday impact in adults with ABI. Results of the meta-analyses showed that memory interventions that focus on teaching compensatory memory strategies are effective at improving specific aspects of memory, including immediate verbal recall, participant-reported memory ability, and strategy use, and that improvements are maintained months following the intervention. Risk of bias assessments also revealed that a majority of controlled trials of memory training programs for ABI populations are of moderate to high quality. However, selection bias, masking procedures, and withdrawal and drop-out rates are common contributors to study bias.

These results build on the findings from two previous meta-analyses (Elliot & Parente, 2014; Rohling et al., 2009) by providing an extensive examination of which types of memory interventions yield which types of benefits. Although those reviews contain several analyses that are beyond the scope of this review, both studies reported results from a meta-analysis of memory outcomes from a sample of cognitive rehabilitation studies. Our results were consistent with the review conducted by Elliot and Parente (2014), in which the authors reported a small but significant effect of memory training. It was not possible to compare which memory outcomes were most impacted by training, as the previous review looked at memory more broadly. In contrast, the review conducted by Rohling et al. (2009) reported that no significant effect of memory rehabilitation was observed compared to controls, which is inconsistent with the present review's finding of intervention benefits on participant-reported memory ability, strategy use, and immediate verbal recall.

There are a number of factors that may explain this discrepancy. First, the Rohling et al. (2009) article focused on providing a large-scale view of cognitive rehabilitation in general, and therefore only five out of the 45 controlled trials included in their review involved memory rehabilitation. In contrast, the current review employed a more focused approach that exclusively examined compensatory memory interventions. Second, Rohling et al. (2009) categorized all outcomes into broad cognitive domains (i.e., attention, memory, or language), whereas the current review assessed several outcomes encompassing specific components of memory. Thus, it is possible that our more focused approach enabled us to capture specific benefits that are unique to compensatory memory interventions.

No significant effect was found for several of the objective memory outcomes. Most studies in our review examined memory training in samples of patients with severe brain

injuries, and thus it is likely that participants had high levels of cognitive impairment prior to training. As mentioned in past research, the cognitive resources required to effectively learn and apply internal memory strategies such as visual imagery, association, and other mnemonic strategies may make these techniques less useful for patients with extensive cognitive deficiencies (Ryan & Ruff, 1988). This idea is consistent with previous literature that has suggested that persons with mild to moderate cognitive impairments may be better suited to cognitive rehabilitation in general (Silver et al., 2009), and that those with more severe memory impairment may benefit from less complex strategies, such as the use of external memory aids (Cicerone et al., 2011). Considering that most studies included in our review focused on teaching internal memory strategies with less emphasis on external aids, it is possible that the content of the included intervention programs may not be well suited to persons with more severe memory impairments.

Furthermore, the absence of improvement across many of the memory outcomes reported in the current review does not necessarily indicate that compensation-based memory programs provide little benefit to participants. Instead, it is possible that the objective measures commonly used to assess performance in memory rehabilitation studies are not sensitive enough to capture the impact of memory training on patients' everyday functioning. Previous studies on the impact of memory rehabilitation that incorporated a qualitative component have found that in the absence of improvement on quantitative measures, important gains were found in participants' memory self-efficacy, memory knowledge, self-awareness of cognitive strengths and weaknesses, emotional adjustment, and compensatory strategy use (Chouliara & Lincoln, 2016). Thus, to better understand the benefit of memory training, laboratory-based psychometric tests should be complemented by evaluation methods that are more sensitive to the meaningful

changes experienced by participants, such as the use of qualitative interviews and participant-reported measures of memory, well-being, and everyday function.

No significant improvements were found on measures of quality of life and mental health, and there are several factors that may help explain this. First, as mentioned by Aben et al. (2013), it is possible that improvements on these types of outcomes may depend on individuals applying the newly learned information in their daily lives. Thus, immediate postintervention assessments may not capture these benefits because more time may be required before memory training has a noticeable effect on quality of life or mental health. Second, very few studies reported data from a quality of life (n = 2) or mental health (n = 5) outcome, so it is difficult to draw conclusions from these analyses, and they should be interpreted with caution. More studies utilizing everyday impact outcomes are needed to determine the benefit of memory training on these domains in persons with ABI.

Although a majority of controlled trials included in this review were of moderate or strong quality, the risk of bias assessment identified several sources of bias that were present in individual studies. First, many studies recruited self-and-clinic-referred samples from rehabilitation units for persons with ABI, and thus it is possible that interested participants may have been more motivated to participate due to a high degree of memory impairment. This has implications for the generalization of the findings, as participants from these settings may not be representative of all persons with ABI. Second, several studies did not utilize a double-masked research design, as it is not always possible or feasible in rehabilitation trials to conceal group allocation from participants or outcome assessors. This can influence the magnitude of results, as masking outcome assessors ensures that there is an unbiased ascertainment of outcomes, and keeping participants unaware of group assignment reduces the chance of performance bias.

Although it is important to consider these influences when interpreting the results of the current review, our sensitivity analyses on the impact of studies with a high risk of bias revealed that the present findings held true even when those studies were removed.

Overall, the results of the current review suggest that memory strategy training programs can improve immediate verbal recall, participant-reported memory ability, and strategy use. This review is the first to quantitatively examine how compensatory memory programs impact different aspects of memory and shows that memory training has a meaningful impact on persons with ABI. Although the present study found significant benefits of memory training programs on broad samples of individuals with ABI, further exploration on the impact of these interventions in specific subpopulations of brain injured persons would be a welcome contribution to the rehabilitation literature. Future studies that provide a more rigorous investigation into the effectiveness of compensation-based memory techniques in ABI populations with mild-to-moderate cognitive impairments or in less heterogenous populations (e.g., focusing on specific types of traumatic or non-traumatic brain injuries) may help reconcile some of the inconsistent findings often seen in the cognitive rehabilitation literature. Further, there is opportunity to examine potential benefits of memory rehabilitation more thoroughly at the level of individual, everyday impact, by using qualitative approaches and participant-reported outcomes.

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Appendix A

Search Strategy for MEDLINE® and Embase

Database: MEDLINE® and Embase

Search Strategy:

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1 Adult/ or "Aged, 80 and over"/ or Aged/ or Middle Age/ or Young Adult/

2 Brain injury, chronic/ or Brain Injuries, Traumatic/ or Brain Injuries/ or Brain ischemia/ or Central nervous system infections/ or Craniocerebral Trauma/ or Hypoxia, brain/ or Stroke Rehabilitation/ or Stroke/ or (ABI or Acquired brain injur* or Brain injur* or Cerebrovascular accident* or Cva or Head injur* or Head trauma or Post stroke or Post-stroke or Poststroke or Stroke or TBI or Traumatic brain injur*).ti,ab,kw.

3 Brain training/ or Cognitive remediation/ or (Brain train* or Cognitive intervention or Cognitive rehabilitat* or Cognitive training or Compensatory mem* or Compensatory strateg* or Memory aid* or Memory compensation or Memory intervention* or Memory program* or Memory rehabilitat* or Memory remediation or Memory retraining or Memory skill* or Memory self-efficacy or Memory strateg* or Memory training or Memory treatment* or Mnemonic strateg* or Mnemonic training or Mnemonic*).ti,ab,kw.

4 1 and 2 and 3

5 limit 4 to English language

6 (multiple sclerosis or Alzheimer* disease or Parkinson* disease).ti,ab,kw.

7 5 not 6

Appendix B

The EPHPP Quality Assessment Tool for Quantitative Studies Dictionary

Quality Assessment Tool for Quantitative Studies Dictionary

The purpose of this dictionary is to describe items in the tool thereby assisting raters to score study quality. Due to under-reporting or lack of clarity in the primary study, raters will need to make judgements about the extent that bias may be present. When making judgements about each component, raters should form their opinion based upon information contained in the study rather than making inferences about what the authors intended. Mixed methods studies can be quality assessed using this tool with the quantitative component of the study.

A) SELECTION BIAS

(Q1) Participants are more likely to be representative of the target population if they are randomly selected from a comprehensive list of individuals in the target population (score very likely). They may not be representative if they are referred from a source (e.g. clinic) in a systematic manner (score somewhat likely) or self-referred (score not likely).

(Q2) Refers to the % of subjects in the control and intervention groups that agreed to participate in the study before they were assigned to intervention or control groups.

B) STUDY DESIGN

In this section, raters assess the likelihood of bias due to the allocation process in an experimental study. For observational studies, raters assess the extent that assessments of exposure and outcome are likely to be independent. Generally, the type of design is a good indicator of the extent of bias. In stronger designs, an equivalent control group is present and the allocation process is such that the investigators are unable to predict the sequence.

Randomized Controlled Trial (RCT)
An experimental design where investigators randomly allocate eligible people to an intervention or control group. A rater should describe a study as an RCT if the randomization sequence allows each study participant to have the same chance of receiving each intervention and the investigators could not predict which intervention was next. If the investigators do not describe the allocation process and only use the words 'random' or 'randomly', the study is described as a controlled clinical trial.

See below for more details.

Was the study described as randomized?

Score YES, if the authors used words such as random allocation, randomly assigned, and random assignment.

Score NO, if no mention of randomization is made.

Was the method of randomization described?

Score YES, if the authors describe any method used to generate a random allocation sequence.

Score NO, if the authors do not describe the allocation method or describe methods of allocation such as alternation, case record numbers, dates of birth, day of the week, and any allocation procedure that is entirely transparent before assignment, such as an open list of random numbers of assignments.
If NO is scored, then the study is a controlled clinical trial.

Was the method appropriate?

Score YES, if the randomization sequence allowed each study participant to have the same chance of receiving each intervention and the investigators could not predict which intervention was next. Examples of appropriate approaches include assignment of subjects by a central office unaware of subject characteristics, or sequentially numbered, sealed, opaque envelopes.

Score NO, if the randomization sequence is open to the individuals responsible for recruiting and allocating participants or providing the intervention, since those individuals can influence the allocation process, either knowingly or unknowingly.

If NO is scored, then the study is a controlled clinical trial.

Controlled Clinical Trial (CCT)
An experimental study design where the method of allocating study subjects to intervention or control groups is open to individuals responsible for recruiting subjects or providing the intervention. The method of allocation is transparent before assignment, e.g. an open list of random numbers or allocation by date of birth, etc.

Cohort analytic (two group pre and post)
An observational study design where groups are assembled according to whether or not exposure to the intervention has occurred. Exposure to the intervention is not under the control of the investigators. Study groups might be non-equivalent or not comparable on some feature that affects outcome.

Case control study
A retrospective study design where the investigators gather 'cases' of people who already have the outcome of interest and 'controls' who do not. Both groups are then questioned or their records examined about whether they received the intervention exposure of interest.

Cohort (one group pre + post (before and after)
The same group is pretested, given an intervention, and tested immediately after the intervention. The intervention group, by means of the pretest, act as their own control group.

Interrupted time series
A study that uses observations at multiple time points before and after an intervention (the 'interruption'). The design attempts to detect whether the intervention has had an effect significantly greater than any underlying trend over time. Exclusion: Studies that do not have a clearly defined point in time when the intervention occurred and at least three data points before and three after the intervention

Other:
One time surveys or interviews

C) CONFOUNDERS

By definition, a confounder is a variable that is associated with the intervention or exposure and causally related to the outcome of interest. Even in a robust study design, groups may not be balanced with respect to important variables prior to the intervention. The authors should indicate if confounders were controlled in the design (by stratification or matching) or in the analysis. If the allocation to intervention and control groups is randomized, the authors must report that the groups were balanced at baseline with respect to confounders (either in the text or a table).

D) BLINDING

(Q1) Assessors should be described as blinded to which participants were in the control and intervention groups. The purpose of blinding the outcome assessors (who might also be the care providers) is to protect against detection bias.

(Q2) Study participants should not be aware of (i.e. blinded to) the research question. The purpose of blinding the participants is to protect against reporting bias.

E) DATA COLLECTION METHODS

Tools for primary outcome measures must be described as reliable and valid. If 'face' validity or 'content' validity has been demonstrated, this is acceptable. Some sources from which data may be collected are described below:

Self reported data includes data that is collected from participants in the study (e.g. completing a questionnaire, survey, answering questions during an interview, etc.).

Assessment/Screening includes objective data that is retrieved by the researchers. (e.g. observations by investigators).

Medical Records/Vital Statistics refers to the types of formal records used for the extraction of the data.

Reliability and validity can be reported in the study or in a separate study. For example, some standard assessment tools have known reliability and validity.

F) WITHDRAWALS AND DROP-OUTS

Score **YES** if the authors describe BOTH the numbers and reasons for withdrawals and drop-outs.

Score **NO** if either the numbers or reasons for withdrawals and drop-outs are not reported.

Score **NOT APPLICABLE** if the study was a one-time interview or survey where there was not follow-up data reported.

The percentage of participants completing the study refers to the % of subjects remaining in the study at the final data collection period in all groups (i.e. control and intervention groups).

G) INTERVENTION INTEGRITY

The number of participants receiving the intended intervention should be noted (consider both frequency and intensity). For example, the authors may have reported that at least 80 percent of the participants received the complete intervention. The authors should describe a method of measuring if the intervention was provided to all participants the same way. As well, the authors should indicate if subjects received an unintended intervention that may have influenced the outcomes. For example, co-intervention occurs when the study group receives an additional intervention (other than that intended). In this case, it is possible that the effect of the intervention may be over-estimated. Contamination refers to situations where the control group accidentally receives the study intervention. This could result in an under-estimation of the impact of the intervention.

H) ANALYSIS APPROPRIATE TO QUESTION

Was the quantitative analysis appropriate to the research question being asked?

An intention-to-treat analysis is one in which all the participants in a trial are analyzed according to the intervention to which they were allocated, whether they received it or not. Intention-to-treat analyses are favoured in assessments of effectiveness as they mirror the noncompliance and treatment changes that are likely to occur when the intervention is used in practice, and because of the risk of attrition bias when participants are excluded from the analysis.

Component Ratings of Study:

For each of the six components A – F, use the following descriptions as a roadmap.

A) SELECTION BIAS

Good: The selected individuals are very likely to be representative of the target population (Q1 is 1) **and** there is greater than 80% participation (Q2 is 1).

Fair: The selected individuals are at least somewhat likely to be representative of the target population (Q1 is 1 or 2); **and** there is 60 - 79% participation (Q2 is 2). 'Moderate' may also be assigned if Q1 is 1 or 2 and Q2 is 5 (can't tell).

Poor: The selected individuals are not likely to be representative of the target population (Q1 is 3); **or** there is less than 60% participation (Q2 is 3) **or** selection is not described (Q1 is 4); and the level of participation is not described (Q2 is 5).

B) DESIGN

Good: will be assigned to those articles that described RCTs and CCTs.

Fair: will be assigned to those that described a cohort analytic study, a case control study, a cohort design, or an interrupted time series.

Weak: will be assigned to those that used any other method or did not state the method used.

C) CONFOUNDERS

Good: will be assigned to those articles that controlled for at least 80% of relevant confounders (Q1 is 2); **or** (Q2 is 1).

Fair: will be given to those studies that controlled for 60 – 79% of relevant confounders (Q1 is 1) **and** (Q2 is 2).

Poor: will be assigned when less than 60% of relevant confounders were controlled (Q1 is 1) **and** (Q2 is 3) **or** control of confounders was not described (Q1 is 3) **and** (Q2 is 4).

D) BLINDING

Good: The outcome assessor is not aware of the intervention status of participants (Q1 is 2); **and** the study participants are not aware of the research question (Q2 is 2).

Fair: The outcome assessor is not aware of the intervention status of participants (Q1 is 2); **or** the study participants are not aware of the research question (Q2 is 2).

Poor: The outcome assessor is aware of the intervention status of participants (Q1 is 1); **and** the study participants are aware of the research question (Q2 is 1); **or** blinding is not described (Q1 is 3 and Q2 is 3).

E) DATA COLLECTION METHODS

Good: The data collection tools have been shown to be valid (Q1 is 1); **and** the data collection tools have been shown to be reliable (Q2 is 1).

Fair: The data collection tools have been shown to be valid (Q1 is 1); **and** the data collection tools have not been shown to be reliable (Q2 is 2) **or** reliability is not described (Q2 is 3).

Poor: The data collection tools have not been shown to be valid (Q1 is 2) **or** both reliability and validity are not described (Q1 is 3 and Q2 is 3).

F) WITHDRAWALS AND DROP-OUTS - a rating of:

Good: will be assigned when the follow-up rate is 80% or greater (Q1 is 1 and Q2 is 1).

Fair: will be assigned when the follow-up rate is 60 – 79% (Q2 is 2) **OR** Q1 is 4 or Q2 is 5.

Poor: will be assigned when a follow-up rate is less than 60% (Q2 is 3) or if the withdrawals and drop-outs were not described (Q1 is No or Q2 is 4).

Not Applicable: if Q1 is 4 or Q2 is 5.