

**BEST PRACTICE INTERVENTIONS FOR IMPROVING
EXECUTIVE FUNCTIONING IN INDIVIDUALS RETURNING
TO WORK POST TRAUMATIC BRAIN INJURY:
A SYSTEMATIC REVIEW**

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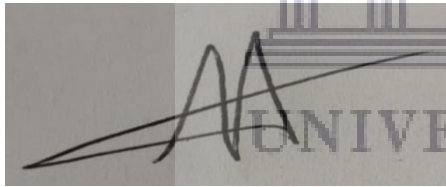
DECLARATION

I, Lauren Hutchinson, hereby declare that this thesis titled “**Best practice intervention for improving executive functioning in individuals returning to work post traumatic brain injury: A systematic review**” is my own original work (except where indicated otherwise an acknowledgement has been made), and the work done within this document either whole or part of it has not been or is to be submitted for another degree in this or any other university. Sources used within this document have been acknowledged by complete references.

Name: Lauren Hutchinson

Date: July 2021

Signed:

A handwritten signature in black ink, appearing to be 'LAH', is written over a grey rectangular background.

ABSTRACT

Background: The recovery process for traumatic brain injuries (TBIs) can be lengthy and taxing on the patient, family and healthcare resources. Part of this recovery process includes interventions for the improvement of executive functioning (EF) required for high level functioning such as return to work (RTW). However, evidence for best practice interventions to improve EF for RTW post TBI is lacking. Randomised control trials (RCTs) evaluating interventions for EF for RTW post TBI are available but have not been synthesised. The review aimed to determine the best practice interventions for improving EF for successful RTW post TBI. **Method:** A systematic review using a predetermined search strategy to find relevant titles published from inception to June 2020 in six electronic databases (EBSCOhost and PUBMED [both including MEDLINE]; CINAHL, Cochrane Database for Systematic Reviews, OT Seeker, and Taylor and Francis Online) was conducted following ethics approval by the Institutional Ethics Review Board. Two reviewers reviewed the titles, abstracts and full-text papers based on predetermined inclusion and exclusion criteria (PICOS). Final papers included were peerled and additional identified titles were reviewed by these reviewers at each level. Final included full-text studies were appraised by these reviewers using the CASP for RCT, RE-AIM Framework (score criteria $\geq 66\%$) and Cochrane Risk of Bias appraisal tools. No papers were excluded based on the appraisal criteria. A third reviewer was used for consensus. Both reviewers extracted the data using Microsoft Excel data sheets. A meta-analysis was not possible as population characteristics, interventions and outcomes measured were heterogeneous. Results were summarised as a narrative synthesis using text and tables. **Results:** Six full-text papers included were all published in the USA between 2000 and 2015. Studies included sample sizes of 35 to 360 TBI adult veterans or military personnel, mainly males, with varying TBI severity and a mean age ranging from 25–39 years. A variety of individual- and/or group-based interventions (Intensive Cognitive Rehabilitation, Categorization Program, In-hospital based Rehabilitation with Work Integration Therapy, CogSMART with Enhanced Supported Employment and Cognitive Didactic Rehabilitation) for improving cognitive, emotional and behavioural EF were implemented by different implementers in each experimental group

compared to either standard or other interventions in the control groups. Outcomes measured at baseline, post-treatment and at 6 and 12 months in some studies, included RTW in percentage as measured through an interview or obtained from medical records and work productivity using the Community Integration Questionnaire Productivity (CIQ[prod]) and Vocational Integration Scale (VIS). EF-related and quality of life (QOL) outcomes were also measured. Two studies included RTW as their primary outcome of EF intervention; however, one of these combined the RTW with return to school results and therefore did not provide a clear indication of RTW alone, which was the outcome of interest in this review. The other study had a high RTW rate of 90% and 94% at 12 months in the in-hospital intervention (EF plus Work Integration Therapy) versus the home-based control group, respectively, with no significant difference between groups ($p=0.51$). However, a post hoc analysis of TBI participants in the intervention group who were unconscious for >1 hour ($n=75$) had a significantly higher (80%) RTW rate versus the control (58%, $p=0.05$). A study measuring attainment of competitive work as a secondary outcome of EF intervention found that at 4 weeks CogSMART plus enhanced supportive employment resulted in a higher (50%) but non-significant ($p=0.15$) RTW than the control (26%) receiving supported employment only and a moderate effect size ($d=0.46$) favouring CogSMART. **Conclusion:** The review could not provide evidence for a best practice intervention for improving EF for RTW post TBI but provides insight for future studies and practice. Evaluation of EF interventions alone in specific TBI severity groups for successful RTW is needed. Heterogeneity of TBI severity and level of post-injury disability may require case/individual based EF interventions to significantly improve RTW rates. RCTs evaluating EF interventions for successful RTW are needed in developing and other developed countries where TBI incidence is high, the burden of TBI on patients and family increased and healthcare resources and employment opportunities limited. Increasing awareness among occupational and vocational therapists for EF rehabilitation for improving RTW post TBI is also advocated.

Keywords: *best practice; executive function; intervention; productivity, quality of life; RE-AIM Framework; return to work; traumatic brain injury.*

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DEDICATION

To those who have survived a traumatic brain injury, I hope your rehabilitation team lifts you up to your full potential so that when you look down you realise you are standing on the shoulders of giants.



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My sincere thanks and appreciation goes out to the following people:

I would like to give honour to God, who opened this door for me when I had felt like nothing in my life had meaning. He blessed me with wise supervisors and a supportive family that guided me all the way.

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Thank you to the funders for sponsoring this thesis and allowing me to complete this degree.

ETHICS

Ethics approval was obtained from the Humanities and Social Sciences Research Ethics Committee. Ethics Number: HS19/6/4 (Appendix A).



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The researcher/reviewer would like to acknowledge the NRF and Neuroscience Research Project

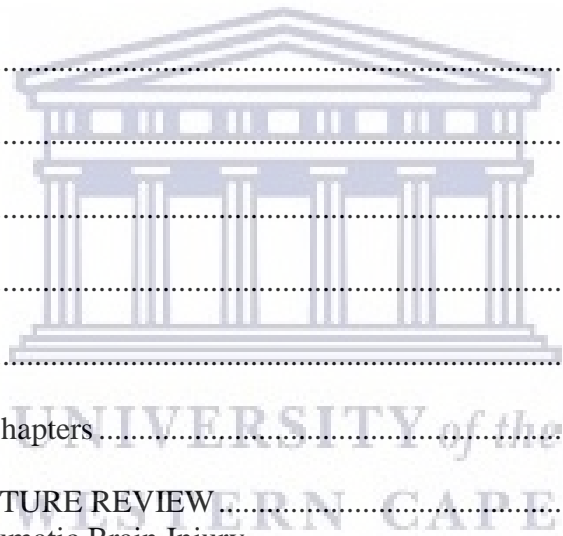
Collaboration of UWC for funding this research and confirms no conflict of interest.



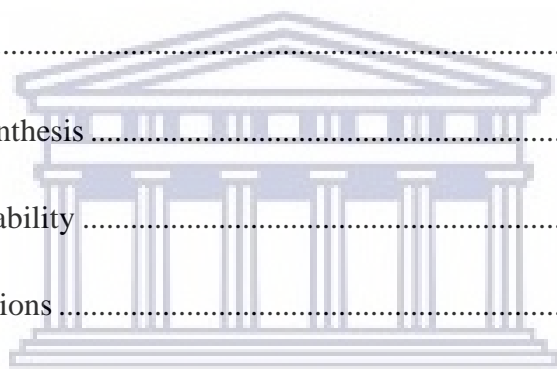
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DEFINITION OF TERMS

Categorization Program: Constantinidou et al. (2008) defines the Categorization Program (CP) as a systematic hierarchical training programme that consists of a total of eight levels and provides a standard approach to categorisation training. There are mastery criteria for each level of the programme to account for individual differences and systematic cueing hierarchies and errorless learning that facilitates the training and learning of the patient. Theories of implicit and explicit categorisation systems form the basis of the programme with two groups of tasks that include the recognition and categorisation of common everyday objects with a more basic identification and extraction of features such as colour, size and shape, and progresses to concept formation and abstraction as a higher level of function that includes logical rule decision making and is considered new category learning (Constantinidou et al., 2008).

Cognitive-didactic Protocol Treatment: This is an intervention developed by Sohlberg and Mateer as early as 1986. The intervention targets four cognitive domains namely attention, memory, executive functions, and pragmatic communication that are commonly affected in TBI individuals (Vanderploeg et al., 2008).

CogSMART: This is an acronym for an executive functioning intervention namely Cognitive Symptom Management and Rehabilitation Therapy. The therapy is a form of cognitive training that is intended to assist people and those with neurological disorders including TBI to improve their ability to remember to do things (prospective memory), improve attention, learning/memory skills, and executive functioning skills such as problem solving, planning, organisation, and cognitive flexibility. By improving the latter skills, it is possible that individuals with cognitive symptoms or impairments can perform better in activities of daily living and reach their school, work, social functioning, and/or independent living goals. It is an individual- or group-based

portable intervention (<http://www.cogsmart.com/> accessed 03.07.2021). The intervention uses compensatory cognitive training and not extensive drills and practice whereby individuals are taught how to improve their cognitive skills by strategies that must be practised in the real world to troubleshoot any difficulties that arise. The goal of CogSMART is to make a habit of the strategies so that individuals can use them automatically as needed in reality (<http://www.cogsmart.com/> accessed 03.07.2021).

Control/Comparison Group: The control or comparison group within this review is defined as the comparing intervention used or the standard to which comparisons are made in an experiment (Godby, 2020). It may either be another executive functioning intervention, a standard intervention given by the organisation where the study is conducted or simply no intervention at all.

Enhanced Supported Employment: A strategy that facilitates the inclusion of individuals with disabilities into the open labour market (OLM) (Engelbrecht et al., 2017). An enhanced version of this is by providing support over a longer duration or through the use of more healthcare workers carrying on this strategy.

Executive Functioning: Is considered within this study to be a higher cognitive component that consists of working memory, attention, organisation, planning, judgment, decision-making, and initiation of activities, emotional and behavioural control and regulation (Diamond, 2013).

Experimental Group: In this review the experimental group will always be defined as the rehabilitation intervention based on executive functioning that the studies make use of as their primary form of intervention. It is usually defined as the group that receives treatment of the variable that is at question within the study (Glen, 2015).

Implementation Evaluation: This is the process of determining whether a programme or intervention has been implemented as intended. The evaluation of this implementation is measured

through the effects it has on the target population as well as outcomes assessed and objectives achieved (Gaglio et al., 2013).

Intervention: It is defined as any therapeutic act, that is performed on a person or population, to assess, maintain, improve, promote or modify the functioning of an individual (Merriam-Webster, 2020).

Intervention Implementation: This is defined as the clinical process, through the use of therapeutic interventions or strategies, of causing change in a person's health status, function and performance that will in turn lead to engagement in occupations or activities (<https://medical-dictionary.thefreedictionary.com/intervention+implementation> accessed 07 July 2021).

Outcome Measure: This is the impact of healthcare services or interventions on the status of health of a patient. Within this review outcome measures that are mentioned will be in the form of standardised assessments or non-standardised assessments (Outcome Measure, 2020).

Return to Work: Return to work is defined as starting work again (*Merriam-Webster.com Dictionary*, Merriam-Webster, <https://www.merriam-webster.com/dictionary/return%20to%20work>. Accessed 10 Feb. 2021). Hees, Nieuwenhuijsen, Koeter, Bültmann, and Schene, (2012, p. e39947) states that in physical health studies “employees regarded their productivity, a sense of having done something meaningful, their job satisfaction, and the relationship with their supervisor as much more significant than the criteria traditionally used for evaluating RTW outcomes (e.g. hours worked or income earned)” but that “... other key stakeholders such as supervisors or occupational physicians (OPs) may apply different criteria, depending on their own interests” (Hees et al., 2012, p. e39948). In this study RTW is considered as an outcome that measures how many individuals with TBI returned to voluntary employment or paid (remunerated) employment in any type of employment that would result in productivity as an outcome.

Traumatic Brain Injury: Any assault (blunt, penetrating or acceleration/deceleration force-derived craniocerebral injury) to the head that causes symptoms such as reduced level of consciousness (LOC), amnesia, neurological or neuropsychological impairments including death (Dang et al., 2017). TBI is also defined as a non-degenerative, non-congenital injury to the brain caused by an external mechanical force (Dawodu, 2019).



ABBREVIATIONS

ADLs – Activities of Daily Living

AIS – Abbreviated Injury Score

AMPS – Assessment of Motor and Process Skills

BRIEF – Behaviour Rating Inventory of Executive Functioning

CASP – Critical Appraisal Skills Program

CI – Confidence Interval

CIQ – Community Integration Questionnaire

CogSMART – Cognitive Symptom Management and Rehabilitation Therapy

COMPASS^{goal} – Community Participation through Self-Efficacy Skills Development

COWAT – Controlled Oral Word Association Test

CP – Categorization Program

CT – Computerised Tomography

CVLT II - California Verbal Learning Test II

DEX – Dysexecutive Questionnaire

DNA – Deoxyribonucleic Acid

EF – Executive Functioning

ES – Effect Size

FIM – Functional Independence Measure

GBD – Global Burden of Disease

GCS – Glasgow Coma Scale

GOAT – Galveston Orientation and Amnesia Test

HAM-D – Hamilton Depression Rating Scale

HCT – Halstead Category Test

IADLs - Instrumental Activities of Daily Living

ICF - International Classification of Functioning, Disability and Health

ICRP – Intensive Cognitive Rehabilitation Programme

IQ – Intelligence Quotient

LOC – Loss of Consciousness

MET - Multiple Errands Test

MPAI3 – Mayo-Portland Adaptability Inventory III

MRI – Magnetic Resonance Imaging

MSI – Meta cognitive Strategy Instruction

MVA - Motor Vehicle Accident

NP Test/ing – Neuropsychologic Test/ing

NRS – Neurobehavioral Rating Scale

OLM – Open Labour Market

OP - Occupational Physician

OT – Occupational Therapy/ist

PAPMT – Picture Arrangement and Porteus Maze Test

PQOL – Perceived Quality of Life

PRISMA – Preferred Reporting Items for Systematic Review and Meta-Analysis

PT – Physiotherapy/ist

PTA – Post Traumatic Amnesia

QOL – Quality Of Life

RCT – Randomised Control Trial

RE-AIM – Reach, Effectiveness, Adoption, Implementation, and Maintenance Framework

RLAS – Rancho Los Amigos Scale

ROCF – Ray-Osterrieth Complex Figure Test

RTS – Return To School

RTW – Return To Work

SD – Standard Deviation

SNRP – Standard Neuro-rehabilitation Program

ST – Stoop Test

TBI – Traumatic Brain Injury

TMT – Trail Making Test

VFT – Verbal Fluency Test

VIS – Vocational Integration Scale

WAIS – Wechsler Adult Intelligence Scale

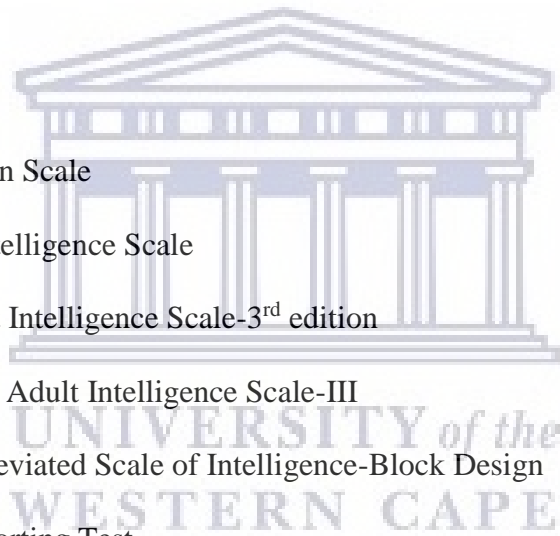
WAIS-III – Wechsler Adult Intelligence Scale-3rd edition

WAISr – Revised Wechsler Adult Intelligence Scale-III

WASIBD – Wechsler Abbreviated Scale of Intelligence-Block Design

WCST – Wisconsin Card Sorting Test

WRAMC – Walter Reed Army Medical Center



CHAPTER ONE: INTRODUCTION

1.1 Background

Traumatic brain injury (TBI) has increased globally and due to its increasing burden of disease has been termed as the “silent” or “hidden” pandemic (Webster, Taylor, & Balchin, 2015). While the awareness of the prevention of chronic diseases of lifestyle is well promoted by healthcare professionals in communities, the lack of the same awareness for the prevention of traumatic brain injury has contributed to this “silent” or “hidden” global pandemic (Webster et al., 2015). A non-degenerative, non-congenital injury to the brain that is brought on by an external mechanical force is referred to as a traumatic brain injury (Purbhoo, 2018). Purbhoo (2018) explains that TBI can be classified as either an impact or non-impact injury. Depending on whether the head makes contact with an object or whether the head was in contact with a blast wave or rapid acceleration and deceleration, TBI will be classified as an impact and non-impact injury, respectively (Prins, Greco, Alexander, & Giza, 2013). Therefore, when there is a traumatic event that causes the brain to rapidly move within the skull that can lead to damage of the brain, a TBI occurs (Prins et al., 2013). Worldwide, motor vehicle accidents (MVAs) and violence-related trauma are the main causes of trauma to the brain causing TBI (Webster et al., 2015; Khan, Baguley & Cameron, 2003a; Naidoo, 2013). Thus, trauma-related brain injury is one of the main contributors to mortality, morbidity and disability in the world (Webster et al., 2015; Zaloshnja, Miller, Langlois, Anbesaw & Selassie, 2008).

It is expected that more than 124 000 out of the 1.4 million people who sustain a traumatic brain injury in the USA, have long-term disabilities (Zaloshnja et al., 2008). Awareness of the estimates of the new cases (incidence) and number of people living with TBI-related disability (prevalence)

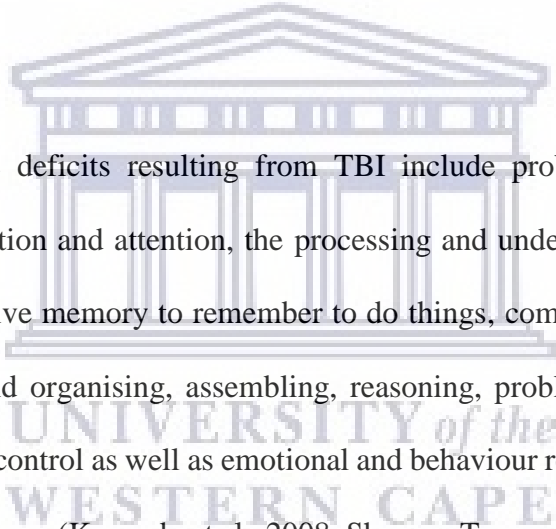
is important, as it affects a country's health resources. These sources of information are therefore very valuable to advocates, policymakers, and healthcare service providers to ensure they have adequate resources and that they adequately plan for the lifelong needs of individuals living with TBI-related disability (Zaloshnja et al., 2008). In a recent study by Webster et al. (2015) in Cape Town, South Africa, it was reported that TBI has a significant impact on the national burden of disease. This burden of disease has a direct impact on the healthcare resources that are already limited in the country. The general expenditure per TBI case is very high and depends on the severity of the condition (mild to moderate) (Humphreys, Wood, Philips, & Macy, 2013) thus using much of a country's resources for the care and rehabilitation of this population group.

Rehabilitation of the traumatic brain injured individual can be a long and taxing journey that affects not only the individual with traumatic brain injury but also their family and/or caregivers due to the financial burden placed on them in relation to receiving costly acute and rehabilitative health services and care (Soeker & Ganie, 2019). These effects are further compounded when the evidence shows that the traumatic brain injured individuals have a low chance of ever returning to a sustainable and fulfilling life, including meaningful occupation and employment (Saltychev, Eskola, Tenovuo, & Laimi, 2013). The latter affecting the earning capacity of these individuals and thus their economic contribution to a country. In a study conducted by Finkelstein et al. (2006) it was estimated that nearly 1 of 5 hospitalised survivors of TBI did not RTW because of work-related disability one year after traumatic brain injury, and that there was a total lifetime productivity loss of \$51.2 billion that was the highest productivity loss among all types of injuries. Furthermore, Zaloshnja et al. (2008) estimated that at the beginning of 2005, 1.1% (3.17 million people, 95% CI:3.02–3.32 million) of the civilian population in the United States were living with

a long-term disability from TBI resulting in limitations in work ability and performance in activities of daily living thus requiring ongoing medical and rehabilitation services and care. Therefore, RTW and/or return to school (RTS) is not only a concern and goal of TBI patients and their families but has become a topic of focus for occupational and/or vocational rehabilitation experts, healthcare funders and policymakers based on the burden of TBI disability reported.

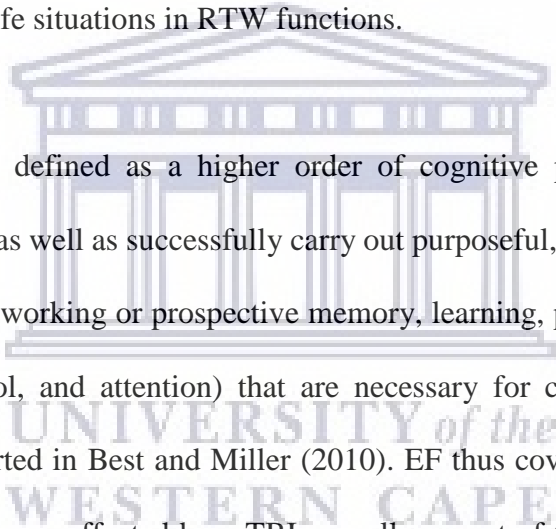
While there is a plethora of evidence on the short- and long-term functional impacts of TBI, only a few of these studies reflect on the outcomes orientated around vocational rehabilitation and return to work. Saltychev et al. (2013) conducted a review on the pre- and post-injury predictors of vocational outcome after traumatic brain injury looking at employment status and RTW as an outcome. The authors concluded that there was no strong evidence for predicting or improving vocational outcomes such as RTW and employment status following TBI and that sound experimental and observational research, including rigorous randomised control trials (RCTs), on this cardinal topic is required. They also encouraged the use of terms and scales that are standardised and unified in these studies by using the International Classification of Functioning, Disability and Health (ICF) (Saltychev et al., 2013, Andelic et al., 2010). Randomised controlled trials that incorporate vocational rehabilitation interventions focused on specific vocation-related activities for TBI individuals for improving employment readiness for return to work should be conducted. The latter is supported by Graham, West, Bourdon, Inge and Seward (2016) in their review of employment interventions for RTW in TBI individuals. Furthermore, components of higher functioning or performance such as cognitive, behavioural or psychological components addressed by appropriate vocational rehabilitation interventions should be included and evaluated for successful RTW (Saltychev et al., 2013).

Potential clinical and performance deficits of TBI such as early physical, cognitive, affective, behavioural and psychological consequences (Webster et al., 2015; Greenwood, 2002) could lead to lifelong disability (Zaloshnja et al., 2008). Eventually one could develop loss in performance components such as attention, executive functioning (EF) including planning and organisation, concentration and memory; however, this is usually dependent on the severity of the injury (Greenwood, 2002). TBI causes functional limitations, as well as sensory, gross and fine motor, physiological, communication and cognitive, emotional, behavioural and physiological impairments that vary in type, duration and intensity (Artman & McMahon, 2013; Webster et al., 2015).

The logo of the University of the Western Cape is centered in the background. It features a classical building facade with a pediment and columns, rendered in a light blue, semi-transparent style. Below the building, the text 'UNIVERSITY of the WESTERN CAPE' is written in a serif font, also in a light blue, semi-transparent color.

The cognitive performance deficits resulting from TBI include problems with higher order functions such as concentration and attention, the processing and understanding of information, memory including prospective memory to remember to do things, communication skills such as verbal fluency, planning and organising, assembling, reasoning, problem solving and decision making, judgment, impulse control as well as emotional and behaviour regulation and behavioural and psychological consequences (Kennedy et al., 2008; Shames, Treger, Ring & Giaquinto, 2007). These components of cognitive functioning, behaviour regulation and psychological consequences form part of a set of skills for higher levels of functioning such as executive functioning (EF) that is required for independent living, social and community participation, work and learning ability, including RTW and/or school for meaningful occupation. Deficits in cognitive performance components and functioning need to be addressed by healthcare practitioners through acute care and rehabilitation, to ensure that high level functions such as executive function are improved post TBI so that participation in occupations could be resumed post TBI.

Research evaluating the cognitive deficits following traumatic brain injury has focused on cognitive performance components such as attention and concentration, processing and understanding information, memory, communication, planning and organising, assembling, reasoning, problem solving and decision making, judgment, impulse control, and behaviour regulation that are needed for high level tasks such as executive function. When reflecting on these performance deficits that link to executive function one would have to isolate each performance component and assess whether prioritising treatment around the deficit would give rise to a more successful RTW programme while also arguing that treating isolated components would not be realistic in mimicking real life situations in RTW functions.



Executive function (EF) is defined as a higher order of cognitive processes that allows an individual to plan, organise as well as successfully carry out purposeful, goal-directed actions and refers to a set of skills (i.e., working or prospective memory, learning, planning, organising, task switching, inhibitory control, and attention) that are necessary for carrying out higher order cognitive processes as reported in Best and Miller (2010). EF thus covers most of the cognitive deficits experienced by a person affected by a TBI as well as most of the cognitive components required for completion of work duties. This is a point of interest when considering which form of intervention for improving executive function would yield greater success to return to work besides the traditional vocational rehabilitation interventions that may not incorporate many if any executive functioning interventions.

RTW has been researched in many populations, including those with traumatic brain injured individuals. Work is considered a high level function with the need to acquire a high level of

physical and cognitive skills. It is one of the main occupations of adults that includes employment interests, employment seeking, job performance, volunteer exploration and participation (Ha, Page, & Wietlisbach, 2013) that enables individuals to find meaning in their lives. Occupational or vocational and other rehabilitation therapists such as physical therapists, neuropsychiatrists, neuropsychologists, speech and language pathologists or therapists, to name a few, are involved in the physical and cognitive rehabilitation of traumatic brain injured individuals in order to assist them in returning to work. However, the time taken for acute care and rehabilitation for each TBI individual case differs, resulting in different levels of financial strain placed on either the TBI individual, family members or the healthcare resources. Purbhoo (2018) notes that there have been major advances in the management of individuals with severe TBI and this has been due to the development of standardised approaches that follow international guidelines using existing evidence to create recommendations for current care, to improve individual outcomes. Outcomes for rehabilitation of TBI can be based on three dimensions. Firstly, the need for assistance with self-care; secondly, the productivity or employment of the individual, and thirdly, the quality of social relationships (Humphreys, Wood, Phillips & Macey, 2013; Purbhoo, 2018). Thus, rehabilitation experts should focus on these outcomes, in particular productivity and employment including RTW that provides meaningful occupation to the TBI individual. The latter in turn can assist in easing the financial strain of rehabilitation through a source of income that in turn can reduce the unemployment rate and number of social disability grants that affect the economy of a country (Soeker & Darries, 2019).

Of all TBI incidences, approximately 63% occur in individuals aged 16-65 years old that represent the working population (Gilworth, Eyres, Bhakta, & Tennant, 2008). Schandelmaier et al. (2012)

state that returning to work requires a person with disabilities or illnesses to overcome challenges. This includes coping with ongoing health problems, restoring work functions and finding sustainable or alternative work tasks (Schandelmaier et al., 2012). RTW for TBI individuals can include returning to previous employment with reasonable accommodation. Many individuals with TBI encounter struggles in meeting work demands due to the limitation in functioning brought on by residual symptoms directly related to the TBI (Artman & McMahon, 2013).

Businesses require high-performing individuals to meet business goals, and to deliver specialised products and services. Good work performance benefits the business and the individual financially and with job satisfaction (Sonnetag & Frese, 2005). Organisations have a variety of job descriptions based on personal skills and capabilities. However, all job tasks require a basic level of competence in all performance components (Diamond, 2013). Almost all job tasks require one to have intact and developed EF components. EF is separated into three core functions: first is inhibitory control and behavioural inhibition that links with social rehabilitation. This can be seen in the worker's ability to interact with others in the workplace in an appropriate way and adapt to the social dynamics that occur within the workplace. Second is selective attention and cognitive inhibition and third is working memory (Diamond, 2013). From these core elements a higher form of EF is built and then this develops into reasoning, problem solving and planning (Diamond, 2013).

Executive function or functioning therefore accounts for a large portion of one's higher cognitive skills, the necessary skills that are required for functioning correctly within the work environment. It can be assumed that if efficient and effective EF rehabilitation can be attained, one can increase

the chances of an individual with TBI to return to work successfully. If a person with TBI can return to the working environment within a limited time period through appropriate vocational rehabilitation focusing on EF, there will be less financial strain and more efficient rehabilitation therapy time to ensure a return to work. Through a preliminary search of the literature, it was noted that there are randomised control studies evaluating interventions for improving executive functioning for the improvement of high level functions including return to work. However, the findings from these randomised control trials have not been synthesised to determine how executive functioning is assessed and which executive functioning interventions exist for improving EF and RTW in TBI individuals. In addition, how these executive functioning outcomes including RTW are evaluated (executive function outcome measures used), and which of these improved executive functioning outcomes is most effective in improving RTW rates and productivity also requires synthesis. Therefore, the aim of this review was to determine the best practice intervention for executive functioning for successful RTW in individuals post TBI with the latter questions in mind.



1.2 Problem Statement

Globally, in both developed and developing countries there is a high prevalence of TBI due to an increase in road accidents and violence-related crimes. TBI contributes heavily to the global burden of disease (GBD) as TBI results in long-term disability and the World Health Organization (WHO) reports TBI as the leading cause of disability (Sun, Luo, Chen & Tao, 2017; Moller, Lingah, & Phehlukwayo, 2017). Most individuals who suffer a TBI are within the working age and are fulfilling the role of being a worker; however, RTW is a term that is not often associated with this group of individuals (Moller et al., 2017). Thus, there is an increase in work-related

disability amongst this group of individuals (Moller et al., 2017) that increases the need for and use of expensive acute and long-term rehabilitation (Moller et al., 2017) and a larger percentage of the healthcare resources in a country. The long-term rehabilitation and costs of such rehabilitation impacts on the TBI individual and also places a burden on the family and/or caregivers together with a strain on already limited rehabilitative services and resources. A National Rehabilitation Policy was developed in South Africa to provide therapeutic and individual-centred rehabilitation to persons within the primary healthcare level; however, there are some implementation challenges to this policy as vocational rehabilitation has become isolated, limited and misunderstood in some urban and rural areas (Moller et al., 2017). As a result of this, return-to-work rehabilitation has been poorly carried out, leaving most of the TBI population unemployed. Similar challenges are faced globally. The realities surrounding RTW post TBI are firstly, that vocational rehabilitation is an important element of the RTW process, but due to the low success rates in therapy programmes many (mostly persons with severe TBI) are marginalised from employment (Moller et al., 2017). Secondly, there is a need to assess executive function (EF) rehabilitation programmes to determine their success rates in ultimately returning a person with TBI back into the workplace. Although data strongly supports the intervention and practice of EF after TBI, there is a lot to learn about the specific intervention techniques (Kennedy et al., 2008). Cramm, Krupa, Missiuna, Lysaght and Parker (2013) in a study on broadening the occupational therapy toolkit by evaluating the way in which occupational therapists view executive functioning in children and youth, found that system and professional barriers create challenges to occupational therapists that constrain their ability to recognise, label, and address EF performance issues. Cramm et al. (2013) also concluded that occupational therapists who have integrated EF into their practice perspective have acquired knowledge and skills through interprofessional collaborations,

individual interactions, and professional development opportunities and that occupational therapists working with children and youth need an occupational EF framework and practice resources, if they are to integrate an EF lens to enable occupational performance more broadly. This applies to the adult TBI population as well. Understanding the best practice interventions for EF for successful RTW in TBI individuals can assist in the development of a framework for EF intervention that is currently lacking for individuals with neurological conditions including TBI. Evidence for randomised control trials evaluating interventions for improving executive functioning for RTW in TBI individuals exist in the current literature but have not been synthesised, leaving a gap in the knowledge base of occupational therapists and vocational rehabilitation specialists regarding an evidence-based framework or guideline on EF interventions for RTW post TBI.

1.3 Review Question

What are the best practice interventions for improving executive functioning in individuals returning to work post traumatic brain injury?

1.4 Review Aim

The aim of this review is to determine the best practice interventions for improving executive functioning in individuals returning to work post traumatic brain injury.

1.5 Review Objectives

The objectives of the review are:

1.5.1 to identify and describe the types of interventions used to improve executive functioning in individuals with TBI for return to work,

1.5.2 to evaluate the implementation of executive functioning interventions for RTW used within the included studies (including the types of outcome measures used to measure EF and how RTW as an outcome of EF is measured), and

1.5.3 to identify and describe the best practice interventions for improving executive functioning in individuals with TBI that are returning to work.

1.6 Significance

The review aimed to synthesise RTW outcomes following interventions to improve EF post TBI from an existing body of evidence, in particular randomised control trial studies. It was hoped that a meta-analysis providing a combined measure of effect size would provide occupational and vocational rehabilitation therapists evidence of the best practice intervention for improving executive functioning such as cognitive, behavioural and psychological functioning required by individuals with TBI for successful employment, RTW and productivity. The review attempts to provide occupational and vocational rehabilitation therapists as well as other healthcare professionals concerned with TBI rehabilitation and RTW with insight into available EF interventions, EF outcomes used to measure effectiveness of EF intervention for different EF components such as cognitive, emotional and behavioural functioning and the success of these interventions in improving EF, RTW and productivity. This may allow these healthcare professionals to develop a more integrated EF and vocational rehabilitation model and programme for TBI individuals, to reduce work-related disability and to increase their chances of employment and return to work. The review provides new knowledge and fills a notable gap in EF and TBI

literature and may assist healthcare practitioners in this field in developing a guideline or framework for EF intervention post TBI for return to work. It provides healthcare policymakers and funders with the information that encourages promotion of and funding for EF interventions post TBI for increased employment and RTW that could reduce the burden on social disability grant funds and the need for prolonged rehabilitative therapies and use of limited healthcare resources, especially in developing countries. The latter may benefit the TBI individual in reducing the financial strain of rehabilitation and the need for a caregiver, and in increasing satisfaction for being able to return to employment. Vocational rehabilitation for persons with TBI has a large financial impact on medical costs and if therapy for RTW is more effective and efficient through the inclusion of evidence-based EF interventions, the time taken in the outpatient rehabilitation process may be shortened and the financial strain that is placed on families of individuals with TBI be reduced. Lastly, the review highlights areas of further research required in EF interventions and RTW post TBI that can add value to the current body of available literature on EF and RTW in TBI.



1.7 Overview of Thesis Chapters

The thesis comprises six chapters:

Chapter one provides a background to the review and includes the problem statement that is orientated around the question of which executive function intervention/s would yield the best RTW outcome for persons who sustained a TBI. Furthermore, the chapter outlines the specific review question, aim and objectives and describes the significance of the study and its contribution to the rehabilitation community, in particular occupational therapists in terms of the improvement of high level executive functioning such as RTW in a group of traumatic brain injured individuals.

Chapter two provides an extensive review of the literature around traumatic brain injuries, its aetiology (including physiology), incidence and occurrence of TBI, consequences of TBI, activity limitations, assessment (including the diagnosis and the classification of TBI), the performance components affected in TBI and the treatment and rehabilitation thereof. Executive functioning, assessments or outcome measures that focus on executive functioning, interventions related to executive functioning and the relationship between RTW and executive functioning in TBI individuals is included and explored in this chapter.

Chapter three describes the method of the systematic review conducted. A comprehensive description of the search strategy, review process (validity and reliability of the process), PICOS including the specific inclusion and exclusion criteria for the review and the critical appraisal of the methodological rigour of the included studies and the rigour of the implementation of interventions of the included studies using the CASP and RE-AIM, respectively. The risk of bias assessment of included studies are also described in detail. Ethics approval for the use of secondary data is also commented on at the end of the chapter.

Chapter four presents the results of the review using tables and narrative text as part of a narrative synthesis as a meta-analysis was not possible due to heterogeneity of the included studies. The chapter describes the outcomes of the database search and review process using the PRISMA, describes the critical appraisal outcomes of the CASP and RE-AIM appraisal, respectively, as well as the risk of bias assessment, followed by a description of the characteristics of the included studies and then the population and sample size characteristics of studies. In answering the

objectives of the review, the results continue to describe the EF interventions, the comparison interventions and their specific characteristics, the outcome measures used to evaluate the interventions implemented, including RTW, EF and QOL as well as additional outcomes measured in the included studies. The results of the RTW, EF, QOL and additional outcomes are documented and a summary paragraph on the best practice EF intervention for RTW concludes the chapter.

Chapter five presents an integrated discussion of the review findings that is orientated around answering of the aim and objectives of the review and critically analysing the findings in relation to other studies and the findings of the methodological and implementation appraisal, risk of bias, characteristics of the included studies and their limitations and strengths identified to provide evidence for an executive functioning intervention that provides the best outcome of return to work. Recommendations for future research and practice in the areas of EF, RTW and the limitations and strengths of the review conclude the chapter.

Chapter six concludes the review and describes the contribution of the review and implications of the review findings for clinical practice and research for occupational, vocational and other rehabilitation experts including occupational therapists. It concludes with the way forward regarding the implementation of executive functioning interventions for RTW that is derived from the review.

CHAPTER TWO: LITERATURE REVIEW

Chapter two provides an extensive review of the literature around traumatic brain injuries, its aetiology (including physiology), incidence and occurrence of TBI, consequences of TBI, activity limitations, assessment including the diagnosis and the classification of TBI, the performance components affected in TBI and the treatment and rehabilitation thereof. Executive functioning, assessments or outcome measures that focus on executive functioning, interventions related to executive functioning and the relationship between RTW and executive functioning in TBI individuals is included and explored in this chapter.

2.1 The Aetiology of Traumatic Brain Injury

A TBI can be classified as either *focal brain damage* due to a contact injury that results from contusion, laceration and intracranial haemorrhage or it could be caused by *diffuse brain damage* due to an acceleration or deceleration injury resulting in a diffuse axonal injury or swelling (Werner & Engelhard, 2007). Focal brain damage can be described as a traumatic injury that occurs in a single location; however, depending on the mechanism of injury there can be multiple areas of the brain affected. Contusions may occur as a result of a TBI as well, this means that blood capillaries of the injured tissue have ruptured and the brain region cannot receive nutrients and oxygen (Werner & Engelhard, 2007). Lacerations (cutting) can occur in the injured region, this is brought on by the tool, weapon or mechanism used to damage the brain. Intracranial bleeding occurs when the blood vessels in the brain are ruptured and blood begins to fill open spaces between the brain tissue and the skull. The next classification is diffuse brain injury which can be progressive depending on the increasing amounts of acceleration-deceleration to the brain. This

leads to diffuse axonal injury which is simply a prolonged post traumatic state where the individual with TBI experiences a loss of consciousness (Werner & Engelhard, 2007).

Thus, a TBI could cause an alteration in function and is often due to external forces affecting the brain (Khan, Baguley & Cameron, 2003a). Thomas and McAllister (2011) give an example of the external forces when a person is struck by an object to the head causing rapid acceleration or deceleration of the brain. This means that the brain inside the skull is experiencing violent motion. It is most commonly known as whiplash injury and is noted by a rapid forwards and backwards motion of the head. In the case of acceleration-deceleration forces affecting the brain, it can be that there was no direct impact to the brain. An example of this is when a restrained passenger comes to a sudden stop when a moving car strikes an immovable object. Others consider this type of force to be a non-penetrating brain injury that can be divided broadly into two types; *firstly, contact and secondly internal forces*. Contact injuries are the result of the brain moving around inside the skull causing the brain to strike the inner surface of the skull. An internal force is a rotational/linear translational force, when combined, can produce an angular acceleration or deceleration resulting in shearing, straining and compression of the brain (Thomas & McAllister, 2011).

External forces can also be described as penetration of the brain by a foreign object. This kind of injury is usually as a result of violence, sport injury or as a result of a transport vehicle accident (Thomas & McAllister, 2011). In this case the individual's head is struck by an object, be it a bullet, baseball bat in a game of baseball or hitting the windshield with your head while involved in a motor vehicle accident (MVA). Lastly an external force causing a TBI can occur when the brain is exposed to a blast wave (Thomas & McAllister, 2011). This is known as a concussive

force, and although not experienced often, can cause lasting damage to regions of the brain and surrounding tissue (Thomas & McAllister, 2011). When a traumatic brain injury occurs, there will be a force transmitted to the head that will then result in neuropathic damage and dysfunction (Mckee & Daneshvar, 2015). Dysfunction within the brain is often directly related to the neuropathic damage assessed after tests are performed on the brain. By understanding which region is affected, there can be clinical deductions made on what performance components will be affected. However, due to the mechanism of injury, one has to be aware that induced secondary consequences of TBI can cause further damage to the brain and thus affect regions of the brain that were not initially damaged at the time of the TBI (Mckee & Daneshvar, 2015). Williamson et al. (2016), explains that TBI can induce focal, vascular, haemorrhagic, cytotoxic and inflammatory injuries. These induced damages are what gave rise to other dysfunctions within the brain that were not initially accredited to the injury.

2.2 Incidence of TBI (Statistics)

Often referred to as a silent epidemic, traumatic brain injury continues to be a growing public health concern. It contributes greatly to the number of death and disability around the world out of all the trauma related injuries present (Dewan et al., 2018). It is estimated that 69 million individuals will suffer a TBI each year. This can range from a mild TBI (81%) to a more moderate TBI (11%) (Dewan et al., 2018). Incidences of TBI amongst South Africans are high, but not all statistics are recorded due to the poor data capturing and infrastructure of South Africa's healthcare system. Pretorius (2013) estimated that in South Africa there are 89 000 incidences of TBI reported each year, and South Africa is one of the countries with the highest rates of new cases. There are no official reasons given by South Africa's department of health regarding poor documentation

and accurate statistical reports of TBI incidences. However, after reviewing the reasoning and limitations of other countries one can assume the following: mild to moderate TBI has often conflicting symptoms with other illnesses and thus often gets misdiagnosed. In addition, South Africa lacks consistent healthcare throughout the country and often faces a lack of staffing and resources. Thus, not all patients with TBI are seen within the hospital and clinical setting or receive proper assessment through use of CT and MRI to identify mild-to-moderate TBI (Pretorius, 2013).

Many institutions concerned with TBI services and/or care give out information on their websites with regards to the causation of TBI. In most developed countries one can see that causes are prioritised mainly around falls, motor vehicle accidents, self-inflicted injuries and then violence- and military-related incidences (Khan et al., 2003a). In developing countries like South Africa one can see that most incidences of TBI are caused by violence or gunshot wounds as well as motor vehicle accidents (Webster et al., 2015). Traumatic brain injury (TBI) has reached epidemic proportions in South Africa. Webster et al. (2015) propose that the increase in incidences is due to the elevation of violence in South Africa, but that is not the only cause. Humphreys et al. (2013) added that the incidence rate of TBI is high in Latin America and sub-Saharan Africa because of road traffic accidents. Currently South Africa faces a variety of healthcare challenges due to the cost per incidence and services required for the treatment of a TBI individual. The high incidence rates put a burden on the already limited rehabilitation services and funding (Webster et al., 2015). As a result of this, not all persons with TBI receive proper healthcare and rehabilitation, which ultimately results in a loss of functioning with increased disability; thus, the prognosis of achieving occupational functioning and participation is poor.

2.3 Consequences of TBI

Traumatic brain injury is a critical issue faced by many countries (Khan et al., 2003a). It is noted that there are very few therapeutic interventions that can be successfully used within TBI clinical practice (Khan et al., 2003a). Researchers believe that by understanding the long-term consequences of TBI, further development in therapeutic processes can take place to successfully address all limitations (Khan et al., 2003a). Literature shows that the direct consequence of a single or repetitive insult to the brain can result in not only death but also morbidity including a number of secondary pathological conditions (Bramlett & Dietrich, 2015; Sun et al., 2018). These include seizures, sleeping disorders, neurodegenerative diseases, psychiatric problems and neuroendocrine deregulation (Bramlett & Dietrich, 2015). Bajwa, Kesavan and Mohan (2018) add that TBI can lead to long-term behavioural, cognitive, affective deficits and increase neurodegenerative diseases.

According to Englander, Cifu and Diaz-Arrastia (2015), most seizures happen within the first several days or weeks after a brain injury. Seizures are usually a result of scar tissue in the brain that results from the traumatic brain injury. A seizure is classified as a sudden abnormal electrical disturbance in the brain that can cause abnormal motor movements, unresponsiveness, fumbling movements, abnormal sensory inputs, tiredness or dizziness or not being able to verbally communicate or understand others. Seizures can occur often for the person affected by a TBI if there has been significant damage to the brain. Due to the debilitating effect of a seizure one can see that there will be a significant loss of independence for the person affected by it. Adaptations to the environment as well as other forms of therapeutic processes will need to be implemented to ensure that the individual affected is safe when experiencing a seizure (Englander et al., 2015).

Other common secondary conditions of TBI are sleep disturbances and objective sleep disorders. According to Zuzuarregui, Bickart and Kutscher (2018), of those who suffer a TBI, 30%-66% of patients experience some form of sleep problem. Sleeping disturbances post TBI can occur acutely after injury or can manifest as a chronic issue during the recovery phase, and on occasion can persist for years to follow. Practitioners found it vitally important to manage sleep disorders as they can impair the recovery process of the patient affected by TBI. The causation of sleep disorders after TBI can be due to pain, injury to sleep/wake regulatory nuclei as well as pathways in the brain. Post-traumatic stress disorders and maladaptive behaviours can also prevent the occurrence of sleep and affect function (Viola-Saltzman & Watson, 2012).

Many researchers have the same understanding as Viola-Saltzman and Watson (2012) with regards to depression and anxiety becoming a bi-product of sleep disorders, although the connection is unclear. It is important to note that depression and anxiety alone or together with sleeping disorders can contribute to outcomes and goals of therapy not being met. This is due to depression, anxiety and negativity affecting motivation and participation in activities of daily living. Moreover, sleeping disorders contribute to fatigue, restlessness and the general feeling of being unwell and thus limiting function that can include both basic and higher level functions such as personal, home and work-related activities.

2.4 Activity Limitations in TBI Individuals

In a study by O'Connor, Colantonio and Polatajko (2005), it was found that after a lengthy follow up of ten years, persons who experienced a TBI had concerns around certain limitations still being experienced. They went on to explain that persons who sustained a TBI found that they were

irritable, had a misplaced temper and suffered severe anxiety (O'Connor et al., 2005). Other participants observed that they struggled with communication problems such as not being able to talk in groups and others explained that they had been experiencing limitations with regard to cognition, attention and information processing speed especially during social interactions (O'Connor et al., 2005).

Artman and McMahon (2013) indicated that the most common functional limitation reported by persons who had a TBI were that of memory loss and attention and concentration deficits. It became evident that those with memory deficits forgot important meetings, directions, deadlines as well as work procedures, thus their functioning in the workplace was hindered. Those with attention and concentration limitations had their productivity and safety at work affected. Their flow of work procedure became hindered as the relationship with supervisors was negatively affected due to disputes. Artman and McMahon (2013) explain that emotional dysregulation causes individuals with TBI to be unable to maintain and gain employment as these people are prone to anger outbursts, crying or verbal attacks, which is on occasion a violation of the workplace rules and regulations.

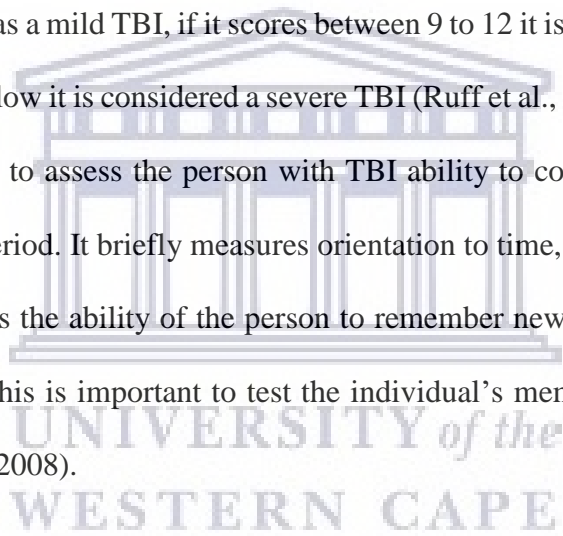
More recent studies come to the same conclusion; that a large portion of patients with moderate or severe TBI sustain long-term effects with physical, neurological, cognitive, personality, behaviour and emotional impairments that result in common lifestyle consequences including a decrease in employment rates (Andelic et al., 2018; Andelic, Sigurdardottir, Schanke, Sandvik, Sveen & Roe, 2010; Khan et al., 2003a). In a study by Andelic et al. (2018), they compared a 10-year to 20-year follow-up after TBI and found that if reduced depression or increased productivity was not

achieved at the 10-year mark, there would less likely be an improvement in this at the 20-year follow-up. The authors concluded that there should be a follow-up long-term assessment in place to provide further intervention for persons with TBI that are experiencing residual limitations due to their diagnosis so that community integration and participation in productive activities can occur (Andelic et al., 2018).

2.5 Clinical Diagnosis and Assessment of TBI

TBIs are diagnosed by observing the signs and symptoms when the patient enters the emergency room. According to McKee and Daneshvar (2015), the severity of a TBI is quantified using a variety of measurements and the most common being the Glasgow Coma Scale (GCS). The GCS measurement allows practitioners to identify the severity of the TBI (McKee & Daneshvar, 2015). Rogers and Trickey (2017) added that there are two methods used to designate the severity of traumatic brain injury i.e., the GCS and the head Abbreviated Injury Score (AIS) (Rogers & Trickey, 2017). The AIS head score is based on a computerised tomography (CT) scan that gives an anatomic score (Rogers & Trickey, 2017). Walker et al. (2018) indicate that the clinical measurement for brain injury severity includes the initial GCS motor scale as well as the post-traumatic amnesia (PTA) duration. The PTA measurement can indicate the length of stay of the patient (Walker et al., 2018). Similarly, to PTA, Loss of Consciousness (LOC) is described as a period of unresponsive time that happens immediately after an injury. According to Luoto (2014), LOC is believed to occur because of a cellular dysfunction of one or more parts of the ascending reticular activating system. The ascending reticular system is found in the central pons, midbrain, hypothalamus and thalamus, and dysfunction of this area results in LOC. (Luoto, 2014). The LOC measurement is extended to a maximum of 30 minutes (Luoto, 2014).

Many practitioners make use of the Glasgow Coma Scale (GCS,) the Post Traumatic Amnesia scale (PTA) as well as the Loss of Consciousness scale (LOC) (Ruff, Iverson, Barth, Bush, & Broshek, 2009; Khan et al., 2003a). The GCS measures the TBI patient's ability to speak; this accounts for the person being able to speak correctly for his age and stage, if he or she speaks in a manner that cannot be understood or if the patient does not speak at all. It also assesses the person's ability to open their eyes and to do so when asked to. Then it looks at the person's movements, this can range from basic movements of the hands to more complex movements in response to a stimulus such as pain. The healthcare provider can then score the GCS and if the score is 13 and higher it will be considered as a mild TBI, if it scores between 9 to 12 it is considered as a moderate TBI and if it scores 8 and below it is considered a severe TBI (Ruff et al., 2009; Khan et al., 2003a). The PTA scale was created to assess the person with TBI ability to consciously remember new memories over a 24-hour period. It briefly measures orientation to time, place and person (Shores et al., 2008). It also assesses the ability of the person to remember new information from day to day (Khan et al., 2003a). This is important to test the individual's memory if there is suspected PTA present (Shores et al., 2008).



The GCS is divided into three elements, this being the best eye response, verbal response and motor response, these responses all equal to 15. Each element of the GCS has its own scale, 4 values are given for the eye-opening response, 5 values are given for the verbal response and 6 values are given for the motor response. Thus 3 is the lowest one can score and 15 the highest one can score. The severity of a TBI is measured using the GCS and divided into three groups: mild (score 13–15), moderate (score 9–12) and severe (score 3–8). These groups link severity of injury to an individual's assumed functional loss (Khan et al., 2003a; Moen et al., 2012). Once the patient

is declared medically stable, the multidisciplinary team will commence with assessments. The assessments done within this phase are complex and cannot be carried out over one session with the patient. Impairments in physical, cognitive, perceptual, behavioural and emotional functioning need to be extensively assessed by the rehabilitation team (Khan et al., 2003a). Making use of magnetic resonance imaging (MRI) can assist in predicting functional outcomes. MRI can detect Traumatic Axonal Injury, and this in turn can predict cognitive outcomes (Moen et al., 2012).

Muscle paresis and spasticity is seen mostly in people who sustained a traumatic brain injury. It is found to often occur as part of an upper motor neurone syndrome (Ivanhoe & Reistetter, 2004). The individual is likely to experience impairments in their motor control, their coordination as well as an alteration in muscle tone. The assessment of tone is noted as a functional assessment as human beings exert tone onto their muscles to ensure postural stability and use of limbs in a functional and accurate way. The Ashworth Scale and modified versions of this scale is commonly used for the clinical assessment of tone whereby the therapist rates the patient's spasticity by quickly moving the affected limb from the full maximal range of flexion to extension (Ivanhoe & Reistetter, 2004). A comprehensive assessment is done by physiotherapists to assess tone and strength through hands-on passive and active movement of the joints as well as observing the individual within functional activities (Hellweg & Johannes, 2008). A range of motion assessment can accompany this allowing for the physiotherapist to get concrete results and changes while making use of the goniometer as an assessment tool (Hellweg & Johannes, 2008).

When trauma occurs at the back of the head and there is resulting damage to the cerebellum, coordination is likely to be affected (Kleffelgaard, Soberg, Bruusgaard, Tamber, & Langhammer,

2016). Assessments orientated around ataxia, dyspraxia, motor control and dyskinesia need to be done to rule these diagnoses out (Kleffelgraard et al., 2016). It is vital to also ensure that there is no balance or vestibular dysfunction when assessing for cerebellum dysfunctions (Kleffelgraard et al., 2016). Other assessments include assessments related to assessing pain and speech dysfunction. Pain is an often missed assessment, or not seen as significant when carrying out functional assessments. More than 50% of people who sustained a TBI often experience pain (Widerström-Noga, 2016). Pain not only resonates from the site of the injury, which would in this case be the head, but also from regions of the body that were affected by the mechanism of injury such as broken bones, muscle and nerve damage that can often result from an MVA and assault, that both are contributing factors to TBI (Widerström-Noga, 2016).

Speech and language pathologists and occupational therapists use assessments that are tailored to assess cognitive functioning similar to real world functioning (Stephens, Williamson & Berryhill, 2015). According to Stephens et al. (2015) these specialist rehabilitative therapists prefer to use the following valid assessment such as the Multiple Errands Test (MET), that tests the TBI patients cognitive functioning in the community setting, the Assessment of Motor and Process Skills (AMPS) for the testing of daily life skills and lastly a measure to assess self-care, productivity such as work and leisure namely the Canadian Occupational Performance Measures (COMP). These tools are considered to be invaluable in rehabilitation settings as the tools are designed to specifically identify deficit areas affecting the TBI patients' functional performance during daily living. The therapeutic interventions implemented by these therapists will continue until the patients' gain a plateau (Stephens et al., 2015). Occupational therapists are concerned with participation within each occupational domain that an individual engages in, in their daily lives.

Assessments are thus orientated around cognitive abilities of the TBI patient as well as functional outcome measures. With regards to cognitive deficits, the OT will assess attention, information processing, memory, learning, executive functioning, behavioural control and regulation (Stephens et al., 2015). Rehabilitation approaches in the early stages of recovery take the form of remediation and then shift towards compensation approaches as recovery continues (Stephens et al., 2015). This means that when deficits are assessed by the multidisciplinary team the remediation approach will take effect. This is when the rehabilitation team will focus on rehabilitation on improving a component that may have been negatively affected after TBI (Khan et al., 2003a). After carrying out different forms of therapy, intervention assessment of these affected components will be assessed again. What cannot be resolved will be compensated for through adaption so that the individual can accomplish what he or she sets out to do.

2.6 Executive Functioning and its Related Components

The term executive functioning (EF) is considered to be a broad term or concept that consists of a wide range of cognitive processes, as well as behavioural regulation and control (Chan et al., 2008). Due to the broadness of the term executive functioning, EF skill sets are defined differently among healthcare researchers and practitioners. Executive functioning is referred to as higher-level interconnected control processes that allow an individual to create, identify, choose, organise and regulate goal-directed behaviour (Murray & Ramage, 2000). Goal-directed behaviour is orientated towards achieving or attaining a particular set out goal, as when an individual experiences barriers or obstacles and problem-solves in order to achieve their set out goal. Executive functioning is not a common term used among therapists in the multidisciplinary team, even though EF is needed in order to engage in a significant portion of the activities an individual

would utilise within their daily life (Chan et al., 2008). Occupational therapists can enhance the EF of individuals with TBI by enhancing their coping mechanisms and facilitating compensatory techniques such as their use of assistive devices. Executive functioning in TBI is an important rehabilitation goal that requires focus in research and practice and thus requires assessment and interventions in TBI populations to improve outcomes and reduce TBI-related disability.

2.7 Assessments that Focus on Executive Functioning

The assessments used in order to determine whether an individual with TBI has problems with EF consist of the Wisconsin Card Sorting Test (WCST), Ray-Osterrieth Complex Figure test (ROCF), Halstead Category Test (HCT), Trail Making Test (TMT), Controlled Oral Word Association Test (COWAT), Wechsler Adult Intelligence Scale-Revised/Wechsler Adult Intelligence Scale-III (WAISr/WAIS-III), Wechsler Abbreviated Scale of Intelligence-Block Design (WASIBD), Stoop Test (ST), Picture Arrangement and Porteus Maze Test (PAPMT) (Constantinidou, Wertheimer, Stanadis, Evans, & Paul, 2012). Constantinidou et al. (2012) further indicate that these assessments measure executive function components according to a hierarchy, for example, dysfunction within low-level skills such as perception, attention will affect performance in higher-level skill demanding tasks (tasks that require one to use problem solving or abstract thinking). One of the concerns highlighted in the review by Constantinidou et al. (2012) was that the above-mentioned tests and assessments could not stand alone and require contextual information in addition to psychometric test results. Thus, behaviour rating scales need to be used to complement these assessments when identifying any manifestations of dysexecutive syndrome. These rating scales are often narrative with very few formal assessments available. Constantinidou et al. (2012) regard the Behaviour Rating Inventory of Executive Functioning (BRIEF) as a standardised but self-

report measure that captures adults' views on their own behaviour. It is not known what set of executive function assessments are used in existing randomised control trials that assess executive function efficacy following EF intervention implementation in TBI individuals especially for improving RTW outcomes and this requires investigation and synthesis.

2.8 Interventions for Improving EF in TBI Individuals

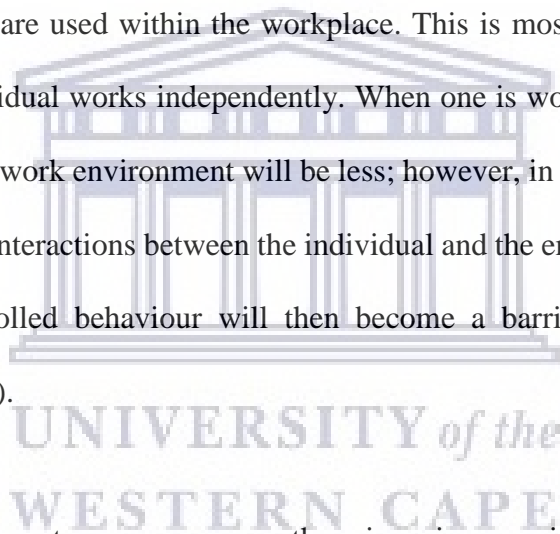
Cognitive retraining and holistic neuropsychological rehabilitation are typical examples of interventions or programmes developed in order to enhance the EF of TBI individuals (Constantinidou et al., 2012). Ruff, Baser, Johnston, and Marchalle (1989) conducted one of the first controlled pilot experiments evaluating the efficacy of neuropsychological treatment that included computer-assisted training modules for EF components such as spatial integration, selective attention, memory, and problem solving between TBI individuals assigned to a control and experimental group using quasi-randomisation. A recently published protocol by Krawczyk et al. (2019) for a RCT, planned to compare the effects of two 1-month electronic cognitive rehabilitation programmes namely an active programme (Expedition: Strategic Advantage) and a control intervention (Expedition: Informational Advantage) in military veterans with chronic TBI individuals. The active programme focuses on improving goal-directed executive functions such as working memory, long-term memory, planning and inhibitory control by challenging the TBI participant to accomplish life-like cognitive simulations, increasing the challenge level of the simulations according to the TBI participant's achievement. The researchers intend to assess EF outcomes including cognitive function skills and daily life functions. The EF components such as inhibitory control, planning, memory and attention will be assessed using a neuropsychological test battery and include neuroimaging measures to evaluate changes in brain networks supporting

cognition pre and post intervention but does not include RTW as an outcome of the EF intervention. In a systematic review conducted by Kennedy et al. (2008), focusing on EF components that addressed the planning and organising, problem solving and multitasking skills of adults with TBI the following EF interventions were identified: namely, metacognitive strategy instruction (MSI), training strategic thinking and training multitasking that trained multiple steps. Teaching internal memory strategies, problem-solving therapy (PST), goal attainment scaling (GAS) technique, time pressure management training (TPM) or concentration therapy (CT) and goal management training (GMT) were also identified in this review. While the review investigated EF programmes that are used to improve certain aspects of cognition in TBI individuals, the review did not provide information on how these improved EF skills improved RTW rates, productivity and maintained employment if these were measured by their included studies. It would be beneficial to investigate which EF skills in TBI individuals for their return to their specific occupation and work require intervention and training. An evaluation of the EF interventions that are best suited to improving the skills identified in the latter and that result in the successful RTW, productivity and maintenance of employment post TBI is also recommended. Currently it is not known what EF interventions are used and assessed for efficacy in EF and RTW or productivity of TBI individuals in existing randomised control trials and this needs synthesis.

2.9 Relationship Between EF and RTW in TBI Individuals

Planning abilities are essential especially when individuals want to RTW after sustaining a TBI (Cortés Pascual, Moyano Muñoz & Quílez Robres, 2019). Without effective planning abilities, an individual cannot keep track of available options to them and identify the consequences of these options especially when solving problems. When planning cannot be attained, the individual will

end up taking unnecessary and inefficient steps to complete a task. The work environment is likely to be influenced by the individuals executive functioning abilities as this environment focuses mainly on productivity, efficiency and quality of work being done in a specific period of time. Judgment and decision-making are cognitive components that can also be impaired when an individual experiences a moderate-to-severe TBI. Rabinowitz and Levin (2014) show that deficits within these components can lead to impulsivity and irrational behaviour. Once there is a deficit in behaviour control, TBI individuals begin to withdraw from social interactions and soon the importance of self-care activities does not get recognised. Judgment and decision-making are important components that are used within the workplace. This is mostly seen in highly skilled jobs or jobs where an individual works independently. When one is working under a supervisor, decision-making within the work environment will be less; however, in this scenario there will be an increase in professional interactions between the individual and the employer or supervisor and thus impulsive or uncontrolled behaviour will then become a barrier within the workplace (Rabinowitz & Levin, 2014).



RTW has been viewed as an outcome measure as there is an increase in workers who have been booked off work due to illness and thus begin to negatively impact the economy. Steenstra, Lee, De Vroome, Busse, and Hogg-Johnson (2012) indicates that RTW cannot be consistently defined by one phrase but is rather a dynamic outcome measure depending on the individual or patient being treated. The authors further indicate that the definition of RTW can be based on what outcomes the practitioner is looking to achieve; these outcomes could be productivity, retention of work, job satisfaction as well as advancements in work tasks (Steenstra et al., 2012). Currently RTW measures are based on the convenience of attaining the measure, thus simply checking

collateral information or administrative data can give a researcher the information they require on whether or not a patient is working. However, it is up to the researcher to have a more in-depth understanding on the outcome, by including measures such as days at work, hours spent productively, completion of job duties and to what extent, social appropriateness within the working environment and quality of work is completed. Therefore, measures such as days at work and hours spent productively are viewed as outcome-related data linked to an intervention that focuses on enhancing the individual's executive functioning. There is currently no systematic review that particularly focuses on the best intervention for executive functioning that enables the individual with TBI to return to and maintain employment as an outcome of this intervention. Information that highlights the best intervention for executive functioning to enhance the ability of an individual with TBI to return to and maintain employment will provide rehabilitation providers and employers with information that could assist in improving this outcome and reduce the economic burden that the sequelae of TBI has on the economy.

2.10 Summary

In summary, the literature review highlighted the aetiology of TBI, incidence and consequence of TBI (statistics) as well as activity limitations and clinical diagnosis and assessments of TBI. It described the components of EF and particularly described the assessments, strategies and tests used in order to assess EF. Finally, RTW as an outcome measure related to EF was discussed. While there is available literature regarding EF assessments and RTW programmes and outcomes, there is limited or no synthesis of available RCTs on specific EF interventions that are used to retrain EF in TBI individuals focused on the successful RTW post TBI.

CHAPTER THREE: REVIEW METHOD

This chapter describes the methodology of the systematic review conducted. A comprehensive description of the search strategy, review process (validity and reliability of the process), PICOS including the specific inclusion and exclusion criteria for the review and the critical appraisal of the methodological rigour of the included studies and the rigour of the implementation of interventions of the included studies using the CASP and RE-AIM, respectively. The risk of bias assessment of included studies is also described in detail. Ethics approval for the use of secondary data is also commented on at the end of the chapter.

3.1 Methodological Design

A systematic review was chosen and used to synthesise the results from existing randomised control trials conducted to evaluate the interventions for improving executive functioning for RTW in individuals post TBI. A systematic review is defined as a comprehensive review of the available literature in a methodical manner and carried out according to a specified protocol to minimise bias. The aim of this systematic process is to synthesise the information that has been retrieved (Hanley & Cutts, 2013). Aromataris and Pearson (2014) explain that traditional literature reviews have major setbacks in allowing for decision-making in the allied health sector. Literature reviews rely heavily on the author's knowledge, which may be limited as studies selected and used are based on the researcher's selection that may be bias due to a preference towards a particular author, journal, database or outcome (Aromataris & Pearson, 2014). It is noted that a systematic review puts together a pre-planned methodology of how to carry out literature searches and this is done in a way to limit the latter mentioned biases. In a systematic review the reviewer searches for studies from a wide range of databases using a predetermined search strategy and these studies go

through an intense review process and critical appraisal before being included in the review. By following this systematic process one can eliminate the threat of bias when selecting studies to be included to answer the specific researched question on a related topic (Hanley & Cutts, 2013). A systematic review is the search for and synthesis of the best available evidence to inform decision-making (Shorten & Shorten, 2013) and is the highest level of evidence. Noble and Smith (2018) agree with the latter by stating that a systematic review is seen as one of the best standards of reviews as it follows a structured procedure that overcomes the risk of bias. The systematic review can include a meta-analysis and/or a narrative synthesis. Shorten and Shorten (2013, p.3) state: “Meta-analysis is a research process used to systematically synthesise or merge the findings of single, independent studies, using statistical methods to calculate an overall or ‘absolute’ effect.” According to Shorten and Shorten (2013, p.3), the meta-analysis is not just a process of pooling data from smaller studies to achieve a larger sample size but “uses well-recognised, systematic methods to account for differences in sample size, variability (heterogeneity) in study approach and findings (treatment effects) and test how sensitive their results are to their own systematic review protocol (study selection and statistical analysis)”. As a meta-analysis was not possible to determine the best practice intervention to improve executive functioning for RTW in TBI individuals due to the heterogeneity of the included studies in this review, a narrative synthesis was employed to present the findings of this review. A narrative synthesis is an approach used in systematic reviews whereby the findings from multiple included studies is reliant primarily on the use of words and text to describe and explain the findings of the synthesis of the results of these studies (Popay et al., 2006). The manipulation of statistical data can be part of a narrative synthesis; however, the defining characteristic of a narrative synthesis is the adoption of a more textual approach to the synthesis process that helps to ‘tell the story’ of the findings from the included

studies (Popay et al., 2006). Thus, it is a process of synthesis used in systematic reviews that can focus on a wide range of questions, not only questions relating to the effectiveness of a particular intervention of the data as in a meta-analysis (Popay et al., 2006). A narrative synthesis however is not based on a trusted or accurate body of knowledge or on reliable and rigorous techniques that have been developed and tested over time as in a meta-analysis. Thus, the Cochrane Handbook argues that given the lack or absence of an authoritative body of knowledge there is a possibility that adopting a narrative approach to the synthesis of findings in a systematic review will be prone to bias, with the possibility of generating unsound conclusions that may lead to harmful decisions. This is of importance to intervention reviews when making clinical decisions regarding treatment and effect (Popay et al., 2006).

3.2 The Review Method

The systematic review process followed the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) guidelines and the results of the review process were reported according to this guideline.

3.2.1 Study Inclusion Criteria

Before starting the review process, the problem to be addressed by the review should be explained in the form of a specific and clear structured question that defines the Population, Intervention, Comparison, Outcomes and Study design known as the acronym PICOS (Khan, Kunz, & Antes, 2003b). The studies to be included in this review were based on the PICOS as one aspect of the inclusion criteria for the review. The PICOS for this study is described in Table 3.1 and is based on the following review question: “*What is the best practice intervention for improved executive*

functioning for RTW in individuals post TBI?” In addition to the PICOS, the inclusion criteria based on the critical appraisal of the included studies conducted are also described in Table 3.1.

Table 3.1 Description of the PICOS and Quality Appraisal Criteria for Inclusion of Studies

STUDY INCLUSION CRITERIA	
P- Participants	Adult persons of the ages 18 to 65 years old who were employed prior to sustaining a traumatic brain injury.
I- Interventions	Interventions that focus on improving executive functioning for RTW post traumatic brain injury. Interventions that look at one or more of the following executive functioning components: attention, concentration, planning, goal setting, initiating and controlling behaviour, problem solving, understanding of consequences and the action of being flexible and adapting to different scenarios (see also Appendix B).
C- Comparisons	Studies that compare single or multiple executive function interventions for; attention, concentration, planning, goal setting, initiating and controlling behaviour, problem solving, understanding of consequences and the action of being flexible and adapting to different scenarios with or without other interventions for RTW to either another single or multiple set of executive functioning interventions or conventional/standard interventions with or without other interventions or no intervention for RTW was included in the review. Studies comparing a single to a single/multiple group of executive functioning intervention or a group of multiple executive functioning interventions to a single/multiple group of executive functioning interventions or comparing a single/multiple group of executive functioning intervention to no intervention was included.
O- Outcomes	Executive functioning outcomes measures (specifically looking at one or more of executive functioning interventions such as planning and setting goals as well as initiating and controlling behaviour, attention and concentration, memory, problem solving, understanding consequences, acting in a flexible manner and adapting to different scenarios and environments for the purpose of return to work). The measurement of executive functioning can be the Question Completion Time, Trail Making Test and the Wechsler Test of Adult Reading and more as outlined in Appendix C on Executive Functioning Outcome measures. However, the main interest of executive functioning outcome in this review is RTW (how many or the percentage of individuals with TBI returned to voluntary or paid/remunerated employment or to any type of employment resulting in productivity as an outcome) and thus studies had to include this particular outcome related to executive functioning.
S- Study Designs	Randomised control trial designs and systematic reviews of RCTs
Q- Quality Criteria	Critical Appraisal Skills Programme (CASP) Appraisal Checklist (see Appendix D), the Reach, Effectiveness, Adoption, Intervention, Maintenance (RE-AIM) Framework (inclusion: score of 66%) (Appendix E) & the Cochrane Risk of Bias Assessment (Higgins, Altman, & Sterne, 2011).

Further **inclusion** and **exclusion criteria** for the selection of studies is described below. The selection of studies for inclusion in this review was also based on the following **inclusion criteria**:

- i) free full-text articles,
- ii) English language studies, and
- iii) studies published from the date of inception of the database until June 2020.

The selection of studies not included in this review was based on the following **exclusion criteria**:

- i) unpublished thesis or dissertations, conference proceedings, abstracts without full text available,
- ii) not a randomised control trial,
- iii) a protocol for a randomised control trial,
- iv) available only in another language that is not English, and
- v) was not accessible either from the library nor authors.

3.2.2 Search Strategy (Identification of Studies)

The primary reviewer in consultation with the review supervisors and trained librarian developed a predetermined search strategy (see Appendix G) consisting of the relevant search terms and limitations set for each electronic database included in order to identify the appropriate studies. The following electronic databases, namely PUBMED (including MEDLINE); CINAHL, Cochrane Database for Systematic Reviews, OT Seeker, Taylor and Francis and EbscoHost (including MEDLINE), were searched from inception to 30 June 2020 by the primary reviewer [LH] using the predetermined search strategy to identify the relevant studies.

3.2.3 Review Process (Selection of Studies)

The selection of studies followed four steps as per the PRISMA guidelines. The primary reviewer firstly identified the potential titles per database and collated the titles into a Microsoft Excel spreadsheet and removed duplicate titles. Two reviewers [LH & FK] independently reviewed the studies at title level and together decided on the final selection of titles. A third reviewer [SS] was consulted in the event of disagreement. The primary reviewer [LH] then collated the abstracts of all the included titles in the Microsoft Excel spreadsheet. The abstracts were reviewed independently by the primary [LH] and secondary [FK] reviewers and the third reviewer [SS] was consulted in the event of disagreement of abstracts to be included, Lastly the primary reviewer [LH] created a folder with all full-text copies of the included abstracts. The primary [LH] and secondary [FK] reviewers independently reviewed the full-text studies and decided on the final inclusion. The third reviewer was consulted in the event of disagreement and to validate the final included full-text studies. Thus, a rigorous process of identification and selection of studies for this review was followed using the PICOS and specific inclusion and exclusion criteria. Further to this, the primary reviewer [LH] pearled the reference lists of all included full-text studies and identified relevant titles in one of the included studies to be included in this review. Duplicate titles found were removed. The primary [LH] and secondary [FK] reviewer followed the same process of review and independently reviewed the titles, then abstracts and full texts to be included in the review and consulted the third reviewer [SS] in the event of disagreement and for validation of the studies included. The original study from which the pearled titles were selected was then excluded as only the studies identified and selected through the pearling of the studies reference list were relevant to this review. The fourth and final step of the review process for the selection of final included full-text studies included the critical appraisal using the critical appraisal criteria on which

to base the final inclusion as described in 3.2.4. The outcome of this process is presented in the results chapter. All excluded full-text studies were tabulated and a reason for their exclusion was included in Appendix F.

3.2.4 Critical Appraisal (Eligibility, Validity and Risk of Bias) of Included Studies

According to Seo and Kim (2012), when conducting a systematic review, one must ensure that one uses the best available evidence on clinically safe healthcare interventions as a systematic review including a meta-analysis of intervention studies is the highest level of evidence (Noble & Smith, 2018). The critical appraisal of the included studies ensures that studies selected for inclusion in the review are eligible, validated and free from risk of bias and should be included in the final review. In order to critically appraise the randomised control trial studies included in the review and ensure the eligibility of these included studies for final inclusion in the review the primary reviewer [LH] made use of two critical appraisal tools namely the Critical Appraisal Skills Programme (CASP) checklist designed for use with Randomised Controlled Trials (see Appendix D) and the Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) Framework (Appendix E), as well as the Cochrane Risk of Bias Assessment (Higgins et al., 2011; Higgins, Thomas, Chandler, Cumpston, Li, Page & Welch, 2020). All included studies were subjected to all three appraisal tools. The critical appraisal using the three appraisal tools was conducted independently by the primary [LH] and secondary [FK] reviewer and the third reviewer [SS] was consulted in the event of disagreements and to ensure validity of the process. Based on the appraisal criteria set, the final eligible studies were selected and included in the review.

3.2.4.1 CASP for the Methodological Appraisal of RCT studies

The Critical Appraisal Skills Programme (CASP) checklist designed for use with Randomised Controlled Trials (see Appendix D) was used in this review to appraise the methodological rigour of the included randomised control trial studies. The CASP includes questions on whether the study has focus, randomisation, accountability, blinding, use of similar groups, equal treatment of the intervention arms, treatment effect size and outcomes measured, precision of the estimate of the treatment effect, application of the results to local population, consideration for clinically important outcomes and benefits worth the cost of intervention implementation. Three broad issues need to be considered when appraising a randomised control trial namely: i) “Are the results of the study valid?” (Section A), ii) “What are the results?” (Section B), and iii) Will the results help locally? (Section C). The eleven questions are designed to think about the issues systematically. The first three questions are screening questions. These three screening questions can be quickly and easily answered and if the answer to both is “yes”, it is worth proceeding with the remaining questions and including the selected study in the review. The CASP questions are scored as either “Yes”, “No” or “Can't tell” for most questions (except 7 and 8) that allows for further evaluation of the studies that were initially under consideration and included for review. The more questions marked as “No” or “Can't Tell”, the poorer the methodological rigour. The outcomes of the CASP appraisal are described in the results chapter and the appraisal completed for each included study can be found in Appendix H.

3.2.4.2 RE-AIM Framework for the Appraisal of the Implementation of the Interventions

The Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) Framework (see Appendix E) is just over 20 years old with the first publication of this framework in 1999 (Gaglio, Shoup, & Glasgow, 2013). This framework or model was developed as there was a need

that grew for the improvement of reporting on key issues related to the implementation and the external validity of health promotion and healthcare research evidence. Part of the development of the RE-AIM was in response to research trends that occurred where research was conducted under optimal efficacy conditions instead of in real-world complex settings as the concern was that studies conducted in these optimal conditions is often still considered the “gold standard” for decision-making and guidelines (Gaglio et al., 2013). The RE-AIM Framework is intended to be used at all stages of implementation research from planning through evaluation and reporting, and across different programmes, policies, and environmental change interventions and its elements follow a logical sequence, that starts with adoption and reach (Gaglio et al., 2013). Implementation and efficacy or effectiveness then follows and the framework finishes with the element linked to maintenance of intervention implementation (Gaglio et al., 2013). These elements of the RE-AIM framework are defined in Table 3.2.

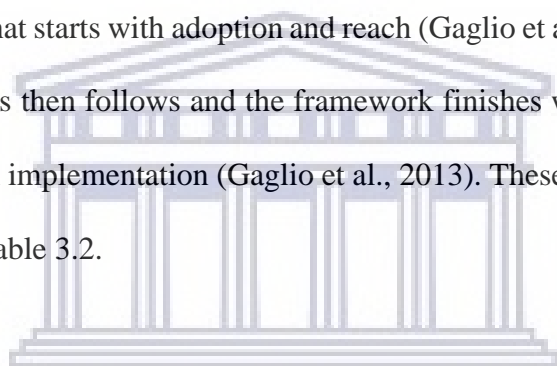


Table 3.2 The Elements of the RE-AIM Framework Defined

Elements	Definition
Reach	“The absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative (Gaglio et al., 2013)”.
Effectiveness	“The impact of an intervention on outcomes, including potential negative effects, quality of life, and economic outcomes (Gaglio et al., 2013)”.
Adoption	“The absolute number, proportion, and representativeness of settings and intervention agents who are willing to initiate a program (Gaglio et al., 2013)”.
Intervention	“Refers to the intervention agents’ fidelity to the various elements of an intervention’s protocol that includes consistency of delivery as intended and the time and cost of the intervention (Gaglio et al., 2013)”.
Maintenance	The extent to which a programme or policy becomes institutionalised or part of the routine organisational practices and policies. Maintenance also has referents at the individual level that is defined as the long-term effects of a programme on outcomes 6 or more months after the most recent intervention contact (Gaglio et al., 2013).

The RE-AIM elements and their sub-items are scored as “yes done” = 1 or “no, not done = 0. The RE-AIM elements, their sub-items as well as the scoring and scoring sheet used can be found in Appendix E and J. The outcomes of the RE-AIM appraisal are described in the results chapter and the appraisal completed for each included study can be found in Appendix I.

3.2.4.3 Risk of Bias Assessment

According to Higgins et al. (2011) the effect of an intervention can be underestimated or overestimated due to flaws in the design, conduct, analysis, and reporting of randomised trials. In order to assess whether the findings of the randomised control studies are valid and the effectiveness of the intervention accurately reported, the Cochrane Collaboration’s tool for assessing risk of bias can be used. Systematic reviews of intervention studies intend to provide high level evidence of measures of effectiveness but must include an assessment of risk of bias in intervention or randomised control trial studies in order to provide reliable conclusions and to highlight potential limitations of the included studies (Higgins et al., 2011). The Cochrane risk of bias assessment tool assesses the overall quality of the randomised control trial and even though the idea of study “quality” is not well defined it has been explained as the extent to which the design and conduct of the trial, analysis procedures, and presentation were appropriate to answer its research question. The Cochrane risk of bias tool includes the following items for assessment of bias: i) Random sequence generation (selection bias); ii) Allocation concealment (selection bias); iii) Blinding of participants and personnel (performance bias); iv) Blinding of outcome assessment (detection bias) self-reporting outcomes; v) Blinding of outcome assessment (detection bias) objective measure; vi) Incomplete outcome data (attrition bias); vii) Selective reporting (reporting bias); and viii) Other bias (issues specific to the study design such as carry-over in cross-

over trials, recruitment bias in cluster-randomised trials and non-randomised studies, baseline imbalance, blocked randomisation in unblinded trials, differential diagnostic activity and other bias). The items are rated as “Low Risk”, Unclear Risk” or “High Risk” in the risk of bias tool for each item (Higgins et al., 2011). The risk of bias outcome for each study is presented in the results chapter.

3.2.5 Data Extraction

The primary [LH] and secondary [FK] reviewers who extracted the data had a good understanding of the topic in this review. It is important that the primary reviewer pay attention to the details while following the extraction procedure as it is found that errors are often missed by peer reviewers in this section. Thus, the primary reviewer [LH] made use of Microsoft Office Excel data extraction sheets to ensure that all information was clearly displayed so as to minimise errors and note missing data due to the lack of attention to detail in the extraction process. A data extraction and scoring sheet was used for the CASP (see Appendices D) and RE-AIM Appraisal and Scoring Sheet (see Appendices E and J), respectively, as well as the extraction of the characteristics (authors, year, design, participants) of the included studies; their intervention (experimental versus control); implementation process (duration, frequency, timing); and outcomes (executive functioning outcomes including return to work) measured (see Appendix K). In order to ensure the validity of the data extracted, the primary [LH] and secondary [FK] reviewer independently extracted data, discussed the data extracted and used the third reviewer [SS] in the event that there was disagreement in the data extracted and/or if the primary [LH] and secondary [FK] reviewers were unsure of the data to be extracted. This allowed for improved rigour and validity in the data extraction process and the review findings or results.

3.2.6 Data Analysis/Synthesis

The data from included studies was synthesised using a narrative approach to the synthesis of the data using text summaries and tables. The data from the excel spreadsheets were abstracted and combined in tables that referred to a similar set of characteristics, for example study characteristics, appraisal outcomes, interventions and intervention implementation and outcome measures including statistical results. While a priori decision was made to incorporate a meta-analysis for the evaluation of the effectiveness of interventions to improve executive functioning for RTW as an outcome in TBI individuals, a meta-analysis of the RTW outcomes was not possible due to the lack of homogeneity in the participants' characteristics, the interventions used, implementation processes including individual or group therapy and differences in units and/or timing of measurements for RTW and other outcome measures of effectiveness measured in the included studies. Due to this identified heterogeneity a narrative synthesis was best suited to present the outcomes of the review.

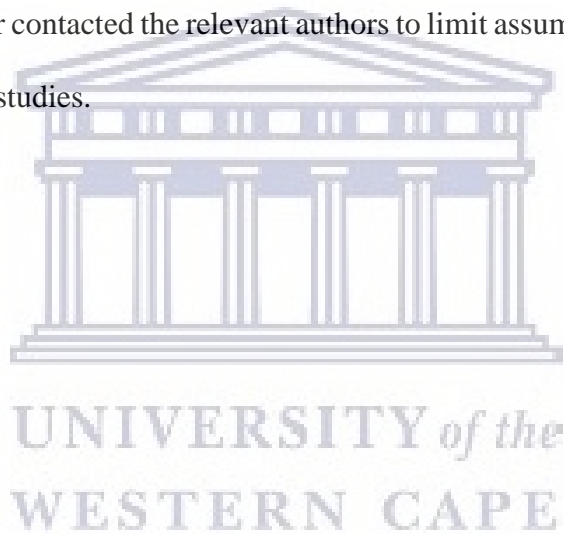
3.2.7 Validity and Reliability

To ensure the validity and reliability of the studies selected and included in this systematic review, the reviewer ensured that more than one person reviewed each study selected for this systematic review and that each reviewer independently reviewed the titles, abstracts and full-text studies and extracted data and used a third reviewer in the event of disagreements and for the validation of selection, eligibility and data extracted and final synthesis of the results. In addition, to clarify assumptions, authors were contacted for clarification (see Appendix L). Ethics principles regarding the use of secondary data and accurate and detailed reporting of the review method and findings also contribute to the validity and reliability of this review.

3.2.8 Ethics Considerations

Systematic reviews do not have the luxury of direct access to the participants of the research study that are included in the review (Suri, 2019). Thus, the information the researcher will obtain is through the lens of the author/s of those included studies (Suri, 2019; Vergnes, Marchal-Sixou, Nabet, Maret, & Hamel, 2010). The primary reviewer [LH] took the following criteria into consideration: namely, reducing potential biases and honouring the representations of the participants within the research studies. To ensure that the primary reviewer [LH] maintained the quality of the systematic review, strategies such as collaborative sense-making, utilising feedback from reviewers [FK & SS] (at each level of the review: namely, selection, eligibility (appraisal), data extraction and synthesis) and from key stakeholders (authors), identifying disconfirming cases and exploring challenging connections were considered and used during the systematic review process. The primary reviewer [LH] only conducted the study after it had been approved by the Humanities and Social Sciences Research and Ethics Committee at the University of the Western Cape (Appendix A). Due to the inherent nature for conducting a systematic review there is nothing that prevents the inclusion of unethical studies (Vergnes et al., 2010). In order to prevent doubts on the morality of using results from the occasional studies that were unethical, reviewers are encouraged to assess ethics in a systematic review to identify these studies and report on them (Vergnes et al., 2010; Weingarten, Paul, & Leibovici, 2004). Vergnes et al. (2010) state that traditionally a systematic review is performed using the data from the original authors' publications. Therefore, the primary reviewer [LH] who is a registered student at the UWC and has access to all the library databases, used original authors' publications available to the public, thus ensuring transparency. The primary reviewer [LH] used the principles of transparency, being non-bias during data extraction and the avoidance of plagiarism during the systematic review

process as described by Vergnes et al. (2010). Wager and Wiffen (2011) indicate that these good practices ensure that potential conflict of interest is acknowledged, the review does not contain plagiarised material, and that all contributors are recognised and accredited. Additionally, the primary reviewer [LH] assessed the methodological rigour (CASP) and rigour of the implementation of interventions and intervention validity as well as risk of bias of the included studies, independently from the second reviewer [FK], evaluating selection; allocation; performance; detection; attrition, self-reporting and other bias and consulted a third reviewer in the event of disagreement. Where clarity was required regarding the methodological design and results, the primary reviewer contacted the relevant authors to limit assumptions made with regards to the latter in the included studies.



CHAPTER FOUR: RESULTS

This chapter presents the results of the review using tables and narrative text as part of a narrative synthesis as a meta-analysis was not possible due to the heterogeneity of the included studies. The chapter describes the database search outcomes, review process using the PRISMA, the critical appraisal outcomes of the CASP and RE-AIM appraisals, risk of bias assessment followed by a description of the characteristics of the included studies. In answering the objectives of the review, the results continue to describe the EF interventions and comparison interventions, the outcome measures used to measure the effectiveness of the EF interventions including RTW and a description of how RTW was measured. The measures of effectiveness for all RTW, EF and QOL outcomes measured is included. The review results also include a narrative of the results found in the included studies regarding RTW as the primary outcome of interest of this review, the EF and QOL outcomes and additional assessments of the interventions included in some of the included study trials. The chapter ends with a narrative addressing the final review objective related to the identification and description of the best practice interventions for improving executive functioning in individuals with TBI that are returning to work.

4.1 Database Search Results

The electronic database search of eight electronic databases yielded a total of 299 studies. A total of 21 duplicates were removed and a total of 278 titles were identified for screening and selection as can be seen in Table 4.1 below.

Table 4.1 Description of the Databases Searched, Total Hits, Duplicates and Titles Identified

ELECTRONIC DATABASES	TOTAL HITS	DUPLICATES	TOTAL TITLES
PUBMED	9	0	9
EBSCOHOST	15	1	14
COCHRANE	14	6	8
CINAHL	3	2	1
OT SEEKER	1	1	0
SCIENCE DIRECT	78	1	77
WEB OF SCIENCE	43	9	34
TAYLOR AND FRANCIS	136	1	135
TOTAL	299	21	278

A total of 278 titles were reviewed at title level as shown in Figure 4.1.

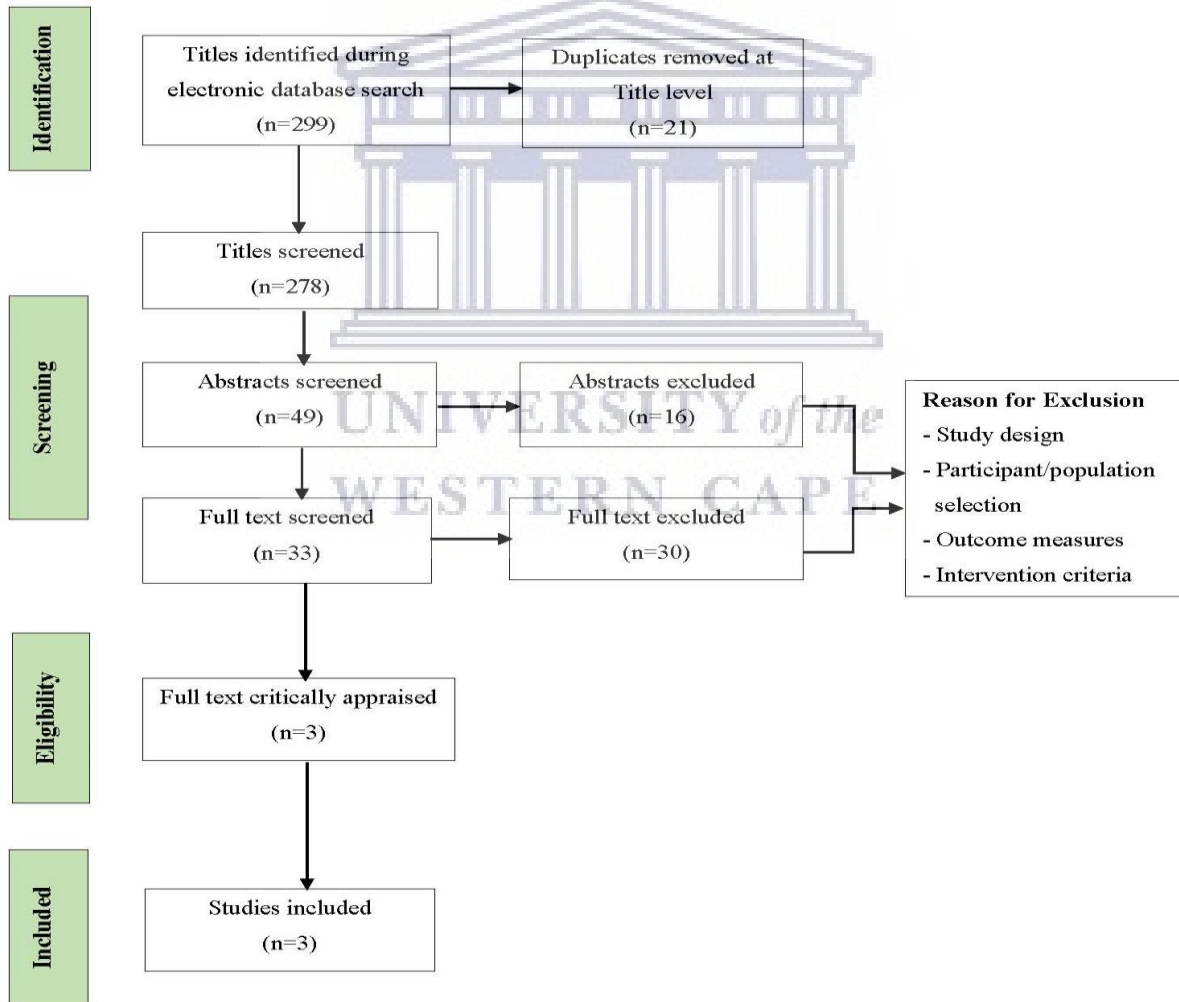


Figure 4.1 PRISMA Flow Diagram: Review Process and Study Selection (Moher, 2009, p. 267).

Forty-nine abstracts were selected for review. A total of 33 abstracts were finally selected and the full-text papers for these abstracts were retrieved and reviewed. From the 33 full-text studies reviewed, three namely Kumar, Samuelkamaleshkumar, Viswanathan, and Macaden (2017); Twamley, Jak, Delis, Bondi, and Lohr, (2014) and Vanderploeg et al. (2008) were included. The reference list of each of the three papers included following the electronic review process were pearled and 13 studies were identified in the included systematic review by Kumar et al. (2017) as can be seen in Figure 4.2.

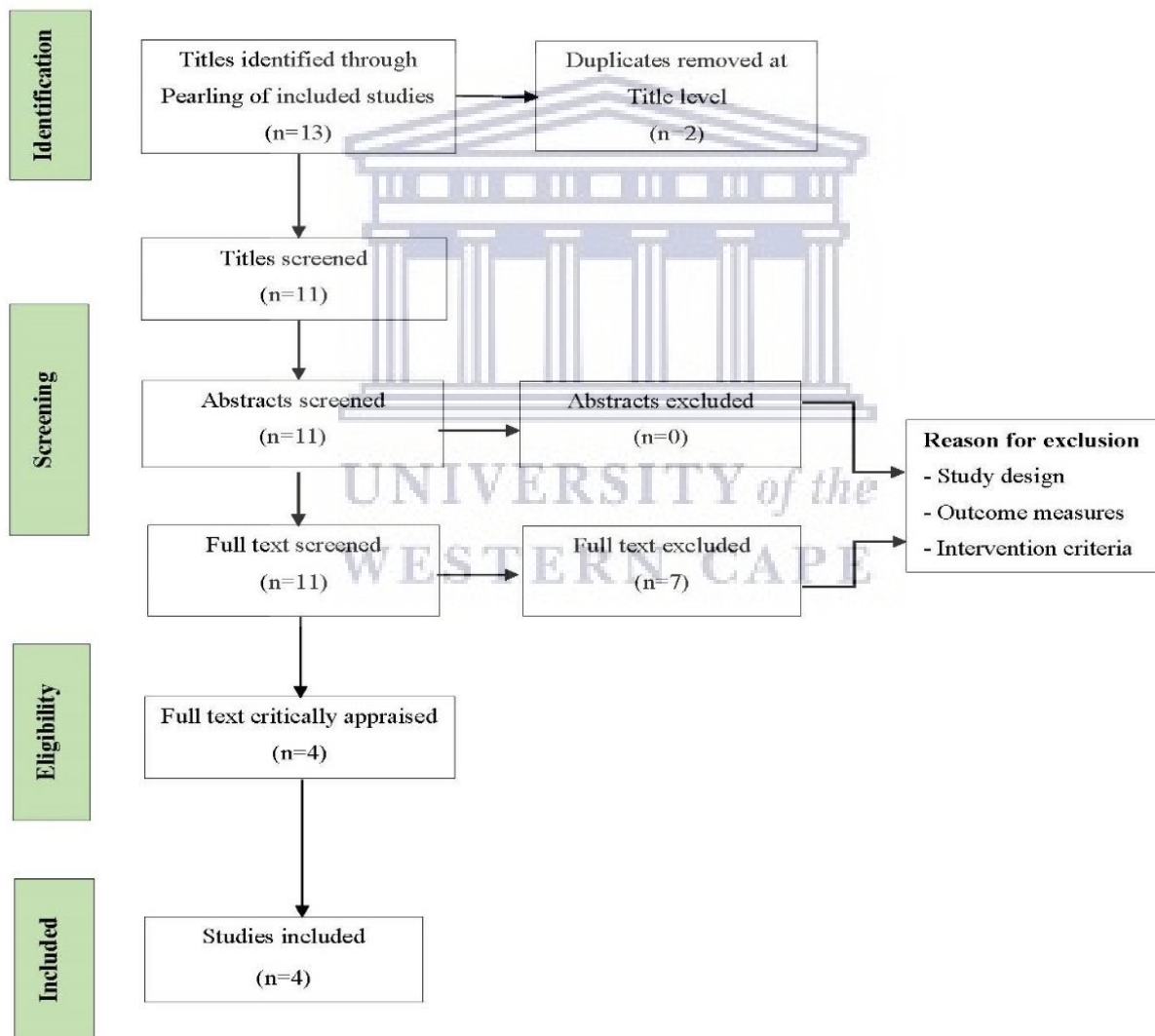


Figure 4.2 PRISMA Flow Diagram: Review Process and Study Selection for Pearled Studies (Moher, 2009, p. 267).

Two of the 13 studies identified were duplicates and removed and 11 titles and abstracts were reviewed. All 11 abstracts were selected and the full-text studies were retrieved and reviewed. Four of the 11 full-text studies identified through the pearling review process (Cicerone et al., 2008; Constantinidou, Thomas, & Robinson, 2008; Salazar et al., 2000; Twamley et al., 2015) were selected for inclusion in this review. These four studies were included in the review by Kumar et al. (2017) identified through the electronic database review process. Thus Kumar et al. (2017) was excluded in the end as only these four studies from his review were relevant to this review and not his full review.

Finally, a total of six randomised control studies (Cicerone, et al., 2008; Constantinidou et al., 2008; Salazar et al., 2000; Twamley et al., 2014; Twamley et al., 2015 and Vanderploeg et al., 2008) were included in the review. One [n=1, 17%] of the six studies (Twamley et al., 2015) was just a follow-up at 12-months from the original study and publication by Twamley in 2014 and thus the method and implementation process in 2015 was the same as the 2014 study. A list of all the excluded full-text articles with reasons for exclusion are in Appendix F. The selected studies were then appraised as described in section 4.2 for final selection and inclusion. All six studies [n=6, 100%] were included in the review after the critical appraisal was completed. It must be noted that as Twamley et al. (2015) is a 12-month follow-up assessment study of the same participants in Twamley et al. (2014), the appraisal outcomes, study and population characteristics, interventions and outcome measures used are the same and are thus combined in all tables reporting on the latter.

4.2 Critical Appraisal (Eligibility, Validity and Risk of Bias) of

Included Studies

The results of the critical appraisal using the CASP, RE-AIM Framework and Cochrane Risk of Bias Assessment tools are presented in this section. None of the six studies were excluded from this review based on the critical appraisal process.

4.2.1 CASP Methodological Appraisal Outcome

The six included randomised control trial studies were appraised using the CASP methodological appraisal checklist and the completed CASP checklists for each study can be found in Appendix H and referred to for more detail. Table 4.2 summarises the CASP appraisal outcomes for the six studies. All six [n=6, 100%] studies answered “yes” to the first three questions on the CASP checklist as each study addressed a clearly focused issue (study aim and objectives), identified a specific study population and specific primary outcomes, presented a clear description of the interventions versus the comparison interventions. All six studies clearly documented the randomisation process followed in the assignment of participants into treatment conditions. The studies properly accounted for all participants who entered their trials at the conclusion of their trials and analysed the participant outcomes in the groups to which they were randomised (see Table 4.2). Blinding was problematic in all six [n=6, 100%] studies. Three studies [n=3, 50%] had no blinding (Salazar et al., 2000; Twamley et al., 2014; Twamley et al, 2015) and three studies [n=3, 50%] had some form of single blinding that mostly included the blinding of outcome measures but not the interventions implemented due to an inability to blind either participants or therapists/investigators (Cicerone et al., 2008; Constantinidou et al., 2008; Vanderploeg). In three studies [n=3, 50%] treatment groups were similar at the start (baseline) of the trials. In the other

three studies [n=3, 50%] there was a difference between groups on one or two of the baseline characteristics of participants reported (Salazar et al., 2000; Twamley et al., 2014; Twamley et al., 2015). Salazar et al. (2000) reported that the control group had fewer motor vehicle-related injuries, more assault injuries, and fewer patients who were unconscious for an hour than the intervention group. Twamley et al. (2014, 2015) reported that the intervention group was five years younger on average than the control but adjusted for age on their secondary analysis by removing the two older participants from each group. However, removing the two older participants from each group did not change their results. In two studies [n=2, 33%], aside from the experimental intervention, the experimental and control groups were not treated equally (Constantinidou et al., 2008; Salazar et al., 2000). Constantinidou et al. (2008) reported that the participants in their experimental group needed 13 weeks to complete the intervention and received 57 hours of individual cognitive treatment versus 80 hours in the control group that was provided over 18 weeks of treatment. Salazar et al. (2000) had an in-hospital rehabilitation group as an experimental group and a home-based rehabilitation group as the control group and the treatments offered in each group were different in type, frequency and dosage. Not all studies [n=3,50%] (Constantinidou et al., 2008; Salazar et al.,2000, Vanderploeg et al., 2008) reported on the size of the treatment effect on outcomes measured and thus the reviewers calculated the effect size (ES) using the means and standard deviations, 95% confidence interval (95%CI), the Chi-square (X^2) statistic, t-statistic or F-statistic provided in these studies of the reported outcomes to determine the effect sizes (ES). Three studies [n=3, 50%] reported on the ES using different methods (Cicerone et al., 2008; Twamley et al., 2014; Twamley et al., 2015). Cicerone et al. (2008) reported on the ES of their outcomes using Hedge's 'g' and Twamley et al. (2014, 2015) reported the ES using Cohen's 'd'. While some outcomes reported had moderate or large ES, there were other

outcomes that had small ES across all studies. While the majority of studies [n=5, 83%] showed high precision for the ES of their outcomes based on calculated 95% CIs that were small, only one study [n=1, 17%] (Salazar et al., 2000) reported a small effect size for all outcomes measured and was considered to have low precision as the calculated 95% CI ranges using means and SDs were wide or large. With regards to applicability of the results of the studies to the local and other contexts, all studies [n=6, 100%] were conducted in one setting, the USA, and the studies had included mostly males and TBI individuals who were military personnel, war veterans. Thus, the application of the results to the local population or to populations in other contexts was deemed not applicable. While all studies [n=6, 100%] had considered all clinically important outcomes relevant to the interventions that were implemented, the reviewers appraised two studies [n=2, 33%] as not considering relevant outcomes measured with regards to the RTW outcome that was not measured by these two studies (Cicerone et al., 2008; Constantinidou et al., 2008). This review was interested in the RTW outcome defined in this review as the number (in percentage) of TBI individuals who return to voluntary or paid employment. However, Cicerone et al. (2008) measured productivity using the Community Integration Questionnaire productivity scale (CIQprod) and the Vocational Integration Scale (VIS) to determine the number of participants who were employed in some type of work and those not employed or employed in sheltered employment and converted the scales to a dichotomous yes/no variable and did not provide the results for each scale on the VIS which, would be more informative and useful as well. Constantinidou et al. (2008) also used the CIQ productivity scale to measure productivity but did not report on the number of participants who returned to work in percentage. The primary reviewer contacted the author for this information (see Appendix L) but was informed that the data was not available. All studies [n=6, 100%] were considered to have benefits worth the cost of the trials

conducted according to the reviewers' evaluation of their outcomes. The majority [n=5, 83%] of the trial studies did not discuss the cost-effectiveness of their interventions. Only one study [n=1, 17%] (Salazar et al., 2000) included a cost analysis measure stating that the in-hospital rehabilitation intervention (experiment) implemented was less cost-effective than the home-based rehabilitation intervention (control) and argued that their trial identified the therapeutic benefits of home-based therapy that can be evaluated in future studies.

Table 4.2 CASP Methodological Appraisal Outcome

Authors	Cicerone et al., 2008	Constantinidou et al., 2008	Salazar et al., 2000	Twamley et al., 2014 and 2015	Vanderploeg et al., 2008
Questions					
1. Is the study focused?	✓	✓	✓	✓	✓
2. Randomisation	✓	✓	✓	✓	✓
3. Accountability	✓	✓	✓	✓	✓
4. Blinding	✓*	✓*	✗	✗	✓*
5. Similar groups used	✓	✓	✓#	✓#	✓
6. Equal treatment of intervention arms	✓	✗	✗	✓	✓
7. Treatment effect size (all outcomes)	ES _S ; ES _M	ES _M - ES _L , ES _S	ES _S	ES _S - ES _M (2014) ES _M - ES _L (2015)	ES _S , ES _L
8. Precision of the estimate of the treatment effect	P _H	P _H	P _L	P _H	P _H
9. Application of the results to local population or own context	✗	✗	✗	✗	✗
10. Consideration for clinically important outcomes	✗	✗	✓	✓	✓
11. Benefits worth the cost	✓	✓	✓	✓	✓

✓ - means question was answered "yes"; ✗ - means question was answered "no"; ES_S - Small Effect Sizes; ES_M - Moderate Effect Sizes; ES_L - Large Effect Sizes; P_H: High Precision; P_L: Low Precision, * - single blinded (patient, therapist or outcome assessors), # - 1 and more baseline characteristics different between groups.

4.2.2 RE-AIM Framework Appraisal of the Implementation of the Interventions Outcome

All six studies (n=6, 100%) were included after appraisal with the RE-AIM as they scored between 79% and 93%. With regards to the reach of the intervention (absolute number, proportion, and representativeness of individuals who are willing to participate in the intended intervention) all studies [n=6, 100%] reported on the inclusion and exclusion criteria for participation and the

participation rate, as set out in Table 4.3 following. However, with regards to the representativeness of the target population one study [n=1, 17%] (Constantinidou et al., 2008) did not report on this as the author did not document or completely describe the population in terms of gender and therefore was considered to not have reported on the representativeness of the sample participants. All studies [n=6, 100%] reported on all aspects related to the effectiveness of the intervention (intended objectives, limitations of the intervention, outcomes of intervention and attrition rate) and the adoption of the intervention (description of setting and adoption of intervention by participants or organisation reported and who implemented the intervention). In terms of implementation, the majority of studies [n=5, 83%] did not involve the staff/participants of the organisation/intervention in delivering the programme that may have had cost implications for the implementation of the interventions (Cicerone et al., 2008; Salazar et al., 2000; Twamley et al., 2014; Twamley et al., 2015; Vanderploeg et al., 2008). All studies [n=6; 100%] described the duration and frequency of the interventions and reported on the intended and delivered interventions. Regarding the evaluation of the maintenance of interventions (after 6-months) implemented, only three studies [n=3, 50%] (Salazar et al., 2000; Twamley et al., 2015; Vanderploeg et al., 2008) followed up on outcomes of the interventions at one year and also reported on the indicators used for intervention follow-up. One study [n=1, 17%] (Cicerone et al., 2008) scored one point for reporting on the indicators used for intervention follow-up but their follow-up was only up to 6-months post intervention.

Table 4.3 RE-AIM Appraisal Outcomes (RE-AIM Items and Description Adopted from Gaglio et al., 2013).

AUTHOR		Cicerone et al. (2008)	Constantinidou et al. (2008)	Salazar et al. (2000)	Twamley et al. (2014)	Twamley et al. (2014)	Vanderploeg et al. (2008)
ITEM	DESCRIPTION (SCORE 1 = YES or 0 = NO)						
R: REACH	<ul style="list-style-type: none"> • “Does the article indicate who the programme is intended for (inclusion and exclusion criteria)?” • “Does the article report on the representativeness of the target population?” • “Does the article report on participation rate?” 	1 1 1	1 0 1	1 1 1	1 1 1	1 1 1	1 1 1
TOTAL SCORE	3	3	2	3	3	3	3
E: EFFECTIVENESS	<ul style="list-style-type: none"> • “Did the programme achieve the intended objective?” • “Do they report on the limitations of the intervention?” • “Reports on at least one outcome of the intervention.” • “Reports on attrition.” 	1 1 1 1	1 1 1 1	1 1 1 1	1 1 1 1	1 1 1 1	1 1 1 1
TOTAL SCORE	4	4	4	4	4	4	4
A: ADOPTION	<ul style="list-style-type: none"> • “Is the setting clearly described?” • “Does the evaluation report on the adoption of the intervention by the participants or the organisation?” • “Who delivered the programme? (NO SCORE – see narrative text in section 4.5.1.3)” 	1 1	1 1	1 1	1 1	1 1	1 1
TOTAL SCORE	2	2	2	2	2	2	2
I: IMPLEMENTATION	<ul style="list-style-type: none"> • “Describe the duration and frequency of the interventions?” • “Has the staff/participants of the organisation/intervention been involved in delivering the programme (cost implication?).” • “Reports on intended and delivered interventions.” 	1 0 1	1 1 1	1 0 1	1 0 1	1 0 1	1 0 1
TOTAL SCORE	3	2	3	2	2	2	2
M: MAINTENANCE	<ul style="list-style-type: none"> • “Does the article report on long-term effects of the intervention (after 6 months).” • “Do they report on the indicators used for intervention follow-up?” 	0 1	0 0	1 1	0 0	1 1	1 1
TOTAL SCORE		1	0	2	0	2	2
OVERALL SCORE	14	12	11	13	11	13	13
OVERALL PERCENTAGE	(100%)	86	79	93	79	93	93

4.2.3 Risk of Bias Assessment Outcome

All studies [n=6, 100%] were unable to achieve blinding of participants and personnel (performance bias) as described in Figure 4.3. Four studies [n=4, 67%] (Cicerone et al., 2008; Salazar et al., 2000; Twamley et al., 2014; Twamley et al., 2015) could not achieve blinding of the outcome assessments as they were self-reporting outcomes (detection bias). Three of these four studies [n=3, 50%] (Salazar et al., 2000; Twamley et al., 2014; Twamley et al., 2015) could also not blind the outcome assessors therefore data from objective measures were also not blinded.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias) self-reporting outcomes	Blinding of outcome assessment (detection bias) objective measure	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Cicerone et al. (2008)	Low	Low	High	High	Low	Low	Low	Low
Constantinidou et al. (2008)	Low	Low	High	Low	Low	Low	Low	Low
Salazar et al. (2000)	Low	Low	High	High	High	Low	Low	Low
Twamley et al. (2014)	Low	Low	High	High	High	High	Low	Low
Twamley et al. (2015)	Low	Low	High	High	High	High	Low	Low
Vanderploeg et al. (2008)	Low	Low	High	Low	Low	High	Low	Low

Figure 4.3 Risk of Bias Outcomes

While all studies [n=6, 100%] reported dropout or loss to follow-up, only three of the six studies (Twamley et al., 2014; Twamley et al., 2015; Vanderploeg et al., 2008) did not account for these participants in their analysis of outcomes measured and scored high for incomplete outcome data (attrition bias). Five studies [n=5, 83%] also had other bias which could be attributed to the fact that these studies were either unblinded with the use of block randomisation (Salazar et al., 2000) or not completely blinded with the use of block randomisation (Cicerone et al., 2008; Twamley et

al., 2014; Twamley et al., 2015; Vanderploeg et al., 2008) but still scored low for this bias as even though they used block randomisation they reported no significant difference between intervention and control groups at baseline. Besides performance, detection, attrition and other bias in the included three studies [n=3, 50%] (Cicerone et al., 2008; Constantinidou et al., 2008; Vanderploeg et al., 2008) had an overall low risk of bias.

4.3 Characteristics of Included Studies

The characteristics of the included studies are summarised in Table 4.4. All included studies [n=6, 100%] were conducted in the United States of America, which is classified as a well-developed country. The year of publication of these studies range from the year 2000 to 2015. It can be noted that the studies were released in clusters with each cluster being about seven years apart from each other. The setting in which the studies were conducted were mostly rehabilitation centres as well as acute based treating hospitals for military personnel from which the population was sourced. In four studies [n=4, 67%] the study duration (sample recruitment time) ranged from 1 – 5 years (Constantinidou et al., 2008; Salazar et al., 2000; Twamley et al., 2014; Twamley et al., 2015). Two studies [n=2, 33%] (Cicerone et al., 2008; Vanderploeg et al., 2008) did not state the specific study duration (sample recruitment time). The populations were recruited from a variety of different settings using different referral, selection and screening assessments for inclusion in the studies. The inclusion and exclusion criteria for selection of participants also varied between studies especially regarding the length of time since injury; TBI diagnosis; clinical criteria and outcomes of different types of assessments (functional and cognitive) conducted before inclusion in their studies. All six studies [n=6, 100%] randomly allocated participants but used different methods of randomisation including block randomisation.

Table 4.4 Characteristics of Included Studies

Author	Year	Country	Study Design	Study Duration	Recruitment Strategy	Sampling Participant Inclusion and Exclusion	Allocation of sample
Cicerone et al.	2008	USA	RCT	January 2003 - December 2006 (3-years)	clinically referred for post-acute rehabilitation, self-referrals, community referrals, primary recruitment through state wide support groups and organisation outreach for TBI, contact of community hospitals and physicians.	<p>Inclusion:</p> <ul style="list-style-type: none"> - medical records of TBI based on “primary source within 24 hours post injury” - at least 3-months’ post injury - ages 18 to 62 - adequate language comprehension and expression - judged to require comprehensive treatment for 4months - appropriate clinical presentation for either study intervention arm - able to attend the intervention treatment 3 days a week - informed consent (capability to do this was required) 	random allocation, “web-based interactive statistical calculation pages” was used for random allocation (www.statpages.org)
Constantinidou et al.	2008	USA	RCT	Not stated	residential rehabilitation centres that served as collaborating sites, a rolling admission process where participants were identified and selected based on inclusion and exclusion criteria, screened using assessments to test eligibility for inclusion	<p>Inclusion:</p> <ul style="list-style-type: none"> - adult male and female - 18 to 55 years of age - moderate to severe TBI as the primary diagnosis - scored VI and higher on the RLAS - must not have aphasia present - PTA resolution, scoring 76 and more on GOAT - enrolment in a residential comprehensive post-acute rehab programme - time since injury less than four years <p>Exclusion:</p> <ul style="list-style-type: none"> - penetrating head injury - diagnosis of stroke at any time - premorbid learning disability or central nervous system disorder - major depression documented - other significant psych disorders documented - current Beck Depression II score must be 25 or more - substance abuse - deficits in auditory comprehension or word finding issues - English as a second language - colour blindness 	randomly assigned. project investigators were off location and did not have direct contact with participants when doing the assignment

Salazar et al.	2000	USA	RCT-parallel group trial	January 1992 – February 1997 (5-years)	273 consecutive hospitalised TBI patients who were referred to the Walter Reed Army Medical Center	Inclusion: <ul style="list-style-type: none"> - moderate to severe closed head injury - TBI within 3-months of randomization - cognitive Level 7 on RLAS - active duty military member - home setting required with at least one responsible adult available - independent ambulation - no other severe disability or prior severe TBI that would affect RTW Exclusion: <ul style="list-style-type: none"> - mild TBI 	Blocked randomisation was done by an independent statistician using variable-sized blocks (2:1 weighting for first 40 and 1:1 for last 79) to prevent investigators from guessing the code.
Twamley et al.	2014 and 2015	USA	Pilot RCT	1-year	Veterans at the VA San Diego Healthcare System Wellness and Vocational Enrichment Clinic, TBI Cognitive Rehabilitation Clinic, Poly trauma Clinic, Neuropsychological Assessment Unit	Inclusion: <ul style="list-style-type: none"> - OIF/OEF veteran - mild to moderate TBI - documented impairment in at least one neuropsychological domain - unemployed but stating a goal to work Exclusion: <ul style="list-style-type: none"> - participants not meeting the above inclusion - current alcohol and/or substance abuse or dependence - participation in other intervention studies 	Randomisation by the principal investigator using a randomisation scheme generated by Randomization.com, with 50 participants in one block.
Vanderploeg et al.	2008	USA	RCT – intent to treat	Subjects recruited 1996-1999 and 2000 to end of study which is unclear as its not stated.	All patients admitted to the Commission for Accreditation of Rehabilitation Facilities-accredited acute inpatient rehabilitation brain injury programs at 4 participating Veterans Administration Medical Centres (Minneapolis, Palo Alto, Richmond, and Tampa)	Inclusion: <ul style="list-style-type: none"> - moderate to severe non penetration TBI within the preceding 6 months - cognitive level 5 to 7 on the RLAS - 18 years of age or older - active duty military member or veteran - anticipated length of needed acute interdisciplinary TBI rehab of 30 days or more Exclusion: <ul style="list-style-type: none"> - history of prior inpatient acute rehab for current TBI - history of prior moderate to severe TBI or other severe neurological or psych condition or stroke 	Randomised to the comparative treatments by an independent study statistician using random number tables

Abbreviations: GOAT =Galveston Orientation and Amnesia Test, OIF/OEF = Veterans of Operation Iraqi Freedom/Operation Enduring Freedom, PTA =Posttraumatic Amnesia , RLAS = Rancho Los Amigos Scale, RCT = Randomised Control Trial, TBI = Traumatic Brain Injury

4.4 Population and Sample Characteristics of Included Studies

The population size varied from as small as 49 to as large as 360 individuals with TBI, as seen in Table 4.5. Only two studies [n=2, 100%] (Salazar et al., 2000; Constantinidou et al., 2008) had unequal group sample sizes due to the method of recruitment and randomisation. Five studies [n=5, 83%] included military personnel or veterans (Cicerone et al., 2008; Salazar et al., 2000, Twamley et al., 2014; Twamley et al., 2015; Vanderploeg et al., 2008) and one study [n=1, 17%] (Constantinidou et al., 2008) included individuals with TBI from residential rehabilitation centres that were not all necessarily military personnel or veterans. All studies [n=6, 100%] included male and female adults (studies were limited to adult studies due to the interest in RTW in this review) and the mean age for the sample groups ranged between 25 and 39 years. The severity of TBI in individuals included in the studies was different. Three studies [n=3, 50%] (Cicerone et al., 2004; Twamley et al., 2014; Twamley et al., 2015) included all three levels of TBI severity and three studies [n=3, 50%] (Salazar et al., 2000; Constantinidou et al., 2008; Vanderploeg et al., 2008) included only moderate to severe TBI individuals. Three studies [n=3, 50%] reported on the causes of TBI (Constantinidou et al., 2008; Salazar et al., 2000 and Vanderploeg et al., 2008) with motor vehicle accidents as the primary cause of TBI in their study populations. The majority of studies [n=5, 83%] included mostly males. One study [n=1, 17%] (Constantinidou et al., 2008) did not comment on the percentage of males and females in his study.

Table 4.5 Population and Sample Characteristics of Included Studies

Author	TBI Severity and Causes	Population and Sample Size	Worker Role	Age (years)	Gender (percentage [%])
Cicerone et al. (2008)	Mild (12%) Moderate-severe (88%) (cause of injury not stated)	N=68 (I: n=34) (C: n=34)	military personnel in acute recovery	18-62 years (I: 34.5 [SD±12.4]) (C: 38.7 [SD±11.1])	(I: [Male]: n= 62%) (C: [Male]: n =74%)
Constantinidou et al. (2008)	Moderate-severe (70% Motor Vehicle Accidents and 30% Falls)	Trial Start N=49 (I: n=29) (C; n=20) Trial End: N=35 (I: n=21) (C: n=14)	TBI individuals from residential rehabilitation centres	18-55 years (I: R=19 to 54 years, mean = 32.1 [SD±11.67]) (C: R=19 to 48 years, mean = 27.57 [SD±9.85])	Males and females included. % male versus female not documented in study
Salazar et al. (2000)	Moderate to Severe (59% Motor Vehicle Accidents; 29% Alcohol-related Injury and 18% Assault)	N=120 (I: n=67) (C: n=53)	active duty military personnel	(I: 25 [±6.63]) (C: 26 [±6.22])	(I: [Male]: n= 93%) (C: [Male]: n =96%)
Twamley et al. (2014 and 2015)	Mild to Moderate (cause of injury not stated)	N=50 (I: n=25) (C: n=25)	veterans	Mean population age = 32 years (I: 29.4 [± 6.2]) (C: 34.3 [±7.4])	Male = 96% (I: [Male]: n=93.8%) (C: [Male]: n=94.4%)
Vanderploeg et al. (2008)	Moderate-severe (67% Motor Vehicle Accidents; 14% Falls; 7% Blunt Trauma; 3% Sports and Training Accident and 9% Unknown Cause)	N=360 (I: n=180) (C: n=180)	adult veterans or active military service members	≥18 years (mean population age:32.4 [±13.2]) (I: 33.2 [±13.5]) (C: 31.7 [±12.9])	Male = 93% (I: [Male]: n= 91.7%) (C: [Male]: n =94.4%)

Abbreviations: C = Control; I = Intervention; R= Range; SD = Standard Deviation; TBI = Traumatic Brain Injury

4.5 Interventions to Improve EF in TBI Individuals for RTW

4.5.1 Executive Functioning (EF) Interventions Implemented

All six studies implemented an intervention that included some component of executive function as a treatment. The combination of EF components included in each intervention differed between the six study trials included in the review as set out in the following Table 4.6. However, the interventions implemented in all six study trials included EF treatments specifically for cognitive deficits. Two studies [n=2, 33%] (Cicerone et al., 2008; Salazar et al., 2000) included EF interventions for improving **planning and organisation** and four other studies [n=4, 67%] (Constantinidou et al., 2008; Twamley et al., 2014; Twamley et al., 2015; Vanderploeg et al., 2008) included EF interventions for improving **memory and attention**. Two studies [n=2, 33%] (Twamley et al., 2014; Twamley et al., 2015) included executive functioning, which was mainly **problem solving and self-monitoring**. Two studies [n=2, 17%] (Cicerone et al., 2008; Constantinidou et al., 2008) included **problem solving and functional skills** and two other studies [n=2, 33%] (Salazar et al., 2000; Vanderploeg et al., 2008) included **pragmatic speech and communication**. Besides these similarities in some of the cognitive related EF interventions between studies each study also included a number of other cognitive related EF components for treatment thus the difference in combinations of EF interventions implemented in the experimental groups. Furthermore, one study [n=1, 17%] (Cicerone et al., 2008) included EF interventions for **emotional regulation** such as **emotional difficulties** and **behavioural regulation** in terms of **interpersonal behaviour**. The latter was facilitated by using the Cognitive Energy Scale that was specifically developed for the Intensive Cognitive Rehabilitation Program (ICRP) intervention implemented in the study. One other study [n=1, 17%] (Constantinidou et al., 2008) included **psychosocial therapy**, and another final study [n=1, 17%] (Salazar et al., 2000) included

psychotherapy as part of the **psychological component of executive function** affected by TBI. In addition, Salazar et al. (2000) combined the components of EF in their intervention with **work integration therapy** in a therapeutic environment and Twamley et al. (2014, 2015) combined components of EF in their intervention with **supportive employment**. All six studies [n=6, 100%] included different interventions for their control groups. The majority of studies [n=4, 83%] except the two studies (Twamley et al., 2014; Twamley et al., 2015) included some form of EF intervention as part of their comparison (control) interventions.



Table 4.6 Interventions Used in the Intervention (Experimental) Group versus the Comparison (Control) Group

Author	Intervention	
	Intervention (Experimental Group)	Comparison Intervention (Control Group)
Cicerone et al. (2008)	<p>Executive function components</p> <p>“Intensive Cognitive Rehabilitation Program (ICRP) – based on principles of comprehensive holistic neuropsychological rehabilitation emphasising the integration of interventions for cognitive deficits (metacognition: self-monitoring and self-regulation), emotional difficulties (emotional regulation), interpersonal behaviours (facilitated by using the Cognitive Energy Scale specifically developed for the ICRP) and functional skills within the context of the therapeutic environment. Emphasis was on performance feedback and active self-evaluation throughout the group process. Treatment was centred on participants’ adaptation to the chronic limitations imposed by their injury to alleviate restrictions in everyday functioning. The programme was used in 4 phases of treatment similar to that described by Ben-Yishay and Gold:”</p> <p>“Week 1-4: included strategies to maintain attention, didactic and experiential exercises to facilitate awareness of limitations and the use of compensatory strategies.”</p> <p>“Week 5-8: Exercises focused on task analysis, planning and organization, goal setting, and social problem solving, emphasis on relating the problems and compensations experienced within treatment sessions to similar situations in participants’ daily activities.”</p> <p>“Week 9-12: focused on independent application and carryover of compensatory strategies, refinement of participant’s goals and expectations, and finding the benefits of new roles.”</p> <p>“Week 13-16: focused on generalisation of strategies to everyday functioning, positive acceptance of role limitations, and transition to the community.”</p>	<p>Executive function components</p> <p>“Standard Multidisciplinary Neuro-rehabilitation - Standard conducted as a comprehensive, interdisciplinary day treatment programme and was designed to be responsive to the stage and rate of recovery after brain injury. Treatment orientation was largely guided by discipline-specific interventions targeting specific deficit areas, including retraining of discrete cognitive functions. The structure of Standard Neurorehabilitation Program treatment consisted of individual therapies including physical therapy, occupational therapy, and speech therapy. All patients were followed by a neuropsychologist, and most participants received 1 hour a week of individual NP treatment.”</p>
Constantinidou et al. (2008)	<p>Executive function components: Individual Therapy</p> <p>“Categorization Program (CP) – “based on theories of implicit and explicit categorisation systems. Tasks were grouped into two different major parts: 1) recognition and categorisation of every object and 2) new category learning. Principles of learning, concept formation and rehabilitation were incorporated to develop the hierarchical tasks. They incorporated retraining therapy programmes to improve attention, memory, problem solving and also integrated functional skills such as time and money management and psychosocial training as part of their treatment regime.”</p>	<p>Executive function components: Individual Therapy</p> <p>“Standard treatment regimen typically followed at their rehabilitation site.”</p>
Salazar et al. (2000)	<p>Executive Function Components: Group Therapy</p> <p>“In-hospital rehabilitation: EF plus integrated work therapy - Specific group therapies were orientated around EF skills of planning and organisation as well as milieu (social environment and integration). Other therapies given were coping skills therapies, pragmatic speech, and psychotherapy and community re-entry. Participants also underwent integrated work therapy done by the occupational therapist.”</p>	<p>Executive Function Components: Individual Therapy</p> <p>“Home Rehabilitation: Education and Counselling only -patient together with their families received TBI education and individual counselling from a psychiatric nurse.”</p>
Twamley et al. (2014 and 2015*)	<p>Executive Function Components: Individual Therapy</p> <p>“Supported employment and CogSMART - a twelve week compensatory cognitive training intervention focusing on habit learning and compensatory strategies to improve post concussive symptoms (e.g., sleep disturbance, fatigue, headaches, and tension), prospective memory, attention and vigilance, learning/memory and executive functioning (including mainly problem solving and self-monitoring).”</p>	<p>*No Executive Function Components: Individual Therapy</p> <p>“Enhanced supported employment”</p>

Vanderploeg et al. (2008)	Executive Function Components: Individual Therapy “Cognitive-didactic treatment – implementation of interventions and approaches developed by Sohlberg and Mateer to target 4 cognitive domains often impaired by TBI: attention, memory, executive functioning and pragmatic communication . Subjects participate in progressively more difficult paper-and-pencil or computerised cognitive tasks in one on one cognitive therapy sessions. A trial and error learning approach is used.”	Executive Function Components: Group Therapy “Functional-experiential treatment by Giles and colleagues. Experiential interventions, Errorless learning, Focus on developing useful functional abilities or skills, Interventions target functional behaviours, such as the Compensation techniques, Environmental management (vs self-management) and Functional task-specific checklists. It uses real life performance situations and common tasks to remediate and compensate for functional deficits after TBI. It was implemented in group settings within the natural environment. Treatment was focused on learning through doing functional daily activities using an errorless treatment strategy in real life.”
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Abbreviations: CogSMART = Cognitive Symptom Management and Rehabilitation Therapy, CP = Categorisation Programme, EF = Executive Function/ing, ICRP = Intensive Cognitive Rehabilitation Programme

*This is a one year follow up on the original 14-week intervention on Twamley et al. (2014)



4.5.2 Characteristics of the Interventions Implemented

The characteristics of the interventions implemented are described in Table 4.7 in terms of whether therapy was implemented individually, in groups or both in either the intervention or control groups, the duration of the interventions that were implemented in each treatment group and the healthcare professionals/implementers who implemented the interventions.

4.5.2.1 Individual or Group Therapy in the Intervention Groups

As depicted in Table 4.7, the studies either used individual, group or a combination of individual and group therapy when implementing the interventions (experimental and control). Three studies [n=4, 67%] (Constantinidou et al., 2008; Twamley et al., 2014; Twamley et al., 2015) implemented individual therapy for both groups. One study [n=1, 17%] (Cicerone et al., 2008) used a combination of individual and group therapy for both groups while another study [n=1, 17%] (Salazar et al., 2000) used a combination of individual and group therapy in their experimental group versus individual therapy in their control group and a final study [n=1, 17%] (Vanderploeg et al., 2008) used individual therapy in the experimental group versus group therapy in the control group. The way in which interventions were implemented were thus different between studies.

4.5.2.2 Duration of Interventions Implemented

The duration of interventions implemented differed between trial studies and varied between 16 weeks and 26-84 calendar days (approximately 2-months). Salazar et al. (2000) had the lowest duration of intervention given and while Vanderploeg et al. (2008) had the second lowest duration of intervention, it was noted that their intervention was given daily. Twamley et al. (2014, 2015) had a longer duration of intervention, but it was noted that their intervention was only given once a week for one hour with an additional 2 hour supported employment visit. Participants in Constantinidou et al. (2008) received the intervention for the longest duration that averaged to 4.5

hours per week. It was noted in their study that the control group received a longer length of treatment than the experimental group (Constantinidou et al., 2008). Participants in Cicerone et al. (2008) received 15 hours of intervention a week over three days for 16 weeks. In two studies [n=2, 33%] the treatment duration was different for the intervention group versus the control group (Constantinidou et al., 2008; Salazar et al., 2000). The treatment durations were thus different for each study trial included in this review.

4.5.2.3 Health Practitioners (Implementers) Involved in Intervention Implementation

Each trial study used a number of different individual healthcare practitioners or a team of healthcare practitioners. Two studies [n=2, 33%] (Salazar et al., 2000; Vanderploeg et al., 2008) specifically mentioned the use of occupational therapists within the team that carried out their interventions and are also the only two studies that stated the use of a variety of therapists in their intervention process. The majority of studies [n=5, 83%] (Cicerone et al., 2008, Constantinidou et al., 2008; Twamley et al., 2014; Twamley et al., 2015; Vanderploeg et al., 2008) included speech and language therapists or pathologists in their intervention as therapists and/or assessors. Two studies [n=2, 33%] (Twamley et al., 2014; Twamley et al., 2015) made use of two supported employment specialists and one study [n=1, 17%] (Cicerone et al., 2008) only stated the use of a primary therapist but did not describe their medical background or profession. Thus, while there were studies that used similar teams of therapists, others used one or more individuals from different professions, showing a notable variability in the implementers used across the included studies.

Thus, heterogeneity within the implementation (individual or group therapy, duration of therapy and implementers of the therapy) of interventions between studies exists.

Table 4.7 Type of Therapy, Implementers and Duration of the Experimental versus Control Interventions

Author	Type of Therapy		Implementer		Duration	
	Experimental	Control	Experimental	Control	Experimental	Control
Cicerone, 2008	Combination of Individual & Group Therapy	Combination of Individual & Group Therapy	Primary therapist that implemented all treatments and a neuropsychologist	physical therapists, occupational therapists, speech therapists, neuropsychologist,	15 hours per week for 16 weeks – Four Phases with each phase = 4weeks. 15 hours of individual & group therapies conducted 3 days a week. 11 hours of group treatment a week: cognitive group (2h/d, 3d/wk), communication group conducted twice a week (2h 1 day, 1h 1 day), life skills group (1h/d, 2d/wk) and 3 hours of individual therapy from a primary therapist.	15h/wk for 16 wks included: 1h a week of individual neuropsychological treatment, 1h of psychologic counselling & 1h of recreation therapy, vocational or educational counselling. Received a limited number of group treatments (≤3h/wk). Amount & combination of specific treatments for each participant in the Standard NP condition varied based on individual needs & routine clinical decision-making.
Constantinidou, 2008	Individual Therapy	Individual Therapy	Trained clinicians including Neuropsychologist, Speech and language pathologists/team	Trained clinicians including Neuropsychologist, Speech and language pathologists/team	13 weeks for CP study protocol. 57 hours of individual cognitive treatment, averaging between 2 and 3 hours per week on the CP-related tasks, for a total of 27 hours of CP treatment and about 4.5 hours of total individual therapy per week.	18 weeks' average of 80 hours of individual cognitive treatment over an 18-week period, averaging 4.5 hours of individual therapy per week.
Salazar, 2000	Combination of Individual & Group Therapy	Individual Therapy	Independent Team: Board-Certified Neuropsychologist experienced in milieu, certified occupational therapist, speech pathologist & rehabilitation assistants. Physical therapy, neurological & psychiatric consult as needed	Psychiatric Nurse and Family/Caregiver to assist with home-based therapy.	8 week in hospital rehabilitation.	8 weeks home-based rehabilitation receiving 30 minute weekly calls offering support.
Twamley, 2014, 2015*	Individual Therapy	Individual Therapy	One supported employment specialist	Another supported employment specialist	14wks plus 1-year supported employment for attaining competitive employment. CogSMART for 1h/wk in addition to standard supported employment (2visits/wk).	14 weeks plus one years supported employment for attaining competitive employment. Enhanced supported employment (2 visits/wk) to control for the nonspecific therapeutic factors provided in CogSMART.
Vanderploeg, 2008	Individual Therapy	Group Therapy	Independent team of certified/licensed speech language, occupational & physical therapists & neuropsychologists.	Independent team of certified/licensed speech language, occupational & physical therapists & neuropsychologists.	1.5 to 2.5h daily protocol specific therapy plus another 2 to 2.5h daily of occupational & physical therapy. (1.5-2.5h daily) 26-84 calendar days. Discharged appropriately after 60 days, standard CARF accredited rehabilitation of 3h of formal therapy with no experimental treatment if additional treatment needed.	1.5 to 2.5 hours daily of protocol specific therapy plus another 2 to 2.5 hours daily of occupational and physical therapy. (1.5-2.5 hours daily) 26-84 calendar days.

Abbreviations: CogSMART = Cognitive Symptom Management and Rehabilitation Therapy, CP = Categorisation Programme, d = day, h = hour, NP = Neuropsychological Programme, wk/s = week/s

* Twamley et al. (2015) = this was a 12month follow-up of Twamley et al. (2014) thus the details for type of therapy, implementer and duration are the same.

4.6 Evaluation of the Implementation of Interventions for

Improving Executive Functioning in TBI Individuals for RTW

The six included studies evaluated a number and variety of primary and/or secondary EF and Quality of Life (QOL) outcomes of interest including RTW. This section reports on the outcomes measured in each study in 4.6.1 and includes the results of these outcomes measured in 4.6.2 with a focus on RTW as the main outcome of interest for the review.

4.6.1 Outcome Measures used to Evaluate the Interventions Implemented

4.6.1.1 Return to Work (RTW)

The most common method of evaluating **RTW** was the use of structured telephonic interviews, in person evaluations and extracting RTW outcomes from patient records as recorded in Table 4.8. The majority of studies [n=4, 67%] (Salazar et al., 2000; Twamley et al., 2014 and 2015 and Vanderploeg et al., 2008) used either one or both of the latter and measured RTW as a yes/no dichotomous variable in percentage as their primary outcome. Vanderploeg et al. (2008) also include return to school (tertiary level).

Two studies [n=2,33%] included productivity (reported as mean and standard deviation) as a measure of RTW using the standardised CIQ(prod) as their primary outcome (Cicerone et al., 2008; Constantinidou et al., 2008). The productivity variable measured by the CIQ has three questions with specific responses related to work (not working/not looking for work, not working/looking for work, retired due to age, part time or full time work), school (no school, part time or fulltime schooling [tertiary level]) and volunteer work (no volunteer work, 1-4 times a week or 5 and more times a week) respectively. The productivity variable is calculated or scored

depending on the combination of answers for the three questions. The scores from the specific combinations are from 0 to 5 with a higher score relating to higher productivity (see Appendix M).

One study [n=1, 17%] (Cicerone et al., 2008) measured RTW in percentage using the standardised Vocational Integration Scale (VIS) that is a self-reporting productivity measure with a 5-point Likert-scale. The five scales are as described by Cicerone et al. (2008, pp. 2243-2244) as “(1) unemployed, (2) sheltered employment, (3) supported employment (i.e., job coaching/other permanent supports), (4) transitional employment (education, job coaching/other temporary supports), and (5) competitive employment”. Cicerone et al. (2008) reported that they changed the ratings to a dichotomous yes and no variable to classify the TBI participants as engaged in either community-based employment (scales 3-5) or as unemployed (scale 1 and 2) and presented the data in percentages. Cicerone et al. (2008) used the VIS as their secondary outcome.

One other study [n=1,17%] (Salazar et al., 2000) reported on an outcome of fitness for duty defined as all patients still on active military duty/who received a normal discharge from the service and excludes those with medical discharge or whose discharge was pending, measured in percentage at different time periods post-intervention. Four studies (n=4, 67%) reported on RTW as either yes or no in percentages (Salazar et al., 2000; Twamley et al., 2014; Twamley et al., 2015; Vanderploeg et al., 2008) and one of these studies [n=1, 17%], Vanderploeg et al. (2008) described the total percentage for RTW or school and did not separate the results for work and school. In addition, the latter four studies [n=4, 67%] (Salazar et al., 2000; Twamley et al., 2014; Twamley 2015; Vanderploeg et al., 2008) also described the type of RTW data that was collected such as work

hours, weeks worked, paid or part-time employment or the exclusion of sheltered employment but did not report on this specific data, only the percentage of participants that returned to work.

4.6.1.2 Executive Function (EF)

A variety of **Executive Function (EF) outcome measures or assessments** were used to evaluate the different components of cognitive, behavioural, affect/emotional and psychological deficits assessed in the TBI individuals based on the executive functioning components that were assessed at baseline and treated in the intervention (experimental) groups in the trial studies. The EF outcome measures included **neuropsychologic performance tests, functional outcome tests, perceived self-efficacy** (social, cognition, emotional), **categorisation and probe tests and post concussive symptoms** using the **Neurobehavioral Symptom Inventory (NSI)**.

Table 4.8 shows that all studies [n=6, 100%] used a variety of **Neuropsychologic Performance tests** for assessing the cognitive, behavioural, affect/emotional and psychological components of EF affecting TBI individuals that were addressed by the interventions implemented in each study; however, there were some common tests used among the included six studies. Half of the studies included the NP tests as their primary outcome (Constantinidou et al., 2008; Twamley et al., 2014; Twamley et al., 2015) and the other half (Cicerone et al., 2008; Salazar et al., 2000; Vanderploeg et al., 2008) as their secondary outcomes.

The majority of studies included the CVLT [n=5, 83%] (Cicerone et al., 2008; Constantinidou et al., 2008; Twamley et al., 2014; Twamley et al., 2015; Vanderploeg et al., 2008) and the Wisconsin Card Sorting Test (WCST) [n=5, 83%] (Constantinidou et al., 2008; Salazar et al., 2000; Twamley

et al., 2014; Twamley et al., 2015; Vanderploeg et al., 2008) respectively. Two studies [n=2, 33%] (Twamley et al., 2014; Twamley et al., 2015) included the D Kaplan Test, three studies used the trail making tests B for higher cognition (Cicerone et al., 2008; Constantinidou et al., 2008; Vanderploeg et al., 2008) and two of these studies also used the trail making tests A for attention and memory (Cicerone et al., 2008; Constantinidou et al., 2008). One study [n=1, 17%] (Salazar et al., 2000) used a completely different set of neuropsychological tests than the other five studies except for the WCST and the Weschler Memory Scale.

One study [n=1, 17%] (Constantinidou et al., 2008) also included the 8 Levels of the Categorization Program (CP) namely Part A that included Level 1: Perceptual feature training and application, Level 2: Similarities and Differences Level 3: Functional Categorization, Level 4: Analogies, Level 5. Abstract word Categorization and Part B. New category learning tasks including Level 1: Progressive rule learning 1, Level 2: Progressive rule learning 2, Level 3: Progressive rule learning 3 and used CP test one and two to assess Level 2 and 5 and the Probe Tests 1-3 to assess Part B of the CP intervention.

Three studies assessed functional outcomes of which two used the CIQ social and emotional scales as primary outcomes (Cicerone et al., 2008; Constantinidou et al., 2008) and one study used a variety of other functional outcome measures as secondary outcomes including behaviour, mood and motivation as part of behavioural and psychological functioning (Vanderploeg et al., 2008).

Only one study [n=1, 17%] (Cicerone et al., 2008) included **Perceived Self Efficacy (SEsx)** (Social, Cognition & Emotional) and the **Mayo-Portland Adaptability Inventory III (MPAI-3)**

(Constantinidou et al., 2008) as part of their secondary and primary EF outcomes in their studies respectively. Therefore, heterogeneity in the EF outcomes used exists.

4.6.1.2 Quality of Life (QOL)

The majority [n=5, 83%] of the included studies also used **Quality of Life (QOL) outcome measures** to assess various aspects of QOL such as social and behavioural/emotional aspects or life satisfaction following EF interventions (Cicerone et al., 2008; Salazar et al., 2000; Twamley et al., 2014; Twamley et al., 2015, Vanderploeg et al., 2008) of which four used these as their primary outcomes (Cicerone et al., 2008; Twamley et al., 2014; Twamley et al., 2015, Vanderploeg et al., 2008).

Different QOL outcome measures were used in each trial study including the CIQ emotional and social scales, Perceived QOL Scales, QOL in Katz Adjustment Scale, QOL Interview-Brief Version for Global QOL (subjective judgment of global quality of life, rated by the participants on a 1 to 7 scale ranging from “terrible” to “delighted”) and Mean Satisfaction Scale and measured life satisfaction or social, cognitive and emotional scales or belligerence, antisocial behaviour, social withdrawal and apathy or a global quality of life scores.

One study [n=1,17%] measured independent living using the Functional Independence Measure (FIM) as a measure of QOL (Vanderploeg et al., 2008) (see Table 4.8). Therefore, heterogeneity in the QOL outcomes used exists.

Table 4.8 Outcome Measures Used in the Included Studies

Author	Outcome Measures		
	Return to Work	Executive Function	Quality of Life
Cicerone et al. (2008)	<p>i.) Community Integration Questionnaire Productivity Scale [CIQ (prod)] #</p> <p>ii.) Vocational Integration Scale [VIS]</p>	<p>i.) Neuropsychologic test battery to assess higher cognitive functioning, memory and attention:</p> <ul style="list-style-type: none"> - Booklet Category Test - California Verbal Learning Test-II (CVLT-II) - Memory functioning using the Total Acquisition Score and - Controlled Oral Word Association Test (COWAT) - Rey Complex Figure Test (RCFT) - immediate recall score - Trail Making Test A (TMT-A) - Attention and processing speed - Trail Making Test B (TMT-B) - Higher Cognitive Function <p>ii.) Perceived Self Efficacy (SEsx): Social, Cognition & Emotional</p> <p>iii) Functional Outcomes:</p> <ul style="list-style-type: none"> - Community Integration Questionnaire Social [CIQ (social)] and Emotional [CIQ (emotional)] Scales# 	<p>i.) Perceived Quality of Life – life satisfaction (PQOL)#</p>
Constantinidou et al. (2008)	<p>i.) Community Integration Questionnaire Productivity Scale [CIQ (prod)] #</p>	<p>i.) The 8 Levels of the Categorization Program (CP) #</p> <ul style="list-style-type: none"> - Category Program Test 1 (CP Test 1) - Category Program Test 2 (CP Test 2) <p>ii.) Neuropsychologic tests & Functional Outcomes#</p> <ul style="list-style-type: none"> - Booklet Category Test - California Verbal Learning Test II (CVLT-II) - Control Oral Word Association Test (COWAT) - Rey Complex Figure Test (RCFT) - Scales of Cognitive Ability for Traumatic Brain Injury (SCATBI) - Perception and discrimination, organization, and reasoning scales - Symbol Digits Modalities Test (SDMT) - Trail Making Test A (TMT-A) - Attention and processing speed - Trail Making Test B (TMT-B) - Higher Cognitive Function - Wechsler Abbreviated Scale of Intelligence (WASI) - Wechsler Memory Scale III (WMSIII) - Digit span forward and backwards and visual span forward and backwards - Wisconsin Card Sorting Test (WCST) - Woodcock-Johnson III (WJIII) - picture recognition, spatial relations, analysis and synthesis, concept formation, decision speed, and verbal comprehension subtests (tests of cognitive abilities) <p>iii) Functional Outcomes#</p> <ul style="list-style-type: none"> - Community Integration Questionnaire Social [CIQ (social)] and Emotional [CIQ (emotional)] Scales# - Mayo-Portland Adaptability Inventory III (MPAI-3) 	<p>None</p>
*Salazar et al. (2000)	<p>i) RTW# measured as a percentage as yes employed or no unemployed. Interview, Military Records or Both.</p> <p>Work defined as full-time (\$35 h/wk) or part-time (\$35 h/wk) gainful military or civilian employment.</p>	<p>i.) Neuropsychologic test performance –including cognitive, psychiatric, and neurological outcomes (cognition, behaviour, mood):</p> <ul style="list-style-type: none"> - Auditory Consonant Trigrams (ACT) - Buschke Selective Reminding Test (BSRT) - Halstead-Reitan Neuropsychological Impairment Index (H-RNII) - major depression, generalized anxiety, aggression (verbal or physical) - Paced Auditory Serial Addition Test (PASAT) - Trahan Continuous Visual Memory Test (TCVMT) 	<p>i.) Quality of Life (QOL) in (Katz Adjustment Scale):</p> <ul style="list-style-type: none"> - Belligerence (aggressive/warlike behaviour), - Social irresponsibility, -Antisocial behaviour, -Social withdrawal, and -Apathy scores

	ii.) Fitness for Duty [#] measured in percentage. Fitness for duty: all patients still on active military duty/received a normal discharge from the service, excluded those with medical discharge or whose discharge was pending.	- Wechsler Memory Scale Revised (WMS-R) - Wisconsin Card Sorting Test (WCST)	
Twamley et al. (2014)	i) RTW [#] measured as a percentage as yes employed or no unemployed. (Data regarding competitive work attainment, hours worked, and wages earned were collected weekly for 14weeks).	i.) Post concussive Symptoms [#] - Neurobehavioral Symptom Inventory (NSI) ii.) Neuropsychologic test performance [#] - California Verbal Learning Test-2nd edition (CVLT-II) - Long Delay Free Recall Z-Score; Trials 1-5 Learning T-Score), - Clinician-Administered Posttraumatic Stress Disorder Scale (CAPS) - Delis-Kaplan Executive Function System (D-KEFS) - Hamilton Depression Rating Scale (HAM-D) - Memory for Intentions Screening Test (MIST), - Wechsler Adult Intelligence Scale-3rd edition (WAIS-III), - Wisconsin Card Sorting Test-64 card version (WCST-64)	i.) Quality of Life (QOL) Interview-Brief Version [#] for Global QOL
Twamley et al. (2015)	i) RTW [#] measured as a percentage as yes employed or no unemployed. (Data regarding competitive work attainment, hours worked, and wages earned were collected weekly for 14weeks).	i.) Post concussive Symptoms [#] - Neurobehavioral Symptom Inventory (NSI) ii.) Neuropsychologic test performance [#] - California Verbal Learning Test (CVLT); - Delis-Kaplan Executive Function System (D-KEFS); - Memory for Intentions Screening Test (MIST); - UCSD Performance Based Skills Assessment (UPSA); - Wechsler Adult Intelligence Scale-3rd Edition (WAIS-III); - Wisconsin Card Sorting Test-64 card Version (WCST-64).	i.) Quality of Life (QOL) interview -Brief Mean Satisfaction Scale [#]
Vanderploeg et al. (2008)	i) RTW [#] measured as a percentage as yes employed or no unemployed (current status of paid employment or school enrolment, either full or part time, not sheltered workshop) (RTW /School mostly by in-person evaluations and rest by structured telephonic interview).	i.) Neuropsychologic test performance - California Verbal Learning Test-2nd edition (CVLT-II): Learning Acquisition Sum of 5 Learning Trials (CVLT), Long Delay Free Recall (total words recall out of 16) (CVLT) and Delay Recognition Discriminability - Lexical Fluency (total words in three 60-s trials) - Semantic Fluency (total Animals and Supermarket items) - Trail-Making Test Part B (TMT-B) - total seconds to completion - Wechsler Memory Scale - Revised Visual Reproduction I (WMS-RVRI) - Wechsler Memory Scale - Revised Visual Reproduction II (WMS-RVRI) - Wisconsin Card Sorting Test (WCST) - total perseverations ii) Functional Outcomes: - Apathy Evaluation Scale – motivation - Disability Rating Scale Score (DRS) at discharge post Rx. - Functional Independence Measure (FIM) - motor and cognitive scores - Neurobehavioral Rating Scale (interview version) - self-perceived memory problems - Present State Exam used to capture mood and behaviour	i.) Functional Independence Measure (FIM) - Living Independently [#] – 1-year post treatment ability to live independently with less than 3 hours of assistance a week. Life satisfaction and change in marital status as well as angry behaviour and getting away from the house were captured by self-ratings through clinical interview and history questions.

Primary outcomes measured. * - This study also estimated treatment costs between groups as an outcome.

4.6.2 Outcome Results of the Intervention Implementation

4.6.2.1 Return to Work (RTW)

Three studies [n=3, 50%] (Salazar et al., 2000; Twamley et al., 2015; Vanderploeg et al., 2008) assessed long-term (12-months' post-treatment/intervention) RTW (yes/no; percentage of individuals who returned to work). All three studies showed no significant differences ($p > 0.05$) between the intervention and control groups with regard to RTW at 12-months as displayed in Figure 4.4.

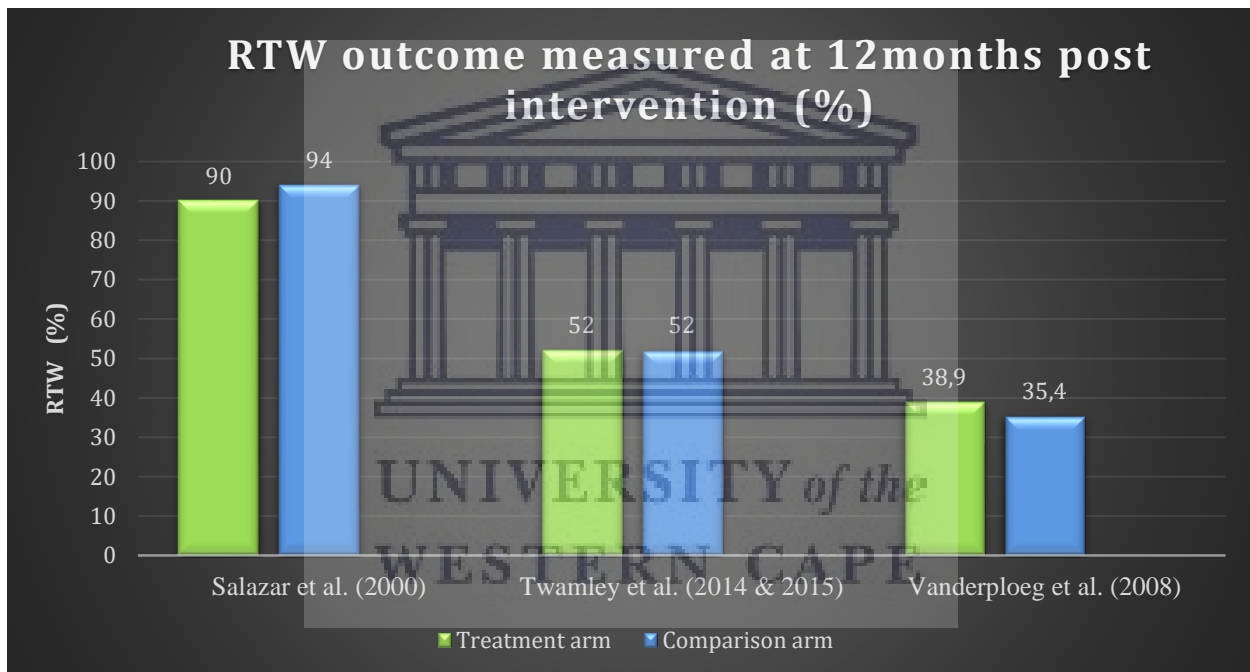


Figure 4.4 RTW Outcome 12-months Post Intervention Between Groups

One study [n=1, 17%] (Vanderploeg et al., 2008) included a baseline assessment of RTW/school (i.e., current status of paid employment or school enrolment, either full or part time, not sheltered workshop) and reported an almost equal percentage of TBI individuals who were employed or in school before the injury. Vanderploeg et al. (2008) reported the percentage of return to work or school as 38.9% for the cognitive (experimental) arm and 35.4% for the functional (control) arm ($X^2_{1, n=329} = 0.45, p = 0.50$). An exploratory subgroup analyses conducted by Vanderploeg et al.

(2008) on the RTW/school outcomes showed that younger participants less than 30 years of age in the cognitive arm had a higher rate of returning to work or school (53.3%) than younger participants in the functional arm (37.8%) at 1-year post treatment ($\chi^2_{1, n=190}=4.61, p<0.03$) (refer to Table 4.9).

Salazar et al. (2000) also measured fitness for duty between the groups at 12-months post treatment but found no significant difference between the intervention and control groups ($p>0.05$) as can be seen from the data in Table 4.9. However, in a post-hoc subset analysis of participants' who were unconscious for >1hour ($n=75$), Salazar et al. (2000) found a significant difference ($p=0.05$) in RTW between the two groups where the intervention in hospital rehabilitation group had higher rates of RTW than the control home based rehabilitation group.

Twamley et al. (2014) had a non-significant difference ($p=0.15$) in percentages between the participants in the supported employment – CogSMART intervention (50%) compared to the participants in the enhanced supported employment (26%) control group with a moderate effect size of $d=0.49$ that favoured the CogSMART with supportive employment intervention for the attainment of competitive work within 4 weeks compared to the control group that only had supportive employment. There were no group differences in competitive work attainment with 13 of the 25 participants (52%) obtaining competitive jobs in each group ($\chi^2=0, df=1, p=1.000$) at 12-months (Twamley et al., 2015). When controlling for age and education using an analysis of variance, Twamley et al. (2015) revealed no group differences in competitive work outcomes, including the number of weeks and hours worked and the wages earned (all F-values <0.73 , all p-values >0.397).

Two studies [n=2,33%] included a baseline and post treatment assessment of the CIQ productivity (Cicerone et al., 2008; Constantinidou et al., 2008) and one of these studies (Cicerone et al., 2008) also assessed the CIQ (prod) at 6-months post intervention. Cicerone et al. (2008) found that post treatment and 6-months following intervention the intervention group (ICRP) had a significant improvement in productivity compared to the control group (SNRP) who only significantly improved their productivity at 6-months. Based on the inferential statistics for intention to treat analyses of the CIQ (prod) scores, Cicerone et al. (2008) reported a significant main effect for treatment [F=4.55, p=0.037] but no significant change in CIQ (prod) for treatment by condition interaction effect [F=2.81, p=0.099] with a small to moderate ES of 0.46. However, for the overall CIQ score (social, home and productivity), there was a significant treatment by condition interaction effect (F=2.9, p=0.042) attributed to the gains made by participants in the intervention (ICRP) group (t=3.1, p=0.004) with no significant change among the participants in the control (SNRP) group with a moderate ES of 0.59 (variant of Hedge's g scores). Constantinidou et al. (2008) reported improvements in the CIQ (prod) scale in each group from baseline to post-treatment but no significant difference in productivity between groups post intervention. The mean CIQ productivity variables for the TBI population (mild and moderate to severe TBI) studied by Cicerone et al. (2008) were lower suggesting lower productivity than the TBI population (moderate to severe TBI only) studied by Constantinidou et al. (2008) suggesting higher productivity levels.

Cicerone et al. (2008) was the only study [n=1, 17%] that included a baseline, post treatment and six month follow up assessment of the Vocational Integration Scale dichotomised into yes working and no not working. At the completion of treatment, significantly more participants in the experimental (ICRP) group compared with the control (SNRP) group ($X^2=5.32$; p=0.02) were

engaged in community-based employment. After 6 participants who did not complete the clinical treatment and evaluation (all considered unemployed) were excluded from the analysis, the comparison between treatment conditions in Cicerone et al. (2008) remained significant ($X^2=4.72$; $p=0.03$). At the 6-month follow-up 59% of the ICRP participants were engaged in community-based employment compared with the 41% in the SNRP with the difference between groups no longer significant ($X^2=0.59$, $p=0.44$) and the ITT analysis also not significant ($X^2=2.12$, $p=0.15$).

No assessments to assess the quality of job productivity were included in the six included studies. Due to the heterogeneity of the EF interventions used for the RTW and the differences in RTW outcome measures between studies, the best practice EF interventions for the improvement of EF and RTW could not be measured for effectiveness using a meta-analysis.

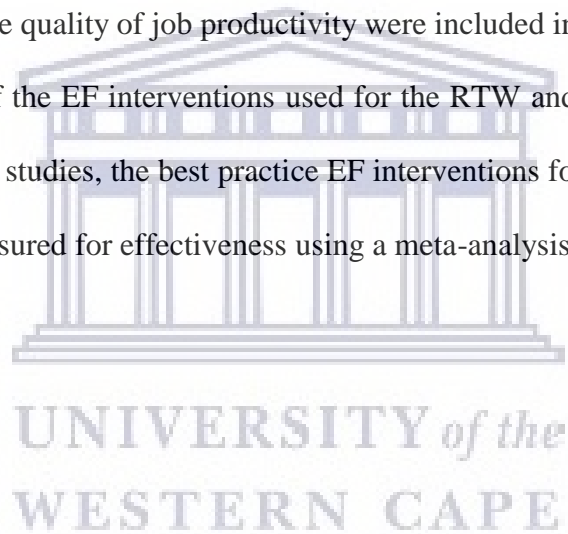


Table 4.9 RTW as a Primary or Secondary Outcome of Executive Function

Author	RTW Assessment Instrument or Method	Measurement Intervals	Experimental Group Outcome		Measurement Intervals	Control Group Outcome	
			VIS (prod)	CIQ(prod) mean		VIS (prod)	CIQ(prod) mean
Cicerone et al. (2008)	CIQ productive activity (CIQ prod) & VIS – converted into dichotomous data namely non-productive (level 1-2) productive (level 3-5).	Baseline Post treatment 3 months 6 months 12 months	9% 47%* - 59% - (*p=0.02)	1.0 SD±1.5* 1.8 SD±1.6* - 2.0 SD±1.5* - (*p<0.05)	Baseline Post treatment 3 months 6 months 12 months	12% 21%* - 41% - (*p=0.02)	0.9 SD±1.5 1.0 SD±1.5 - 1.6 SD±1.8* - (*p<0.05)
Constantinidou et al. (2008)	CIQ productivity scale	Baseline Post treatment 3 months 6 months 12 months	Mean score 2.35(SD±2.17) Mean Score 4.05 (SD±2.98) * - - - (*p<0.05 within group, p>0.05 between groups)		Baseline Post treatment 3 months 6 months 12 months	Mean score 1.63(SD±1.74) Mean score 4.09 (SD±2.11) * - - - (*p<0.05 within group, p>0.05 between groups)	
Salazar et al. (2000)	Interview, Military Records or Both Work defined as full-time (≥35h/wk) or part-time (<35h/wk) gainful military/civilian employment Fitness for duty: “...all patients still on active military duty/received a normal discharge from the service, excluded those with medical discharge or whose discharge was pending.” (Salazar et al., 2000) Post-hoc Subset Analysis (unconscious>1hr [n=75])	Baseline 3 months 6 months 12 months Baseline 3 months 6 months 12 months Baseline 3 months 6 months 12 months	Active duty military member - - 90% (p=0.51) - - - 73% (p=0.43) - 80% (p=0.05)*		Baseline 3 months 6 months 12 months Baseline 3 months 6 months 12 months Baseline 3 months 6 months 12 months	Active duty military member - - 94% (p=0.51) - - - 66% (p=0.43) - 58% (p=0.05)*	
Twamley et al. (2014 and 2015#)	Data regarding competitive work attainment, hours worked, and wages earned were collected weekly for 14weeks, then at 3, 6 and 12 months	Baseline Post treatment 3 months 6 months 12 months#	Unemployed, goal for work 50% (p=0.15; d=0.49) (not reported) (not reported) 52% (p=1.00)		Baseline Post treatment 3 months 6 months 12 months#	Unemployed, goal for work 26% (p=0.15, d=0.49) (not reported) (not reported) 52% (p=1.00)	
Vanderploeg, et al. (2008)	RTW/School mostly by in-person evaluations and rest by structured telephonic interview. Exploratory subgroup analysis (<30 years old)	Baseline 3 months 6 months 12 months 12 months	86.0% (p=0.32) - - 38.9% (p=0.50) 53.3% (p<0.03)*		Baseline 3 months 6 months 12 months 12 months	89.4% (p=0.32) - - 35.4% (p=0.50) 37.8% (p<0.03)*	

Abbreviations: CIQ(prod)=Community Integration Questionnaire productivity; VIS(prod)=Vocational Integration Scale productivity; #Twamley et al. (2015) reports on the 12month outcome; * = p-value significant

4.6.2.2 Executive Function (EF) as a Primary or Secondary Outcome of Intervention

Due to the differences in EF interventions implemented between studies, a meta-analysis for the measure of effect size of EF outcomes could not be done.

All six studies measured **neuropsychologic (NP) test outcomes** following the implementation of EF interventions. Cicerone et al. (2008) found based on the NP tests performed in their study that neuropsychological functioning improved in both groups with a significant treatment main effects for all NP tests with small effect sizes (ES), as depicted in Table 4.10. No main effect of condition was noted for the NP scores. Cicerone et al. (2008) reported that for NP functioning a significant effect of treatment ($F=7.5$, $p=0.001$) was observed but that no interaction of treatment by condition was found, with both the control (SNRP) and experimental (ICRP) participants displaying significant NP function improvements ($ES= -0.05$). Significant improvements were apparent on all measures except the trail making test (TMT-A) and with a similar pattern of NP improvement for both groups. Only those participants who completed the treatment and evaluation in both groups showed a similar overall improvement on NP measures ($ES= - 0.09$). Cicerone et al. (2008) did not measure the changes in NP tests at the 6-month follow-up.

Constantinidou et al. (2008) reported that there were participants in the experimental group that showed significant improvements (no p-values provided) on 12 neuropsychological measures (specifically in the formal neuropsychological tests) compared to the participants in the control group that showed significant improvement (no p-values provided) on only seven measures.

Twamley et al. (2014) found significant improvements in the experimental group (supported employment plus CogSMART) compared to the control (only supported employment) in four NP

tests following 14 weeks of the intervention. Twamley et al. (2014) reported that the experimental group had a significant decrease in post-traumatic stress disorder (CAPS) and depression symptoms (HAM-D) in the experimental group post-treatment (after 14 weeks) with effect sizes favouring CogSMART for posttraumatic stress disorder symptom severity and depressive symptom severity that were in the small to medium range Cohen $d=0.37$ and Cohen $d=-0.49$ respectively (see Table 4.10). The experimental group also showed significant reductions in post-concussive symptoms with a large ES (Cohen $d = 0.97$) on the Neurobehavioral Symptom Inventory NP test and improvements with a large ES (Cohen $d = 0.72$) in prospective memory functioning on the Memory for Intentions Screening (MIST)-24hour probe NP Test. Twamley et al. (2015), the follow-up study, used a hierarchical linear modelling analyses using 4 time points (post-treatment at 14 weeks, 3, 6 and 12-months) to analyse the improvements in NP tests between the experimental (CogSMART and supported employment) and the control (supported employment only) groups. Twamley et al. (2015) found significant CogSMART-associated reductions in post concussive symptoms ($r = -0.28$, $p = 0.026$, $d = 0.64$) on the NSI and significant improvements in prospective memory ($r = 0.35$, $p = 0.031$, $d = 0.55$) on the MIST-24hour probe NP tests with medium effect sizes.

Salazar et al. (2000) and Vanderploeg et al. (2008) found no difference between the intervention and control groups on neuropsychologic testing for cognitive and behavioural components of EF.

Three studies [$n=3$, 50%] measured **functional outcomes** following EF interventions (Cicerone et al., 2008; Constantinidou et al., 2008; Vanderploeg et al., 2008) as seen in Table 4.10. Cicerone et al. (2008) reported the ICRP (intervention) participants showed greater improvements in

functional outcomes with a significant treatment by condition interaction effect with a moderate effect size for the social ($F=6.78$; $p=0.011$; $ES=0.46$) and total $F=2.89$; $p=0.042$; $ES=0.59$ ($t=3.1$, $p=0.004$) CIQ scores.

Constantinidou et al. (2008) reported that participants in both groups demonstrated significant improvements ($\alpha=0.01$) on the two functional outcome measures namely the CIQ and MPAI-3. Participants in the experimental group showed significant improvements on the total score of the CIQ and on the home integration, the social integration, and the social productivity subscale scores and participants in the treated control group also showed improvement in the total score of the CIQ and only in the social productivity subscale score. Participants in the treated control group performance on the home integration and social integration subscales was not significantly improved (Constantinidou et al., 2008).

Vanderploeg et al. (2008) reported that fewer cognitive arm participants reported moderate-to-severe memory problems ($X^2_{2, n=278}=5.94$; $p=0.05$) as reported on the Neurobehavioral Rating Scale (NRS) and that the cognitive (experimental) arm participants had improved cognitive FIM scores than the functional (control) arm participants ($p=0.01$) as a measure of their functional outcomes.

One study [$n=1$, 17%] measured **perceived self-efficacy** following EF interventions (Cicerone et al., 2008). Cicerone et al. (2008) found that perceived self-efficacy in the experimental (ICRP) versus the control (SNRP) group was higher post treatment and at 12-month follow-up. There was no effect of condition on total self-efficacy scores. There was both a significant main effect of treatment and significant treatment by condition interaction effect for overall total self-efficacy

scores (Main Effect: $F=3.01$; $p=0.024$; Interaction effect: $F=2.70$; $p=0.040$) and self-efficacy for the management of emotional symptoms (Main Effect: $F=9.38$; $p=0.003$, Interaction effect: $F=7.16$; $p=0.009$) with a small ($ES=0.26$) and medium ($ES=0.50$) effect size respectively as reflected in Table 4.10. There was a significant main effect of treatment (Main Effect: $F=5.51$; $p=0.022$) but no significant treatment by condition interaction for cognitive self-efficacy and no main nor treatment by condition effect for social self-efficacy scores.

Cicerone et al. (2008) conducted a post hoc analyses on the secondary self-efficacy outcomes that indicated a significant improvement of total self-efficacy scores ($t=3.1$, $P=.004$), self-efficacy for management of cognitive symptoms (cognitive self-efficacy) ($t=3.0$, $P=.006$), and self-efficacy for the management of emotional symptoms ($t=4.0$, $P<.001$), in the experimental (ICRP) participants but no significant improvements in participants in the control group after Standard Neurorehabilitation Program treatment. For participants completing treatment, the analysis showed similar results, with a clinical ES of 0.29 for overall total self-efficacy scores. Cicerone et al. (2008) examined the maintenance of gains from post study treatment to follow-up with paired sample t tests within each treatment condition by using ITT analyses with the last observation carried over. Intensive Cognitive Rehabilitation Program participants maintained their gains from post treatment to follow-up, with no significant changes on any outcome measure. Follow-up functioning remained significantly different from pre-treatment for the CIQ ($t=2.49$, $P=.018$). Although the small decline of total self-efficacy scores from post treatment to follow-up was not a significant change ($t=0.41$, $P=0.69$), follow-up total self-efficacy scores were no longer significantly different from pre-treatment ($t=1.48$, $P=0.148$). There were no changes on total self-

efficacy scores among Standard Neurorehabilitation Program participants from discharge to follow-up.

One study [n=1, 17%] (Constantinidou et al., 2008) measured **CP** (category program) and **probe tests** which were assessments based on the categorisation programme implemented in their intervention group. CP test 1 tested the participants' ability to categorise common or familiar objects and CP test 2 assessed the participants' ability to implement logical rules to categorize objects. The baseline scores for CP test one ($t(32) = 0.804; p = 0.427$). and CP test two ($t(32) = 1.78, p = 0.083$). were the same at baseline for the two groups as depicted in Table 4.10. They used a mixed model analysis of variance ($\alpha = .05$) to compare the pre- and post- performance of the two groups on the CP Test 1 and CP Test 2 within and between groups. The analysis found that there was a significant difference in the CP Test 1 performance scores ($F_{1,32} = 50.555, p = 0.0001$) and the CP Test 2 performance scores ($F_{1,32} = 6.699, p = 0.014$). with therapy but that participants in the CP experimental group performed significantly better ($F_{1,32} = 4.634, p = 0.039$) on the post-test for CP Test 1 and significantly superior ($F_{1,32} = 7.45, p = 0.010$). on the post-test for CP Test 2 when compared to participants in the control group. The group by test interaction was not significant. The treated control group showed slight gains in CP Test 2 performance, although their gains were not significant. The patterns of performance on CP 1 Test ($F_{1,32} = 3.28, p = 0.079$). and CP Test 2 ($F_{1,32} = 0.01, p = 0.921$) were however similar for the two groups as the interaction effect was not significant. Constantinidou et al. (2008) used three probe tasks designed to assess the participants' ability to implement skills learned during the CP training and categorize new objects administered to both groups before the CP training (baseline), after level 2 (at 5 weeks after the onset of treatment) and after level 5 (at 8 weeks after the onset of treatment). Groups were similar ($t(32) =$

0.441, $p=0.661$) at baseline (probe test 1) before therapy started. As with the CP tests a mixed model analysis of variance was performed within (probe tasks) and between (groups factor) with a significant multivariate probe effect ($F_{2,34}=4.012$, $p=0.027$) and a significant between-groups effect ($F_{1,35}=4.990$, $p=0.032$) and a univariate analysis indicated that participants in the experimental groups demonstrated significant improvement ($F_{2,19}=6.640$, $p=0.008$) across time on the probe tasks, that followed a linear trend with no change in the control group ($F_{2,14}=0.549$, $p=0.589$).

Lastly, Constantinidou et al. (2008) explored the correlation (Pearson) between the NP tests and CP Test 1 and 2. The NP test scores were combined to create five composite scores for the conceptually motivated constructs of memory processing, executive functioning (Wisconsin Card Sorting test not included), perceptual/visual processing, conceptual reasoning, and organization/attention with lower scores indicating poorer outcome and correlated these to the CP Test pre-test scores. The CP Test 1 (pre-test) correlated significantly ($p<0.05$) with the Perceptual Composite ($r=0.433$; $p=0.011$) and the Conceptual/Reasoning Composite ($r=0.343$; $p=0.047$) and the CP Test 2 (pre-test) scores were significantly correlated ($p<0.05$) with all measures, except the Memory Composite. Constantinidou et al. (2008) also explored whether some of the neuropsychological measures could predict who benefited the most from experience in the CP intervention (data from experimental group) and correlated the composite measures with the post-test measures (CP Test 1, CP Test 2, Probe 2, Probe 3) and the three difference scores (CP Test 1 post/pre-test, CP Test 2 post/pre-test, Probe 3/Probe 1). The Organization/Attention Composite measure predicted the post-test performance on CP Test 2 ($r=0.488$; $p=0.029$) and the improvement on CP Test 1 (post/pre-test; $r=0.466$; $p=0.038$). While the Perception Composite were negatively

correlated with 2 difference score outcomes, CP Test 2 (post/pre-test; $r=-0.503$; $p=0.024$) and Probe 3/Probe 1 ($r=0.423$; $p=0.063$), it was suggested that this was a possible ceiling effect in that patients who were better performers on the neuropsychological measures did better on the categorization tests (especially CP Test 2) at pre-test so they had less room to improve on the post-test.



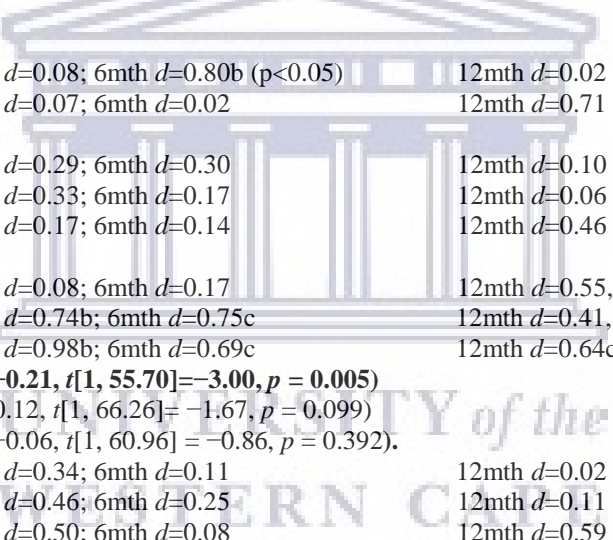
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Table 4.10 Executive Function Outcome Findings

Author	Executive Function Outcome Measure	Results (mean and SD)
Cicerone et al. (2008)	<p>i.) Neuropsychologic Test Scores</p> <ul style="list-style-type: none"> - Booklet Category Test. - CVLT-II (memory function) - Mean NP - RCF- IR - TMT-A (attention & processing speed) - TMT-B (higher cognitive functioning) - Verbal Fluency (COWAT) and Fluency Assessment Scale (FAS) 	<p>I: Pre=37.9±14.3; Post=43.0±15.8*; F/up= (no data), C: Pre=39.1±13.8; Post=44.3±18.2*; F/up= (no data) Rx Main Effect: F=24.77; p=0.000*, Rx by condition Interaction effect: F=0.01; p=0.943, ES=-0.02</p> <p>I: Pre=42.1±15.1; Post=46.4±15.6*; F/up= (no data), C: Pre=38.6±11.7; Post=44.2±14.3*; F/up= (no data) Rx Main Effect: F=23.31; p=0.000*, Rx by condition Interaction effect: F=0.37; p=0.546, ES= -0.20</p> <p>I: Pre=36.6±8.5; Post=39.5±9.1*; F/up= (no data), C: Pre=35.9±9.0; Post=39.5±9.6*; F/up= (no data) Rx Main Effect: F=7.52; p=0.000*, Rx by condition Interaction effect: F=0.16; p=0.985, ES=-0.05</p> <p>I: Pre=35.8±15.1; Post=38.3±15.5*; F/up= (no data), C: Pre=32.5±12.7; Post=35.9±14.6*; F/up= (no data) Rx Main Effect: F=7.49; p=0.008*, Rx by condition Interaction effect: F=0.18; p=0.669, ES=-0.10</p> <p>I: Pre=32.2±12.9; Post=33.5±12.7; F/up= (no data), C: Pre=34.9±13.2; Post=36.9±12.8; F/up= (no data) Rx Main Effect: F=2.62; p=0.110, Rx by condition Interaction effect: F=0.13; p=0.721, ES 0.09</p> <p>I: Pre=33.0±14.1; Post=36.4±10.7*; F/up= (no data), C: Pre=33.3±11.4; Post=36.7±13.7*; F/up= (no data) Rx Main Effect: F=8.21; p=0.006*, Rx by condition Interaction effect: F=0.00; p=0.990, ES=-0.06</p> <p>I: Pre=38.8±7.1; Post=39.7±9.1*; F/up= (no data), C: Pre=37.2±12.3; Post=39.3±11.3*; F/up= (no data) Rx Main Effect: F=4.19; p=0.045*, Rx by condition Interaction effect: F=0.58; p=0.450, ES=-0.04</p>
	<p>ii.) Perceived Self Efficacy (SEsx)</p> <ul style="list-style-type: none"> - SEsx Total - SEsx Cognitive - SEsx Emotional - SEsx Social 	<p>I: Pre=84.3±28.9; Post=94.1±29.2*; F/up= 92.4±22.7, C: Pre=82.6±27.9; Post=84.8±28.9; F/up=81.9±30.0 Rx Main Effect: F=3.01; p=0.024*, Rx by condition Interaction effect: F=2.70; p=0.040*, ES=0.26, post-hoc analysis: (t=3.1; p=0.004)</p> <p>I: Pre= 25.5±10.7; Post=28.9±8.7*; F/up=27.6±7.8, C: Pre=24.5±9.4; Post=25.6±7.5; F/up=24.8±9.9 Rx Main Effect: F=5.51; p=0.022*, Rx by condition Interaction effect: F=1.45; p=0.233, ES=0.20, post-hoc analysis: (t=3.0; p=0.006)</p> <p>I: Pre=24.4±10.5; Post=30.1±8.4*; F/up=27.9±8.1, C: Pre=24.9±10.4; Post=25.3±9.4; F/up=24.2±11.0 Rx Main Effect: F= 9.38; p=0.003*, Rx by condition Interaction effect: F=7.16; p=0.009*, ES=0.50, post-hoc analysis: (t=4.0; p<0.001)</p> <p>I: Pre=27.8±9.1; Post=28.1±7.1; F/up=29.4±7.6, C: Pre=27.6±8.9; Post=27.4±8.2; F/up=27.4±9.4 Rx Main Effect: F=0.01; p=0.922, Rx by condition Interaction effect: F=0.07; p=0.794, ES=0.05</p>
	<p>iii.) Functional Outcomes:</p> <ul style="list-style-type: none"> CIQ CIQ (<i>Home competency</i>) CIQ (<i>Social</i>) CIQ (<i>Total Score</i>) 	<p>I: Pre=4.1±2.7; Post=3.8±2.5; 6mth F/up=4.1±1.7, C: Pre=4.0±2.4; Post=4.1±2.6; F/up=4.3±2.0 Rx Main Effect: F=0.67; p=0.42, Rx by Condition Interaction Effect: F=0.34; p=0.562, ES=0.08</p> <p>I: Pre= 6.4±2.2; Post=7.0±1.9; 6mth F/up= 6.9±2.2, C: Pre=7.3±2.2; Post= 6.7±2.2; 6mth F/up=7.1±1.9 Rx Main Effect: F=0.00; p=1.00, Rx by Condition Interaction Effect F=6.78; p=0.011* ES=0.46</p> <p>I: Pre=12.1±4.0; Post=11.7±4.4; 6mth F/up=12.9±4.4, C: Pre=11.2±3.4; Post=12.9±3.4*; 6mth F/up=13.2±4.3* Rx Main Effect: F=1.72; p=0.17, Rx by Condition Interaction effect: F=2.89; p=0.042*, ES=0.59(t=3.1, p=0.004)</p>

<p>Constantinidou et al. (2008)</p> <p>i.) The Categorisation Program (CP) Outcomes</p> <ul style="list-style-type: none"> - CP Test 1 (common objects) - CP Test 2 (implement logical rules to categorise) - Probe Test 1 (at baseline) - Probe Test 2 (level 2, 5wks post CP) - Probe Test 3 (level 5, 8wks post CP) <p>Mixed model ANOVA within and between group/s for Probe Tests:</p> <ul style="list-style-type: none"> -multivariate probe effect: -between groups effect: -univariate change across time on probe tasks <p>ii.) Neuropsychologic Test Scores</p> <p>Booklet Category Test COWAT CVLT-II/CVLT-R RCFT: - RCF copy - RCF immediate - RCF delayed SCATBI: - SCATBI: reasoning - SCATBI: organization - SCATBI: perception & discrimination Trail Making Tests - TMT-A - TMT-B WASI WCST - number of categories completed - trials to complete first category</p>	<p>I: Pre=61.30 (9.31); Post=92.45 (17.62), C: Pre=57.50 (11.30); Post=76.00 (26.14), (t[32] =0.804, p=0.427) Mixed model ANOVA within group (F_{1,32}=50.555, p=0.0001), between groups (F_{1,32}=4.634, p=0.039), group by test interaction: (F_{1,32} = 3.28, p=0.079),</p> <p>I: Pre=29.70 (3.70); Post= 31.75 (2.57), C: 26.86 (4.64); Post=29.07 (4.21), (t[32] =1.78, p=0.083) Mixed model ANOVA within group (F_{1,32}=6.699, p=0.014), between groups (F_{1,32}=7.45, p=0.010), group by test interaction: (F_{1,32}=0.01, p=0.921)</p> <p>I: 23.48 (6.97); C: 23.25 (8.12), (t [32] =0.441, p=0.661) I: 27.76 (3.90); C: 23.00 (7.60) I: 29.33 (2.22); C: 24.94 (6.08)</p> <p>(F_{2,34}=4.012, p=0.027) (F_{2,34}=4.990, p=0.032) I: (F_{2,34}=6.640, p=0.008); C: (F_{2,34}=0.549, p=0.589)</p> <p>I: Pre=40.76 (9.33); Post=45.72 (10.39), C: Pre=39.75 (9.14); Post=43.46 (11.73) I: Pre=32.53 (8.99); Post=38.73 (11.96), C: Pre=33.08 (11.59); Post=35.50 (12.36) I: Pre=44.55 (12.88); Post=51.61 (11.42), C: Pre=42.00 (13.01); Post=43.30 (13.56)</p> <p>I: Pre=28.28 (8.13); Post=30.53 (5.25), C: Pre=29.80 (6.14); Post=30.80 (5.52) I: Pre=15.94 (7.75); Post=19.43 (7.42), C: Pre=17.19 (8.46); Post=20.11 (8.43) I: Pre=17.05 (6.92); Post=19.25 (8.20), C: Pre=16.61 (8.07); Post=20.69 (8.82)</p> <p>I: Pre=42.05 (6.43); Post=46.00 (6.79); C: Pre=40.00 (10.09); Post=45.30 (9.13) I: Pre=29.73 (2.60); Post=29.52 (0.90); C: Pre=26.21 (4.67); Post=29.92 (2.69) I: Pre=52.36 (5.08); Post=55.84 (1.70); C: Pre=52.64 (4.20); Post=54.07 (no SD)</p> <p>I: Pre=39.57 (15.07); Post=32.34 (16.00), C: Pre=46.82 (24.02); Post=42.42 (23.09) I: Pre=87.21 (48.18); Post=79.71 (45.07), C: Pre=98.07 (40.41); Post=83.01 (46.62) (no data reported on post interventions)</p> <p>I: Pre=5.52 (1.17); Post=5.68 (.79), C: Pre=5.28 (1.63); Post=5.71 (1.06) I: Pre=13.68 (5.48); Post=11.12 (1.36), C: Pre=10.23 (3.19); Post=12.53 (4.40)</p>
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	<p>WMS-III</p> <ul style="list-style-type: none"> - WMSIII Digit Span Total Score - WMSIII forward - WMSIII backwards <p>WJ-III</p> <ul style="list-style-type: none"> - WJ-III: picture recognition - WJ-III: spatial relations - WJ-III: analysis/synthesis - WJ-III: concept formation - WJ-III: decision speed - WJ-III: verbal comprehension <p>SDMT</p> <p>iii) Functional Outcomes:</p> <p>CIQ</p> <ul style="list-style-type: none"> - CIQ total score - CIQ home integration - CIQ social integration <p>MPAI-3</p> <ul style="list-style-type: none"> - MPAI-3 total score - MPAI-3 social participation - MPAI-3 physical/cognition - MPAI-3 pain/emotion 	<p>I: Pre=16.82 (3.52); Post=18.35 (5.67), C: Pre=15.16 (6.36); Post=16.41 (4.54), p>0.05 I: Pre=8.42 (1.7); Post=8.70 (2.02), C: Pre=7.92 (2.49); Post=8.30 (2.17), p>0.05 I: Pre=7.57 (1.67); Post=7.76 (2.10), C: Pre=7.14 (2.21); Post=7.53 (2.14), p>0.05</p> <p>I: Pre=48.78 (3.45); Post=50.63 (3.71), C: Pre=44.07 (23.87); Post=49.28 (8.75) I: Pre=70.31 (5.45); Post=72.31 (6.55), C: Pre=66.07 (18.08); Post=70.92 (4.69) I: Pre=26.52 (3.28); Post=27.73 (3.38), C: Pre=24.15 (8.13); Post=26.78 (3.01) I: Pre=26.10 (7.12); Post=32.94 (5.29), C: Pre=23.07 (10.77); Post=31.14 (7.73) I: Pre=26.10 (7.39); Post=30.73 (6.20), C: Pre=24.91 (7.95); Post=26.14 (7.95) I: Pre=52.42 (5.51); Post=55.89 (5.86), C: Pre=45.35 (13.13); Post=52.14 (8.00) I: Pre=44.56 (23.08); Post=28.15 (12.88), C: Pre=44.07 (23.87); Post=34.00 (21.80)</p> <p>I: Pre=11.04 (5.75); Post=17.35 (5.087), C: Pre=10.14 (5.88); Post=17.59 (5.79) I: Pre=2.16 (2.58); Post=4.41 (3.21), C: Pre=2.70 (2.74); Post=5.30 (2.82) I: Pre=6.52 (2.45); Post=8.88 (2.02), C: Pre= 6.45 (2.33); Post=8.07 (3.27)</p> <p>I: Pre=2.20 (0.67); Post=1.09 (0.52), C: Pre=2.20 (0.70); Post=1.34 (0.34), (p<0.01) I: Pre=2.50 (0.86); Post=1.31 (0.80), C: Pre=2.60 (0.81); Post=1.65 (0.60) I: Pre=2.10 (0.65); Post=0.95 (0.51), C: Pre=2.08 (0.81); Post=1.16 (0.36) I: Pre=1.83 (1.2); Post=1.00 (0.78), C: Pre=1.50 (0.94); Post=0.94 (0.65)</p>
Salazar (2000)	<p>i.) Neuropsychologic Test Scores (cognitive, psychiatric & neurological outcomes: cognition, behaviour, mood): ACT (total correct ≤40) BRST H-RNII (≥0.5)</p> <ul style="list-style-type: none"> - Major depression - Generalized anxiety - Aggression (verbal or physical) <p>PASAT TCVMT WCST WMS-R (general memory quotient <75)</p>	<p>Baseline: I: 37; C: 39, p>0.99, 12months: I: 12; C: 29, p=0.08 Baseline: I: 53 (34); C: 47 (33), p=0.33, 12months: I: 67 (34); C: 63 (40), p=0.68 Baseline: I: 36; C: 30, p=0.55, 12months: I: 8; C: 15, p=0.46 Baseline: I: 18; C: 19, p>0.99, 12months: I: 16; C:27, p=0.26 Baseline: I: 9; C: 10, p>0.99, 12months: I: 9; C: 20, p=0.33 Baseline: I: 18; C: 19, p>0.99, 12months: I:37; C: 41, p=0.82 Baseline: I: 117 (33); C:109 (32), p=0.18, 12months: I: 147 (42); C: 145(50), p=0.84 Baseline: I: 34 (6); C: 36 (5), p=0.08, 12months: I: 38 (3); C: 39 (3), p=0.29 Baseline: I: 12 (10); C: 16 (16), p=0.15, 12months: I: 7 (5); C: 9 (9), p=0.34 Baseline: I: 12; C: 14, p=0.79, 12months: I: 3; C: 6, p=0.58</p>
Twamley et al. (2014)	<p>i.) Neuropsychologic Test Scores</p> <p>CAPS CVLT-II - Long Delay Free Recall Z-Score</p>	<p>I: -10.0 ± 17.8; C: -2.4 ± 17.4, X_{1,2(31)}; p=0.22; d=0.43</p> <p>I: 0.7 ± 1.1; C: 0.8 ± 1.0, X_{0,2(31)}; p=0.89; d=0.05</p>

	<ul style="list-style-type: none"> - Trials 1–5 Learning T-Score D-KEFS - D-KEFS Letter Fluency - D-KEFS Category Fluency - D-KEFS Category Switching HAM-D MIST -MIST Summary Score -MIST 24-Hour Probe NSI WAIS-III WCST-64 	<p>I: 6.9 ± 10.8; C: 7.7 ± 9.1, $X_{0.2(31)}$; $p=0.82$; $d=0.08$</p> <p>I: 0.6 ± 3.4; C: -0.2 ± 2.4, $X_{0.8(31)}$; $p=0.42$; $d=0.28$</p> <p>I: 0.3 ± 3.7; C: -0.6 ± 3.0, $X_{0.8(31)}$; $p=0.42$; $d=0.28$</p> <p>I: 1.3 ± 4.7; C: 0.7 ± 2.6, $X_{0.5(31)}$; $p=0.64$; $d=0.16$</p> <p>I: -2.2 ± 4.5; C: -0.6 ± 3.9, $X_{1.0(29)}$; $p=0.31$; $d=0.37$</p> <p>I: 4.9 ± 7.1; C: 5.4 ± 7.6, $X_{0.2(31)}$; $p=0.83$; $d=0.08$</p> <p>I: 0.1 ± 0.7; C: -0.5 ± 0.9, $X_{0.2(31)}$; $p=0.05$; $d=0.72$</p> <p>I: -7.9 ± 5.2; C: -0.4 ± 9.6, $X_{2.7(31)}$; $p=0.01$; $d=0.97$</p> <p>I: 0.0 ± 1.5; C: 0.7 ± 1.6, $X_{1.2(31)}$; $p=0.23$; $d=-0.43$</p> <p>I: -0.1 ± 4.9; C: 1.9 ± 8.0, $X_{0.9(31)}$; $p=0.40$; $d=-0.30$</p>
<p>Twamley et al. (2015*)</p>	<p>i.) Neuropsychological Test Score</p> <p>CVLT-II</p> <ul style="list-style-type: none"> - Long Delay Free Recall Z-Score - Trials 1–5 Learning T-Score D-KEFS - D-KEFS Letter Fluency - D-KEFS Category Fluency - D-KEFS Category Switching MIST -MIST Summary Score -MIST 24-Hour Probe NSI -Affective Subscale -Cognitive Subscale -Somatic Subscale UPSA WAIS-III Digit Span WCST-64 	 <p>3mth $d=0.08$; 6mth $d=0.80b$ ($p<0.05$) 12mth $d=0.02$</p> <p>3mth $d=0.07$; 6mth $d=0.02$ 12mth $d=0.71$ ($p<0.1$)</p> <p>3mth $d=0.29$; 6mth $d=0.30$ 12mth $d=0.10$</p> <p>3mth $d=0.33$; 6mth $d=0.17$ 12mth $d=0.06$</p> <p>3mth $d=0.17$; 6mth $d=0.14$ 12mth $d=0.46$</p> <p>3mth $d=0.08$; 6mth $d=0.17$ 12mth $d=0.55$, ($r=0.35$, $t[1, 35.49]=2.25$, $p=0.031$)</p> <p>3mth $d=0.74b$; 6mth $d=0.75c$ 12mth $d=0.41$, ($r=0.21$, $t[1, 63.55]=1.71$, $p=0.093$)</p> <p>3mth $d=0.98b$; 6mth $d=0.69c$ 12mth $d=0.64c$ ($r=-0.28$, $t[1, 62.08]=-2.29$, $p=0.026$)</p> <p>($r=-0.21$, $t[1, 55.70]=-3.00$, $p=0.005$)</p> <p>($r=-0.12$, $t[1, 66.26]=-1.67$, $p=0.099$)</p> <p>($r=-0.06$, $t[1, 60.96]=-0.86$, $p=0.392$).</p> <p>3mth $d=0.34$; 6mth $d=0.11$ 12mth $d=0.02$</p> <p>3mth $d=0.46$; 6mth $d=0.25$ 12mth $d=0.11$</p> <p>3mth $d=0.50$; 6mth $d=0.08$ 12mth $d=0.59$</p>
<p>Vanderploeg, et al. (2008)</p>	<p>i.) Neuropsychological Test Score</p> <p>CVLT-II</p> <ul style="list-style-type: none"> - Long Delay Free Recall Z-Score - Trials 1–5 Learning T-Score - Delay Recognition Discriminability WMSRVR-I WMSRVR-II Semantic Fluency (total Animals & Super market items) 	<p>I: 2.9 ± 3.3 ($n=134$); C: 3.4 ± 3.6 ($n=134$), ($t_{266}=1.09$; $p=0.28$)</p> <p>I: 26.0 ± 11.2 ($n=134$); C: 25.5 ± 11.8 ($n=134$), ($t_{266}=0.33$; $p=0.74$)</p> <p>I: 75.8 ± 14.0 ($n=134$); C: 74.9 ± 15.8 ($n=134$), ($t_{266}=0.45$; $p=0.66$)</p> <p>I: 25.5 ± 8.9 ($n=134$); C: 24.4 ± 9.4 ($n=128$), ($t_{260}=1.01$; $p=0.32$)</p> <p>I: 14.3 ± 11.6 ($n=133$); C: 12.1 ± 11.2 ($n=127$), ($t_{258}=1.52$; $p=0.13$)</p> <p>I: 22.0 ± 11.1 ($n=132$); C: 21.5 ± 10.8 ($n=136$); ($t_{266}=0.38$; $p=0.71$)</p>

<p>Lexical Fluency (total words in 3 60-sec trials) TMT-B WCST (Total Perseverations)</p> <p>ii) Functional Outcomes: Functional Independence Measure (FIM) - cognitive - motor DRS at discharge post intervention Present State Exam (mood & behaviour) - Social Withdrawal - Worrying - Depressed Mood - Irritability Apathy Evaluation Scale (feels motivated a lot, slightly/somewhat, not at all) - NRS (self-perceived memory problems at 1-year F/up rated as none, mild, moderate to severe)</p>	<p>I: 19.1±8.7 (n=133); C: 18.2±9.6 (n=138); $t_{69} = 0.85$; $p = 0.40$ I: 154.8±78.7 (n=103); C: 166.5±82.2 (n=105); $t_{206} = 1.04$; $p = 0.30$ I: 35.3±27.8 (n=109); C: 34.4±25.8 (n=107); $t_{214} = 0.26$; $p = 0.80$</p> <p>I: 27.3±6.2 (n=171); C: 25.6±6.0 (n=163); $t_{332} = 2.56$; $p = 0.01$ I: 82.7±14.1 (n=171); C: 80.5±14.7 (n=163) $t_{332} = 1.38$; $p = 0.17$ I: 7.6±4.8 (n=152); C: 8.2±5.3 (n=150); $t_{300} = 1.07$; $p = 0.29$</p> <p>$X^2_{2, n=273} = 0.49$; $p = 0.78$ $X^2_{2, n=274} = 0.18$; $p = 0.91$ $X^2_{2, n=274} = 1.37$; $p = 0.50$ $X^2_{2, n=273} = 1.27$; $p = 0.53$ $X^2_{2, n=273} = 0.51$; $p = 0.77$</p> <p>$X^2_{2, n=278} = 5.94$; $p = 0.05$ (<i>fewer cognitive arm participants reported moderate-to-severe memory problems</i>)</p>
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Abbreviations: ACT: Auditory Consonant Trigrams; BRST: Buschke Selective Reminding Test; CAPS: Clinician-Administered Posttraumatic Stress Disorder Scale; CIQ: Community Integration Questionnaire; CVLT-II: California Verbal Learning Test-2nd edition; CVLT-R: California Verbal Learning Test-Revised; DRS: Disability Rating Scale Score; H-R NII: Halstead-Reitan Neuropsychological Impairment Index; HAM-D: Hamilton Depression Rating Scale; MPAI: Mayo-Portland Adaptability Inventory; MIST: Memory for Intentions Screening Test; NSI: Neurobehavioral Symptom Inventory; NRS: Neurobehavioral Rating Scale; PASAT: Paced Auditory Serial Addition; RCFT: Rey Complex Figure Test; SCATBI: Scales of Cognitive Ability for Traumatic Brain Injury; TCVM: Trahan Continuous Visual Memory Test, TMT: Trail Making Test; Wechsler Adult Intelligence Scale-3rd edition (WAIS-III), WMS-III: Wechsler Memory Scale III; WMS-R Wechsler Memory Scale Revised; WMSRVR-I Wechsler Memory Scale—Revised Visual Reproduction I; WMSRVR-II Wechsler Memory Scale—Revised Visual Reproduction II; WCST Wisconsin Card Sorting; Wisconsin Card Sorting Test-64 card version (WCST-64), WJ-III: Woodcock Johnson III; UCSD Performance Based Skills Assessment (UPSA)

4.6.2.3 Quality of Life (QOL) Outcome Results

The quality of life outcomes measured across five of the six studies varied. Due to the heterogeneity of the EF interventions between studies and the quality of life measures used, the results cannot be combined for a measure of effect size of the quality of life outcomes that were significant across studies and can only be reported on per study. Table 4.11 summarises the QOL outcomes per study.

Cicerone et al. (2008) reported that there was no main effect for condition on the PQOL but a significant main effect for treatment ($F=6.9$, $p=0.011$) and a significant treatment by condition interaction ($F=4.0$, $p=0.049$), caused by the significant improvement by the ICRP (experimental) participants ($t=3.1$, $p=0.004$), with no significant change among the SNRP (control) participants with a small ES of 0.30 and found the same effect size for the analysis of treatment effects only for those participants completing the interventions and evaluations post treatment intervention. At 6-months follow-up, the PQOL remained significantly different ($t=2.38$, $p=0.023$) from pre-treatment (Cicerone et al., 2008).

Salazar et al. (2000) reported no difference between groups for quality of life outcomes on the Katz adjustment scale. Twamley et al. (2014) reported that the quality of life outcome comparisons did not show statistically significant differences between groups post-treatment (at 14 weeks). In the follow-up study by Twamley et al. (2015) a hierarchical linear modelling analyses using 4 time points namely post treatment, 3, 6 and 12-months post treatment showed significant CogSMART-associated (experimental group) improvements in quality of life ($r = 0.34$, $p = 0.009$, $d = 1.0$) (see Table 4.11).

Vanderploeg et al. (2008) showed no difference in the quality of life outcomes between groups but a subset analysis of age and education showed that older (>30 years) individuals (59,1%; $X^2_{1, n=141}=3.79$; $p=0.05$) with more years of education (69.1%; $X^2_{1, n=112}=5.42$; $p=0.02$) in the functional arm (control group) had higher rates of independent living (FIM) at 12 months (1-year) post treatment than similar individuals in the cognitive arm (experimental group).

Vanderploeg et al. (2008) also examined the cognitive FIM change scores from the beginning to the end of protocol treatment due to differences found in the cognitive FIM scores. A separate analysis for persons who started with lower (5–18) versus higher (19 – 35) pre-treatment cognitive FIM scores was conducted. The latter was done as the FIM scores tend to have a ceiling effect limiting responsiveness for higher initial FIM scores. Vanderploeg et al. (2008) found a beneficial effect of the intervention (cognitive rehabilitation) over the control (functional rehabilitation) groups in those who began treatment with lower cognitive FIM scores. The mean \pm SD of cognitive FIM change was significantly ($p<0.02$) higher in the intervention (cognitive) than the control (functional) rehabilitation groups and showed an overall differential benefit of 12.5% in cognitive independence in the intervention (cognitive rehabilitation) participants.

Table 4.11 Quality of Life Outcome Findings

Author	Quality of Life Outcome Measure	Results (percentages or mean and SD)
Cicerone et al. (2008)	i.) PQOL (<i>Life Satisfaction</i>)	I: Pre=59.0±21.7; Post=66.8±17.5; 6mth F/up=66.1±20.8 C: Pre=61.2±16.5; Post=62.2±17.2; 6mth F/up=59.6±17.2 Rx Main Effect: F=6.84; p=0.011* Rx by Condition Interaction Effect: F=4.02; p=0.049*, ES=0.30 (t=3.1, p=0.004)
Constantinidou et al. (2008)	Not Applicable	Not Applicable
Salazar (2000)	i) Katz Adjustment Scale - Belligerence, - Social irresponsibility, - Antisocial Behaviour - Social Withdrawal - Apathy	I: 17.1 (4.8); C: 19.8 (9.7), p=0.19 I: 29.3 (6.1); C: 29.4 (6.1), p=0.99 I: 9.5 (3.2); C: 11.1 (6.8), p=0.24 I: 10.8 (2.9); C: 11.6 (4.2), p=0.40 I: 6.9 (3.0); C: 8.2 (4.4), p=0.21
Twamley et al. (2014)	QOL Interview-Brief Version for global QOL	I: 0.3 ± 1.0; C: 0.1 ± 1.0, $X_{0.6(31)}$, p=0.55; d=0.21
Twamley et al. (2015*)	QOL Interview –Brief: Mean Satisfaction Scale	3mths: d=0.48; 6mths: d=-0.19; 12mths: d=1.00, (r=0.34, t [1, 56.47] = 2.69, p = 0.009)
Vanderploeg, et al. (2008)	i.) Functional Independence in Living (<3hrs assistance/wk) ii.) Clinical Interview and History Questions: - Satisfied with Life - Change in marital status since injury - Angry Behaviour (<i>not present during last month, keeps irritation to himself; shows anger outwardly</i>) - Get away from the house (<i>Daily, Several times a week or less</i>) <u>Exploratory subset analysis of FIM</u> - Education • ≤High School • >High School - Age (<i>at randomization</i>) • <30 years • >30 years - Cognitive FIM Change Score: Randomization to End of Protocol Treatment: Baseline cognitive FIM, raw total Score: • Scores 5-18: • Scores 19-35:	I: 93/167 (56.3%); C: 101/164 (61.6%), $X^2_{1,n=329} = 1.20$; p=0.27 I: 80/130 (61.5%); C: 81/124 (65.3%); $X^2_{1,n=254} = 0.39$; p=0.53 I: 23/151 (15.2%); C: 19/150 (12.7%); $X^2_{1,n=301} = 0.41$; p=0.78 $X^2_{2, n=262} = 2.36$; p=0.31 $X^2_{1, n=282} = 0.39$; p=0.54 I: 67/109 (61.5%); C: 63/109 (57.8%); $X^2_{1, n=218} = 0.31$; p=0.58 I: 27/57 (47.4%); C: 38/55 (69.1%); $X^2_{1, n=112} = 5.42$; p=0.02* I: 62/92 (67.4%); C: 62/98 (63.3%); $X^2_{1, n=190} = 0.36$; p=0.55 I: 32/75 (42.7%); C: 39/66 (59.1%) $X^2_{1, n=141} = 3.79$; p=0.05* I: 12.7±7.1; C: 10.3±5.1; $t_{163} = 2.53$; p=0.02* I: 4.9±4.3; C: 4.5±4.7; $t_{163} = 0.57$; p=0.57

Abbreviations: C = control; d = Cohen's d for effect size; ES = effect size; F = FIM=Functional Independence Measure; I = intervention; hr = hour; mth = months; p = significant value; PQOL = Perceived Quality of Life QOL = Quality of Life; Rx = treatment; SD = standard deviation; t= t-test; wk = week, * = significant p-value

4.6.4 Additional Outcome Evaluations

4.6.4.1 Effect of time since injury

Only one study [n=1, 17%] (Cicerone et al., 2008) assessed the effect of time since injury on outcomes to address the concerns about the influence of spontaneous recovery and time since injury on the observed outcomes. Cicerone et al. (2008) conducted additional analyses of these relationships by creating logical groups based on time since injury. There was no difference between treatment conditions on the distribution of participants by time since injury ($X_2=0.13$, $p=0.99$) and using one-way ANOVAs to compare the time since injury groups on the difference scores from pre-treatment to post treatment for primary and secondary outcome measures also did not show any an effect of time since injury on overall CIQ ($F=0.37$, $p=0.78$), PQOL ($F=0.72$, $p=0.54$), total self-efficacy scores ($F=0.98$, $p=0.41$), or NP ($F=1.11$, $p=0.35$).

4.6.4.2 Protocol Adherence or Treatment Fidelity

Three studies [n=3, 50%] (Cicerone et al., 2008; Twamley et al., 2014; Vanderploeg et al., 2008) assessed the fidelity of the interventions [protocol adherence and treatment fidelity]. Cicerone et al. (2008) and Twamley et al. (2014) assessed treatment fidelity known as the extent to which the study team complied with the study protocol. Cicerone et al. (2008) examined the ratings of 12 therapists using dependent sample Wilcoxon signed-rank tests with p set to < 0.003 to suggest differences between the treatment conditions. The control intervention (SNRP) was strongly characterised by individual, discipline-specific therapies with a more individualised and flexible structure whereas the experimental intervention (ICRP) was characterised by group therapies and the integration of interventions addressing cognitive, interpersonal, and functional deficits that was considered very consistent with the design and therapeutic intent of the planned interventions in

this trial. Twamley et al. (2014) ensured treatment fidelity by audiotaping all CogSMART sessions and 20 percent of these recordings were randomly selected for fidelity rating every two weeks. The adherence rates for the sessions were consistently between 90 and 100 percent. Vanderploeg et al. (2008) assessed protocol adherence known as the extent to which the participant complies with the intervention or outcome measure to be administered. The mean (SD) of protocol treatment was 32.7 ± 12.9 calendar days overall. The results of the protocol adherence assessment showed the mean (SD) calendar days as similar mean (SD) calendar days overall ($t_{358} = 0.79, p = 0.43$), between the cognitive (intervention) treatment group ($32.2 \pm 12.2d$) and functional (control) treatment group ($33.3 \pm 13.6d$). However, calendar days did vary over time being longer during the first half of recruitment [1996 –1999], 35.2 ± 15.2 calendar days versus 29.9 ± 8.9 calendar days ($t_{358} = 4.07, p < 0.001$). Furthermore, Vanderploeg et al. (2008) reported that 74 (20.6%) of their participants received less than the intended minimum 20 protocol treatment days (26 calendar days) and 3 participants (0.8%) received over the intended maximum of 60 protocol treatment days (84 calendar days) but the underexposed or overexposed participants were equally distributed across the two treatment groups (38 cognitive arm vs 39 functional arm). Vanderploeg et al. (2008) also qualitatively monitored the therapists' knowledge of and adherence to the differential treatment interventions by site visits but did not report on the qualitative outcomes and did not measure the latter quantitatively.

4.6.4.3 Cost of Interventions

One study [n=1, 17%] (Salazar et al., 2000) measured an estimate of treatment costs per group and highlighted the potential therapeutic benefits of the home setting that is a more cost-effective approach to rehabilitation. Both the intervention and control groups in this study received basic

TBI evaluation, education, and counselling over an average of 5 days in the hospital. The authors reported that the estimated additional rehabilitation cost for each patient in the hospital (intervention) group was \$51,840, based on the standard Walter Reed Army Medical Center (WRAMC) psychiatry service costs of \$864 per day compared to the home-based rehabilitation intervention (control group) whose costs were estimated at \$504 per patient, based on therapist time for the weekly home telephone calls (\$63 per hour), including overhead and occasional physician back-up consultation.

4.6.4.4 Qualitative Evaluation of Intervention

One study [n=1, 17%] (Twamley et al., 2014) asked the participants in their intervention group (CogSMART plus supported employment) to rate the components of the CogSMART intervention on a scale from 1 to 5 (“not helpful” to “extremely helpful”) and provide written qualitative comments following completion of the CogSMART sessions. Twamley et al. (2014) reported that the intervention group (those who received CogSMART) rated it highly with regard to helpfulness of information regarding TBI and post-concussive symptoms, information on post traumatic distress syndrome, headache, fatigue, sleep, prospective memory, attention, learning and memory, problem solving strategies and information regarding additional department of veteran affairs services with all means scoring 3.5 on a 5-point scale, where 3 = “moderately helpful” and 5 = “extremely helpful”. The prospective memory strategies received the highest mean rating of 4.3. They also reported that many participants noted in their qualitative comments that they had begun using a calendar system (paper or smart phone). The study provided six qualitative quotes from participants who received the CogSMART intervention (experimental group) describing the positive outcomes of the intervention. The participants stated that they wished the intervention was

used while they were still in service and that everyone should go through it, that the intervention allowed them to keep up with their schedule and confidence with schooling taking the pressure off family, helped them to relax, concentrate and remember things that were important, helped with organisational skills, improved their ability to see to their finances, stay on top of class work and apply for competitive jobs as well as reduce stress and get better rest.

4.7 Best Practice Interventions for Improving EF for RTW post TBI

In order to provide statistical data on the measure of effectiveness (meta-analysis) of the interventions with executive functioning components in the experimental group versus a control group it is necessary to have a level of homogeneity within the interventions implemented and their duration, the inclusion of similar participants in terms of age and gender, TBI severity, outcome measures and unit of measurements. Although it was decided a priori that a meta-analysis to determine the measure of effectiveness for interventions for improving executive functioning for RTW in TBI individuals would be conducted, the results displayed in the narrative synthesis of results from the included studies confirmed the inability to combine specific RTW, EF and QOL outcomes to provide a measure of effectiveness of the interventions implemented due to heterogeneity of the interventions in the experimental groups versus comparison interventions in the control groups, the differences in intervention implementation and duration, individual versus group therapy or both combined, participant characteristics (TBI severity) and types of outcome assessments. The review cannot provide evidence for a best practice intervention for improving EF for RTW in TBI individuals through a meta-analysis and the findings from this review are therefore inconclusive but do provide evidence for two possible interventions that obtained good RTW rates and form part of the discussion in the next chapter.

CHAPTER 5: DISCUSSION

Chapter five presents an integrated discussion of the findings of the review. The discussion is orientated around answering of the aim and objectives of the review and critically analysing the findings in relation to the RTW outcomes, EF assessments, outcome measures and interventions, QOL outcomes and additional outcomes evaluated in the trial studies. The preface discusses the characteristics of included studies such as their population and sampling, interventions and outcomes which is then followed by a discussion of the best practice EF interventions for successful RTW and outcomes measured in the trials and the relation of these outcomes to RTW as an outcome. A discussion on the methodological, implementation appraisal and risk of bias is integrated into the discussion on study characteristics, interventions implemented and outcomes and further elaborated on towards the end of the discussion chapter. The strengths and limitations of studies in attempting to provide evidence for an executive functioning intervention that provides the best outcome or success of RTW in TBI individuals are also noted. The discussion is concluded with a list of recommendations for future research and practice and with the limitations and strengths of this review.

5.1 Preface

The review was successfully conducted and yielded six relevant trial studies that evaluated interventions for improving executive functioning for improving RTW (as well as productivity as related to RTW) in TBI individuals. The six studies included in the review had good methodological and intervention implementation rigor. Most, if not all, had a low risk of bias. One of the six studies namely Twamley et al. (2015) was a follow-up study of their intervention study conducted in 2014 (Twamley et al., 2014) whereby this follow-up study measured outcomes at 3,

6 and 12-months post intervention in the participants who participated in the trial published in 2014.

It was interesting to note that while TBI is considered a “silent” pandemic with high incidence rates globally and especially so in middle- to low-income or developed and developing countries, including South Africa (Webster et al., 2015), all the trials were conducted in only one country namely the USA that is considered a developed country. The latter has been therefore identified as a gap in the literature. Since studies were mainly from the United States of America that is considered a developed country the results may not be contextual to other developing countries globally where incidence rates of TBI are higher, the causes of TBI different (example violence-related TBI) and where healthcare resources for rehabilitation and employment opportunities are limited (Naidoo, 2013). As part of the CASP appraisal for RCTs all studies therefore scored a no for whether the results of the studies could be applied locally or in other contexts. Another interesting point was that while the electronic database search was conducted from inception, all studies identified and included were published within the 21st century from 2000 – 2015 in clusters that were seven years apart. This shows that the topic is well within its infancy stage as all studies have been published only in the last two decades and thus the review highlights that the research area of executive functioning rehabilitation in TBI individuals is relatively new and thus further research can possibly still contribute more evidence within this field of executive functioning for successful return to work rates in TBI individuals in different contexts. The fact that there are no studies from other continents adds to the lack of evidence of executive functioning rehabilitation and RTW in the TBI population globally.

The trial studies showed differences in the inclusion and exclusion criteria for selection of their population such as length of time since injury; TBI diagnosis including TBI individuals with different levels of TBI severity; differences in clinical criteria and outcomes of different types of assessments (functional and cognitive) conducted before inclusion in their studies or at baseline assessment. Vanderploeg et al. (2008), Salazar et al. (2008) and Constantindou et al. (2008) included participants with moderate to severe TBI, while Twamley et al. (2014, 2015) included mild to moderate TBI and Cicerone et al. (2008) included all mild, moderate and severe TBI individuals. None of the studies separated the outcomes including RTW for each of their TBI severity groups preventing the pooling of outcomes for a meta-analysis.

When taking a closer look at the characteristics of the population and samples in each treatment/intervention group, it was clear that the focus of the majority of studies was on TBI and executive functioning in a group of military personnel and veterans in particular. Thus, a specific population or sample group was evaluated and the outcomes may be very different in a different set of TBI individuals from other occupational groups or even the general population who were previously in employment. Military personnel's work can be deemed intensive with minimal room for a lack of higher functional abilities such as abilities related to planning, organisation, concentration, attention and more (Halvorson, 2010). The cause of TBI in most of the study participants was due to motor vehicle accidents which has been reported in the literature as the primary cause of TBI globally (Webster et al., 2015; Humphreys et al., 2013). The mean age of the population who were mostly males was below 40 and therefore the population can be considered young although the ages ranged from 18 to 62. Libeson, Downing, Ross and Ponsford (2020) note that TBI is a leading cause of disability in the young and that return to work (RTW) is

a key and prime goal of their recovery. Halvorson (2010) reported that the majority of active military personnel in 2005 were between 18 and 24 years old and that the reserve personnel were also a youthful population. Some incidence and epidemiological studies also state that more males sustain TBI than females (Khan et al., 2003a). In addition, a smaller percentage of women are in the military and as per Halvorson (2010) 16 percent of females work in the military. Munivenkatappa, Agrawal, Shukla, Kumaraswamy, and Devi (2016) have stated that while both genders are affected by TBI little is known about female TBI. Therefore, studies were appraised on the CASP appraisal for RCTs as not presenting the local or other contexts as the majority of participants, more than 90 percent were male and therefore the outcomes for EF, RTW for females are not clear. The latter is also due to the fact that studies do not report on the differences in outcome between the male and female groups that could be due to the lack of statistical power due to the small percentage (10% and less) of females. In an Indian based study Munivenkatappa et al. (2016) noted that the females with TBI differed significantly from males with TBI in the severity of injury and mortality. The females reported higher percentages in manifesting symptoms, injuries due to falls and surgical interventions and were significantly higher in mild head injury group and mortality in paediatric and elderly age group and severities of injuries were more among female patients than male patients in the middle and elder age groups. Farace and Alves (2000) in a meta-analysis of gender differences in TBI observed that there are significant differences in outcomes between males and females. The latter could have an effect of EF, RTW and QOL outcomes in females and thus would have been good to note in the included review studies. Age was a factor affecting independent living in the older population who had higher scores for independent living than the younger TBI group in Vanderploeg et al. (2008) and this was also the only study that conducted a post-hoc analysis showing that TBI individuals younger than 30 years of age in their

study had a significant higher RTW rate at 12-months post intervention in the intervention versus the control group where their intervention group had short daily individual therapy focusing on planning, organisation, memory, attention and pragmatic speech and communication in a cognitive didactic intervention compared to the control who had group therapy including functional experimental treatment.

Population samples of studies will differ as the decision on how many participants need to be recruited is dependent on how many participants are needed to produce statistical power to achieve a desirable effect or intervention magnitude for the particular primary outcome of interest. The sample size and structure of the RCT is dependent on what the study considers to be a primary hypothesis or outcome (Wittes, 2002). The CASP appraisal for RCTs identified that not all studies were interested in RTW as their primary outcome but looked at EF, functional or QOL outcomes as their primary outcome and thus would require a sample size sufficiently powered for these outcomes to provide significant outcomes. Vanderploeg et al. (2008) and Salazar et al. (2000) included RTW as a primary outcome while the rest of the studies considered it to be a secondary outcome therefore the latter studies would have determined their study size and design based on this outcome. Studies that considered RTW as a secondary outcome such as by Cicerone et al. (2008); Constantiniduo et al. (2008) and Twamley et al. (2014, 2015) may not have statistically conclusive results on RTW since their trials may have not been powered to obtain statistically significant results for RTW but rather on their primary outcome. Vanderploeg et al. (2008) and Salazar et al. (2000) therefore had the largest samples by far compared to the latter studies when evaluating the effect of intervention on RTW as their primary outcome. In terms of the REAIM appraisal, the first scoring item includes Reach that is defined by Gaglio et al. (2013) as the

absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative. It was noted that Constantinidou et al. (2008) did not provide information regarding the gender of their population and therefore affected the reporting on the representativeness of the population that is necessary in providing context for the results and also comparison between male and female outcomes which may be different in the TBI population. When assessing the risk of bias, no population selection bias nor problems with allocation concealment or randomisation processes were noted. The only aspect that may have affected the outcomes or results of the included trial studies was the use of block randomisation by some studies which is considered other bias. While block randomisation is supposed to assist in balancing the sample size, groups generated are generally not comparable and can differ drastically in terms of certain covariates example comorbidities and thus influence the results of the study. However, since all studies provided information that groups were equal with no significant difference in baseline characteristics this risk was considered minimal or low.

Cognitive EF interventions were the most common interventions and some trials included emotional or behavioural EF interventions and psychotherapy as well as an addition of work integrated therapy or supportive employment to improve outcomes including RTW. However, heterogeneity in the EF interventions between included trial studies existed as interventions differed with regards to the combination of EF interventions implemented in the experimental groups. The differences in intervention also differed in the type of therapy (individual, group or both), duration (hours per week and number of weeks) and implementers of the EF interventions. The implementers of the interventions were different for each study and only Salazar et al. (2000) and Vanderploeg et al. (2008) who focused their primary outcome on RTW had occupational

therapists implement their interventions. According to Desiron, Rijk, Van Hoof and Donceel (2011), occupational therapists concern themselves with rehabilitation programmes and interventions that enable persons with disability to participate in activities of daily living, which includes the ability to work if the individual is between the ages of 18-65 years. Phillips, Drummond, Radford and Tyerman (2010) note that within TBI vocational rehabilitation there is little harmony with regards to who should deliver the intervention and how it should be delivered to ensure success. The latter was attributed to that fact that vocational rehabilitation has become a broad concept that is used by health care professionals in a variety of ways. The authors go onto explain that the reason why occupational therapists carry out vocational rehabilitation for persons with TBI, is because the assessments the profession makes use of has valuable information that in turn can predict the success or failure of RTW (Phillips, Drummond, Radford, & Tyerman, 2010). Occupational therapists are usually the professionals who concern themselves with RTW and this can be attributed to the skills set of the OT in activity analysis, problem solving as well as goal setting.

There seems to be a similar lack of standardisation in Executive Functioning Rehabilitation Programmes and decisions around which healthcare professional should implement the EF interventions and how these EF interventions are delivered to ensure successful RTW in the studies included in this review. Since executive functioning (EF) is broad term that consists of a wide range of cognitive processes, as well as behavioural regulation and the control of behaviour (Chan et al., 2008) and executive functioning skill sets are defined differently among healthcare researchers and practitioners due to the diversity related to executive functioning (Murray & Ramage, 2000) the lack of standardisation could similarly be attributed to the broadness of the EF

concept that may be used by health care professionals in a variety of ways. In South Africa, TBI is also one of the leading causes to lasting disability in the population with very few individuals with TBI having success in regaining all their prior occupations such as return to work. In many first world countries such as the United Kingdom, vocational rehabilitation for RTW is often given by the occupational therapist in the community rehabilitation process after receiving primary care at the hospital (Phillips et al., 2010). In South Africa, occupational therapists and case managers are involved in vocational rehabilitation programmes but there is a dearth of evidence for the involvement of occupational therapists in implementing EF intervention for successful RTW in TBI individuals. It is not clear which healthcare professionals primarily would be involved in EF rehabilitation and whether occupational therapists in South Africa are fully aware of EF interventions and their implementation and success in RTW in the TBI population. Furthermore and in addition to other aspects of heterogeneity in the included studies the lack of standardisation in EF intervention therapy done individually or in groups, different intervention duration and implementers of EF interventions noted in studies may therefore contribute to the differences in the RTW, EF and QOL outcomes within and between studies therefore creating a challenge for vocational and rehabilitation or occupational therapists who rehabilitate TBI individuals for RTW in choosing the best EF interventions for implementation and decision making on therapy type, duration and implementers for EF intervention implementation in the TBI population. Thus, each study intervention and its outcomes need to be individually considered by vocational and rehabilitation therapists working with TBI patients and thus the review discusses and critically analyses the best practice EF interventions and RTW outcomes as the main aim of this review and continues with a discussion of the EF and QOL outcomes, additional outcomes and further discussion relating to the appraisal of studies.

5.2 Best Practice Interventions for Improving EF for RTW Post TBI

5.2.1 Return to Work Following EF Intervention

As the point of interest in this review, RTW as an outcome of EF intervention and improvement, was assessed. According to Wasiak et al. (2007), the measurement of RTW as an outcome is completed through the use of a variety of assessments that are based on the participant's physical, mental and functional abilities. Employment status is not the only assessment for RTW as Wasiak et al. (2007) explains that instruments used to measure the outcome of RTW can be in the form of questionnaires that assess work participation and disability or assess time spent at work and the maintenance of employment. However, Wasiak et al. (2007), also stated that they struggled to find formal assessments for measuring RTW as well as vocational goal setting. This lack of formality and standardisation in RTW assessment was noted in the trial studies included in this review. Literature states that there is no clear or standardised definition for RTW and therefore RTW as an outcome should be described when conducting studies evaluating such outcome. The studies included in this review indicated what was being measured in terms of return to work such as return to community work, the attainment of competitive work, paid employment or school enrolment, either full- or part-time work but not employment in sheltered workshops, as well as other measures such as fitness for duty and weeks and hours worked, and wages earned. RTW assessments in the included studies were done either through collecting collateral information from medical folders within the military documentations, completing a questionnaire that asks if the participant achieved employment or through a telephonic conversation where the outcome assessor asked the participant whether they achieved meaningful employment. It is concerning that there is no real formal assessment that can be utilised in measuring RTW and its related outcomes. This

leads to many assessments on RTW being subjective, meaning that participants may exaggerate their achievement and participation in employment. Furthermore, documented closed ended results for either yes or no for RTW does not provide detail on the specific work (level of advanced skill required) in which the TBI individual is employed or whether work is part-time or full time. Outcome measures used to assess RTW in the studies in this review included mainly dichotomous yes/no evaluation and in addition the Community Integration Questionnaire Productivity (CIQprod) scale and Vocational Integration Scale (VIS). These outcomes were considered at baseline and at various periods post intervention. Salazar et al. (2000) who used RTW as their primary outcome defined work in their study as part-time being less than 35 hours per week and full time being more than 35 hours per week but did not split these results in their RTW outcomes and thus leaves a gap in the understanding of how many were able to return to longer hours of work per week in their intervention group. The same study also measured fitness for duty post EF intervention (Salazar et al., 2000). Productivity scales on the Community Integration Questionnaire for measuring RTW were used in two studies (Cicerone et al., 2008; Constantinidou et al., 2008) included in this review and was measured as a mean and standard deviation compared to other studies who reported on RTW as a percentage of the sample population who returned to work. The study conducted by Cicerone et al. (2008) also measured RTW using the Vocational Integration Scale (VIS) that is a 5-point Likert scale that provides more depth regarding the type of employment or work the participant is involved in and if unemployed. The items on this scale as described by Cicerone et al. (2008) included the following: namely, “(1) unemployed, (2) sheltered employment, (3) supported employment (i.e., job coaching or other permanent supports), (4) transitional employment (education, job coaching, or other temporary supports), and (5) competitive employment”. They converted the ratings to a dichotomous variable (yes/no) to

classify participants (percentage as unit of measurement) as engaged in community-based employment (scales 3-5) or unemployed (scale 1 and 2) as a self-report of productivity. The study does not provide the specific number of participants in each category of the VIS thus there is a lack of detail regarding the statistics per RTW category. The problem with breaking down the scale into a dichotomous yes and no variable is that it then classifies those TBI individuals who are in sheltered employment as unemployed and also does not differentiate the number of TBI individuals who actually attained competitive employment that is a major outcome for successful RTW. For this study (Cicerone et al., 2008) the RTW outcome for consideration was the attainment of competitive work (open labour market) and thus it was appropriate in their context as sheltered employment is not considered competitive employment but one must be careful with regards to how outcomes are transformed and also what outcomes are appropriate for different contexts. For example, in the South African context TBI individuals may also be allocated to a form of employment categorised as protective employment (the regulations for hiring, productivity and discharge favours previously disadvantaged individuals) and this is not included in the VIS. The outcome of protective employment is to provide capacity building programmes, allow for work skills training and adhere to the correct supported services as a standard of the Department of Social development (<https://longwoodvillage.co.za/protective-employment> - accessed 16 December 2020). It is therefore recommended that RTW outcomes be standardised when conducting such trials in order to make appropriate and accurate comparisons that are also context specific in relation to employment types and opportunities in different countries around the world.

RTW was only the primary outcome of interest in a third (two out of six) of the studies and therefore it was noted that RTW may not yet be considered as an important outcome of TBI

rehabilitation post executive functioning intervention but that higher level functions or tasks in terms of cognitive, emotional and behavioural EF outcomes are still of primary interest and concern in trials on EF interventions in the TBI population and thus RTW outcomes needs to be promoted through further EF intervention studies. Due to the heterogeneity of the included trial studies, RTW outcomes in particular as well as EF outcomes could not be pooled for statistical analysis (meta-analysis) to provide a measure of effectiveness to determine the best practice EF intervention for successful RTW outcomes and thus the latter still remains unknown as results from the review are inconclusive in this regard. We can only therefore provide a critical analysis of the findings through this discussion on the RTW outcomes found in the included trials.

In considering which studies provided the best RTW outcomes we decided that those who evaluate RTW as their primary outcome and then provide a high level of methodological design and intervention implementation as well as low risk of bias and is considered most cost-effective if this was measured, will be evaluated for possible effectiveness of EF interventions in successful return to work. Two studies namely Salazar et al. (2000) and Vanderploeg et al. (2008) that fit the latter criteria were identified. Both these studies had a low risk of bias and a high level of methodological and intervention implementation rigour and measured RTW as a dichotomous variable. However, both studies report no significant difference in RTW outcomes at 12-months post EF intervention. The EF intervention in Vanderploeg et al. (2008) was effective in the RTW/school (tertiary level schooling) rate in younger participants less than 30 years of age in the intervention (cognitive) arm who showed a significantly higher rate of return to work or school (tertiary) than younger participants in the control (functional) arm at 1-year post treatment. However, the problem with the reported results is that it did not separate the outcome for RTW

and return to school and thus it is not clear for which category of participants (working or schooling) the intervention was most effective. The latter is supported by Graham et al. (2016) who stated in their review on employment interventions for RTW that outcomes for RTW and school should be separated. While Salazar et al. (2000) also included a measure of fitness for duty, they did not find any significant difference in this outcome between groups and thus we do not have evidence for an effective EF intervention for successful RTW or outcome related to being able to work. These studies had large populations but produced small effect sizes for their EF and QOL outcomes thus the question whether the EF interventions implemented were suitable for the TBI population included and whether the level and type of EF required for the occupations these TBI participants required to RTW were appropriately addressed by the included EF interventions. Salazar (2000) conducted in-hospital rehabilitation that focused on executive functioning skills orientated around planning and organisation together with integrated work therapy that was carried out by an occupational therapist and yielded the highest percentage or rate (intervention: 90% and control: 94%) of RTW from their population sample than Vanderploeg et al. (2008) and the other four studies even though the improvements were not significantly different between or within groups.

In an attempt to provide some evidence for occupational, vocational or rehabilitation therapists on EF interventions and successful RTW we critically analyse the other four studies who evaluated RTW as a secondary outcome and focused more on EF as their primary outcome. These four studies by Cicerone et al. (2008); Constantinidou et al. (2008) and Twamley et al. (2014, 2015) also had a high level of methodological and intervention implementation rigour and a low risk of bias except for Twamley et al. (2014; 2015) who had detection, performance and attrition bias that

may have affected their outcomes. Twamley et al. (2014, 2015) included a CogSMART intervention with enhanced supportive employment in the intervention group with successful RTW specifically in attaining competitive employment in this group at four weeks following the trial as 50% of participants in this group returned to work. However, the difference was not significant but the moderate effect size favoured the CogSMART intervention. This RTW improvement however plateaued between the two groups at 12 months and thus we see that early EF intervention increases the RTW rate but that rates can plateau in the long term. This plateau effect could be explained by the natural process of neuroplasticity that occurs following recovery from a head injury over time or that over time in this study supportive employment on its own can successfully improve RTW and therefore the latter needs to be further explored. It may have also been useful to determine whether CogSMART on its own would have yielded a significant increase in RTW at 12 months than supportive employment alone. Evidence for the use of CogSMART as an EF intervention together with enhanced supportive employment for successful RTW (attainment of competitive employment) in TBI may be useful for occupational, vocational and rehabilitation therapists in practice and researchers looking to further evaluate the CogSMART EF intervention in TBI groups. Interestingly, it was noted that the population in Twamley et al. (2014, 2015) was as young as that of Salazar et al. (2000) and Vanderploeg et al. (2008) but who included moderate to severe TBI participants compared to Twamley et al. (2014, 2015) who included mild to moderate TBI individuals that may affect the RTW outcomes in these studies. Furthermore, it seems to be evident that supplementing the EF interventions with supported employment or integrated work therapy yields good or high percentage of RTW outcomes even though not significantly different within or between groups. This can be seen in Twamley et al. (2015) who did not use RTW as a primary outcome and supplemented their executive functioning intervention

with an enhanced supported employment intervention which assisted in them achieving the second highest RTW percentage (52%) at 12-month follow-up. Wehman et al. (2003) conducted a longitudinal prospective study to investigate the long-term follow-up costs of supported employment provided by vocational specialists and the wage and employment characteristics for individuals with moderate to severe TBI who participated in supported employment services over a 14-year time period. The study was conducted at a university-based supported employment programme that used the individual placement model of supported employment and found that TBI individuals earned an average of US dollars 17,515 more than the costs associated with their supported employment and thus concluded that supported employment is cost effective for individuals with disabilities, including individuals with TBI, and that the costs of supported employment decrease over time. However, it must be noted that adding supported employment implemented by supported employment specialists (vocational specialists) in Twamley et al. (2014, 2015) results in difficulty in determining whether the EF intervention included is effective in itself when compared to supported employment alone. Within the South African context, supportive employment may be too costly based on the lack of healthcare resources and the lack of employment opportunities in general which in turn means that TBI individuals may not earn enough to support themselves and their families as well as pay for the cost of this supportive employment (Engelbrecht, Van Niekerk, Coetzee, & Hajwani, 2017). Therefore, providing evidence for EF interventions alone that may be more cost-effective compared to supportive employment in this setting is required. In South Africa, the occupational therapists and case managers play the role of the vocational specialists referred to in other contexts (Engelbrecht et al., 2017).

As earlier discussed, Cicerone et al. (2008) did not provide detail regarding the RTW percentages per category on the VIS used and thus it was not clear how many attained competitive employment post EF intervention, as the researchers combined items three (supported employment), four (transitional employment) and 5 (competitive employment) into a dichotomous variable namely “yes” as employed. However, as it was reported that significantly more participants in the intervention group who received intensive cognitive rehabilitation return to community-based employment we have evidence for the use of intensive cognitive rehabilitation as a possible EF intervention in a group of mild, moderate and severe TBI participants only, with no analysis of which group had a more significant RTW outcome. At 6 months Cicerone et al. (2008) also found a plateau of RTW outcomes as there was no significant difference between the two groups; thus, again the hypothesis or postulation of neuroplasticity changes occurring during long-term recovery following TBI. Constantinidou et al. (2008) did not have results for the number of participants who reported improved productivity on the CIQ productivity scale that could have been compared in terms of the number who RTW and the number who did not. The latter was confirmed through email correspondence with the author by the primary reviewer (LH). Constantinidou et al. (2008) also did not state whether they were interested in a particular work category (sheltered, transitional, community or competitive). Both Cicerone et al. (2008) and Constantinidou et al. (2008) measured productivity using the CIQ productivity scale. Constantinidou et al. (2008) did not find a significant difference in mean CIQ(prod) between groups but a significant difference within separate groups. Their mean scores were above four which is the highest score in the CIQ(prod) that refers to part of full-time work or school or some form of volunteering work referring to a higher level of productivity. Cicerone et al. (2008) only showed a significant change in the CIQ(prod) within the intervention group post treatment but no difference in the outcome between

groups post treatment. However, at 6 months both groups showed a significant improvement in CIQ(prod) from baseline. Thus, the latter provides some usefulness of the intensive cognitive rehabilitation programme used in intervention group in Cicerone et al. (2008). Mean CIQ(prod) scores for Cicerone et al. (2008) in their group of mild, moderate and severe TBI individuals were observed to be in the lower range between 0.9 and 2, which shows lower productivity levels than the moderate to severe TBI individuals in Constantinidou et al. (2008).

It is clear that the different reporting methods and definitions of RTW for each study make it difficult to make conclusive recommendations for EF interventions and specific RTW goals. What is also considered to be lacking in these trials is an evaluation of the specific EF skills required in the specific work or occupation and how long the TBI individuals maintained their individual employment as well as whether employment was in their same previous or different worker role. Another limitation noted was that these studies did not analyse which EF skill/s were improved following intervention in those who successfully returned to work compared to those who did not in both groups. The studies merely identified improvement in the EF and QOL outcomes measured. It is not therefore clear which EF skills were more improved in the RTW group in both the experimental and control groups that will inform rehabilitation specialists on which EF skill or set of skills to improve on for example memory or organisation and planning or attention to increase successful RTW. The latter would be useful in focusing EF interventions and rehabilitation when attempting to increase RTW in the TBI population. The lack of reporting on RTW for different levels of TBI severity as all studies included more than one level of TBI severity was a further limitation of the included trials. This distinction would be recommended as literature has reported that TBI severity affects the ability to improve activities of daily living (ADLs) and RTW (Shames

et al., 2007). Kennedy et al. (2008) also indicate that evidence available shows that interventions for executive functions are efficacious for some TBI subgroups with much yet to be investigated.

5.2.2 Executive Functioning Assessment, Interventions and Outcomes

Executive functioning problems are not diagnosed as an illness and thus there are no set criteria for its diagnosis. For this reason, executive functioning problems may not be easily recognised, assessed and diagnosed as it may not be the first aspect or component of normal daily functioning to be identified as lacking in individuals with or without brain or neurological functioning deficits including TBI. EF could be seen as the underlying component of a limitation in higher functional activity including work or occupation. Poor EF can limit the individual's ability to participate in normal daily activities such as occupation in various roles. There are tests that assess limitations in cognitive, emotional and behavioural executive function in individuals with a variety of neurological disorders or who are born with weak EF (<https://www.webmd.com/add-adhd/executive-function>, accessed 06 December 2020, Constantinidou et al., 2012).

To formally assess executive functioning, it would be best to use common standardised EF related outcomes. This would allow for benchmarking of EF interventions and outcomes amongst different TBI population groups. Constantinidou et al. (2012) mentioned the *top ten* frequently used outcome measures for executive function namely the Wisconsin Card Sorting Test, Rey-Osterrieth Complex Figure Test, Halstead Category Test, Trail Making Test, Controlled Oral Word Association Test, Wechsler Adult Intelligence Scale-revised/Wechsler Adult Intelligence scale-III, Wechsler Abbreviated Scale of Intelligence-Block Design, Stoop Test, Picture Arrangements

and Porteus Maze Test. These tests are grouped under the term Neuropsychological Performance Tests.

In the trial studies included in this review many of the formal standardised tests in the top ten list identified by Constantinidou et al. (2012), were used to assess EF performance tasks treated in the intervention (experimental) groups versus the comparison (control) groups and thus their results for EF improvements can be considered to be based on valid and reliable measures of EF assessment. Some studies in the review however included other measures to evaluate EF such as Auditory Consonant Trigrams, Buschke Selective Reminding Test and Halstead-Reitan Neuropsychological Impairment Index for major depression, generalised anxiety and aggression (verbal or physical) as in Salazar et al. (2000) and Booklet Category Test as in Cicerone et al. (2008) to name a few. Other EF related outcomes in the trial studies in this review also included Perceived Self Efficacy in Social, Cognition & Emotional components, Functional Independence Measure consisting of motor and cognitive scores, Disability Rating Scale Score measured at discharge from protocol treatment, Present State Exam used to capture mood and behavioural variables, Apathy Evaluation Scale to capture motivation, and the Neurobehavioral Rating Scale Interview version (Vanderploeg et al., 2008) that assessed self-perceived memory problems and the eight Levels of the Categorization Program (Constantinidou et al., 2008) that assessed eight levels of categorization tasks for EF performance.

The review therefore highlights that a number of different interventions for addressing EF deficits or performance areas in TBI in the intervention (experimental) groups were evaluated for efficacy in EF, RTW and QOL in the included trial studies. The interventions (experimental) tested for

effectiveness in improving EF and thus RTW and QOL included an Intensive Cognitive Rehabilitation Program (Cicerone et al., 2008), the Categorization Program including the use of object organisation and categorisation as well as new category learning, analysis, linguistic flexibility and abstract reasoning (Constantinidou et al., 2008), In-hospital rehabilitation for specific EF deficits (Salazar et al., 2000), CoGSMART (Twamley et al., 2014, 2015) and Cognitive-didactic treatment (Vanderploeg et al., 2008). These addressed EF performance deficits such as planning and organisation, memory and attention, problem solving and functional skills, pragmatic speech and communication, emotional regulation, emotional difficulties and behavioural regulation in terms of interpersonal behaviour, psychosocial therapy, psychotherapy as part of the psychological component of executive function. The trial studies included one or more of any of these EF performance tasks as part of their intervention to evaluate the effect on outcomes including RTW and productivity resulting in the heterogeneity of EF interventions implemented. The comparison (control) groups received a form of standard intervention that may or may not have purely focused on EF components for RTW and were either in-hospital (rehabilitation centre, acute care setting) or home based. It was noted that it may not be possible to have a comparison (control) intervention that does not have some element of EF in it due to the nature of TBI vocational rehabilitation and thus it was understood that it would be difficult to control for no EF treatment component in the comparison groups in these studies. However, it is recommended that researchers attempt to evaluate one or more set of EF components in an intervention against one EF component if possible. The latter may provide a set of EF components that could then be combined as a holistic intervention that can be used to improve RTW and productivity in RTW. The trial studies did not evaluate which EF outcomes were positively correlated to the RTW group in both the intervention and control groups. That could provide

vocational or rehabilitation therapists with information on EF interventions needed to improve more specific EF skills for successful RTW in TBI patients.

Executive functioning can be described as a top-down process whereby inhibition, working memory and cognitive flexibility is used in context to achieve goal-directed behaviour (Serpell & Esposito, 2016). This component helps manage problem-specific information and keep it active in the working memory while ignoring information that is deemed to be distracting and prevents task-relevant goals. Serpell and Esposito (2016) explain that executive functioning encompasses higher order executive functioning skills such as planning, reasoning and problem solving. Executive functioning is a dynamic skill that allows a person to adjust in order to meet task demands through the use of planning and organising as well as utilising previously learnt knowledge and insight gained during tasks, in a flexible manner. Constantinidou et al. (2012) records that executive functioning intervention is orientated around three domains. The first domain being planning and initiating, consists of planning tasks and setting goals. It then looks at initiating goal-directed behaviour and the allocation of attention in a resourceful manner. Inappropriate and impulsive behaviours need to be controlled and constant monitoring in this domain needs to take place. The second domain is concerned with maintenance and flexibility, which is found in behaviour maintenance when completing tasks and cognitive flexibility when approaching a problem from different angles. The third domain looks at regulation and effective performance, this is found in self-awareness of strengths and identifying weaknesses in oneself and others. It also refers to the self-regulation of behaviour and the emotions based on the type of goals set out and self-awareness. The studies included in the review are not necessarily orientated around the three domains described as the EF interventions necessarily follow all three domains and the EF interventions

were mainly focused on cognitive deficits and the variety of EF interventions combined in studies resulting in the heterogeneity between study EF interventions. As stated previously the use of EF interventions in the rehabilitation of TBI individuals seems to be a fairly recent area of research and therefore there is currently no standardisation between intervention studies conducted. Authors of the included studies also did not report on how they chose their EF interventions for investigation and evaluation in the TBI population or sample. fairly recently investigated and evaluated.

As previously stated, Salazar et al. (2000) and Vanderploeg et al. (2008) were the only studies that evaluated RTW as the primary outcome but both evaluated EF as their secondary outcomes. These two studies did not find significant changes in the EF NP Test outcomes between the intervention and control groups. The two studies both used pragmatic speech and communication as one of their EF interventions but Vanderploeg et al. (2008) added memory and attention while Salazar added planning and organisation as well as work-integrated therapy in their intervention group. The assumption would be that improvements in EF NP Test outcomes would successfully increase RTW. But while the RTW outcomes in these studies were not significantly different between groups they did have a large percentage of their sample returning to work or returning to work/school as measured by the two studies. Salazar et al. (2000) had work-integrated therapy in addition to EF interventions and thus work-integrated therapy could be a confounding factor that attributed to the very high (>90%) RTW rate in both groups at 12 months. Vanderploeg et al. (2008) implemented the Cognitive Didactic EF intervention against functional-experiential intervention in the control group and had no significant changes in EF NP Test outcomes within and between groups and their RTW rate was much lower under 40% at 12 months. These findings

do not provide enough evidence on which to make clinical decisions about which EF interventions are best for successful return to work as the findings are different across these two studies that use different EF interventions and TBI participants of different severity preventing pooling of their results to determine the estimate of the measure of effectiveness of the EF interventions to improve EF outcomes and RTW.

When analysing the findings from the four studies who evaluated RTW as their secondary outcome we noted that the EF interventions showed significant changes either within the intervention group and control groups on some EF outcomes with few studies showing a difference between groups on the EF outcomes. Constantinidou et al. (2008) who implemented the Categorization Program only reported that the intervention group had significantly improved outcomes for twelve EF NP Tests compared to the seven in the control groups with no p-values thus making it difficult to determine effect size and clinical significance. Cicerone et al. (2008) also could not provide information on the best EF intervention as they had no significant change in outcome between groups. Lastly, Twamley et al. (2014, 2015) was the only study that showed significant changes on EF between groups with moderate to large effect sizes but the CogSMART EF intervention was combined with supported employment making it difficult to differentiate which component EF or supported employment had the bigger effect. However, aspects such as reduced post-concussive symptoms measured using the Neurobehavioral Symptom Inventory (NSI), post traumatic distress and depression and improved prospective memory showed long-term improvement at 3, 6 and 12 months supporting the CogSMART and supportive employment intervention for improving these specific EF outcomes which are important for military personnel who live in closed communities and work under stressful conditions.

The initial training of military personnel include immersion in the military lifestyle and culture including military history, customs and courtesies, dress code, values and ethics. They learn how to listen to and follow orders and how to function within the military chain of command. Military service members are taught discipline, focus, and control and are expected to be disciplined in their actions and words, to maintain control of their emotions and their physical selves at all times and remain focused in all but especially in challenging situations (lack of sleep, physical exhaustion, extreme stress) as they are faced with uncertain and often dangerous situations. Thus, it can be very difficult for military personnel who sustain TBI injuries to possibly return to the level of function required as described in the latter and therefore difficult to RTW even through the improvement of EF skills. Since executive functioning components have a functional, real-life, element to them, intervention that focuses on this skill would be seen to have a high effectiveness rating. All of the studies make use of practice-based research that is conducted within a therapeutic environment that may not fully simulate the work required of these military personnel.

Other EF outcomes such as functional outcome tests, perceived self-efficacy (social, cognition, emotional), categorisation and probe tests were also measured following EF interventions. While three studies measured functional outcomes, two used the CIQ and reported different findings where either the intervention group only or both groups had some significant changes in function such as social and home integration (Cicerone et al., 2008; Constantinidou et al., 2008). Cicerone et al. (2008) note the long term maintenance of function on the CIQ at 6-month follow-up thus their intensive cognitive rehabilitation programme was successful in long-term maintenance of functional outcomes necessary for RTW. Vanderploeg et al. (2008) however, noted that their intervention group that had cognitive didactic therapy had significantly fewer participants with

moderate to severe memory problems and significantly better cognitive FIM scores than the control groups who received functional-experiential therapy. This outcome provides some evidence for cognitive therapy for the improvement of memory and cognitive function in TBI individuals which is required to maintain work-related skills and perform well at work and specifically for those in the military who require high levels of cognitive function (Halverson, 2010). Cicerone et al. (2008) found that the perceived self-efficacy in the management of both emotional and cognitive symptoms in the intervention group improved more than the control and was sustained at 6 months. The latter is important for military personnel who are required to be disciplined in their actions and words and to maintain control of their emotions and their physical selves at all times according to Halverson, (2010). Lastly, Constantinidou et al. (2008) found that participants in the intervention were better at categorising common objects and new category learning (follow a logical rule in categorising objects) from baseline to post intervention but were not significantly different to the control group.

Cram et al. (2013) found in a scoping review of EF in occupational therapy literature that occupational therapists who are involved in occupational or work rehabilitation are not always aware of executive functioning problems, assessments and possible interventions that are required for such high level, advanced skills and functioning. Cram et al. (2013) concluded that: “EF is a complex construct that is conceptualized with considerable variance within the occupational therapy literature, creating barriers to effective service delivery”. The latter may thus affect the service delivery in TBI individuals in returning to work. Bade (2010) expounds that while everyone makes use of executive cognitive function to complete everyday tasks since cognitive EF forms the basis of performing complex tasks, the use of high levels of executive functioning is crucial in all types of home and work tasks and demands. Bade (2010) also notes that Occupational

Therapy (OT) work rehabilitation services frequently focuses on EF. Matheson, Dodson and Wolf (2011) go on to describe that when there is an inadequacy in cognitive components in response to occupational demands, by improving executive functioning, occupational performance barriers can be overcome. However, when there is a notable shortcoming in executive functioning, even fully-remediated cognitive components will be insufficient in supporting occupational demands (Matheson et al., 2011). Occupational therapists find themselves in a unique position when assessing and identifying executive functioning as unlike neuropsychologists who assess and evaluate EF in the quiet of an office on the couch the occupational therapist is found in the real-life setting assessing the work performance and work capability of individuals with neurological disability including TBI (Matheson et al., 2011). When identifying the profession that is most concerned with areas orientated around vocational rehabilitation assessment, it is noted that occupational therapy assesses vocational handicap, employability, vocational feasibility, occupational disability, functional limitations and impairments. Thus, executive function limitations should be easily identified by therapists that carry out assessments orientated around these spheres of work rehabilitation. Studies included in this review used mostly speech and language therapists or pathologists, supportive employment specialists, a multidisciplinary team and psychiatric nurses. Only two studies (Vanderploeg et al., 2008; Salazar et al., 2000) who evaluated RTW as their primary outcome used occupational therapists to implement their interventions. The implementer of the interventions in these studies could influence the buy in of TBI individuals into the programme, the quality of implementation and thus intervention outcomes. However, within all the studies reviewed, it was noted that the implementers/ healthcare practitioners who carried out the interventions received adequate training that increases the probability that the intervention was delivered in a consistent way. Lastly, studies used individual

and/or group therapy or both in the different groups. There is however no clear evidence that can prove the benefits of individual therapy compared to group therapy and vice versa. Thus, the benefits of the mechanism of therapy needs to be considered in light of what intervention is being used. A group therapy environment can foster efficient and controlled social interactions that are required for behaviour regulation, while the strength of individual therapies lies in its ability to tailor therapy to the individual in a more streamline manner.

In conclusion, the EF outcomes were very variable and no conclusive evidence for EF interventions to improve EF in TBI and specifically for the successful RTW for TBI has been found by the reviewers. An analysis of which EF outcomes are predictors of successful RTW for TBI was not conducted and it may have been beneficial to assess which EF functions were improved in the RTW TBI groups in both treatment arms. Another factor to consider is the ceiling effect of certain EF outcomes used as if TBI individuals have already high scores at baseline, the improvements post-intervention or at long-term follow-up may not be detectable and thus lack significance. EF is a component of work rehabilitation that needs further exploration especially in the TBI population.

5.2.3 QOL after EF Interventions

Lastly, trial studies in this review also evaluated QOL as an outcome of their EF interventions but could not be combined in a meta-analysis due to the use of different QOL outcomes. Thus, quality of life outcomes measured were not standardised across studies. Interestingly none of the study trials included the QOLIBRI QOL outcome which has been developed to assess QOL in the TBI population (von Steinbuechel et al., 2005). QOLIBRI includes measures of improvement in social, emotional, physical and functional activity including executive functioning or performance satisfaction with thinking speed, the ability to concentrate when reading or when having a

conversation, verbalise and understand, make decisions, plan and work out solutions to everyday problems, remember things, manage finances, participation in domestic activities, work and social activities following TBI that are classified as executive functioning skills (von Steinbuechel et al., 2005). Since QOL measures improvement in social, emotional, physical and functional activity, RTW which is a high level function that requires good social, emotional, physical or functional ability, could enhance the self-reported QOL of individuals including those with a TBI. Notably the two studies of Salazar et al. (2000) and Vanderploeg et al. (2008) who included RTW as their primary outcome also included QOL as their primary outcome of their EF interventions. While Salazar et al. (2000) found no change in QOL outcomes between the two treatment arms, Vanderploeg et al. (2008) also found no general difference in the Functional Independence Measure (FIM) for QOL but showed that TBI individuals who were older and had a higher level of education in the control group scored better than the intervention group but when looking at lower FIM baseline scores, the TBI individuals with these lower FIM baseline scores had a better QOL outcome post EF intervention in the intervention versus the control group. This shows that a variety of factors can play a role in the QOL outcomes following EF interventions in TBI individuals and should be considered when expecting QOL improvements following EF interventions. Cicerone et al. (2008) and Twamley et al. (2015) also showed that QOL could be improved in their intervention group in the long-term after 6 and 3, 6, and 12-months, respectively. These improvements could be as a result of the improvement in RTW outcomes that increased in both their experimental and control groups as literature states that employment is a major determinant of quality of life (Dijkers, 2004). Dijkers (2004) supports the latter as he states that employment affects many other important factors in QOL, such as the standard of living, financial security, and opportunities to meet people. Dijkers, (2004) further states that employment is a

major marker of responsible adulthood in Western Societies in addition to marriage. In an older study by O'Neill et al. (1998) it was reported that even after controlling for severity of and time since TBI, gender, education, marital status, and other predictors, employment had an impact on both perceived needs satisfaction and global QOL ratings in the TBI population. The trial studies did not analyse the difference in QOL outcomes in the RTW groups between the intervention and control groups and this would have provided an in-depth understanding of whether those who received EF intervention and returned to work had a better QOL than those who did not receive EF and returned to work that could have provided a better understanding of the success of EF interventions on QOL in the TBI population that returned to work.

5.2.4 Additional Outcomes Evaluated

Some studies evaluated or analysed other aspects that can be thought to support the reliability and validity of their study outcomes. These were whether time of injury had an effect on outcome as time since injury could affect the overall results if different TBI individuals were at different phases of healing since their time of injury. This could possibly explain the plateau in outcome results noted in studies that evaluated long-term (12 months) outcomes in RTW and EF. Another additional outcome evaluated included protocol adherence or fidelity that is defined as the level or percentage of attendance of patients in the intervention programme and received the protocol treatment as attendance in the intervention programme could affect the number of hours or days of treatment received and thus the effectiveness of the outcomes of each patient and thus the overall measure of effectiveness of the interventions. Vanderploeg et al. (2008) was the only study that evaluated protocol adherence and while they noted some differences in attendance (exposure) to interventions they noted that the differences were equal between groups and thus may not influence the outcomes per group. A third additional outcome identified in the studies included in the review

was treatment fidelity that is defined as the compliance of the implementers/therapists to the study intervention protocols. If treatment fidelity is not met the effectiveness of the intervention may be limited. Cicerone et al. (2008) and Twamley et al. (2014, 2015) were the only studies that reported on this and thus provides validation of the intervention implemented and reliability of their outcome results from this perspective. It would be considered good practice for RCTs to include and report on both protocol adherence and treatment fidelity to provide further evidence for the validity and reliability of their outcomes. Cost effectiveness was also only measured in one study by (Salazar et al., 2000) who stated that their home-based rehabilitation programme intervention in the control group that included some EF intervention as well was much more cost effective than the in-hospital based EF rehabilitation programme with the added benefit of family support. Cost effectiveness should therefore be considered and reported on for all RCTs as it will allow researchers and practitioners to determine whether the cost of the intervention is worth the outcome as some studies showed small effect sizes but may have been very costly and therefore not worth the cost. However, since employment in TBI would allow for improved financial freedom, reduced burden on social grants and family support and therefore improve quality of life (Dijkers, 2004), each study intervention was thought to be worth the cost as it resulted in an outcome that was invaluable to TBI individuals who now could return to work, earn money and improve their QOL. In South Africa, the healthcare system is under pressure due to the increased burden of disease including TBI (Naidoo, 2013) and health care resources are limited. The diseased population also has limited access for a number of reasons (lack of transport and funds for transport and rehabilitation) to regular intervention sessions that can aid or assist in return to work at community rehabilitation centres. Thus, the home-based intervention including EF used in Salazar et al. (2000) that seemed to show a consistent improvement in RTW outcomes may be something healthcare

professionals in South Africa who are involved in RTW rehabilitation interventions in TBI should consider by working together with home-based carers available in communities in South Africa. Lastly, it is becoming more common for RCTs to include a qualitative component of assessment to determine whether participants found the interventions useful and effective in improving their health outcomes. One study of the six include such evaluation and found positive feedback on the intervention implemented and also used a quantitative rating scale to rate the participants perceived effectiveness of the intervention and may be a useful assessment to include besides only including objective outcomes of efficacy of interventions as it may not reflect the participants' views of intervention efficacy.

5.2.5 Methodological and Intervention Implementation Rigour, Risk of Bias Affecting the Outcomes of the EF Interventions

The studies showed good methodological rigour as assessed by the items of the CASP appraisal for RCTs. One of the difficulties presented by some if not all of the studies was evaluating the effect sizes of their outcomes and the precision of the effect size on their interventions as not all studies reported on these directly and those who did used different measures of effect size namely Cohen's d and Hedge's g to calculate effect sizes that are computed differently but are very similar except the Hedge's g is more preferred as it is considered the true effect size. The reviewers had to therefore calculate and determine the effect sizes to determine whether the effect sizes were small, medium or large and what the precision of the effect sizes for outcomes were based on the available results. The effect sizes should be reported on considering the appraisal of methodological rigour includes questions on the latter but also because the effect size communicates the practical significance of results. We found that most of the effect sizes for the

EF outcomes in particular were small to moderate with few of the outcomes having a large effect size even though the Hedge's g , Cohen's d calculations are deemed to inflate effect sizes. The effect size and precision of the effect of outcomes measured in these studies provide healthcare practitioners with information regarding the effect of the intervention (treatment) on the outcome of interest but also allow one to evaluate whether the benefits or harm of the intervention affects the cost in terms of resources required to obtain significant results from such intervention (treatment). Therefore, the cost (resources) for the implementation of the interventions (experiment) in these studies could be seen as not worth the benefit or harm introduced by the interventions (experiment). However, due to the high rates of improvement in RTW post-treatment or at 6 months and the sustainability of the increase at 12 months in some studies as well as the income that the participants could generate due to being employable were deemed as a benefit worth the cost (resources) of implementation.

Similar to the risk of bias assessment of attrition, the CASP appraisal for RCTs interrogated whether studies accounted for all patients at the end of their trials. Twamley et al. (2014, 2015) had a dropout rate of 16% within the first three months as well as missing data from the three-month assessment period. Vanderploeg et al. (2008), had an 8% loss of participants on follow up at 12 months and thus these participants' outcomes could not be measured and reported on. Attrition was therefore due to drop out and the depletion of medical aid funds of some participants. This in turn affected the outcome measures of the study as not all participants' follow-up assessments could be carried out. Although these studies encountered attrition, the loss was equal between groups and may not have affected the outcomes of the studies much. In addition, the studies by Cicerone et al. (2008), Constantinidou et al. (2008) and Salazar et al. (2000) also had

dropout or loss to follow-up but included statistical analysis to minimise the effect of the attrition on outcomes. Thus, we scored these as a low risk of attrition bias as they accounted for missing data in their analysis using mainly intention to treat.

While the CASP appraisal for RCTs assessed blinding, the risk of bias assessment provided more detail with regards to the types of blinding issues affecting studies and thus their outcomes. All studies could not blind the participants nor personnel, followed by some studies who used self-reported outcomes that would not allow for blinding and lastly objectives measures that were measured by personnel who could not be blinded to treatment groups and therefore these issues with blinding could have some effect on the outcomes measured post EF interventions. The CASP appraisal for RCTs also evaluated whether studies provided equal treatment to each treatment group or arm. The lack of effectiveness therefore in Salazar et al. (2000) whose primary outcome included RTW could have been due to the unequal treatment of their two groups. Furthermore, Salazar et al. (2000) had a different number of participants in each treatment arm and there were fewer motor vehicle-related injuries, more assault injuries, and fewer patients who were unconscious for an hour or more in the in-hospital rehabilitation group (intervention group) than their home-based rehabilitation group (control). In Constantinidou et al. (2008), the control group received a longer duration of intervention than their experimental intervention arm that could affect the outcomes for EF and productivity. The CASP appraisal for RCTs asks reviewers of studies to reflect on whether all clinically relevant outcomes were measured and the reviewers concurred that while Cicerone et al. (2008) and Constantinidou et al. (2008) measured productivity, they should have included RTW in percentage as a clinically relevant outcome.

With regards to the rigour of the EF interventions and implementation of the EF interventions the REAIM framework for the appraisal of interventions provide a list of items to consider when assessing the rigour of intervention implementation and maintenance. While the lowest percentage scored was 79%, the item appraising intervention implementation scored zero for all studies as the staff/participants of the organisation/intervention of all studies were not involved in delivering the intervention thus possibly affecting the cost of the intervention as other implementers had to be employed and possibly paid for their time. Maintenance is defined as the extent to which the intervention becomes institutionalised or part of the routine organisational practices and policies. The studies did not report on whether their interventions were absorbed and became institutionalised or part of the routine organisational practices and policies. However, the REAIM did not include the latter definition as part of its scoring item for maintenance. Maintenance also has referents at the individual level. At the individual level, it is defined as the long-term effects of a programme on outcomes 6 or more months after the most recent intervention contact. The latter was included as part of the scoring for the Maintenance item on the REAIM and therefore only those studies who followed outcomes after 6 months received a score. Since Cicerone et al. (2008) stopped at 6 months they scored zero for this item. Maintenance can only occur however if the intervention is fully adopted by the participants and thus adoption should be evaluated.

5.3 Recommendations for Future EF Intervention Studies and RTW of TBI Individuals

The reviewers recommend the following for future EF intervention trials for successful RTW in TBI individuals:

- A gap in the evidence on best practice interventions for improving executive functioning in TBI individuals for successful RTW exists with no studies of this nature conducted in developing and other developed countries on the other five continents. As outcomes may differ based on the context of healthcare resources and TBI incidence and characteristics in other countries, evaluating EF interventions for successful RTW in these contexts could provide a larger body of evidence from which to base TBI EF rehabilitation intervention for RTW. It is therefore recommended that good quality Randomised Control Trials (RCTs) that focus on the effectiveness of executive functioning intervention in developing countries including South Africa that has a high incidence of non-fatal violence related TBI (Naidoo, 2013) and other developed countries are needed. Studies in South Africa could be conducted in collaboration with research units such as the Medical Research Council of South Africa who are specialists in designing and conducting randomised control trials.
- Since each TBI patient may present differently in terms of clinical characteristics and level of previous occupation, it may be required to tailor EF interventions to each specific TBI individuals EF deficits for example memory or attention, planning or organisation, behaviour and RTW requirements or needs. Furthermore, providing RTW outcome data post EF interventions for each mild, moderate and severe TBI group will also provide useful information for vocational and rehabilitation specialists and enable researchers to estimate RTW for each group and provide an estimate of effectiveness for EF intervention for RTW for each TBI severity level or category.
- It is recommended that RTW outcomes are well defined in RCTs evaluating the effectiveness of EF interventions for successful RTW in TBI individuals. Besides evaluating dichotomous variables such as yes/no in percentage for RTW, other aspects of

RTW measured such as time spent in work activity or productivity in work over a period of time should also be included as part of the reported RTW outcomes. RTW in different work categories such as sheltered, protected and competitive (open labour market) employment outcomes should also be clearly reported on so as to identify the level of EF improvement and thus level of productivity.

- RCTs focusing on RTW as the primary outcome of EF interventions in TBI individuals should be conducted in more countries affected by increased TBI incidence.
- It would also be useful to determine which set of EF interventions specifically increase the RTW outcome or have a significant effect on RTW and RTW related outcomes such as time spent in work and productivity so that vocational and other rehabilitation specialists have evidence for the development of a RTW rehabilitation programme using the most effect EF interventions identified.
- Due to the variation in the definition of executive functioning, studies had minimal overlap in the components of executive functioning they prioritised in treatment. They made use of different healthcare practitioners and different treatment approaches to carry out their intervention, which added to the heterogeneity of the review. Researchers should therefore be encouraged to develop a standardised definition for executive functioning and a standardise team for EF intervention. Furthermore, a framework for the implementation of EF interventions in TBI for return to work should be developed to assist therapists globally in implementing such treatments in a standardised manner.
- It is not clear whether one can effectively conduct an RCT comparing EF interventions to no EF interventions due to the real life nature of rehabilitation therapy where certain therapies will include some form of EF intervention to improve activity level and

participation. However, it is recommended that evaluating EF interventions singularly against each other or against no EF intervention may provide results for which interventions are more effective for RTW outcomes or for particular occupations as it may be that not all aspects of EF are required in all occupations.

- It also should be determined whether EF interventions are beneficial in RTW in the early stage of TBI rather than the later stage as it was seen that long-term outcomes showed no difference in TBI groups at 12 months which could be explained by normal changes in neuroplasticity. It may be that earlier EF intervention results in better work performance in the long term but this needs to be evaluated.

5.4 Strengths and Limitations of the Review

This review was the first to synthesis information regarding best practice intervention for RTW. Thus, this novel work is the strength of this review. The review had a clear aim and set of objectives. Its strength lies within the predetermined methodological process which makes use of sound strategy development in all steps of the review. A predetermined search strategy was developed in collaboration with a librarian and the reviewers. The databases searched within this review were appropriate for the studies of interest. The researcher made use of multiple databases to achieve an inclusive screening where all concerning research can be assessed. Study selection using PICOS and a clear set of inclusion and exclusion criteria, appraisal and data extraction was done in duplicate by the researcher and supervisors to ensure that no studies were lost during the review process. All data synthesised is transparent and there was no known conflict of interest within the review conducted. The latter all therefore contribute to the strength of the review and the validity of its results.

The only limitation of the review was its inability to produce a measure of effectiveness; however, this is more in part due to the availability of RCTs on the topic and the lack of homogeneity of their studies. Due to the characteristics of the studies in terms of their populations and samples, interventions and outcomes used and the results being heterogeneous a meta-analysis could not be conducted. This is not seen as a limitation of the review itself, however it is a limitation for identifying a best practice intervention for EF to RTW as there is no conclusive answer to the review question asked. The findings though do suggest that maybe executive function treatments should be individual-based and specific and that there is not necessarily any single EF treatment that is best for RTW. This has broadened our understanding of executive function assessment, treatment and outcomes in TBI individuals and may suggest the need for the development of an executive functioning management framework for RTW for TBI individuals, that can be utilised by vocational and rehabilitation therapists for individual TBI individuals.



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CHAPTER 6: CONCLUSION

This review is one of the first to synthesise the RTW and productivity outcomes of randomised control trials that evaluate the interventions for improving executive functioning components for successful RTW and productivity in TBI individuals. The findings of the review provide information on executive function components that have an effect on RTW and productivity in individuals with TBI. Information on the corresponding EF baseline assessments and post-treatment and long-term outcomes based on these assessments can be used by occupational and vocational rehabilitation therapists when considering assessing and treating executive function in TBI individuals for improving RTW outcomes by reducing work-related disability. Occupational and vocational rehabilitation therapists can also use the findings of this review to decide on the use of individual or group therapy or both and the duration of this therapy when treating executive functioning deficits that can improve RTW and productivity outcomes. In addition, quality of life assessments used to assess the outcomes post EF interventions for RTW and productivity have been highlighted for those interested in assessing the holistic benefits of EF improvement, productivity and RTW in individuals with TBI.

As a meta-analysis was not possible, the most effective EF intervention for RTW and productivity in TBI individuals is still unknown and the review findings remain inconclusive, highlighting a gap in the evidence that can be evaluated through further rigorous RCTs in this area of occupational and vocational rehabilitation. While this review provides relevant information and adds to the evidence base on EF in TBI and RTW and productivity, there is a need for RCTs in determining the effectiveness of EF interventions for improving RTW in individuals with TBI in other contexts, namely, in developing and other developed countries that have a high incidence and prevalence of

TBI as well as a poor RTW rate. These studies should attempt to include homogeneous populations (either mild, moderate or severe TBI), large populations and/or samples or powered well for the RTW outcomes in order to provide a significant measure of effect or effect size and a control group that has no EF intervention in an attempt to provide evidence for the best practice EF intervention for successful RTW and productivity. The latter would be a valuable addition to the body of knowledge on executive function in TBI and return to work.

While it is not clear which component of EF results in a greater RTW and productivity outcome, the review does provide evidence for the inclusion of EF in RTW rehabilitation and programmes. From the studies included in the current systematic review, executive functioning intervention yields a positive outcome of RTW immediately after intervention has been implemented, to a 12-month follow-up. When the executive functioning based intervention is accompanied with an element of work integration or supported employment it yields a greater success in RTW than when not included. This finding can be used to supplement guidelines and protocols for RTW in patients that suffered a TBI and can be assessed further to provide evidence for its efficacy in different contexts. Occupational and vocational rehabilitation can use the information from the current systematic review to make decisions on what performance components need to be assessed and addressed in the rehabilitation process and what other supplementary interventions can be added to yield improved results in RTW. Furthermore, the results of the current systematic review could provide researchers with information pertaining to the development of a set of robust findings that can be combined to develop a framework for the inclusion of EF intervention and RTW and productivity for individuals with TBI individuals to be used across settings. The findings of the current systematic review would also be able to provide researchers with information related

to the duration of intervention implementation required to obtain successful RTW and possible insight into the number of resources required to implement these interventions. All members of the multidisciplinary rehabilitation team involved in the rehabilitation of TBI individuals in RTW can use the findings of this review to assist in setting goals for TBI patient rehabilitation and RTW and conduct further research for the development of a rehabilitation framework for the management of TBI individuals in improving EF for successful return to work.

There are huge financial implications on the TBI individual, their families or caregivers and on the healthcare system, in particular acute and long-term rehabilitation facilities both governmental and private due to the intensive rehabilitation needed to treat TBI individuals with long-term disability including work-related disability. As the systematic review provides information supporting EF interventions and the supplementation of work integration or supported employment in improving RTW and productivity rates, government, healthcare policymakers and funders and other relevant stakeholders supporting rehabilitation services and care can use the review findings to advocate for the inclusion of EF interventions in acute and rehabilitation settings for improving TBI executive functioning for successful RTW in the open labour market. This in turn can increase the earning power of these individuals and reduce the financial strain on them, their families and/or caregivers and the healthcare system and provide meaning in the lives of TBI individuals through their contribution to society, community and broader economy.

In conclusion the review highlights the lack of occupational therapists' involvement in EF intervention research as other healthcare professionals were more involved in the implementation of EF interventions in the studies included in this review, the lack of EF intervention studies in the

other five continents of the world and highlights and supports the use of EF intervention in the TBI population for successful RTW and productivity. However, the review recommends further research to provide measures of effectiveness for the EF interventions that are best in achieving these outcomes for use in occupational and vocational rehabilitation programmes globally and to provide more conclusive evidence in this regard.



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APPENDIX A: ETHICS



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26 July 2019

Mrs L Hutchinson
Occupational Therapy
Faculty of Community and Health Sciences

Ethics Reference Number: HS19/6/4

Project Title: Best practice interventions for improving executive functioning in individuals returning to work post traumatic brain injury: A systematic review

Approval Period: 26 July 2019 – 26 July 2020

I hereby certify that the Humanities and Social Science Research Ethics Committee of the University of the Western Cape approved the methodology and ethics of the above mentioned research project.

Any amendments, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.

Please remember to submit a progress report in good time for annual renewal.

The Committee must be informed of any serious adverse event and/or termination of the study.

A handwritten signature in blue ink that reads 'Josias'.

*Ms Patricia Josias
Research Ethics Committee Officer
University of the Western Cape*

HSSREC REGISTRATION NUMBER - 130416-049

FROM HOPE TO ACTION THROUGH KNOWLEDGE.

APPENDIX B: LIST OF EXECUTIVE FUNCTIONING INTERVENTIONS

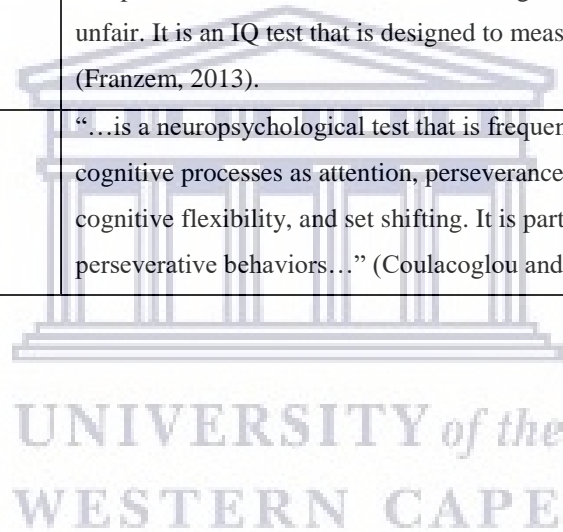
Executive Functioning	
Name of Intervention	Short Description
Attention process training	A form of intervention that makes use of a restorative approach, its gradable progression in tasks increase attention demands and thus in turn facilitates the development or improvement of focused attention, sustained attention, alternating attention, divided attention and selective attention (Barman, Chatterjee and Bhide, 2016).
Awareness Intervention Program	A form of intervention that focuses on improving awareness of patient deficits in relation to their physical and cognitive functioning. It makes use of educational sessions that are based on the types of deficits that can manifest in the patient due to their diagnosis. It also makes use of functional training sessions in setting performance goals and evaluating patients own performance against the set goals. It is thought that this form of intervention can facilitate the improvement of self-awareness. (Cheng & Man, 2006)
Cognitive behavioural therapy	This is not a definable single form of intervention, but rather a class of interventions. Its premise is that maladaptive cognition leads to changes in emotional distress and therefore gives rise to problematic behaviour and thus the use of therapeutic strategies (Cognitive behavioural therapy) can change maladaptive cognition. The family of interventions make use of a variety and a combination of cognitive, behavioural as well as emotion-focused techniques in order to treat behavioural components (Hofmann, Asnaani, Vonk, Sawyer & Fang, 2012).
Cognitive rehabilitation therapy	Consists of a family of interventions that make use of restorative and compensatory approaches. The restorative approaches aim to reinforce, strengthen and restore impaired skills through the use of repeated exercises and standardized cognitive tests that increase in difficulty. This facilitates the improvement in selective attention and memory. While compensatory approaches give information on ways of bypassing or compensating for any impaired function experienced through the use of assistive technologies (Barman, Chatterjee and Bhide, 2016).
COMPASS goal	COMPASS is an acronym for Community Participation through Self-Efficacy Skills Development. It is a protocol that includes three descending strategies of goal manipulation, arousal management (relaxation and motivation), and cognitive self- regulation (including self-monitoring, evaluation and flexibility of performance). The intervention consists of negotiating goals, establishing a hierarchy of goals and breaking down of goals into more manageable tasks. This is thought to improve executive functioning and RTW in

	veterans (Libin et al, 2015).
Dual-Task Training	An intervention used within Couillet et al. (2010), study that is based on progressive training of dual-task processing through the use of relatively automatic tasks and then including more complex, resource demanding tasks. The objective of this intervention was to train patients to carry out concurrent tasks. As this was achieved the tasks were made more difficult through the use of time pressure, executive demands as well as working memory load (Couillet et al, 2010)
Executive functioning plus model	A form of intervention that is based on a top-down approach of learning. It makes use of problem-solving training, emotional regulation training and attention training to facilitate the improvement of executive functioning. (Gordon, Cantor, Ashman and Brown, 2006)
Goal management training	This is an intervention developed from the theory of goal neglect. The training consists of self-instruction strategies, self-monitoring exercise, planning improvement metacognitive strategies, prospective memory with gradable goal management, mindfulness practice exercise and discussions around executive functioning in daily life with homework assignments given. This intervention facilitates the treatment of planning, goal-attainment and executive functioning (Krasny-Pacini, Limond, Evans, Hiebel, Bendjedlida, & Chevignard, 2014).
Metacognitive strategy training	Is an intervention that through the use of compensatory strategies improves self-monitoring as well as self-regulation. These compensatory strategies consist of structured-repetitive cuing, repeated assessment and self-monitoring. This interventions main focus is to facilitate treatment of attention, language deficits, memory and social skills (Barman, Chatterjee and Bhide, 2016).
Multi domain intervention	Is not necessarily a form of EF intervention, but rather a process of carrying out an EF intervention that has seen to have a positive impact on cost outcomes in return to work. Its premise is that by incorporating a number of domains of treatment such as making use of healthcare workers, service coordinators as well as work accommodation components, this will in essence facilitate successful return to work (Cullen et al., 2018)
Perception Attention Therapy (PATH)	This intervention comes from the assumption that by improving low level movements and the discrimination thereof will improve high level cognition. It is a form of intervention that makes use of visual timing training tasks (left and right movement discrimination) in order to improve one's visual processing as well as attention. This in turn facilitates the treatment of attention and executive functioning (Lawton and Haug, 2019).
Time pressure management	An intervention that makes use of cognitive strategies that allow for persons with TBI to compensate for slow information processing. These strategies are based on attention, memory, executive functioning and/or environmental modifications to prevent or manage time pressure. (Fasotti, Kovacs, Eling & Brouwer, 2000)

APPENDIX C: LIST OF EXECUTIVE FUNCTIONING OUTCOME ASSESSMENTS

Executive Function Outcome Measure	Description
Behaviour Rating Inventory of Executive Functioning (BRIEF)	Developed for children and adolescents. The measure is composed of 75 items that measure executive functions such as inhibition, self-monitoring, planning, organising, problem-solving, initiating tasks, emotional control and working memory. The scales form two broad indexes behavioral regulation and metacognition, which form the overall summary score. There is also an adult version of this measure (Gillen, 2009).
Clock Drawing Test (CDT)	Assesses a patient's planning through the mechanism of drawing a clock with the pointers at a particular number (de Assis Faria, Alvas & Charchat-Fichman, 2015).
Controlled Oral Word Association Test	"...The Controlled Oral Word Association Test (COWAT) – FAS (for Verbal Fluency – see verbal fluency test) and Category Fluency test have been used as measures of both language and executive function domains..." (Malek-Ahmadi et al, 2011, p. 236)
Halstead Category Test (HCT)	The HCT is a measure of concept formation, where the client is required to categorise underlying concepts for each of the seven subsets within the test (Boyle, 1986)
Porteus Maze Test	The Porteus Maze series is a useful nonverbal test that measures ones executive functioning ability as well as general adaptation capacity and planning (Krikorian & Bartok, 1998).
Rey-Osterrieth Complex Figure Test (ROCF)	"...is a popular measure of visuospatial construction, perceptual organization, and short-term visual retention..." (Lu, Boone, Cozolino and Mitchell, 2003, p. 427)
Stroop Test	"...The Stroop Color and Word Test (SCWT) is a neuropsychological test extensively used to assess the ability to inhibit cognitive interference that occurs when the processing of a specific stimulus feature impedes the simultaneous processing of a second stimulus attribute, well-known as the Stroop Effect..." (Scarpina & Tagini, 2017, p. 1)
Trail making Test	"...The trail making test (TMT) is a short and convenient estimate of cognitive functions, principally attention and working memory..." (Bhatia et al, 2007, p. 113)
Verbal Fluency Test (VFT)	"...The test entails saying as many words a possible beginning with F, A and S in 1 minute. Participants cannot use proper nouns or use a stem word with different endings..." (de Assis Faria, Alvas & Charchat-Fichman, 2015, p. 151)
Verbal Fluency Test (VFT) Animal category	"...This test entails saying as many animal names, as quickly as possible, in 1 minute, with no restrictions on first letter or any other characteristics..." (de Assis Faria, Alves & Charchat-Fichman, 2015, p.151)

Wechsler Abbreviated Scale of Intelligence-Block Design	This is a short version of the WAIS assessment used to measure intellectual ability including the block design subset of the WAIS and measures of the ability to perceive and then analyse, synthesise and reproduce abstract visual stimuli (Volkmad et al., 2013)
Wechsler Adult Intelligence Scale (WAIS)	A popular method for estimating IQ in the clinical setting, developed in 1955. There are eleven subsets that measure intelligence. Wechsler Adult Intelligence Scale and Wechsler Adult Intelligence Scale-Revised provided a new baseline and incorporated scores for Verbal IQ, performance IQ and Full scale IQ (Franzem, 2013).
Wechsler Adult Intelligence Scale-III- Picture Arrangement	A subset assessment of the Wechsler Adult Intelligence Scale that assesses the ability to quickly perceive visual details (Volkmad et al., 2013).
Wechsler Adult Intelligence Scale-Revised (WAISr)	The Wechsler Adult Intelligence Scale-Revised is as its name implies, simply a revised version of the Wechsler Adult Intelligence Scale. This was done as some of the components of the Wechsler Adult Intelligence Scale was outdated as well as culturally unfair. It is an IQ test that is designed to measure intelligence and cognitive ability (Franzem, 2013).
Wisconsin Card Sorting Test	“...is a neuropsychological test that is frequently used to measure such higher-level cognitive processes as attention, perseverance, working memory, abstract thinking, cognitive flexibility, and set shifting. It is particularly used in clinical fields to measure perseverative behaviors...” (Coulacoglou and Saklofske, 2017, p. 94)



APPENDIX D: CASP CRITICAL APPRAISAL FOR RCTs



CASP Checklist: 11 questions to help you make sense of a **Randomised Controlled Trial**

How to use this appraisal tool: Three broad issues need to be considered when appraising a trial:

- ▶ Are the results of the study valid? (Section A)
- ▶ What are the results? (Section B)
- ▶ Will the results help locally? (Section C)

The 11 questions on the following pages are designed to help you think about these issues systematically. The first three questions are screening questions and can be answered quickly. If the answer to both is “yes”, it is worth proceeding with the remaining questions. There is some degree of overlap between the questions, you are asked to record a “yes”, “no” or “can’t tell” to most of the questions. A number of italicised prompts are given after each question. These are designed to remind you why the question is important. Record your reasons for your answers in the spaces provided.

About: These checklists were designed to be used as educational pedagogic tools, as part of a workshop setting, therefore we do not suggest a scoring system. The core CASP checklists (randomised controlled trial & systematic review) were based on JAMA 'Users' guides to the medical literature 1994 (adapted from Guyatt GH, Sackett DL and Cook DJ), and piloted with health care practitioners.

For each new checklist, a group of experts were assembled to develop and pilot the checklist and the workshop format with which it would be used. Over the years overall adjustments have been made to the format, but a recent survey of checklist users reiterated that the basic format continues to be useful and appropriate.

Referencing: we recommend using the Harvard style citation, i.e.: *Critical Appraisal Skills Programme (2018). CASP (insert name of checklist i.e. Randomised Controlled Trial) Checklist. [online] Available at: URL. Accessed: Date Accessed.*

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Critical Appraisal Skills Programme (CASP) part of Oxford Centre for Triple Value Healthcare Ltd www.casp-uk.net

Paper for appraisal and reference:.....

Section A: Are the results of the trial valid?

1. Did the trial address a clearly focused issue?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: An issue can be 'focused' in terms of

- the population studied
- the intervention given
- the comparator given
- the outcomes considered

Comments:

2. Was the assignment of patients to treatments randomised?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider

- how this was carried out
- was the allocation sequence concealed from researchers and patients

Comments:

3. Were all of the patients who entered the trial properly accounted for at its conclusion?

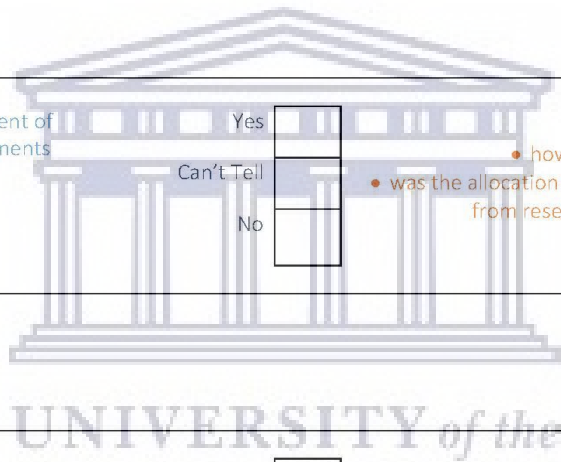
Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider

- was the trial stopped early
- were patients analysed in the groups to which they were randomised

Comments:

Is it worth continuing?



4. Were patients, health workers and study personnel 'blind' to treatment?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

Comments:

5. Were the groups similar at the start of the trial

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider
• other factors that might affect the outcome, such as; age, sex, social class

Comments:

6. Aside from the experimental intervention, were the groups treated equally?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

Comments:

Section B: What are the results?

7. How large was the treatment effect?

- HINT: Consider
- what outcomes were measured
 - Is the primary outcome clearly specified
 - what results were found for each outcome

Comments:

8. How precise was the estimate of the treatment effect?

- HINT: Consider
- what are the confidence limits

Comments:

Section C: Will the results help locally?

9. Can the results be applied to the local population, or in your context?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

- HINT: Consider whether
- the patients covered by the trial are similar enough to the patients to whom you will apply this
 - how they differ

Comments:

10. Were all clinically important outcomes considered?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

- HINT: Consider whether
- there is other information you would like to have seen
 - if not, does this affect the decision

Comments:

11. Are the benefits worth the harms and costs?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider
• even if this is not addressed by the trial, what do **you** think?

Comments:



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APPENDIX E: RE-AIM APPRAISAL TOOL

	ITEMS (Gaglio et al., 2013)	SCORE
R	Reach	Score yes – 1; no - 0
	<ul style="list-style-type: none"> Does the article indicate who the program is intended for (Inclusion and Exclusion criteria)? 	
	<ul style="list-style-type: none"> Does the article report on the representativeness of the target population? 	
	<ul style="list-style-type: none"> Does the article report on participation rate? 	
E	Effectiveness	Score yes – 1; no - 0
	<ul style="list-style-type: none"> Did the program achieve the intended objective? 	
	<ul style="list-style-type: none"> Do they report on the limitations of the intervention? 	
	<ul style="list-style-type: none"> Reports on at least one outcome of the intervention 	
	<ul style="list-style-type: none"> Reports on attrition 	
A	Adoption	Score yes – 1; no - 0
	<ul style="list-style-type: none"> Is the setting clearly described? 	
	<ul style="list-style-type: none"> Does the evaluation report on the adoption of the intervention by the participants or the organisation? Who delivered the program? 	
I	Implementation	Score yes – 1; no - 0
	<ul style="list-style-type: none"> Describe the duration and frequency of the interventions? 	
	<ul style="list-style-type: none"> Has the staff/ participants of the organisation / intervention been involved in delivering the program (cost implication?) 	
	<ul style="list-style-type: none"> Reports on intended and delivered interventions. 	
M	Maintenance	Score yes – 1; no - 0
	<ul style="list-style-type: none"> Does the article report on long term effects of the intervention (after 6 months) 	
	<ul style="list-style-type: none"> Do they report on the indicators used for intervention follow– up? 	

The score range for Re aim framework will be as follows:

0-33% Poor, 33%-66% Satisfactory and 66%- 100% Very Good.

APPENDIX F: EXCLUDED STUDIES

Excluded studies with reasons for exclusion

Allot et al. (2013)	Not a clear RCT, with main focus on psychosis and not TBI
Bell et al. (2011)	Outcomes do not touch on executive functioning
Buunk et al. (2019)	Not a randomized controlled trial
Carney et al. (1999)	Outcomes not linked to executive functioning
Cheng et al. (2006)	Outcomes not linked to EF or vocational rehabilitation
Driver et al. (2019)	Noted to be an RCT, but is a recent 2019 protocol for a RCT
Fogelman & Zafonte (2012)	Not RCT, but rather a review paper
Hamzah et al. (2018a)	Author explained that study has not been released
Hamzah et al. (2018b)	Is a pilot study
Howell et al. (2017)	Participants are adolescents and also matched prospective time series
Klonoff et al. (2007)	Not RCT, rather observational
Law et al. (2004)	Does not consider the TBI population
Libin et al. (2015)	No results available yet
Lippert-Grüner, Lefering & Svestkova (2007)	Not a RCT
McCrimmon & Oddey (2006)	Not a RCT
Mitrushina et al. (2017)	No randomization stated
Robitaille et al. (2016)	Not an RCT, is a case control
Westerhof-Evers et al. (2019)	Not an RCT
Zakzanis et al. (2016)	Not RCT, random archival sample only

APPENDIX G: SEARCH STRATEGY – SEARCH TERMS

The primary reviewer made use of the same search string and constraints within all the databases searched.

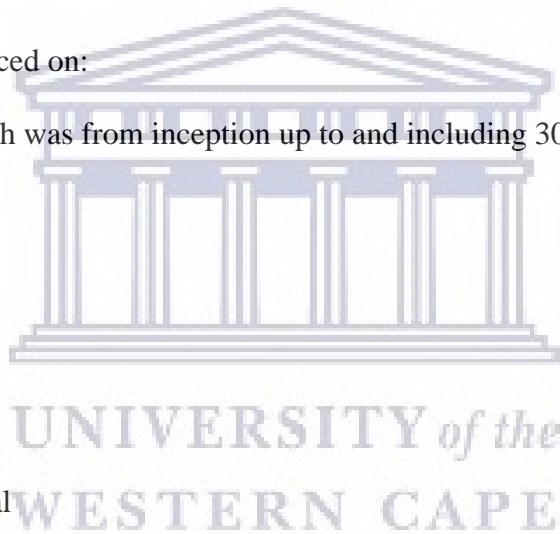
Search String: (Traumatic Brain Injur*) AND (Executive Functioning Intervention) AND (Return to Work)

There was no constraint placed on:

1. year of publication (search was from inception up to and including 30 June 2020)

Constraints were placed on:

1. Adult
2. English only
3. Randomized Control Trial
4. Full Text (Journal Article)
5. Peer Reviewed



APPENDIX H: CASP APPRAISAL OUTCOMES



Paper for appraisal and reference: **Cicerone et al., 2008**

Section A: Are the results of the trial valid?

1. Did the trial address a clearly focused issue?

Yes	X
Can't Tell	
No	

HINT: An issue can be 'focused' in terms of

- the population studied
- the intervention given
- the comparator given
- the outcomes considered

Comments: The objective of this study was to evaluate the effectiveness of a comprehensive, holistic neuropsychologic (NP) rehabilitation compared with standard, multidisciplinary rehabilitation for people with traumatic brain injury (TBI). The population included 68 participants with TBI that were recruited through community based and self-referrals. The experimental intervention included holistic neuropsychologic (NP) (Intensive Cognitive Rehabilitation Program) rehabilitation compared with the comparison intervention that included standard, multidisciplinary rehabilitation (Standard Neurorehabilitation Program). The primary outcomes included the CIQ and PQOL measures and the secondary outcomes included NP tests, functional outcomes, perceived self-efficacy, and community-based employment measured with the Vocational Integration Scale (VIS).

2. Was the assignment of patients to treatments randomised?

Yes	X
Can't Tell	
No	

HINT: Consider

- how this was carried out
- was the allocation sequence concealed from researchers and patients

Comments: Yes, assignments of patients to treatments were randomized through the web-based interactive statistical calculation pages (www.statpages.org). Cicerone et al. (2008), p. 2240 stated that: "Randomization occurred in unequal, blocked multiples of 4 to optimize equal assignment of participants to treatment arms throughout the study period and to prevent anticipation of the randomization sequence. Randomization was stratified by referral source (clinical or community referrals) to optimize equal assignment between treatment arms." "Participants were randomized in the order they provided written informed consent." (Cicerone et al., 2008, p. 2240).

3. Were all of the patients who entered the trial properly accounted for at its conclusion?

Yes	X
Can't Tell	
No	

HINT: Consider

- was the trial stopped early
- were patients analysed in the groups to which they were randomised

Comments: Yes. "Two participants withdrew from Intensive Cognitive Rehabilitation Program treatment: 1 within the first week of treatment and 1 subsequent to an episode of psychiatric symptomatology and substance abuse. Four participants withdrew from the Standard Neurorehabilitation Program treatment: 1 did not complete treatment because of psychiatric hospitalization, and 3 completed the planned treatment but refused post treatment evaluations in association with increased psychiatric symptoms. An additional 4 participants did not respond to requests for 6-month follow-up evaluation: 2 from the Intensive Cognitive Rehabilitation Program and 2 from the Standard Neurorehabilitation Program." (Cicerone et al., 2008; p2241&2242). In addition, the ITT analysis was used including these 6 participants in the analysis to observe any differences.

Is it worth continuing? **YES**

4. Were patients, health workers and study personnel 'blind' to treatment?

Yes	<input checked="" type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

Comments: It was difficult to blind patients and therapists to treatment conditions as this difficulty of blinding is inherent to complex rehabilitation trials. Participants and therapists had knowledge that both treatments were clinically established programs that were expected to be beneficial, with no assumption regarding differential benefits and no further information about the specific intent of the study." (Cicerone et al., 2008, p.2247). "Both treatments were conducted simultaneously within the same post-acute rehabilitation program, with the same therapists providing treatment in both conditions. It was not feasible for therapists to be blind to treatment condition. However, therapists were informed that the study was being conducted because we did not know if 1 form of treatment was better than the other, with no additional information about the full intent of the study. Therapists were not informed about the specific hypotheses or outcome measures." (Cicerone et al., 2008, p. 2242). The researchers did not believe that any subtle expectancies or biases, if they existed, could account for the results of the study. "Primary outcomes in the study relied on participant self-report, which may have influenced the results. NP functioning, based on objective masked evaluations, showed equal improvement under both treatment conditions. Validity of the CIQ findings are supported by indications that self-reports and significant other reports on the CIQ show good agreement and the independent observation of greater rates of community-based employment for Intensive Cognitive Rehabilitation Program participants. The self-appraisal of life satisfaction is inherently germane to the assessment of subjective well-being. The validity of these improvements is further supported by their maintenance at follow-up." (Cicerone et al., 2008, p.2247). Data entry and scoring for these measures were conducted by a research assistant who was blind to treatment condition. The latter indicates some form of blinding thus single blinded RCT and therefore we answered yes to number 4.

5. Were the groups similar at the start of the trial?

Yes	<input checked="" type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider other factors that might affect the outcome, such as; age, sex, social class

Comments: "There were no differences between conditions on demographic characteristics, injury-related characteristics, or pre-treatment measures and the groups were equal on all outcome measures before treatment." (Cicerone et al., 2008, p.2244).

6. Aside from the experimental intervention, were the groups treated equally?

Yes	<input checked="" type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

Comments: Participants in both conditions received the same intensity and duration of treatment, and the same therapists provided the treatment in both conditions. "It is unlikely that these nonspecific factors can account for the differences in treatment effectiveness between conditions." A total of 15 hours per week of therapy for 16 weeks was provided in both treatment arms. During the study treatment, participants' existing medical care was continued and psychological counselling or psychotherapy were allowed to continue but no other therapies. Treatments in both treatment arms were individualized according to participants' clinical needs to the extent possible. Participants in the Control condition initiated treatment on a continuous basis. Participants in the Intervention condition initiated treatment simultaneously in small groups of 5 to 8 participants, and group membership remained consistent throughout each 16-week treatment cycle (Cicerone et al., 2008, p.2242).

Section B: What are the results?

7. How large was the treatment effect?

HINT: Consider

- what outcomes were measured
- Is the primary outcome clearly specified
- what results were found for each outcome

Comments: The CIQ and PQOL were primary outcome measures while the NP functioning, perceived self-efficacy and community-based employment (VIS Scale) were secondary outcomes clearly specified. The Intensive Cognitive Rehabilitation Program produced a moderate clinical effect (ES 0.59 and 0.61 for only those completing all interventions and evaluations) on community functioning (total CIQ) and a small clinical effect (ES 0.30 and 0.30 for only those completing all interventions and evaluations) on life satisfaction (PQOL), neither of which were observed after Standard Neuro-rehabilitation Program treatment. As reported in the abstract: "NP functioning improved in both conditions. Intensive cognitive rehabilitation participants showed greater improvements on the CIQ (effect size [ES] = 0.59) and PQOL (ES = 0.30) as well as improved self-efficacy for the management of symptoms (ES = 0.26) compared with standard neuro-rehabilitation treatment. These gains were maintained at the 6-month follow-up. Standard neuro-rehabilitation participants showed improved productivity at the 6-month follow-up associated with the need for continued rehabilitation." (Cicerone et al., 2008, p.2239). "ITT analyses were conducted by carrying forward the pretreatment baseline scores for the 6 participants who failed to complete their respective treatment protocol and/or posttreatment outcome measures. Post hoc analyses were conducted only after a variable had shown significance on the planned multivariate ANOVA by using within-group paired-sample *t* tests to determine the source of significance. We examined treatment interaction ES for differences between groups from pretreatment to posttreatment by using a variant of Hedge's *g* for the comparison of independent group prepost-treatment scores that accounts for differences in pretreatment variance between groups ([mean intensive cognitive rehabilitation program posttreatment - mean intensive cognitive rehabilitation program pretreatment / SD intensive cognitive rehabilitation program pre-treatment] - [mean standard neurorehabilitation program posttreatment - mean standard neurorehabilitation program pretreatment / SD standard neurorehabilitation program pretreatment])." (Cicerone et al., 2008, p.2244). Thus the ES was moderate for CIQ and small for PQOL.

8. How precise was the estimate of the treatment effect?

HINT: Consider

- what are the confidence limits

Comments: Based on the ES and the significant *p*-values for each of the outcomes of the study, the precision of the estimate of the treatment effect can be deemed as high precision. Even though the sample size is small, the 95% CIs for significant outcomes were small. While no 95% CIs have been provided in the study we calculated those for CIQ and PQOL (95%CI: -0.21-0.74) and found them to be small with the CIQ (95%CI: -0.173-0.78) having the smallest 95%CI range. The ES for the significant difference in PQOL is small and thus this difference may be considered to be trivial improvements in PQOL. The use of a variant of Hedges *g* to calculate treatment effect size adds to the precision of the treatment effect. Cicerone et al., 2008, p.2247 stated that: "The primary outcomes in the study relied on participant self-report, which may have influenced the results. NP functioning, based on objective masked evaluations, showed equal improvement under both treatment conditions. The validity of the CIQ findings are supported by indications that self-reports and significant other reports on the CIQ show good agreement and the independent observation of greater rates of community-based employment for Intensive Cognitive Rehabilitation Program participants. The self-appraisal of life satisfaction is inherently germane to the assessment of subjective well-being. The validity of these improvements is further supported by their maintenance at follow-up."

Section C: Will the results help locally?

9. Can the results be applied to the local population, or in your context?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input checked="" type="checkbox"/>

HINT: Consider whether

- the patients covered by the trial are similar enough to the patients to whom you will apply this
- how they differ

Comments: The results may not necessarily be applicable to other populations as the setting from which the patients are recruited, the demographic and clinical variables of patients in terms of male versus female, educational level, prior employment, TBI severity and availability of employment as well as the patients willingness to work to name but some factors may vary in the local US civilian population or other countries as this study was conducted in one setting in the US at a post-acute brain injury rehabilitation program and TBI Model System of Care in a suburban rehabilitation hospital with the majority of participants being male (more than 90%).

10. Were all clinically important outcomes considered?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input checked="" type="checkbox"/>

HINT: Consider whether

- there is other information you would like to have seen
- if not, does this affect the decision

Comments: The researchers report on the VIS for RTW and although they report on the percentage employed, they do not provide specific results for each scale on the VIS only the combined total from the dichotomous yes/no variable employed/unemployed they transformed the VIS scale into. It would be relevant to know how many of those employed were in supported, transitional or competitive employment.

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11. Are the benefits worth the harms and costs?

Yes	<input checked="" type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider
• even if this is not addressed by the trial, what do you think?

Comments: The benefits of the intervention are worth the costs and the harms even though no adverse events were reported as it was reported that participants in the intervention arm did not require more extensive rehabilitation as the participants in the control arm that would increase treatment costs in the control arm and that the long-term maintenance of improvements of participants in the intervention arm are also beneficial substantiated by the following quotes. "The gains in community integration and life satisfaction appear to be stable and enduring benefits of the Intensive Cognitive Rehabilitation Program, at least for the observed follow-up period. Participants in the Standard Neuro-rehabilitation Program rehabilitation showed continued gains in community integration and productivity from discharge to follow-up, suggesting a more prolonged course of improvement. Standard Neuro-rehabilitation Program participants were also more likely to require continued comprehensive rehabilitation during the 6 months after the study period. Thus, the increased productivity for Standard Neuro-rehabilitation Program participants is associated with the need for more extensive rehabilitation, and Standard Neuro-rehabilitation Program participants still did not achieve the gains in psychological well-being shown by Intensive Cognitive Rehabilitation Program participants." (Cicerone et al., 2008, p.2247). "...the Intensive Cognitive Rehabilitation Program can be a clinically beneficial intervention when implemented in the course of naturally occurring recovery and rehabilitation. More than half of the participants were over 1 year post injury at the time of enrolment, about 40% were over 2 years post injury, and 22% were over 5 years post injury, suggesting that the benefits of NP rehabilitation can be apparent for people with TBI even years after their injury." (Cicerone et al., 2008, p.2247).

Paper for appraisal and reference: **Constantinidou et al., 2008**

Section A: Are the results of the trial valid?

1. Did the trial address a clearly focused issue?

Yes	<input checked="" type="checkbox"/>	<p>HINT: An issue can be 'focused' in terms of</p> <ul style="list-style-type: none"> • the population studied • the intervention given • the comparator given • the outcomes considered
Can't Tell	<input type="checkbox"/>	
No	<input type="checkbox"/>	

Comments: "Deficits in categorization could interfere with the successful execution of activities of daily living because categorization skills are integral to memory and learning of new information, and are essential processes for decision making and successful problem solving. Given the fundamental importance of categorization to all of intelligent behavior, it is surprising to observe the scarcity of investigation specific to the rehabilitation of classification behavior after TBI. This is in contrast to other domains such as attention and memory for which a substantial body of work can be found. This study proposes to fill some of this gap in knowledge and is part of a systematic research program in categorization training. This study has been designed to provide a higher level of evidence than the initial study, supporting the use of categorization training in post-acute rehabilitation." (Constantinidou et al., 2008, p. 313). "This study investigated categorization abilities and neuropsychological performance in participants with TBI who received the CP and in participants with TBI who although did not receive the CP but received other forms of cognitive therapy." (Constantinidou et al., 2008, p. 314). "Twenty-one participants in the experimental group received the CP training, and 14 participants in the control group received the conventional treatment used at their rehabilitation center." (Constantinidou et al., 2008, p. 314).

2. Was the assignment of patients to treatments randomised?

Yes	<input checked="" type="checkbox"/>	<p>HINT: Consider</p> <ul style="list-style-type: none"> • how this was carried out • was the allocation sequence concealed from researchers and patients
Can't Tell	<input type="checkbox"/>	
No	<input type="checkbox"/>	

Comments: Participants who met the inclusion/exclusion criteria for the project were randomly assigned to either the experimental or the control group by the project investigators who were off location and did not have direct contact with the participants. The 2 groups resulting from random assignment did not differ on critical variables such as age, education, and severity. The rolling admission process and the involvement of more than 1 site in this project created some practical challenges, including the unequal number of participants in the 2 groups. (Constantinidou et al., 2008, p. 314).

3. Were all of the patients who entered the trial properly accounted for at its conclusion?

Yes	<input checked="" type="checkbox"/>	<p>HINT: Consider</p> <ul style="list-style-type: none"> • was the trial stopped early • were patients analysed in the groups to which they were randomised
Can't Tell	<input type="checkbox"/>	
No	<input type="checkbox"/>	

Comments: “Originally, 29 subjects were enrolled in this group. Two participants discontinued rehabilitation against medical advice, and 2 participants developed medical complications and could not continue their participation in the study. Five others were discharged from the rehabilitation centers because of insurance complications, and subsequently, their participation was terminated. The remaining 21 participants completed the study.” (Constantinidou et al., 2008, p. 315). ... “Originally, 20 subjects were enrolled in this group. Six participants were discharged from the rehabilitation centers before completing their treatments because of insurance complications and, subsequently, were terminated from the project. The remaining 14 participants completed the study.” (Constantinidou et al., 2008, p. 315). “Data from patients unable to complete the assigned treatment regimen (TBI experimental and TBI control) were included in the analyses to the fullest extent possible. If partial data were useful for certain analyses, then those data were analyzed. Therefore, the intention-to-treat principle was followed as is commonly used in clinical trials research and described in the 1998 statistical guidelines developed by the International Conference on Harmonization.” (Constantinidou et al., 2008, p. 317).

Is it worth continuing? **YES**

4. Were patients, health workers and study personnel ‘blind’ to treatment?

Yes	<input checked="" type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

Comments: While double blinding was not possible as per the following quote: “Behavioural researchers are called to aspire to the “golden standard,” the double-blind randomized controlled trial, implemented in pharmacological research. Whereas this type of elegant research protocol might work in a behavioural neuroscience laboratory, it is certainly not pragmatic for the daily life of the rehabilitation team that is subjected to patient health problems that interfere with treatment, insurance funding cuts, staff turnover, and scheduling conflicts. Yet, it is important that efficacy research demonstrates that the treatment is both effective and efficacious.” (Constantinidou et al., 2008, p. 317), single blinding was done as per the following detail provided by Constantinidou et al., 2008, p. 315-316: “Neuropsychological testing was conducted by a neuropsychologist who was not aware of the participant’s group assignment (ie, experimental or control group) to reduce testing bias. At one of the sites, these services were contracted out. The functional outcome measures in most cases were conducted by the case management staff who was not involved in patient training and, therefore, was not informed of the participant’s group assignment. The CP-related measures were administered by the speech-language pathology team. Typically, there were only a handful of speech-language pathologists at each site; therefore, it was not possible to mask the type of treatment that their patients were receiving from one another. To reduce scoring/testing bias, the CP data score sheets were organized to minimize subjective scoring decisions. Furthermore, the score sheets were double checked by a team of independent researchers at the principal investigator’s institution to ensure correct administration and scoring. The study investigators were not involved in the data collection, scoring, and data entry process.

5. Were the groups similar at the start of the trial?

Yes	<input checked="" type="checkbox"/>
	<input type="checkbox"/>
	<input type="checkbox"/>

HINT: Consider
• other factors that might affect the outcome, such as; age, sex, social class

Comments: “The 2 groups resulting from random assignment did not differ on critical variables such as age, education, and severity.” (Constantinidou et al., 2008, p. 315). ... “One strength of this project was the careful selection of participants to create a homogeneous sample of subjects, improve internal validity, and reduce variability in performance.” (Constantinidou et al., 2008, p. 325).

6. Aside from the experimental intervention, were the groups treated equally?

Yes	
Can't Tell	
No	X

Comments: "Participants in the TBI experimental group required an average of 13 weeks to complete the CP study protocol. Participants received approximately 57 hours of individual cognitive treatment, averaging between 2 and 3 hours per week on the CP-related tasks, for a total of 27 hours of CP treatment and about 4.5 hours of total individual therapy per week. Participants in the non-experimental TBI group received an average of 80 hours of individual cognitive treatment over an 18-week period, averaging 4.5 hours of individual therapy per week." "Both groups received equal amounts of individual treatment per week. Although participants in the control group received, on average, longer treatment than the participants in the experimental group did (18 vs 13 weeks, respectively), their treatment outcomes were not better. **Although this difference (in the length of treatment) was not statistically significant, future studies need to continue investigating the dose-response effect of cognitive treatment.**" (Constantinidou et al., 2008, p. 324).

Section B: What are the results?

7. How large was the treatment effect?

- HINT: Consider
- what outcomes were measured
 - Is the primary outcome clearly specified
 - what results were found for each outcome

Comments: The primary outcomes were not documented as primary outcomes in the study, but the outcomes stated to be measured included CP test 1 and 2, a battery of NP tests, and functional tests including the CIQ and MPAI-3 for social participation, physical/cognition and pain/emotion. The effect size for the CP tests 1 and 2, NP tests and functional tests CIQ and MPAI-3 were mostly moderate to large. Few outcomes had small effect sizes.

8. How precise was the estimate of the treatment effect?

- HINT: Consider
- what are the confidence limits

Comments: Based on the effect size, p-values and small 95% CIs (calculated from the means, SD, F scores and p-values) for the majority of outcomes the precision of the treatment effect was deemed high.

Section C: Will the results help locally?

9. Can the results be applied to the local population, or in your context?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input checked="" type="checkbox"/>

- HINT: Consider whether
- the patients covered by the trial are similar enough to the patients to whom you will apply this
 - how they differ

Comments: The results may not necessarily be applicable to other populations as the setting from which the patients are recruited, the demographic and clinical variables of patients in terms of male versus female, educational level, prior employment, TBI severity and availability of employment as well as the patients willingness to work to name but some factors may vary in the local US population or other countries as this study was conducted in one setting in the US and sourced TBI patients from residential rehabilitation centers with no clarity on the percentage of males versus females or other demographics such as race/ethnicity and clinical variables such as TBI severity, average age at and time since injury.

10. Were all clinically important outcomes considered?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input checked="" type="checkbox"/>

- HINT: Consider whether
- there is other information you would like to have seen
 - if not, does this affect the decision

Comments: The main outcomes measured were NP and functional outcome tests that included the CIQ and two Categorization tests designed for the study and three probe tests. The CIQ Productivity scale provided outcomes on social productivity however there is not a count of how many participants attained return to work on follow-up in this study based on the completion of the CIQ productivity question. The researcher was contacted for this information and replied that no data on the actual RTW numbers and percentages was available for the study groups thus it is not clear whether the productivity outcome translates to return to work of the participants or translates to other forms of productivity.

11. Are the benefits worth the harms and costs?

Yes	X
Can't Tell	
No	

HINT: Consider
• even if this is not addressed by the trial, what do you think?

Comments: The results of this study are consistent with the findings of the preliminary study published in this journal in 2005. The CP seems to be an important therapeutic modality for cognitive rehabilitation. Although participants in both groups demonstrated neuropsychological gains, the participants who received the CP training demonstrated greater gains not only on categorization measures but also on a greater number of neuropsychological tests. Furthermore, the ability of these participants to generalize knowledge into new skills is another important contribution of the CP training. Another improvement is the CIQ total score and home and social integration sub scales and the social productivity scale, including the MPAI-3 that were all significantly improved in the experimental group (p=0.01). Thus the benefits of the study and outcomes are worth the harms or costs although not reported on in terms of adverse events or costs. The study adds value as it provides evidence for the efficacy of CP training in moderate to severe TBI at a particular dose. Studying the effect of a shorter version of the CP training that may provide the same efficacy is suggested as this will increase the utility of the CP training as it will reduce the financial impact of longer stays and can be successfully implemented in the imposed short length of stays for residential post-acute rehabilitation. This would reduce the costs to TBI patients. Furthermore, Constantinidou et al., 2008, p.325-326 stated: "The long-term effects of CP training on categorization performance and functional outcome measures, and the use of CP training in older participants who sustain brain injuries, in survivors of chronic TBI, and in patients who are receiving only out-patient cognitive rehabilitation would be a fruitful line of investigation."

Paper for appraisal and reference: **Salazar et al., 2008**

Section A: Are the results of the trial valid?

1. Did the trial address a clearly focused issue?

Yes	<input checked="" type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: An issue can be 'focused' in terms of

- the population studied
- the intervention given
- the comparator given
- the outcomes considered

Comments: The objective of this study was to evaluate the efficacy of inpatient cognitive rehabilitation for patients with TBI. 120 active-duty military personnel who sustained a moderate-to-severe closed head injury were included. Intensive standardized 8 week in-hospital cognitive rehabilitation program was the intervention arm versus a limited home rehabilitation program as the control arm. The primary outcome (actual return to work and fitness for duty 1year post treatment) and secondary outcomes (cognitive, psychiatric, and neurological outcomes and estimated treatment costs) of interest were clearly described and included.

2. Was the assignment of patients to treatments randomised?

Yes	<input checked="" type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider

- how this was carried out
- was the allocation sequence concealed from researchers and patients

Comments: "After confirmation of eligibility, patients were randomly assigned to receive in-hospital or home rehabilitation. Blocked randomization was done by an independent study statistician (K.S.) using variable-sized blocks to prevent investigators from guessing the code. Randomization for the first 40 participants was weighted at a 2:1 ratio in favour of the in-hospital group to help build that program. The last 79 patients enrolled were randomized at a 1:1 ratio. Analysis of outcomes stratified for these 2 cohorts did not change results. (Salazar et al., 2000, p. 3076). "Sixty-seven patients were randomly assigned to the in-hospital program, and 53 to the home program." (Salazar et al., 2000, p. 3077).

3. Were all of the patients who entered the trial properly accounted for at its conclusion?

Yes	<input checked="" type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider

- was the trial stopped early
- were patients analysed in the groups to which they were randomised

Comments: "Data were analyzed using the intent-to-treat analysis that included all randomized patients." ... "Seven patients failed to complete the full hospital program, 2 for medical reasons and 5 who voluntarily withdrew an average of 3 weeks into the program. Six of them were fit for duty or gainfully employed at 1 year. Likewise, 6 patients in the home treatment group required supplemental therapy because of persistent behavioral or mood problems, 4 of them after completing the home program. Four of the 6 were working or fit for duty at 1 year. All these randomized patients were included in the principal intent-to-treat analysis. However, excluding them from repeat analysis did not change the results substantially." (Salazar et al., 2000, p. 3077-3078).

Is it worth continuing? YES

4. Were patients, health workers and study personnel 'blind' to treatment?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input checked="" type="checkbox"/>

Comments: "Programs were implemented by separate teams of therapists who generally functioned independently of each other and of the outcome evaluation personnel, although complete blinding was not possible. Intermittent reviews and continuing education were conducted to ensure uniformity of treatment over time. A completely independent military physical evaluation board that had 1 physician and 2 senior military officers reviewed all medical recommendations and determined final disposition. Although treatments could not be blinded and study participation was recorded in the patients' chart, the specificity of Army regulations and the various levels of review helped protect against systematic biases in duty fitness determinations." (Salazar et al., 2000, p. 3077). "...although equal percentages of patients from each treatment group were medically separated using predefined standards, and an independent board made final discharge decisions, it was impossible to completely eliminate all possibility of bias in determinations of fitness for duty, partly because the study could not be blinded." (Salazar et al., 2000, p. 3079).

5. Were the groups similar at the start of the trial

Yes	<input checked="" type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider other factors that might affect the outcome, such as; age, sex, social class

Comments: Forty-seven eligible patients who refused participation were similar to the 120 study participants in demographics, injury severity, and clinical status at study entry. There were no significant differences between groups in demographic and injury characteristics, including age, sex, military rank, education, race, type and severity of injury (and if alcohol-related). ... there were fewer motor vehicle-related injuries, more assault injuries, and fewer patients who were unconscious for an hour or more in the in-hospital group. ... both groups had relatively severe traumatic brain injuries, as indicated by the rates of axonal shear injury on MRI, cerebral contusions, posttraumatic amnesia of 7 days or more, and traumatic unconsciousness for 24 hours or more, respectively, in the hospital and home treatment groups. Groups were similar in post-injury symptoms at the time of randomization, including headaches, violent behaviour, seizures, Mini-Mental State Examination scores, major depression or generalized anxiety... Neuropsychologic test performance was not different between groups at baseline. Patients also had a disability profile similar to that associated with Vietnam veterans with head injuries, including posttraumatic epilepsy, hemiparesis, visual field loss, verbal or visual memory loss, psychological problems, and violent behaviour.

6. Aside from the experimental intervention, were the groups treated equally?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input checked="" type="checkbox"/>

Comments: "For example, our standardized inpatient program had morning cognitive, speech, and psychotherapy sessions complementing structured job placement in the afternoon. In contrast, our home program was almost completely functional, providing counselling, exercises, and support, but otherwise minimal intervention in a home setting." (Salazar et al., 2000, p.3080). The two treatment arms had different components and time or doses of treatment. "...for patients with TBI who received inpatient cognitive rehabilitation did not differ from those of patients who received a limited home rehabilitation program..." (Salazar et al., 2000, p.3079).

Section B: What are the results?

7. How large was the treatment effect?

HINT: Consider

- what outcomes were measured
- Is the primary outcome clearly specified
- what results were found for each outcome

Comments: None of the outcomes were significantly different between the two groups and the 95% CI were large for the sample. The effect sizes were not reported on but the change in return to work and fitness to duty were small and the means and SD from the secondary NP test outcomes were used to calculate and determine the ES which was small.

8. How precise was the estimate of the treatment effect?

HINT: Consider

- what are the confidence limits

Comments: they hypothesized that in-hospital rehabilitation program would yield greater return to work and fitness for duty rates than a limited home program at one-year follow-up. Originally projected study cohort of 200 subjects gave 80% power to detect a treatment difference in RTW of 20%. Confidence intervals were separately calculated for the differences in the percentage of individuals who RTW or active military duty. The samples were small and also unequal for each treatment group and the 95% CI was large and thus the precision for the treatment effect considered to be low.

Section C: Will the results help locally?

9. Can the results be applied to the local population, or in your context?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input checked="" type="checkbox"/>

HINT: Consider whether

- the patients covered by the trial are similar enough to the patients to whom you will apply this
- how they differ

Comments: "Other important factors are this population's high preinjury education (all had high school degrees), their 100% employment and military fitness status, the supportive military environment, and the ready availability of (military) employment after injury. Thus, our results might be most applicable to comparable civilian TBI patients with high-preinjury function." (Salazar et al., 2008, p. 3080). The results however may not be applicable to a TBI population with different characteristics and from a different setting as these patients were military personnel and the study was conducted at the US military medical center.

10. Were all clinically important outcomes considered?

Yes	<input checked="" type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider whether

- there is other information you would like to have seen
- if not, does this affect the decision

Comments: Yes, as the primary outcome of interest in this review was RTW (return to gainful employment) which was documented as the primary outcome for the study together with fitness for military duty at 1year post treatment or follow-up. Since these were military personnel, RTW would translate to working in the military as they would have before injury.

11. Are the benefits worth the harms and costs?

Yes	<input checked="" type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

- HINT: Consider
- even if this is not addressed by the trial, what do you think?

Comments: There was no significant difference in the primary outcomes between the two groups although the improvements were higher in percentage for RTW in the home group and higher in percentage for fitness for active military duty in the hospital group. Even though not significant the study yielded high rates of RTW which is beneficial to patients for income generation, to pay for future treatment and rehabilitation and support or contribute to the economy. The cost outcomes measured showed that the home rehabilitation cost much less per patient than the hospital based rehabilitation per patients substantiated by the following quotes. "Our results also highlight the potential therapeutic benefits of the home setting. A more cost-effective approach to rehabilitation might focus on identifying and enhancing the key elements of a home program, including decreased stress of the home environment and the support of loved ones at home, along with appropriate medical evaluation, and education (D.L.W. et al, unpublished data, 2000). While there are no apparent contraindications to a home program in this population, the increase in aggression in both groups at 12 months suggests that ongoing monitoring and support is an important part of treatment in all TBI patients. Another important consideration is that of cost. Both study groups received basic TBI evaluation, education, and counseling over an average of 5 days in the hospital. The estimated additional rehabilitation cost for each patient in the hospital group was \$51,840, based on the standard WRAMC psychiatry service costs of \$864 per day. In contrast, home program rehabilitation costs were estimated at \$504 per patient, based on therapist time for the weekly home telephone calls (\$63 per hour), including overhead and occasional physician back-up consultation." (Salazar et al., 2000, p. 3080).

Paper for appraisal and reference: **Twamley et al., 2014 and 2015**

Section A: Are the results of the trial valid?

1. Did the trial address a clearly focused issue?

Yes	<input checked="" type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: An issue can be 'focused' in terms of

- the population studied
- the intervention given
- the comparator given
- the outcomes considered

Comments: We evaluated a 12week compensatory cognitive training intervention (Cognitive Symptom Management and Rehabilitation Therapy [CogSMART]) in the context of supported employment for Veterans with mild to moderate TBI. "...we evaluated CogSMART within the context of a supported employment program for Veterans with TBI. In this pilot randomized controlled trial, all participants received supported employment for 1 year. Participants were randomized to receive CogSMART, provided by their supported employment specialist (SE-Cog), or additional supported employment sessions (enhanced supported employment; ESE) for the first 3 months of the year-long study. We hypothesized that, compared with ESE participants, those who received supported employment plus CogSMART would report reduced postconcussive symptom severity (primary outcome) and would exhibit improvements in cognitive performance and functional capacity. (Twamley et al., 2014, p. 392). "Measures of cognitive functioning were selected to appropriately characterize the sample and assess change in the four cognitive domains targeted by the CogSMART intervention (prospective memory, attention, learning and memory, and executive functioning)." (Twamley et al., 2014, p. 59). "Assessments measured post-concussive symptoms, neuropsychological performance, functional capacity, psychiatric symptom severity, quality of life, and weeks worked during the 12-month trial." (Twamley et al., 2015, p.391).

2. Was the assignment of patients to treatments randomised?

Yes	<input checked="" type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider

- how this was carried out
- was the allocation sequence concealed from researchers and patients

Comments: "Following baseline assessment, participants were randomized to one of two conditions: supported employment plus CogSMART or enhanced supported employment. Randomization was carried out by the principal investigator using a randomization scheme generated by Randomization.com, with 50 participants in one block. In this pilot randomized controlled trial, all participants received supported employment for 1 year." (Twamley et al., 2014, p.62). "Following baseline assessment, participants were randomized to receive CogSMART, provided by their supported employment specialist (SE-Cog), or additional supported employment sessions (enhanced supported employment; ESE) for the first 3 months of the year-long study. We hypothesized that, compared with ESE participants, those who received supported employment plus CogSMART would report reduced postconcussive symptom severity (primary outcome) and would exhibit improvements in cognitive performance and functional capacity." (Twamley et al., 2015, p.393).

3. Were all of the patients who entered the trial properly accounted for at its conclusion?

Yes	<input checked="" type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider

- was the trial stopped early
- were patients analysed in the groups to which they were randomised

Comments: "First, this was a small pilot study that was affected by 16 percent dropout within the first 3 months as well as missing data at the 3month assessment." (Twamley et al, 2014, p.66). "... there was a 16% dropout rate over the 12-month follow up interval." (Twamley et al., 2015, p. 399). The researchers accounted for the whole sample and transparently reported on patients lost to follow up.

Is it worth continuing? YES

4. Were patients, health workers and study personnel 'blind' to treatment?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input checked="" type="checkbox"/>

Comments: "The research assistant was not aware of participant randomization status at the baseline assessment but was aware of treatment group for subsequent assessments." (Twamley et al. 2014, p.62 and 2015, p.393). "Outcome assessment was not blinded; however, most of our outcome measures were either objective (neuropsychological test performance, attainment of competitive work) or reported by the participant, rather than rated by the examiner. Therapist factors were a potential confound. We considered having a separate "cognitive specialist" deliver the CogSMART intervention instead of the employment specialist, but we believed the CogSMART intervention would be more efficacious in the context of supported employment as well as more cost-effective if delivered by one provider, which was necessarily the employment specialist. An advantage to this approach is that the employment specialist can continue to use and reinforce CogSMART principles throughout supported employment. We considered having the two employment specialists each provide services to participants in each study condition, but we opted to have one employment specialist affiliated with each treatment condition to prevent treatment contamination." (Twamley et al., 2014, p.66). "Second, the examiners administering the follow-up assessments were not blind to the treatment condition of the participants, raising the possibility of experimenter bias." (Twamley et al., 2015, p.399).

5. Were the groups similar at the start of the trial

	<input checked="" type="checkbox"/>
Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider
• other factors that might affect the outcome, such as; age, sex, social class

Comments: "The treatment groups did not differ by sex, race, ethnicity, postconcussive and psychiatric symptom severity, presence of mild or greater depressive symptoms, presence of threshold PTSD, TBI severity (length of LOC in the worst TBI and summed across up to 4 TBIs), years since their most recent TBI, nature of their worst TBI (contact vs blast only), or years since their worst TBI (all $p \geq 0.06$). The group that received supported employment plus CogSMART, however, was about 5 yr younger on average than the group that received enhanced supported employment ($p = 0.05$)." (Twamley et al., 2014, p.62). "Secondary analyses removing the two oldest individuals in the enhanced supported employment group (which made the two groups not significantly different on age) did not change the results." (Twamley et al., 2014, p.64).

6. Aside from the experimental intervention, were the groups treated equally?

Yes	<input checked="" type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

Comments: "All Veterans in the study received supported employment (SE) for 1 yr, the goal of which is competitive employment. Two SE specialists provided all services; one employment specialist delivered CogSMART for 1 h/wk in addition to standard SE (i.e., 2 visits/wk), and the other employment specialist delivered enhanced SE (2 visits/wk) to control for the nonspecific therapeutic factors provided in CogSMART. CogSMART and enhanced supported employment were provided during the first 12 wks of SE so that time and contact with the employment specialist were equivalent across groups. All participants received standard clinical care with their usual providers during the trial. CogSMART completion rates were high; 15 of the 16 participants randomized to receive SE plus CogSMART completed all 12 sessions, and 1 participant completed 8 sessions." (Twamley et al., 2014, p.62 and 2015, p.393).

Section B: What are the results?

7. How large was the treatment effect?

HINT: Consider

- what outcomes were measured
- Is the primary outcome clearly specified
- what results were found for each outcome

Comments: The treatment effect size was large for the NSI and prospective memory performance. "...significant CogSMART-associated improvements in post-concussive symptoms (NSI: $p = 0.01$) and prospective memory performance (MIST 24 h probe: $p = 0.05$) at post treatment. The Cohen d effect sizes for these group differences between change scores were 0.97 and 0.72, respectively." "... supported employment plus CogSMART group showed small to medium effect size improvements in psychiatric symptom severity (CAPS: $d = 0.43$ and HAM-D: $d = 0.37$, based on group differences between change scores) relative to the enhanced supported employment group. Five participants in the enhanced supported employment condition obtained competitive work within the first 14 wk of the study compared with eight participants in the supported employment plus CogSMART condition ($d = 0.49$ – medium effect size)." (Twamley et al., 2014, p.64). The NSI and MIST 24hour probe and QOL outcome at 3, 6 and 12 months also showed moderate to large effects sizes with large effect sizes sustained at 12months as reported in the follow-up study by Twamley et al., 2015, p. 396).

8. How precise was the estimate of the treatment effect?

HINT: Consider

- what are the confidence limits

Comments: The precision of the estimate of the treatment effect is high as the 95% CI for this small cohort of participants per group or treatment arm is small not wide. The means scores and SDs for outcomes were used to calculate the 95% CI for outcomes to check for precision.

Section C: Will the results help locally?

9. Can the results be applied to the local population, or in your context?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input checked="" type="checkbox"/>

HINT: Consider whether

- the patients covered by the trial are similar enough to the patients to whom you will apply this
- how they differ

Comments: "Finally, our results may not generalize to individuals with severe TBI, people with TBI who do not want to work, or non-Veterans." (Twamley et al., 2014, p.66). "Furthermore, this study included a sample of unemployed veterans with a history of mild to moderate TBI who expressed interest in returning to work; therefore, our results may not generalize to individuals with more severe TBI, nonveterans, or those who are not interested in obtaining work." (Twamley et al., 2015, p.399)

10. Were all clinically important outcomes considered?

Yes	<input checked="" type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider whether

- there is other information you would like to have seen
- if not, does this affect the decision

Comments: All relevant outcomes were covered and reported on in these papers and this study particularly looked at the attainment of competitive work that was of interest for this review.

11. Are the benefits worth the harms and costs?

Yes	<input checked="" type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider
• even if this is not addressed by the trial, what do you think?

Comments: "We considered having a separate "cognitive specialist" deliver the CogSMART intervention instead of the employment specialist, but we believed the CogSMART intervention would be more efficacious in the context of supported employment as well as more cost-effective if delivered by one provider, which was necessarily the employment specialist." (Twamley et al., 2014, p.66). The increased attainment of competitive work by the participants and the positive qualitative feedback from participants in the study regarding the CogSMART intervention provide evidence for more benefit than harm and support the cost of the intervention implemented in this real world study in the reviewers opinion. A cost-analysis was not performed in this study.



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Paper for appraisal and reference: **Vanderploeg et al., 2008**

Section A: Are the results of the trial valid?

1. Did the trial address a clearly focused issue?

Yes	<input checked="" type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: An issue can be 'focused' in terms of

- the population studied
- the intervention given
- the comparator given
- the outcomes considered

Comments: The objective of the study was to determine the relative efficacy of 2 different acute traumatic brain injury (TBI) rehabilitation approaches: cognitive didactic versus functional-experiential, and secondarily to determine relative efficacy for different patient subpopulations. The **Participants included** adult veterans or active duty military service members (N=360) with moderate to severe TBI. The **Intervention included** one and a half to 2.5 hours of protocol specific cognitive-didactic therapy (intervention) versus one and a half to 2.5 hours of functional-experiential rehabilitation therapy (control) integrated into interdisciplinary acute Commission for Accreditation of Rehabilitation Facilities-accredited inpatient. The **outcomes** considered in this study were clearly stated by Vanderploeg et al, 2008, p. 2230: "Primary outcome measures at 1-year post protocol treatment were functional independence (ie, ability to live independently with less than 3 hours of assistance a week) and return to work and/or school (ie, current status of paid employment or school enrollment, either full or part time, not sheltered workshop)." ... "The FIM consisting of motor and cognitive scores and the DRS score were measured at discharge from protocol treatment, while quality of life, and psychosocial function, behavior, and mood state were measured at 1-year postprotocol treatment. The Present State Exam was used to capture mood and behavioral variables, the Apathy Evaluation Scale captured motivation, and the Neurobehavioral Rating Scale (interview version) assessed self-perceived memory problems. Life satisfaction and change in marital status were captured by self-ratings and clinical interview, respectively."

2. Was the assignment of patients to treatments randomised?

Yes	<input checked="" type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider

- how this was carried out
- was the allocation sequence concealed from researchers and patients

Comments: "Participants were randomized to the comparative treatments by an independent study statistician (K.S.) using random number tables. Randomization was stratified by center and blocked in randomly ordered block sizes. This method provides approximately even group assignments across centers and is recommended for multicenter clinical trials. Notification of treatment arm assignments occurred after consent and central confirmation of eligibility, in order to shield those enrolling participants from knowledge of the next treatment assignment." (Vanderploeg et al., 2008, p. 2230&2232).

3. Were all of the patients who entered the trial properly accounted for at its conclusion?

Yes	<input checked="" type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider

- was the trial stopped early
- were patients analysed in the groups to which they were randomised

Comments: Despite our best efforts, approximately 8% of the sample was lost to follow-up, and primary outcomes were not obtained. Data were analyzed using an intent-to-treat analysis including all randomized patients.

Is it worth continuing? YES

4. Were patients, health workers and study personnel 'blind' to treatment?

Yes	<input checked="" type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

Comments: "Independent teams of therapists functioned at each site to deliver the separate treatments, and by necessity were not blinded to treatment." (Vanderploeg et al., 2008, p.2229). "Given the interactive nature of the interventions, patients and treating clinicians could not remain blinded. However, independent evaluators collected the outcome data and were blinded to treatment arm assignment." (Vanderploeg et al., 2008, p.2232). Thus single blinding was performed only.

5. Were the groups similar at the start of the trial

Yes	<input checked="" type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider
• other factors that might affect the outcome, such as; age, sex, social class

Comments: "Treatment arms were similar on all baseline demographic (table 1) and injury characteristics (table 2) including age, sex, education, race, ethnicity, active military duty status, percent working prior to injury, and type and severity of brain injury. Treatment arms also were similar in baseline cognitive, physical, and neurobehavioral functioning as measured by RLAS, cognitive and motor FIM, mental status examination, and overall scores on the Neurobehavioral Rating Scale (table 3) Neuropsychologic testing measures were all at least 2 SDs below normative values and similar between groups when obtainable at baseline; 78.1% completed the Memory, Orientation, and Amnesia Test (see table 2), and 75% completed the full battery (table 4)." (Vanderploeg et al., 2008, p. 2232). Thus groups were similar at the start of the trial.

6. Aside from the experimental intervention, were the groups treated equally?

Yes	<input checked="" type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

Comments: "The mean +/- SD duration of protocol treatment was 32.7+/-12.9 calendar days overall and was similar for the cognitive arm (32.2+/-12.2d) and functional arm (33.3+/-13.6d; $t_{358}=0.79$, $P=0.43$), but it did vary over time (longer during the first half of accrual [1996–1999], 35.2+/-15.2 calendar days versus 29.9+/- 8.9 calendar days; $t_{358}=4.07$, $P=.001$). Seventy-four participants (20.6%) received less than the intended minimum 20 protocol treatment days (26 calendar days), and 3 participants (0.8%) received over the intended maximum of 60 protocol treatment days (84 calendar days). Underexposed or overexposed participants were equally distributed across the 2 arms (38 cognitive arm vs 39 functional arm). Therapist knowledge of and adherence to the differential treatment interventions were monitored." (Vanderploeg et al., 2008, p.2232).

Section B: What are the results?

7. How large was the treatment effect?

- HINT: Consider
- what outcomes were measured
 - Is the primary outcome clearly specified
 - what results were found for each outcome

Comments: Treatment ES was small for all outcomes except for exploratory secondary outcome regarding memory problems where the ES was $d=0.71$ with a significant difference between the two groups on memory problems.

8. How precise was the estimate of the treatment effect?

- HINT: Consider
- what are the confidence limits

Comments: The precision of the estimate of the treatment effects was high as the 95%CI limits were small for all outcomes. However, the multiple secondary and sub analyses were conducted without adjustment for multiple comparisons, so some findings may be spurious.

Section C: Will the results help locally?

9. Can the results be applied to the local population, or in your context?

Yes	<input type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input checked="" type="checkbox"/>

- HINT: Consider whether
- the patients covered by the trial are similar enough to the patients to whom you will apply this
 - how they differ

Comments: "Also, the sample was composed primarily of male subjects (93%). Thus, findings may not generalize to female subjects." (Vanderploeg et al., 2008, p.2236). The results may not necessarily be applicable to other populations as the setting from which the patients are recruited, the demographic and clinical variables of patients in terms of male versus female, educational level, prior employment, TBI severity and availability of employment as well as the patients' willingness to work to name but some factors may vary in the local US population or other countries as this study was conducted in the US and sourced TBI patients from Four Veterans Administration acute inpatient TBI rehabilitation programs including adult veterans or active duty military service members (N=360) with moderate to severe TBI.

10. Were all clinically important outcomes considered?

Yes	<input checked="" type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

- HINT: Consider whether
- there is other information you would like to have seen
 - if not, does this affect the decision

Comments: Yes, the researchers considered all clinically important outcomes based on the intervention used and return to work was also measured which was of interest to this review.

11. Are the benefits worth the harms and costs?

Yes	<input checked="" type="checkbox"/>
Can't Tell	<input type="checkbox"/>
No	<input type="checkbox"/>

HINT: Consider
• even if this is not addressed by the trial, what do you think?

Comments: Yes, although not reported the reviewer is of the opinion that the benefits of the intervention are worth the harm or costs as in the exploratory analysis younger TBI in the intervention showed a higher RTW rate and this could assist improved financial status for these TBI individuals and reduce the burden of unemployment and reduced earning income of these individuals.



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APPENDIX I: RE-AIM APPRAISAL OUTCOMES

Cicerone et al. (2008)			
	ITEMS	ITEM DESCRIPTION	SCORE
R	Reach	<ul style="list-style-type: none"> Does the article indicate who the program is intended for (Inclusion and Exclusion criteria)? 	yes - 1; no - 0
		<p>“To be eligible for the treatment study, participants had to (1) have medical documentation of TBI based on a primary source within 24 hours of injury (e.g., emergency medical services or hospital admission records), (2) be at least 3 months post injury, (3) be 18 to 62 years of age, (4) have adequate language expression and comprehension (with or without assistive device) to participate in verbally based group interventions (i.e., participants had to be English speaking and could not be severely aphasic), (5) be judged to require at least 4 months of comprehensive treatment, (6) be clinically appropriate for either arm of treatment, (7) be capable of attending treatment 3 days per week, and (8) be capable of giving informed consent. Participants with a history of prior TBI, premorbid learning disability, psychiatric disorder, or substance abuse were not excluded; participants were excluded if they had active psychiatric illness, substance abuse, or pain considered at the time of enrolment to prevent their compliance with treatment. Patients enrolled in the study were not required to have external funding for treatment, and most participants were unfunded or underfunded for rehabilitation. Participants were allowed to have received prior treatment and to continue treatment after the 16-week study period as clinically indicated.” (Cicerone et al., 2008, p.2240).</p>	1
		<ul style="list-style-type: none"> Does the article report on the representativeness of the target population? 	
		<p>“The study was designed as a practical clinical trial, investigating clinically relevant alternative treatments in a representative sample of people with TBI by using a range of health-related outcome measures.” (Cicerone et al., 2008, p.2240).</p>	1
		<ul style="list-style-type: none"> Does the article report on participation rate? 	
		<p>Yes. “One hundred sixty-four patients were screened for eligibility (fig 1). Ninety-five patients were excluded: 22 refused participation, 37 did not require 4 months of comprehensive treatment, in 3 patients 1 of the treatment arms was believed to be clinically contraindicated (primarily because of the need for physical rehabilitation), 13 patients did not have medical documentation of a TBI, 4 were excluded because of active psychiatric illness, 6 were excluded because of pain as a primary complaint, 1 had severe aphasia, 2 were non-English speaking, 4 did not meet inclusion criteria for age, and 3 did not have transportation to treatment. Sixty-nine participants were randomized. One withdrew consent before completing the baseline evaluation and is not included in the analyses. Of the remaining 68 participants, 34 received the Intensive Cognitive Rehabilitation Program and 34 received the Standard Neurorehabilitation Program treatment. Two participants withdrew from Intensive Cognitive Rehabilitation Program treatment: 1 within the first week of treatment and 1 subsequent to an episode of psychiatric symptomatology and substance abuse. Four participants withdrew from the Standard Neurorehabilitation Program treatment: 1 did not complete treatment because of psychiatric</p>	1

		hospitalization, and 3 completed the planned treatment but refused posttreatment evaluations in association with increased psychiatric symptoms. An additional 4 participants did not respond to requests for 6-month follow-up evaluation: 2 from the Intensive Cognitive Rehabilitation Program and 2 from the Standard Neurorehabilitation Program.” (Cicerone et al., 2008, p.2240-2242).	
E	Effectiveness	<ul style="list-style-type: none"> • Did the program achieve the intended objective? 	
		Yes. “We conducted a practical clinical trial comparing comprehensive holistic NP rehabilitation with standard, multidisciplinary rehabilitation for people with TBI. Both the Intensive Cognitive Rehabilitation Program and the Standard Neurorehabilitation Program were associated with significant improvements in NP functioning. The Intensive Cognitive Rehabilitation Program produced a moderate clinical effect on community functioning and a small clinical effect on life satisfaction, neither of which were observed after Standard Neurorehabilitation Program treatment.” (Cicerone et al., 2008, p. 2246).	1
		<ul style="list-style-type: none"> • Do they report on the limitations of the intervention? 	
		Yes. It is difficult to isolate the effective components of the Intensive Cognitive Rehabilitation Program; indeed, it is the integrated combination of interventions within the therapeutic milieu that is presumed to underlie the effectiveness of the Intensive Cognitive Rehabilitation Program. However, some discussion of the putative contributions of various components of the Intensive Cognitive Rehabilitation Program, in terms of both treatment process and structure, is warranted.” ... “Given the complexity of both interventions, we cannot reliably identify the contributions of specific components of treatment. Additional research investigating the effectiveness of specific treatment components and mechanisms of change is warranted.”	1
		<ul style="list-style-type: none"> • Reports on at least one outcome of the intervention 	
		Yes, they report on all outcomes of the intervention.	1
		<ul style="list-style-type: none"> • Reports on attrition 	
		Yes, Cicerone et al. (2008), p.2245 states: “After excluding from analysis the 6 participants who did not complete the clinical treatment and evaluation (all of whom were considered unemployed), the comparison between treatment conditions remained significant ($X^2=4.72, p=0.03$).”	1
A	Adoption	<ul style="list-style-type: none"> • Is the setting clearly described? 	
		Yes. “Postacute brain injury rehabilitation centre within a suburban rehabilitation hospital.” (Cicerone et al., 2008, p.2239 in abstract). “The study occurred at a post-acute brain injury rehabilitation program and TBI Model System of Care in a suburban rehabilitation hospital in the north eastern United States.” (Cicerone et al., 2008, p.2240).	1
		<ul style="list-style-type: none"> • Does the evaluation report on the adoption of the intervention by the participants or the organisation? 	
		There is no report on the adoption of the intervention except to say that the maintenance of outcomes the post treatment was measured at 6months post treatment. As study therapists were used, it can be assumed that the intervention was not necessarily adopted into	1

		practice. However, based on the definition of adoption the study therapists had adopted the intervention and they reported that 34 participants each received the intervention and control, respectively.	
		• Who delivered the program?	
		“The intervention was done by the study’s therapists.” Cicerone et al. (2008) only mentions the use of the therapist with no description of their medical background.	N/a to score
I	Implementation	• Describe the duration and frequency of the interventions?	yes - 1; no - 0
		The experimental and control interventions including frequency and duration of sessions were explained in detail on page 2242.	1
		• Has the staff/participants of the organisation/intervention been involved in delivering the program (cost implication?)	
		No, the investigators state that study therapists were involved, this would have cost implications for implementation.	0
		• Reports on intended and delivered interventions.	
		They study reports on treatment fidelity and states that the results from assessment of treatment fidelity are very consistent with the design and therapeutic intent of the planned interventions.	1
M	Maintenance	• Does the article report on long term effects of the intervention (after 6 months)	yes - 1; no – 0
		The study only measures 6month outcome and nothing after 6months post-intervention but recommends a longer period of evaluation post intervention. They also do not report on whether the organisation/s in which the intervention was implemented was maintained as part of their own rehabilitation programme.	0
		• Do they report on the indicators used for intervention follow – up?	
		SEsx total as well as vocational % and PQOL was measured at 6 months follow up.	1
Constantinidou et al. (2008)			
	ITEMS	ITEM DESCRIPTION	SCORE
R	Reach	• Does the article indicate who the program is intended for (Inclusion and Exclusion criteria)?	yes - 1; no - 0

		Inclusion: Adult male and female between 18 and 55 years of age; Primary diagnosis moderate to severe TBI (with given assessment parameters); RLAS level VI or higher; No aphasia present; Resolution of PTA (76 or higher on GOAT); enrolment in a residential comprehensive post-acute rehab program; Participants were within 4 years of their injury Exclusion: Penetrating head injury, Diagnosis of stroke at any time, Premorbid central nervous system disorder or learning disability, Documented major depression or other significant psych disorders, Current Beck Depression II score of 25 or higher, Substance abuse use, Deficits in auditory comprehension or word finding issues, English as a second language, Color blindness. (Constantinidou et al., 2008, p.314)	1
		• Does the article report on the representativeness of the target population?	
		The study did not report on the representativeness of the target population as it did not report on the percentage of males and females and did not report on what percentage of the population the sample was from. "Participants were recruited from residential rehabilitation centres that served as collaborating sites for the project. All sites used a rolling admission process to their rehabilitation program." (Constantinidou et al., 2008, p.315)	0
		• Does the article report on participation rate?	
		Yes. They report on who was lost to follow-up during the study in both groups and why. In the control group: "Originally, 20 subjects were enrolled in this group. Six participants were discharged from the rehabilitation centres before completing their treatments because of insurance complications and, subsequently, were terminated from the project. The remaining 14 participants completed the study." In the intervention group: "Originally, 29 subjects were enrolled in this group. Two participants discontinued rehabilitation against medical advice, and 2 participants developed medical complications and could not continue their participation in the study. Five others were discharged from the rehabilitation centres because of insurance complications, and subsequently, their participation was terminated. The remaining 21 participants completed the study." (Constantinidou et al., 2008, p.315). "Furthermore, although conducting the study in the environment that the CP was intended to be administered in (e.g., post-acute rehabilitation) was a strength (for the study), it also created important challenges. For instance, short length of stay in the rehabilitation program (due to discontinuation of insurance funding) resulted in subject attrition." (Constantinidou et al., 2008, p.325).	1
E	Effectiveness	• Did the program achieve the intended objective?	
		Yes. "This study provided additional data to the preliminary findings by Constantinidou et al. (2008) demonstrating that categorization training is an effective cognitive retraining tool after moderate-to-severe TBI." (Constantinidou et al., 2008, p. 321).	1
		• Do they report on the limitations of the intervention?	
		Yes. They state that the application of the intervention posed certain challenges with regards to availability of the site therapists and also the dose, duration and frequency needs further investigation.	1

		• Reports on at least one outcome of the intervention	
		Yes, they report on all outcomes of the intervention.	1
		• Reports on attrition	
		Yes, they state how many participants were lost to follow-up during the study in both groups and why. And they say: “Furthermore, although conducting the study in the environment that the CP was intended to be administered in (e.g., post-acute rehabilitation) was a strength (for the study), it also created important challenges. For instance, short length of stay in the rehabilitation program (due to discontinuation of insurance funding) resulted in subject attrition”	1
A	Adoption	• Is the setting clearly described?	
		Yes, residential rehabilitation centres that served as collaborating sites for the project using a rolling admission process where participants were identified and selected based on inclusion and exclusion criteria and screened using assessments to test eligibility for inclusion.	1
		• Does the evaluation report on the adoption of the intervention by the participants or the organisation?	
		Yes, they seem to report on clinicians implementing the program/intervention. “To enforce consistency among the clinicians who implemented the protocol, Constantinidou trained all clinicians involved in data collection at the collaborating research sites.” (Constantinidou et al., 2008, p. 315). The study report also states that there were only a certain number of speech pathologists available in the research sites on p.315.	1
		• Who delivered the program?	
		“To enforce consistency among the clinicians who implemented the protocol, Constantinidou trained all clinicians involved in data collection at the collaborating research sites. Neuropsychological testing was conducted by a neuropsychologist who was not aware of the participant’s group assignment (i.e., experimental or control group) to reduce testing bias. At one of the sites, these services were contracted out. ... The functional outcome measures in most cases were conducted by the case management staff who was not involved in patient training and, therefore, was not informed of the participant’s group assignment. The CP-related measures were administered by the speech-language pathology team.” (Constantinidou et al., 2008, p.315).	N/a to score
I	Implementation	• Describe the duration and frequency of the interventions?	yes - 1; no - 0
		The experimental and control interventions including frequency and duration of sessions were explained in detail on page 317. “Participants in the TBI experimental group required an average of 13 weeks to complete the CP study protocol. Participants received approximately 57 hours of individual cognitive treatment, averaging between 2 and 3 hours per week on the CP-related tasks, for a total of 27 hours of CP treatment and about 4.5 hours of total individual therapy per week. Participants in	1

		the non-experimental TBI group received an average of 80 hours of individual cognitive treatment over an 18-week period, averaging 4.5 hours of individual therapy per week.” (Constantinidou et al., 2008, p.317).	
		• Has the staff/participants of the organisation/intervention been involved in delivering the program (cost implication?)	
		“To enforce consistency among the clinicians who implemented the protocol, Constantinidou trained all clinicians involved in data collection at the collaborating research sites.” (Constantinidou et al., 2008, p.317) At one site neuropsychologist was contracted out that may have influenced costs and case management staff and a speech pathologist team administered outcome measures.	1
		• Reports on intended and delivered interventions.	
		The author reported on what each treatment arm would receive and in the results reported what was delivered and received by the participants in each group.	1
M	Maintenance	• Does the article report on long term effects of the intervention (after 6 months)	yes - 1; no - 0
		No there was no long term follow-up.	0
		• Do they report on the indicators used for intervention follow – up?	
		No as there was no long term follow up only follow up directly after the intervention.	0
Salazar et al. (2000)			
	ITEMS	ITEM DESCRIPTION	SCORE
R	Reach	• Does the article indicate who the program is intended for (Inclusion and Exclusion criteria)?	yes - 1; no - 0
		“Inclusion criteria were (1) moderate-to-severe closed head injury, manifested by admission Glasgow Coma Scale score of 13 or less, or posttraumatic amnesia of 24 hours or more, or focal cerebral contusion or hemorrhage on computed tomography or magnetic resonance imaging (MRI); (2) head injury within 3 months of randomization; (3) Rancho Los Amigos cognitive level of 7 (oriented, appropriate); (4) active duty military member, not pending medical separation; (5) accompanied home setting with at least 1 responsible adult available; (6) an ability to ambulate independently; and (7) no prior severe TBI or other severe disability that would preclude return to active duty after study treatment.” ... “Patients with mild TBI were excluded.” (Salazar et al., 2000, p.3076).	1
		• Does the article report on the representativeness of the target population?	

		Yes “Our study population had moderate-to-severe injuries by standard criteria (e.g., prolonged unconsciousness or amnesia, evidence of cerebral lesions and axonal shear injury on MRI), but had nevertheless recovered to a Rancho level 7 (oriented) by 12 weeks after injury... Other important factors are this population's high preinjury education (all had high school degrees), their 100% employment and military fitness status, the supportive military environment, and the ready availability of (military) employment after injury. Thus, our results might be most applicable to comparable civilian TBI patients with high-preinjury function. Another important advantage of studying our population is the ability to minimize multiple confounding variables that potentially could affect outcome.” (Salazar et al., 2000, p.3080).	1
		• Does the article report on participation rate?	
		Yes “Seven patients failed to complete the full hospital program, 2 for medical reasons and 5 who voluntarily withdrew an average of 3 weeks into the program. Six of them were fit for duty or gainfully employed at 1 year. Likewise, 6 patients in the home treatment group required supplemental therapy because of persistent behavioural or mood problems, 4 of them after completing the home program. Four of the 6 were working or fit for duty at 1 year. All these randomized patients were included in the principal intent-to-treat analysis. However, excluding them from repeat analysis did not change the results substantially.” (Salazar et al., 200, p.3078-3079).	1
E	Effectiveness	• Did the program achieve the intended objective?	
		Yes. Both the home based and in hospital interventions were implemented as intended.	1
		• Do they report on the limitations of the intervention?	
		Yes. They even included a cost analysis of the interventions. “Although much of what therapists do is still intuitive and reflective of their own training and experience, most rehabilitation programs use various combinations of the 2 approaches, with or without adjunctive pharmacotherapy. For example, our standardized inpatient program had morning cognitive, speech, and psychotherapy sessions complementing structured job placement in the afternoon. In contrast, our home program was almost completely functional, providing counselling, exercises, and support, but otherwise minimal intervention in a home setting. Our results challenge whether a didactic cognitive rehabilitation approach is generally appropriate for patients recovering from moderate-to-severe TBI, but also suggest that institutional therapy may be beneficial for selected patients with severe TBI. It is unknown whether this or a different cognitive rehabilitation program might have provided a greater advantage to our patients, to a more disadvantaged or older group of patients, or to patients treated at a different time postinjury. (The time window postinjury for our study was guided in part by the goal of timely return to military duty.) ... Our results also highlight the potential therapeutic benefits of the home setting. A more cost-effective approach to rehabilitation might focus on identifying and enhancing the key elements of a home program, including decreased stress of the home environment and the support of loved ones at home, along with appropriate medical evaluation, and education (D.L.W. et al, unpublished data, 2000). While there are no apparent contraindications to a home program in this population, the increase in aggression in both groups at 12 months suggests that ongoing monitoring and support is an important part of treatment in all TBI patients.” (Salazar et al., 2000, p.3080).	1
		• Reports on at least one outcome of the intervention	

		Yes, they report on all outcomes of the intervention.	1
		• Reports on attrition	
		Yes. "Seven patients failed to complete the full hospital program, 2 for medical reasons and 5 who voluntarily withdrew an average of 3 weeks into the program. Six of them were fit for duty or gainfully employed at 1 year. Likewise, 6 patients in the home treatment group required supplemental therapy because of persistent behavioural or mood problems, 4 of them after completing the home program. Four of the 6 were working or fit for duty at 1 year. All these randomized patients were included in the principal intent-to-treat analysis. However, excluding them from repeat analysis did not change the results substantially." (Salazar et al., 2000, p.3078).	1
A	Adoption	• Is the setting clearly described?	
		Yes. "Single-centre, parallel-group, randomized trial conducted from January 1992 through February 1997 at a US military medical referral centre." (Salazar et al. 2000, p.3075 in abstract). "Patients were recruited from 273 consecutive hospitalized TBI patients who were referred to Walter Reed Army Medical Center (WRAMC) during the study accession period of January 1992 through February 1997; 167 of these patients met eligibility criteria, according to the study protocol... . Forty-seven eligible patients who refused participation were similar to the 120 study participants in demographics, injury severity, and clinical status at study entry." (Salazar et al., 2000, p.3076).	1
		• Does the evaluation report on the adoption of the intervention by the participants or the organisation?	
		There is no report on the adoption of the intervention/s, however there was a 1year follow-up to assess the outcome measures. However, based on the definition of adoption on the re-aim, the study states that the staff employed to deliver the intervention delivered the intervention and reported on what each set of participants in each group received. In addition, not all participants received the same amount (frequency or dose) of the interventions in the two treatment arms and thus it can be assumed that not all participants adopted the intervention fully.	1
		• Who delivered the program?	
		For the intervention namely in hospital rehabilitation: "The program was conducted by a board-certified psychiatrist (S.B.). Staff included a certified neuropsychologist experienced in milieu TBI rehabilitation (J.S.), a certified occupational therapist, speech pathologist, and 2 rehabilitation assistants." (Salazar et al., 2000, p.3076). For the home based rehabilitation: "Patients assigned to the home group (and their families when available) received TBI education and individual counselling from a psychiatric nurse." (Salazar et al., 2000, p.3077).	N/a to score
I	Implementation	• Describe the duration and frequency of the interventions?	yes - 1; no - 0
		Yes. The experimental and control interventions including frequency and duration of sessions were explained in detail on page 3076 - 3077).	1
		• Has the staff/participants of the organisation/intervention been involved in delivering the program (cost implication?)	

		No. "The program was conducted by a board-certified psychiatrist (S.B.). Staff included a certified neuropsychologist experienced in milieu TBI rehabilitation (J.S.), a certified occupational therapist, speech pathologist, and 2 rehabilitation assistants." (Salazar et al., 2000, p.3076). For the home based rehabilitation: "Patients assigned to the home group (and their families when available) received TBI education and individual counselling from a psychiatric nurse." (Salazar et al., 2000, p.3077). It was not stated where these staff were based and if they were part of the organisation or employed by the researcher but costs for the home based rehabilitation was stated to be lower than the in hospital based rehabilitation as calculated by the researchers as part of their outcomes.	0
		• Reports on intended and delivered interventions.	
		They reported on what was delivered per treatment group but treatment fidelity was not explicitly measured.	1
M	Maintenance	• Does the article report on long term effects of the intervention (after 6 months)	yes - 1; no - 0
		Yes. 1 year follow-up of outcomes was conducted but there was no significant difference between groups.	1
		• Do they report on the indicators used for intervention follow – up?	
		Yes, RTW, fitness for duty and KATZ QOL.	1
Twamley et al. (2014 and 2015)			
	ITEMS	ITEM DESCRIPTION	SCORE
R	Reach	• Does the article indicate who the program is intended for (Inclusion and Exclusion criteria)?	yes - 1; no - 0
		"Inclusion criteria were (1) OIF/OEF Veteran; (2) history of mild to moderate TBI (loss of consciousness [LOC]<6 h; posttraumatic amnesia <7 d) according to the Clinical Practice Guideline [28], documented in a prior clinical neuropsychological evaluation and confirmed by a structured interview; (3) documented impairment (>1 standard deviation below the mean) in at least one neuropsychological domain (i.e., attention, processing speed, working memory, learning, memory, executive functioning), as determined by valid clinical neuropsychological testing by a VA or DOD neuropsychologist using at least one effort test (e.g., Test of Memory Malingering, California Verbal Learning Test-2nd edition [CVLT-II] Forced Choice); and (4) unemployed, but stating a goal of work. Veterans who met criteria for current alcohol and/or substance abuse or dependence or who were participating in other intervention studies were excluded." (Twamley et al., 2014, p.62, Twamley et al., 2015, p.392).	1
		• Does the article report on the representativeness of the target population?	
		"Fifty Veterans receiving healthcare at the VA San Diego Healthcare System enrolled in the study..." (Twamley et al., 2014, p.61, Twamley et al., 2015, p.393). "... our results may not generalize to individuals with severe TBI, people with TBI who do not want to work, or non-Veterans." (Twamley et al., 2014, p.66, Twamley et al., 2015, p.399).	1

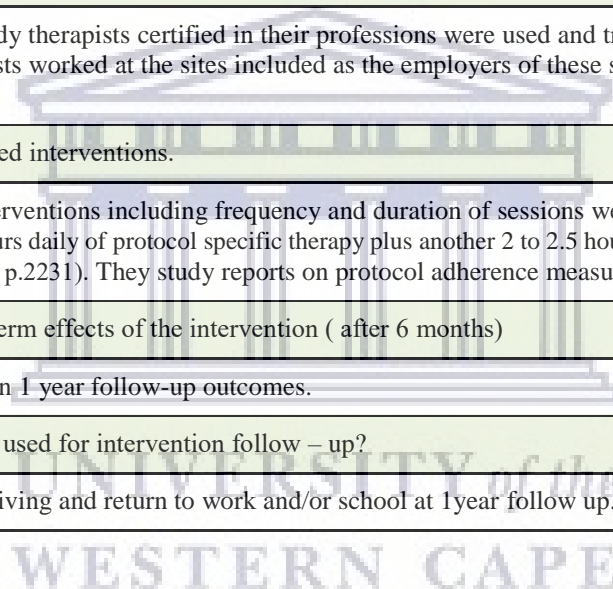
		<ul style="list-style-type: none"> • Does the article report on participation rate? 	
		<p>Yes. "All participants received standard clinical care with their usual providers during the trial. CogSMART completion rates were high; 15 of the 16 participants randomized to receive supported employment plus CogSMART completed all 12 sessions, and 1 participant completed 8 sessions." (Twamley et al., 2014, p.62). "Eight participants dropped out, four from each group (two decided not to pursue work, one moved, and five were lost to follow-up). Post treatment data were available for 34 participants at 3 mo (16 in supported employment plus CogSMART [3 with moderate TBI] and 18 in enhanced supported employment [4 with moderate TBI])." (Twamley et al., 2014, p.62). "Four participants from each group dropped out of the study; 2 participants decided not to pursue work, 1 moved, and 5 were lost to follow up. The 8 participants who dropped out did not differ significantly from participants who were retained..." (Twamley et al., 2015, p.393). "First, our sample was small, limiting our ability to detect small effect size changes, and there was a 16% dropout rate over the 12-month follow up interval." (Twamley et al., 2015, p.399).</p>	1
E	Effectiveness	<ul style="list-style-type: none"> • Did the program achieve the intended objective? 	
		<p>Yes. "CogSMART completion rates were high; 15 of the 16 participants randomized to receive supported employment plus CogSMART completed all 12 sessions, and 1 participant completed 8 sessions. To ensure CogSMART treatment fidelity, all CogSMART sessions were audiotaped and 20 percent were randomly selected for fidelity rating every 2 wk. Adherence rates were consistently in the 90 to 100 percent range." (Twamley et al., 2014, p. 62).</p>	1
		<ul style="list-style-type: none"> • Do they report on the limitations of the intervention? 	
		<p>Yes. "In addition, given the high number of recent Veterans returning to school using post 9/11 GI Bill benefits, the effects of CogSMART within a supported education context should also be investigated. Given our non-significant results on neuropsychological tests of attention, learning/memory, and executive functioning, these modules of the intervention may be less helpful, or less effective for certain individuals, and these are questions for a future dismantling study. Future research with larger samples will be needed to examine whether the presence and severity of psychiatric comorbidities affect CogSMART outcomes, in addition to the mechanisms of effect (e.g., prospective memory strategy use affecting prospective memory performance outcomes)." (Twamley et al., 2015, p.399).</p>	1
		<ul style="list-style-type: none"> • Reports on at least one outcome of the intervention 	
		<p>Yes, they report on all outcomes of the intervention.</p>	1
		<ul style="list-style-type: none"> • Reports on attrition 	
		<p>Yes. "Eight participants dropped out, four from each group (two decided not to pursue work, one moved, and five were lost to follow-up). Post-treatment data were available for 34 participants at 3 mo (16 in supported employment plus CogSMART [3 with moderate TBI] and 18 in enhanced supported employment [4 with moderate TBI])." (Twamley et al., 2014, p.62). "Four participants from each group dropped out of the study; 2 participants decided not to pursue work, 1 moved, and 5 were lost to follow up. The 8 participants who dropped out did not differ significantly from participants who were retained..." (Twamley et al., 2015,</p>	1

		p.393). "First, our sample was small, limiting our ability to detect small effect size changes, and there was a 16% dropout rate over the 12-month follow up interval." (Twamley et al., 2015, p.399).	
A	Adoption	<ul style="list-style-type: none"> • Is the setting clearly described? 	
		Yes. "Study referrals came from the VA San Diego Healthcare System Wellness and Vocational Enrichment Clinic, TBI Cognitive Rehabilitation Clinic, Polytrauma Clinic, and Neuropsychological Assessment Unit" in the USA (Twamley et al. 2014, p.61, Twamley et al., 2015, p.393).	1
		<ul style="list-style-type: none"> • Does the evaluation report on the adoption of the intervention by the participants or the organisation? 	
		Yes. "To ensure CogSMART treatment fidelity, all CogSMART sessions were audiotaped and 20 percent were randomly selected for fidelity rating every 2wk. Adherence rates were consistently in the 90 to 100 percent range." (Twamley et al., 2014, p. 62). They also reported on how many patients completed the intervention.	1
		<ul style="list-style-type: none"> • Who delivered the program? 	
		"Two supported employment specialists provided all services; one employment specialist delivered CogSMART for 1 h/wk in addition to standard supported employment (i.e., 2 visits/wk), and the other employment specialist delivered enhanced supported employment (2 visits/wk) to control for the nonspecific therapeutic factors provided in CogSMART. CogSMART and enhanced supported employment were provided during the first 12 wk of supported employment so that time and contact with the employment specialist were equivalent across groups. Consistent with the supported employment model, services were offered at locations of the participant's choosing (e.g., career centre, home, coffee shop, library, or VA clinic). All participants received standard clinical care with their usual providers during the trial." (Twamley et al., 2014, p.62)	N/a to score
I	Implementation	<ul style="list-style-type: none"> • Describe the duration and frequency of the interventions? 	yes - 1; no - 0
		The experimental and control interventions including frequency and duration of sessions were explained in detail on page 63 and 393 of Twamley et al. (2014) and Twamley et al. (2015) respectively.	1
		<ul style="list-style-type: none"> • Has the staff/participants of the organisation/intervention been involved in delivering the program (cost implication?) 	
		No, the investigators state that two employment specialists were used one to deliver the SE and ESE and one only to deliver the CogSMART and this therefore would have cost implications for implementation.	0
		<ul style="list-style-type: none"> • Reports on intended and delivered interventions. 	
		Yes. "To ensure CogSMART treatment fidelity, all CogSMART sessions were audiotaped and 20 percent were randomly selected for fidelity rating every 2 wk. Adherence rates were consistently in the 90 to 100 percent range." (Twamley et al., 2014, p. 62).	1
M	Maintenance	<ul style="list-style-type: none"> • Does the article report on long term effects of the intervention (after 6 months) 	yes - 1; no - 0

		Yes, the original pilot by Twamley et al. (2014) has a follow-up period of 12months on all outcomes reported on in Twamley et al. (2015).	1
		• Do they report on the indicators used for intervention follow – up?	
		Yes. They assessed post concussive symptoms (NSI), NP performance, psychiatric symptom severity, functional capacity, QOL and weeks worked during the 12month trial.	1
Vanderploeg et al. (2008)			
	ITEMS	ITEM DESCRIPTION	SCORE
R	Reach	• Does the article indicate who the program is intended for (Inclusion and Exclusion criteria)?	yes - 1; no - 0
		“Inclusion criteria were (1) moderate-to-severe non penetrating TBI within the preceding 6 months, manifested by a post-resuscitation Glasgow Coma Scale score of 12 or less, or coma of 12 hours or more, or PTA of 24 hours or more, and/or focal cerebral contusion or haemorrhage on computed tomography or magnetic resonance imaging; (2) RLAS cognitive level of 5 to 7 at time of randomization; (3) age 18 years or older; (4) active duty military member or veteran; and (6) anticipated length of needed acute interdisciplinary TBI rehabilitation of 30 days or more. Exclusion criteria were (1) history of prior inpatient acute rehabilitation for the current TBI and (2) history of a prior moderate to severe TBI or other preinjury severe neuro-logic or psychiatric condition, such as psychosis, stroke, multiple sclerosis, or spinal cord injury. (Vanderploeg et al., 2008, p.2228-2229).	1
		• Does the article report on the representativeness of the target population?	
		“All patients admitted to the CARF-accredited acute inpatient rehabilitation brain injury programs at 4 participating VAMCs (Minneapolis, Palo Alto, Richmond, and Tampa) during the study enrolment period were screened for eligibility.” (Vanderploeg et al., 2008, p.2228). “During enrolment (July 19, 1996–May 16, 2003), 476 patients out of the 897 total rehabilitation admissions fit eligibility criteria and were invited to participate. Of these, 366 subjects consented and were randomized.” (Vanderploeg et al., 2008,p.2232).	1
		• Does the article report on participation rate?	
		“During enrolment (July 19, 1996–May 16, 2003), 476 patients out of the 897 total rehabilitation admissions fit eligibility criteria and were invited to participate. Of these, 366 subjects consented and were randomized... Five subjects rescinded consent before study procedures began, and 1 withdrew consent later, leaving 360 subjects, 180 in each treatment arm, for the intent-to-treat sample. These were distributed among the 4 study sites as follows: Minneapolis (n=65), Palo Alto (n=91), Richmond (n=118), and Tampa (n=86). (Vanderploeg et al. (2008), p.2232). “Despite our best efforts, approximately 8% of the sample was lost to follow-up, and primary outcomes were not obtained. However, these participants were equally divided between the 2 treatment arms, and their absence is unlikely to affect any of the outcomes obtained in this study.” (Vanderploeg et al., 2008, p.2236).	1
E	Effectiveness	• Did the program achieve the intended objective?	

		Yes, the intervention was implemented successfully and the protocol adherence was assessed and reported on page 2232. The intended intervention and control were described in detail on pages 2229-2230.	1
		• Do they report on the limitations of the intervention?	
		Yes. "First, although the cognitive and the functional approaches were based on divergent rehabilitation strategies and learning theories, these 2 approaches had overlap. Both arms used compensatory techniques, although more heavily in the functional arm. By design and because of standards of care issues, use of memory notebooks also was common to both approaches. Therapists in the cognitive arm used memory notebooks as a training tool to build awareness of memory deficits and assist participants in using it as a problem solving tool. In contrast, therapists in the functional arm simply employed memory notebooks as a day-to-day functional compensatory technique. These types of overlap between the 2 treatment arms may have minimized the ability to find differential outcomes." (Vanderploeg et al., 2008, p. 2235).	1
		• Reports on at least one outcome of the intervention	
		Yes, they report on all outcomes of the intervention.	1
		• Reports on attrition	
		Yes. "Five subjects rescinded consent before study procedures began, and 1 withdrew consent later, leaving 360 subjects, 180 in each treatment arm, for the intent-to-treat sample." (Vanderploeg et al., 2008, p.2232). "Despite our best efforts, approximately 8% of the sample was lost to follow-up, and primary outcomes were not obtained. However, these participants were equally divided between the 2 treatment arms, and their absence is unlikely to affect any of the outcomes obtained in this study." (Vanderploeg et al., 2008, p.2236).	1
A	Adoption	• Is the setting clearly described?	
		Yes. "All patients admitted to the CARF-accredited acute inpatient rehabilitation brain injury programs at 4 participating VAMCs (Minneapolis, Palo Alto, Richmond, and Tampa) during the study enrolment period were screened for eligibility." (Vanderploeg et al., 2008, p.2228).	1
		• Does the evaluation report on the adoption of the intervention by the participants or the organisation?	
		They do not say whether the intervention was adopted into practice by the organisation but they do report on the number of participants who received the intervention or did not and the therapist fidelity to implementation. Seventy-four participants (20.6%) received less than the intended minimum 20 protocol treatment days (26 calendar days), and 3 participants (0.8%) received over the intended maximum of 60 protocol treatment days (84 calendar days). Underexposed or overexposed participants were equally distributed across the 2 arms (38 cognitive arm vs 39 functional arm). Therapist knowledge of and adherence to the differential treatment interventions were monitored qualitatively by site visits but not measured quantitatively.	1
		• Who delivered the program?	

		Independent teams of therapists functioned at each site to deliver the separate treatments, and by necessity were not blinded to treatment. All study therapists had at minimum several years of experience, and were certified	N/a to score
I	Implementation	<ul style="list-style-type: none"> Describe the duration and frequency of the interventions? 	yes - 1; no - 0
		“Participants received 1.5 to 2.5 hours daily of protocol specific therapy plus another 2 to 2.5 hours daily of occupational and physical therapy.” (Vanderploeg et al., 2008, p.2231). The experimental and control interventions including frequency and duration of sessions were explained in detail on page 2231-2232.	1
		<ul style="list-style-type: none"> Has the staff/participants of the organisation/intervention been involved in delivering the program (cost implication?) 	
		No, the investigators state that study therapists certified in their professions were used and trained in the use of the protocol but did not confirm whether these therapists worked at the sites included as the employers of these sites and this would have cost implications for implementation.	0
		<ul style="list-style-type: none"> Reports on intended and delivered interventions. 	
		The experimental and control interventions including frequency and duration of sessions were explained in detail on page 2231-2232. “Participants received 1.5 to 2.5 hours daily of protocol specific therapy plus another 2 to 2.5 hours daily of occupational and physical therapy.” (Vanderploeg et al., 2008, p.2231). They study reports on protocol adherence measures assessed.	1
M	Maintenance	<ul style="list-style-type: none"> Does the article report on long term effects of the intervention (after 6 months) 	yes - 1; no - 0
		The study measures and reports on 1 year follow-up outcomes.	1
		<ul style="list-style-type: none"> Do they report on the indicators used for intervention follow – up? 	
		Yes. Functional independence in living and return to work and/or school at 1year follow up.	1



APPENDIX J: RE-AIM SCORING SHEET

	Reach			Effectiveness				Adoption		Implementation			Maintenance		
Author	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Score

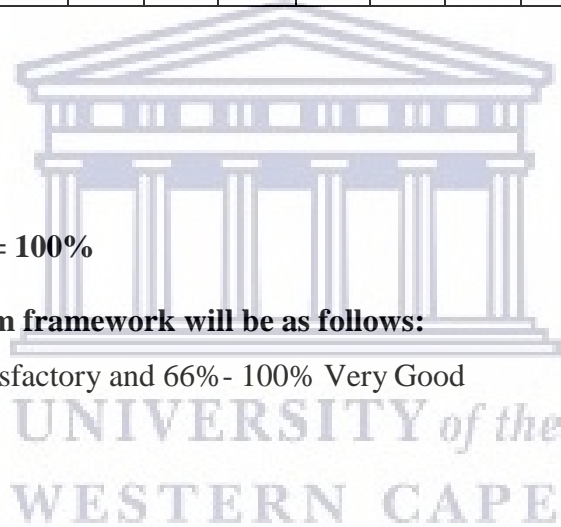
YES = 1

NO = 0

TOTAL SCORE = 14/14 = 100%

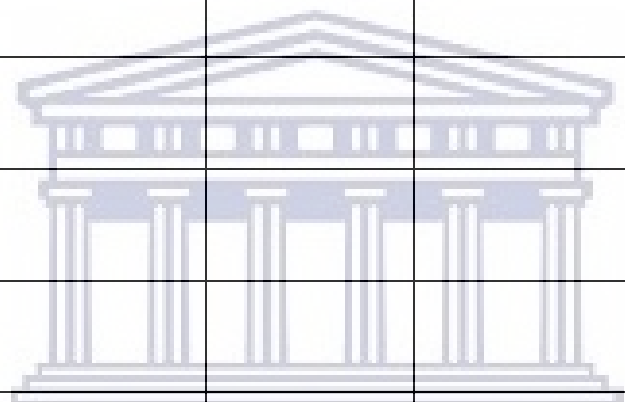
The score range for Re aim framework will be as follows:

0-33% Poor, 33%-66% Satisfactory and 66%- 100% Very Good



APPENDIX K: DATA EXTRACTION SHEET

AUTHOR	YEAR	COUNTRY	DESIGN	STUDY DURATION	APPRAISAL	POPULATION	SAMPLING	INTERVENTION	OUTCOMES



UNIVERSITY *of the*
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APPENDIX L: AUTHOR CORRESPONDENCE

From: Lauren Hutchinson <laurenhutchie@gmail.com>

Sent: Δευτέρα, 23 Νοεμβρίου 2020 8:38 πμ

To: Fofi Constantinidou <fofic@ucv.ac.cy>

Subject: Regarding article "Benifits of categorization training in patients with traumatic brain injury during..."

Good day

My name is Lauren Hutchinson, I am currently carrying out a systematic review and this article by Constantinidou, Thomas and Robinson is within my study.

The main focus of my study is return to work. In this article it uses the measure of CIQ productivity as a measure of productivity which technically measures productivity in the work or schooling field.

I would like to know if you have the number of participants that returned to work after intervention in both the experimental and control group?

If so, could you please furnish me with this as I would like to put it into my review.

Thanking you in advance

Lauren Hutchinson

Occupational Therapist

Chris Steytler Industries & University of the Western Cape

Lauren Hutchinson

Occupational Therapist

Chris Steytler Industries & University of the Western Cape

Subject: RE: Regarding article "Benefits of categorization training in patients with traumatic brain injury during..."

To: Lauren Hutchinson <laurenhutchie@gmail.com>

Hi,

Thank you for your interest in the study. The study included people who were enrolled in residential rehabilitation programs. Unfortunately, I don't know how many of them eventually returned to productive employment as we didn't have the opportunity to follow them up. Also, I am attaching a more recent manuscript for your review.

Best,

Fofi

Fofi Constantinidou, Ph.D., CCC-S, CBIS

ASHA and ACRM Fellow

Professor of Language Disorders and Clinical Neuropsychology

Director, Center for Applied Neuroscience

Board of Governors, American Congress of Rehabilitation Medicine

Board of Directors and Deputy Chair, CPLOL

President, Association of Registered Speech-Language Pathologists Cyprus

University Avenue 1, University of Cyprus

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Voice: +357 22 89 2078

Office: +357 22 89 2070/5190

Fax: +357 22 89 5076

Email: fofic@ucy.ac.cy

URL: www.cancyprus.org

Thanking you in advance for considering my request.
Kind regards
Lauren Hutchinson

--

Lauren Hutchinson
Occupational Therapist
Chris Steytler Industries & University of the Western Cape

" PENAFIAN: E-mel ini dan apa-apa fail yang dikepilkan bersamanya ("Mesej") adalah ditujukan hanya untuk kegunaan penerima(-penerima) yang termaklum di atas dan mungkin mengandungi maklumat sulit. Anda dengan ini dimaklumkan bahawa mengambil apa jua tindakan bersandarkan kepada, membuat penilaian, mengulang hantar, menghebah, mengedar, mencetak, atau menyalin Mesej ini atau sebahagian daripadanya oleh sesiapa selain daripada penerima(-penerima) yang termaklum di atas adalah dilarang. Jika anda telah menerima Mesej ini kerana kesilapan, anda mesti menghapuskan Mesej ini dengan segera dan memaklumkan kepada penghantar Mesej ini menerusi balasan e-mel. Pendapat-pendapat, rumusan-rumusan, dan sebarang maklumat lain di dalam Mesej ini yang tidak berkaitan dengan urusan rasmi Pusat Perubatan Universiti Malaya adalah difahami sebagai bukan dikeluarkan atau diperakui oleh mana-mana pihak yang disebut.

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--

Lauren Hutchinson
Occupational Therapist
Chris Steytler Industries & University of the Western Cape

From: **Fofi Constantinidou** <fofic@ucy.ac.cy>
Date: Mon, Nov 23, 2020 at 9:33 AM

From: NORHAMIZAN HAMZAH <norhamizan@ummc.edu.my>
Date: Mon, Feb 24, 2020 at 5:14 AM
Subject: Re: access to article
To: Lauren Hutchinson <laurenhutchie@gmail.com>

Hi,

There is no article on it because it is a conference presentation.

Here is the link for the abstract:

<http://www.em-consulte.com/showarticlefile/1227664/main.pdf>

The full published article of the completed study may be available hopefully this year.

Regards.

Dr Norhamizan Hamzah
Medical Lecturer & Rehabilitation Medicine Specialist
Dept of Rehabilitation Medicine
Faculty of Medicine
University Malaya
Malaysia

<https://umexpert.um.edu.my/norhamizanhamzah>

Tel: +603-79496677

Fax: +603-79674766



On Sat, Feb 22, 2020 at 6:20 PM Lauren Hutchinson

<laurenhutchie@gmail.com> wrote:

>

Good day

My name is Lauren Hutchinson, I am a postgraduate at UWC in the Western Cape South Africa. I am currently doing my Masters in "Best practice intervention for improving executive functioning in individuals returning to work post traumatic brain injury." the article you wrote: ISPR8-0422 A preliminary report on the effect of cognitive rehabilitation therapy in improving cognitive function of attention following mild traumatic brain injury: A randomised controlled trial falls within my inclusion criteria, and I would like to make use of it within my study, however I cannot gain access to it. I would like to know from you where I can get access to the full text or if you can assist me by making the article available to me. If you require any further information, I can send you the ethics approval forms as well as my proposal.

APPENDIX M: CIQ PRODUCTIVITY VARIABLES

Items 13 to 15 on CIQ by Willer B. (1991)

<https://www.midss.org/sites/default/files/ciq20scoring20key.pdf>

Although these items are collected individually, they will be combined to form one variable, Productivity. The scoring of this variable is dependent on the combination of answers to questions 13, 14 and 15. On page 4, is a listing of answer sets to these questions and their associated score.

Scoring of the Productivity Variable

Question#13	Question #14		Question#15		Score
Work	School		Volunteer Work		
Not working/not looking	+	No school	+	No Volunteering	= 0
Not working/not looking	+	No school	+	1-4 times/month	= 1
Not working/not looking	+	No school	+	5 or more times/month	= 1
Not working/looking	+	No school	+	No Volunteering	= 0
Not working/looking	+	No school	+	1-4 times/month	= 2
Not working/looking	+	No school	+	5 or more times/month	= 2
Retired due to age	+	No school	+	No Volunteering	= 0
Retired due to age	+	No school	+	1-4 times/month	= 2
Retired due to age	+	No school	+	5 or more times/month	= 3
Retired due to age	+	Part time	+	No Volunteering	= 4
Retired due to age	+	Part time	+	1-4 times/month	= 5
Retired due to age	+	Part time	+	5 or more times/month	= 5
Retired due to age	+	Full-time	+	Any answer	= 5
Not working	+	Full-time	+	Any answer	= 3
Not working	+	Part-time	+	Any answer	= 4
Part-time	+	No school	+	Any answer	= 3
Part-time	+	Part-time	+	Any answer	= 4
Part-time	+	Full-time	+	Any answer	= 5
Full time	+	No school	+	Any answer	= 4
Full-time	+	Part-time	+	Any answer	= 5

APPENDIX N: TURNITIN REPORT

Document Viewer

Turnitin Originality Report

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