Goal Management Training combined with external cueing and an emotional regulation module in the chronic phase of acquired brain injury. A randomized controlled trial.

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ABBREVIATIONS

ABI – Acquired brain injury

BHW – Brain Health Workshop

BREQ – The Brain Injury Rehabilitation Trust Regulation of Emotions Questionnaire

BRIEF-A – Behavior Rating Inventory of Executive Function – Adult version

BVMT-R – Brief Visuospatial Memory Test - Revised

CBT – Cognitive Behavioral Therapy

CFQ – Cognitive Failures Questionnaire

CPT-II – Conners Continuous Performance Test - Second Edition

CT – Computed Tomography

CVLT-II – California Verbal Learning Test - Second Edition

CVA – Cerebrovascular accident

CWIT – Color-Word Interference Test

D-KEFS – Delis-Kaplan Executive Function System

ED – Executive dysfunction

EF – Executive function

GMT – Goal Management Training

GLM – General Linear Model

HSCL-25 – Hopkins Symptom Checklist 25

ICF – The International Classification of Functioning, Disability and Health

IQ – Intelligence Quotient

MRI – Magnetic Resonance Imaging

PST – Problem solving therapy

PTA – Post traumatic amnesia

QoL – Quality of life

QOLIBRI – Quality of Life after Brain Injury

RCT – Randomized controlled trial

RM ANOVA – Repeated measures analysis of variance

SAS – Supervisory Attention System

SD – Standard deviation

T1 – Baseline assessments

T2 – Post-training assessments

T3 – Six-month follow-up assessments

TBI – Traumatic brain injury

TMT – Trail Making Test

UPSA – The UCSD Performance-Based Skills Assessment

VFT – Verbal Fluency Test

WAIS III – Wechsler Adult Intelligence Scale - Third Edition

WASI – Wechsler Abbreviated Scale of Intelligence

WM – Working memory

WHO – World Health Organization

GENERAL SUMMARY

Willful control of thoughts, emotions and behavior is an intrinsically human capacity and a prerequisite for adaptive functioning. This capacity relies on complex higher-order mental processes often denoted as executive functions (EF). Executive control is called for in non-familiar situations, in performing activities involving many sub-goals, or when the circumstances change in unpredictable ways – demanding a volitional change in thinking, behavior and emotions in order to adapt. Thus, habitual responses and prior experience will not be sufficient to achieve current goals. When the ability to maintain top-down control over mental processes is impaired, the information processing systems of the brain become more inflexible and reliant on habitual responses and prior experience.

In daily life, executive dysfunction (ED) is often indicated by problems with planning, strategy application, self-regulation, inhibition, goal-directed behavior, initiation of activity, regulation of emotions, and self-awareness. Such impairments may have devastating consequences for the individual's ability to perform daily life activities and participate in society. They result in noticeable handicaps and, sometimes, dependence on others. Several brain regions contribute to executive control, but the prefrontal cortex plays a crucial role. Given the extensive connectivity between the frontal lobes and most other brain areas, ED can result from a wide range of conditions affecting normal brain functioning, and is common following acquired brain injury (ABI).

Metacognitive strategy training, such as Goal Management Training (GMT), is recommended as a practise standard for rehabilitation of EF after ABI. These interventions aim at improving sustained attention and problem solving skills, through the training of verbally mediated metacognitive strategies, closely tied to the individual's daily life activities and goals. Previous GMT studies involving patients with ABI have several limitations, particularly related to study-design and sample size, long-term effects, and lack of knowledge about predictors of outcome.

The main aim of this randomized controlled trial (RCT) was to investigate the efficacy of GMT in patients with ABI in the chronic phase, compared to an active control treatment (Brain Health Workshop; BHW). Secondly, it was a goal to identify possible predictors of treatment outcome. The study included a new module addressing emotional dysregulation to investigate whether the GMT strategy could improve

emotional regulation in addition to cognitive aspects of EF. Both groups also received external cueing short message service in order to facilitate goal management. The study applied a repeated-measures design across three time points; baseline, post-intervention, and six-month follow-up. Neuropsychological tests and questionnaires assessing EF, psychological distress, and QoL were administered at all three time-points.

The aim of **Paper I** was to investigate the efficacy of GMT on cognitive aspects of EF, including attention and measures of daily life EF. **Paper II** aimed at evaluating the efficacy of GMT in improving emotional regulation, while **Paper III** explored possible predictors of outcome, in terms of cognitive EF, emotional regulation, and psychological distress. The results demonstrated that GMT combined with external cueing is effective in ameliorating self-reported ED in daily life for patients with chronic ABI. Improved performance on attention demanding cognitive tests was most prominent for the group receiving GMT, indicating improved executive attention (**Paper I**). Goal Management Training had beneficial effects on emotional regulation skills in everyday life, and was associated with improved QoL (**Paper II**). In **Paper I and II**, the strongest effects were seen at six-month follow-up, suggesting that the GMT strategies were applied and consolidated in everyday life after the end of training. In **Paper III**, the majority of the identified predictors of outcome were unspecific to the interventions, and showed how higher levels of self-reported symptoms predicted weaker treatment effects irrespective of intervention type. Age, IQ, and cognitive impairments related to verbal memory and planning ability, emerged as significant predictors in both interventions. However, inhibitory control was identified as a unique GMT-specific mediator of treatment effects.

In summary, the study confirms that GMT is an efficient metacognitive training for improving EF, including emotional regulation, even many years' post-injury. Of particular interest and in line with the theoretical underpinnings of GMT, the results support a specific improvement of cognitive inhibitory control. Still, the findings underscore that interventions targeting specific cognitive domains, such as attention or working memory (WM), also need to take into account the patients' overall cognitive and emotional functioning in order to facilitate the best possible outcomes.

LIST OF PAPERS

The thesis is based on the following peer-reviewed scientific papers which are referred to in the text by their Roman numbers I – III.

Paper I

Tornås, S., Løvstad, M., Solbakk, A-K., Evans, J., Endestad, T., Hol, P.K., Schanke, A-K. & Stubberud, J. (2016). Rehabilitation of executive functions in patients with chronic acquired brain injury with Goal Management Training, external cuing and emotional regulation: A randomized controlled trial. *Journal of the International Neuropsychological Society, 21,* 1–17. doi:10.1017/S1355617715001344

Paper II

Tornås, S., Løvstad, M., Solbakk, A-K., Schanke, A-K., & Stubberud, J. (2016). Goal Management Training combined with external cuing as a means to improve emotional regulation, psychological functioning, and quality of life in patients with acquired brain injury: A randomized controlled trial. *Archives of Physical Medicine and Rehabilitation, 97*, 1841-52. doi: 10.1016/j.apmr.2016.06.014

Paper III

Tornås, S., Stubberud, J., Solbakk, A-K., Evans, J., Schanke, A-K. & Løvstad, M. (2017). Moderators, mediators, and nonspecific predictors of outcome after cognitive rehabilitation of executive functions in a randomized controlled trial. *Neuropsychological Rehabilitation*. Advance online publication. doi: 10.1080/09602011.2017.1338587

1. INTRODUCTION

1.1 Acquired brain injury

Acquired brain injury (ABI) is defined as damage of brain tissue occurring after initial normal development, either resulting from a traumatic or a non-traumatic event (Turner-Stokes, Nair, Sedki, Disler, & Wade, 2011). Besides Cerebrovascular accidents (CVA) and traumatic brain injury (TBI), a number of other incidents and conditions can lead to permanent damage to the brain, the common denominator being a non-traumatic cause due to infections, toxic conditions, or other causes (Lezak, Howieson, & Bigler, 2012).

The ABI conditions included in this study (**Papers I-III**) were TBI, CVA, brain tumor (abnormal growth of cells within the skull), anoxia/hypoxia (complete or reduced oxygen supply to the brain), and meningitis and encephalitis (viral infections in the brain/meninges). These etiologies are not conclusive for ABI, but are conditions typically seen in brain injury rehabilitation centres (Lezak et al., 2012).

Depending on the nature, severity, localization and clinical course of the injury, there is a wide heterogeneity in outcomes following ABI. Impairments related to physical, cognitive, behavioral, psychosocial, and emotional abilities and functions are, however, frequently reported (Turner-Stokes et al., 2011).

Impaired executive functioning (EF) is often persistent over years (Brown et al., 2011), and can exert a profound effect on everyday living (Tate et al., 2014). Executive dysfunction (ED) and the accompanying consequences for daily life activities and participation in society (Bilbao et al., 2003; Peterson, 2005), are thus typically addressed in brain injury rehabilitation programs (Becker, Kirmess, Tornas, & Løvstad, 2014; Ben-Yishay & Diller, 2011; Prigatano, 1999; Rohling, Faust, Beverly, & Demakis, 2009).

Although a number of different conditions are included in the term ABI, TBI and CVA are the most frequent etiologies. Thus, in the following, definitions, epidemiology, and long-term outcomes related to ED following TBI and CVA will be outlined.

1.1.1 Traumatic brain injury, definition and epidemiology

Traumatic brain injury represents "*an alteration of brain function, or other evidence of brain pathology, caused by an external force*" (Menon, Schwab, Wright, & Maas, 2010,

p. 1637). In addition to the primary damage to the brain, adjourning pathophysiological mechanisms might further aggravate the effects of the brain injury, influencing upon the patterns and extent of damage (Maas, Stocchetti, & Bullock, 2008).

Traumatic brain injury is a significant cause of death and disability worldwide (Langlois, Rutland-Brown, & Thomas, 2006; Tagliaferri, Compagnone, Korsic, Servadei, & Kraus, 2006). It is estimated that 235.000 individuals are hospitalized each year for nonfatal TBI in the USA, with additionally 1.1 million being treated in emergency departments, and 50.000 fatalities (Corrigan, Selassie, & Orman, 2010). In Europe and Australia, the incidence is estimated to be 235 per 100.000 hospitalized persons, including fatal TBI (Hillier, 1997; Tagliaferri et al., 2006), while a Norwegian epidemiological study reported an annual incidence of 83 per 100.000 hospitalized TBIs (Andelic, Sigurdardottir, Brunborg, & Roe, 2008). Despite an increasing incidence of TBI in the elderly population, young male adults constitute the typical TBI patient causing high societal costs in terms of life years lost due to disability and death (Hyder, Wunderlich, Puvanachandra, Gururaj, & Kobusingye, 2007).

Injury-severity is typically classified as mild, moderate and severe (Corrigan et al., 2010). The evaluation is commonly based on degree of impaired consciousness assessed by the Glasgow coma scale (GCS) (Teasdale & Jennett, 1974) in the acute phase, the duration of loss of consciousness, and measures of the time-interval from injury until the patient is oriented and can form and later recall new memories (post-traumatic amnesia; PTA) (Nakase-Richardson et al., 2011).

The relationship between the medical classification of severity in the acute phase, and "severity" related to cognitive, behavioral and emotional functioning in a long-term perspective, is not a fixed equation (Millis et al., 2001). Good recovery has been associated with shorter PTA, absence of intracranial pathology, higher education, good performance on cognitive measures, less fatigue, younger age, being employed at time of injury, and absence of premorbid and/or comorbid psychiatric comorbidities (Chen et al., 2012; Colantonio et al., 2011; Forslund et al., 2017; Ponsford, Draper, & Schönberger, 2008; Rapoport & Feinstein, 2000; Sigurdardottir, Andelic, Roe, & Schanke, 2009).

1.1.2 Long-term outcome following traumatic brain injury

Investigating outcome four years after severe TBI in a study consisting of 245 TBI survivors, the authors reported that persistent cognitive complaints ranged from 25 to 68% among the subjects. The most frequent were irritability and deficits in memory, concentration, and slowing of information processing speed. Furthermore, anxiety (43%) and depression (25%) were frequently reported (Jourdan et al., 2016). Exploring outcome 10 years post-injury for 141 TBI patients, Ponsford, Downing, et al. (2014) reported that more than 60% still had significant problems with fatigue, balance, cognition, communication, behavior, and emotional functioning. A study examining long-term outcome of TBI on average 28.8 years post-injury in 605 former patients, reported persistent problems with memory, thinking, physical and emotional health (Brown et al., 2011). A systematic review of 33 TBI-studies on outcome, ranging from six months to 40 years, reported that impairments related to attention, memory, executive functions, information-processing speed, language functions, and visuospatial processing are common long-term impairments (Dikmen et al., 2009).

Changes in EF and behavior represent a great burden to families after TBI (Ponsford, Olver, Ponsford, & Nelms, 2003), and these are often related to long-term neurobehavioral symptoms like social inhibition, emotional dysregulation, depression, lack of initiative, and irritability (Deb, Lyons, & Koutzoukis, 1999; Hart, Brockway, Fann, Maiuro, & Vaccaro, 2015; Rogers & Read, 2007).

1.1.3 Cerebrovascular accidents, definition and epidemiology

A cerebrovascular accident (CVA) is defined as a *"focal neurological disorder of abrupt development due to a pathological process in blood vessels"(Walton, 1994, p. 23)*, commonly classified into two subgroups; ischemic (infarction; blockage of blood supply) comprising 80-85% of all strokes and haemorrhagic (bleeding; leakage from a blood vessel) constituting 15-20% of the cases (Maasz & Melegh, 2010; Ovbiagele & Nguyen-Huynh, 2011).

Cerebrovascular accidents is a leading cause of acquired disability worldwide (Feigin, Lawes, Bennett, & Anderson, 2003; Lopez, Mathers, Ezzati, Jamison, & Murray, 2006), the fourth leading cause of death and number one cause of adult disability in the United States (Ovbiagele & Nguyen-Huynh, 2011), and a major cause of cognitive and physical disability in Norway (Fjaertoft & Indredavik, 2007). In 2009, the estimated direct and indirect costs of stroke care in the USA alone was estimated to 68.9 billion dollars, and the prevalence and costs will rise as the population increases and ages (Ovbiagele & Nguyen-Huynh, 2011).

A study in ten European countries concluded that the numbers of CVAs would rise from 1.1 million per year in 2000, to more than 1.5 million per year in 2025 (Truelsen et al., 2006). A Norwegian population-based study in the Innherred region 1994-1996 concluded with an annual incidence of 3.12/1000 inhabitants (Ellekjær, Holmen, Indredavik, & Terent, 1997), adjusted for the European population to 2.21/1000. If the incidence rate is evenly distributed all over Norway, there will be approximately 16.000 new strokes per year, estimated to increase by 50% by 2030 (Ellekjaer & Selmer, 2007).

1.1.4 Long-term outcome following cerebrovascular accidents

It has been estimated that more than 50% of CVA survivors will suffer from cognitive (Barker-Collo et al., 2009) or executive deficits (Chung, Pollock, Campbell, Durward, & Hagen, 2013), with impaired attention and WM being most commonly reported (Jaillard, Naegele, Trabucco-Miguel, LeBas, & Hommel, 2009; Loetscher & Lincoln, 2013). Approximately one third of all CVA patients will experience a post-stroke depressive episode (Hackett, Yapa, Parag, & Anderson, 2005), which has been shown associated with a negative impact on recovery (Lenze et al., 2001), reduced social network (Northcott & Hilari, 2011), less cognitive improvement (Austin, Mitchell, & Goodwin, 2001; Butters et al., 2000), and increased risk of suicide (Schulz et al., 2000). Thus, physical, cognitive, emotional, and psychological deficits following CVA contributes negatively to daily-life functioning (Kwakkel & Kollen, 2013; Synhaeve et al., 2015).

In conclusion, although there is considerable variability regarding long-term outcome after ABI, both within and across the diagnostic categories, a significant number of individuals with ABI experience persistent psychological distress, emotional dysregulation and ED.

1.2 Executive function

The concept of EF can be traced back more than a hundred years (Barkley, 2012), to the initial scientific efforts to understand the functions of the frontal lobes in general, and the prefrontal cortex in particular (Bekhterev, 1907; Harlow, 1848; Luria, 1966).

Bekhterev (1907) observed that damage to the frontal lobes resulted in disintegrated goal-directed behavior, and described this as the principle function of the prefrontal cortex. This is considered to be the origin of contemporary definitions of EF (Welsh & Pennington, 1988). The prominent Russian neuropsychologist Luria (1966) described the frontal lobes as responsible for the programming, regulation, and verification of mental activity, and distinguished three frontal lobe syndromes - each related to the particular frontal region that had been damaged (dorsolateral, ventromedial, and/or orbital). Luria considered that failures of problem-solving played an important role in explaining the behavior of patients with frontal lobe lesions. Following this, the term "executive" has been introduced in referring to prefrontal cortex functions (Pribram, 1973), paving the way for the development of the later terms "executive disorder" (Fuster, 1997) and the "dysexecutive syndrome" (Wilson, Alderman, Burgess, Emslie, & Evans, 1996).

One contemporary, widely used definition describes EF as *"those integrated cognitive processes that determine goal-directed behavior and are superordinate in the orderly execution of daily life functions… the ability to formulate goals; to initiate behavior; to anticipate the consequences of action; to plan and organize behavior according to spatial, temporal, topical or logical sequences; and to monitor and adapt behavior to fit a particular task or context"* (Cicerone et al., 2000, p. 1605). Relevant to the field of rehabilitation, Lezak (1995) also underscores the functional importance of EF related to independence, activity and participation in stating that *"executive functions are those capacities that enable a person to engage successfully in independent, purposive, self-serving behavior"* (page 42). While definitions of EF vary somewhat, they share an understanding of EF as representing overarching control processes in the brain. Some of the most robust evidence linking frontal lobe activity to EF has emerged from studies including patients with frontal lesions (Bechara, Damasio, Damasio, & Anderson, 1994; Knight & Stuss, 2002; Shallice & Burgess, 1996). Exploring different aspects of EF, and the effect of focal frontal lobe lesions, Stuss and Benson (1986) emphasized the role of anticipation, goal selection, preplanning, and monitoring.

Embedded in these definitions of EF, is the understanding of attention, WM and EF as closely related cognitive processes (Stuss & Benson, 1986; Stuss, Shallice, Alexander, & Picton, 1995). The regulatory effects of attention are widespread within the brain (Posner & Raichle, 1994), with the executive attention network (Petersen & Posner, 2012; Posner & Petersen, 1990) being involved in the self-regulation of both affect and cognition (Duncan et al., 2000; van der Horn, Liemburg, Aleman, Spikman, & Naalt, 2015). Attention thus underlies voluntary control of thoughts and feelings (Posner & Rothbart, 2007), and is a prerequisite for adequate self-regulation (Dams-O'Connor & Gordon, 2013; Ruff & Rothbart, 1996).

While EF has traditionally been linked primarily to execution of cognition, a division between “cold” and “hot” components of EF has been suggested, with the "cold" EF corresponding closely to cognitive and logical processes, and the “hot" aspects of EF involving regulation of emotion and motivation (Chan, Shum, Toulopoulou & Chen, 2008). Emotional regulation involves the initiation, inhibition, and/or modulation of experience, as well as the expression and direction of emotions (Cattran, Oddy, & Wood, 2011; Cole, Michel, & Teti, 1994). Emotional dysregulation can be a primary symptom of injury due to changes in neuropathological processes, or form part of secondary psychological reactions to the injury and impairments. Pre- and comorbid emotional problems may also modulate symptom presentation after ABI (Dams-O'Connor & Gordon, 2013). Impairments in emotional regulation often undermine the ability to adapt to situations in everyday life, and can further aggravate impairment of cognitive processes (Cicerone & Giacino, 1992; Draper, Ponsford, & Schonberger, 2007; Fleming J, 2006; Rath, Simon, Langenbahn, Sherr, & Diller, 2003).

Goal-directed abilities require substantial cognitive energy, which is a finite resource until restored through rest or relaxation (Dams-O'Connor & Gordon, 2013). Emotional reactions and concerns can deflect a significant proportion of the individuals’ cognitive energy, resulting in mental exhaustion (Beck & Haigh, 2014). The consequence can in turn be fewer resources available for emotional regulation (Maki-Marttunen et al., 2015; van der Horn et al., 2015). Therefore, emotional dysregulation and EF are considered to mutually influence each other (Hart et al., 2015; Medd & Tate, 2000). Emotional regulation lies at the interface of cognition and emotion (Koole, 2009; Zeman, M., Perry-Parrish, & Stegall, 2006), and is understood as a prerequisite for efficient problem-solving and goal management (Dams-O'Connor & Gordon, 2013).

The historical development of the EF concept conflated the term EF with the functions of the prefrontal cortex, and vice versa, and lead to a circularity of reasoning (Barkley, 2012). As a result of the early efforts to understand prefrontal cortical functions, the concept of EF was at first defined by default as what the frontal lobes do (Stuss &

Benson, 1986). However, later studies reported executive impairments in patients with lesions in other areas than the prefrontal cortex (Alvarez & Emory, 2006; Cummings, 1993; Miller & Cohen, 2001). Similarly, functional neuroimaging studies of healthy controls solving EF tasks have shown that EF does not reside in the prefrontal cortex alone (Collette, Hogge, Salmon, & Van der Linden, 2006; Fassbender et al., 2004). Executive functions arise from activity in anatomically and functionally independent, but interconnected networks subserved by widespread brain regions (the anterior cingulate cortex, the thalamus, the basal ganglia, with the cerebellum), where the prefrontal cortex plays a central role (Stuss & Alexander, 2007)

To summarize, EF is challenging to define, and is a multidimensional construct including functions and processes that help to formulate goals, initiate goal-directed behavior, anticipate consequences, and organize, monitor and adapt behavior. This is achieved through top-down control of cognition, emotion and motivation.

1.2.1 Theories of executive function, attention and working memory

Most contemporary theories describe EF as top-down driven processes involved in the control and direction of self-regulatory cognition, emotion and behavior (Cicerone, Levin, Malec, Stuss, & Whyte, 2006; Stuss, 2011), and are closely associated with dominant models of attention (Norman & Shallice, 1986; Petersen & Posner, 2012), and WM (Baddeley, 2010). Posner and Petersen's (1990; 2012) theoretical framework for attention suggests three functionally distinct networks, the alerting (sustained attention or vigilance), the orienting (selective attention or concentration), and the executive attention network (divided attention or conflict). In a similar model for attention, shifting/switching of attention, e.g. the ability to change attentive focus in a flexible and adaptive manner, is included (Mirsky, Anthony, Duncan, Ahearn, & Kellam, 1991).

Investigating the unity and diversity of executive functions, Miyake and colleagues (Miyake et al., 2000) had 137 college students perform a set of simple experimental tasks considered to tap into different executive functions. They identified three separable, although moderately correlated core executive abilities; Information updating and monitoring, response inhibition, and shifting (cognitive flexibility). Information updating and monitoring correspond with the executive component of WM described by Baddeley (1986, 2010), while the two latter EFs partially overlap with the attention model of Posner and Petersen (1990; 2012). Other hierarchical models of EF also suggest an important role for arousal, in addition to sustained attention, underlying and supporting higher-order functions (Dams-O'Connor & Gordon, 2013).

The overlap between these models of attention, WM, and EF illustrate the complex reciprocal interplay between and within these functions, both in terms of theoretical conceptualization and neural underpinnings (Chiesa, Calati, & Serretti, 2011). Common to these conceptualizations, however, is placing executive, or controlled, attention at a cornerstone of the cognitive and anatomical infrastructure underlying EF (Chiesa et al., 2011; Miyake et al., 2000), by making the distinction between routine (or “automatic”) and non-routine (or “controlled”) processing (Gilbert & Burgess, 2008). The concept “automatic” refers to well-rehearsed or overlearned mental operations, while non-routine processing often refers to mental operations carried out in situations where there is no well-established stimulus-response association, or there is a need to correct behavior. Among the first comprehensive theoretical frameworks addressing this distinction was the theory of Supervisory Attention System (Norman & Shallice, 1986).

1.2.2 The Supervisory Attention System

In their influential theoretical framework for attentional control (Norman & Shallice, 1986; Shallice, 1988), behavior is seen as being governed by sets of thoughts or action “schemas” that become activated or suppressed in routine or non-routine circumstances. A schema represents a set of cognitions or actions that have become closely associated through repeated practise. The regulation of schemas for familiar, automatic actions, and in some cases novel situations, is governed by a lower-level mechanism – contention scheduling. Contention scheduling is automatic and fast, and in many everyday situations sufficient to accomplish the necessary and appropriate behavior.

The Supervisory Attention System (SAS) controls contention scheduling, being a higher-level mechanism “monitoring” the planning of actions in (novel) situations that cannot be solved by existing schemata or when the activation of habitual responses is critical. Thus, SAS is considered a slower, voluntary, executive monitoring system, and involved in the executive component of WM to store, control, and process information (Herr Dritschel, Kogan, Burton, Burton, & Goddard, 1998).

1.2.3 Supervisory attention as a framework: A revamped attentional model

Theories advocating that EF comprises a central executive (Baddeley, 2002), with the accompanying existence of a “dysexecutive syndrome” (Baddeley & Wilson, 1988), have been criticized as “homunculistic” models, e.g. replacing the “old homunculus” with a “new homunculus” like the central executive (Stuss et al., 1995). Based on the assumption that there is no unified or singular frontal process, and the theoretical work of Norman and Shallice (1986), Stuss and colleagues (Alexander & Stuss, 2000; Stuss & Alexander, 2007; Stuss et al., 1995) systematically explored whether different areas of the prefrontal cortex mediate distinct cognitive executive processes, guided by an anatomical and functionally reductionist approach as a means to understand the component processes associated with the frontal regions of the brain. Based on studies of patients with focal frontal lesions, Stuss (2011) suggests at least four categories of frontal lobe functioning, each related to a distinct region within the frontal lobes: 1) Energization (the process of initiation and sustaining any response) mediated by the superior medial frontal cortex, 2) Executive functions (monitoring and task setting) mediated by the lateral prefrontal cortex, 3) Behavioral/emotional self-regulation (the integration of motivational, emotional and social behavior) mediated by the ventral prefrontal cortex, and 4) Metacognition/integration (higher order processing) mediated by the frontal poles. As such, the frontal lobes do not represent a single central executive, and EF represents only one out of several processes within the frontal lobes. These processes act in concert to accomplish control, including the *reciprocal connections with virtually all other brain regions* (p. 763).

In summary, contemporary theories of EF emphasize the distinction between automatic and stimulus-driven (i.e. bottom-up) and volitional and controlled (i.e. top-down) processes, with attentional control and WM playing a crucial role. This conceptualization of EF provides a theoretical framework for the GMT-intervention (Levine et al., 2011) employed in this thesis, along with Duncan’s theory of “goal neglect” (1996), and the role of arousal and cueing (Robertson & Levine, 2013) (see chapter 1.6 Goal Management Training).

1.3 Assessment of executive functions

The assessment of the multidimensional construct EF poses a great challenge in clinical neuropsychology (Stuss & Levine, 2002). Royall et al. (2002) noted that there is no “gold” standard against which presumed prefrontal damage can be measured, and questioned whether this will ever be achievable, because: 1) The prefrontal cortex constitutes a large part of the brain, and it is unlikely that any one measure would be able to cover all of its’ functions, 2) The anatomy of the prefrontal cortex implies that lesions in the other lobes and subcortical lesions affect EF, and 3) Since the essence of EF is to influence lower level functions, it is a challenge to obtain measures that distinguish between a deficit in top-down control over the function, and the function itself, also known as the task-impurity problem (Miyake & Friedman, 2012). Because EF can be measured primarily in the context of task execution, scores derived from an EF task will include some variance attributable to non-EF processes that are part of the specific task context such as color processing and articulation speed. This non-EF variance and measurement error (random noise) is substantial, making it difficult to measure the EF variance of interest. Given the multifactorial nature of any test aiming at detecting deficits in complex higher-order functions, patients might fail the same test for different reasons and due to lesions in different parts of the brain (Knight & Stuss, 2002).

1.3.1 The issue of novelty

Executive function processes are activated in novel or complex tasks that require the individual to initiate new plans and strategies, and monitor effectiveness. Simple routine tasks on the other hand, are performed without the activation of executive processes. Walsh (1978) pointed out that a test intended to assess EF needs to be novel, sufficiently complex, and involve information integration. Although many of the traditional EF tests address the issue of complexity and integration, a test can only be novel once, without leading to possibly practise effects (Salthouse, Atkinson, & Berish, 2003). For example, Basso, Lowery, Ghormley, and Bornstein (2010) demonstrated that two administrations of the Wisconsin Card Sorting Test to 53 healthy men over a period of 12 months led to significant improvement on several indices the second time. Furthermore, defining a task as routine or complex, overlearned or novel is not always straightforward. What might be simple or routine for one person, might be complex and new for another (Alexander & Stuss, 2000). Thus, some authors have claimed that outcome measures of EF will never reach high validity (Burgess, Alderman, Evans, Emslie, & Wilson, 1998).

1.3.2 The structure of tests and test administration

A paradox in assessment of ED is the patients who perform well in the formal assessment, but show significant ED in carrying out daily life activities (Knight & Stuss, 2002; Zald, 2002; Zald & Andreotti, 2010). "*It is as if the simplified setting of a laboratory test somehow diminishes demands on frontal systems, concealing the deficits that actually exist"* (Duncan, Emslie, Williams, Johnson, & Freer, 1996, p. 296). Unlike the formalized structure of a test situation, the activities of daily life seldom contain verbal instructions or prompts, no "stereotyped" repetitions of similar trials, and often include multiple concurrent demands. As a result, there is a risk of underestimating the level of ED in standardized neuropsychological assessments.

1.3.3 Ecological validity

Ecological validity in neuropsychological assessment of EF refers to the correspondence between test performance and performance of everyday behavior (Chan, Shum, Toulopoulou, & Chen, 2008; Ready, Stierman, & Paulsen, 2001). Few neuropsychological measures of EF were designed with ecological validity in mind (Lewis, Babbage, & Leathem, 2011). Standardized neuropsychological tests including norms for the normal populations, usually aim at measuring the person's cognitive capacity not predicting the person's cognitive performance or functioning in daily life (Chaytor, Schmitter-Edgecombe, & Burr, 2006). The latter is also known as veridicality - the extent to which a measure is statistically associated with or predictive of everyday functioning, in contrast to verisimilitude – the extent to which a measure appears to reflect cognitive processes necessary to complete an everyday activity (Wood & Liossi, 2006). Furthermore, many tests of EF were developed in experimental studies of cognitive psychology, and not intended for clinical purposes (Burgess et al., 2006).

1.3.4 Measurement levels

The International Classification of Functioning, Disability, and Health model (ICF) provides a system to classify the targeted level of functioning for interventions and outcome measurements (Bilbao et al., 2003). Consequences of disease and disability are described at the impairment-, activity-, and/or participation level. The ICF-model deploys the qualifiers "capacity" and "performance" for assessing activity and participation, the former describing the person's ability to complete a task in a standardized environment, and the latter the person's ability to complete a task in their present environment (WHO, 2001). Traditional neuropsychological tests will typically aim to assess cognitive disabilities and strengths at the impairment level, e.g. examining verbal memory and learning by a standardized word-list test were normative data is available. This might give an adequate description of the individuals' verbal memory capacity, but the evaluation will have limited value for predicting real-life capacity for activity and participation (Lewis et al., 2011), which is the ultimate end-point of cognitive rehabilitation (Peterson, 2005; Wilson, 2008). Although the model provides a standardized analytical framework, acknowledging that different levels of the taxonomy are interrelated in complex ways, the three levels might be difficult to separate in real-life (Whyte et al., 2014).

1.3.5 Questionnaires

A number of questionnaires have been developed to collect information about patients' everyday behavior from both the perspective of the patient, their next-of-kin, and health care professionals.

Some of the issues related to ecological validity might be handled by employing questionnaires about daily living, but self-report measures face other challenges related to accuracy and validity. Reduced self-awareness of the impairments (Prigatano & Altman, 1990), possible demand characteristics when responding (McCambridge, de Bruin, & Witton, 2012), cognitive deficits influencing the answers (Cantor et al., 2014), or social desirability bias when responding (Logan, Claar, & Scharff, 2008) might influence the individuals' response style. In addition, there are other methodological concerns related to self-report data, e.g. acquiescent responding (Watson, 1992) and/or extreme responding (Furnham, 1986). Furthermore, the information obtained by relatives often differs from the patients´, and might also be influenced by factors like the kind of interpersonal relationship they have, possible distress in the family, and/or actual insight into the patients day-to-day functioning (Gioia, Isquith, & Kenealy, 2008; Manchester, Priestley, & Jackson, 2004).

To summarize, EF deficits are challenging to measure. Whilst still useful, traditional neuropsychological tests may not be optimal in assessing EF and particularly not outcomes after interventions. The assessments and outcome measures applied in the present study included measures at the body function-, the activity- and the participation level, and measures aiming at improving ecological relevance.

1.4 Cognitive rehabilitation

1.4.1 Cognitive rehabilitation

The history of cognitive rehabilitation is both old and new. The two world wars led to considerable development of rehabilitation methods of all kinds, including methods targeting cognitive dysfunction after brain damage. During the 1970's and 80's, the field experienced further change and development, not the least because rehabilitation researchers and therapists became interested in cognitive psychology (Parente, 1986). Numerous brain injury centers with programs for cognitive rehabilitation were developed all over the western world, e.g. in Denmark (Christensen, 1999), in the UK (Wilson et al., 2000) and in the United States (Ben-Yishay & Diller, 2011). In Norway, Finset and colleagues conducted the first prospective longitudinal study on cognitive rehabilitation of moderate to severe TBI, enrolling all eligible patients in Norway's largest rehabilitation hospital from 1987-89 (Finset, Dyrnes, Krogstad, & Berstad, 1994). These efforts were continued with the establishment of the Cognitive Rehabilitation Unit at Sunnaas Rehabilitation Hospital in the 1990s (Becker et al., 2014).

The Brain Injury Interdisciplinary Special Interest Group of the American Congress of Rehabilitation Medicine defined cognitive rehabilitation therapy as: *"systematic, functionally-oriented service of therapeutic cognitive activities, based on an assessment and understanding of the person's brain-behavior deficits. Services are directed to achieve functional changes by (1) reinforcing, strengthening, or reestablishing previously learned patterns of behavior, or (2) establishing new patterns of cognitive activity or compensatory mechanisms for impaired neurological systems"(Harley et al., 1992, p. 63).* Later definitions have further emphasized the process, the collaboration between the patient and the healthcare provider, and the participation perspective in cognitive rehabilitation: *"A process whereby people with brain injury work together with professional staff and others to remediate or alleviate cognitive deficits arising from a neurological insult, to enable people with disabilities to function optimally in their environments"* (Wilson, Gracey, Evans, & Bateman, 2009, p. 22). In other words, the end-goal of cognitive rehabilitation is to impact real-life functioning (Cicerone, 2012; Cicerone et al., 2008).

In clinical practice, the aim to impact real-life functioning is pursued by applying a variety of interventions and methods for facilitation of everyday activities. Take for example memory impairment: individual treatment may include approaches like computerized memory training (training of specific cognitive abilities), reduction of number of tasks to be achieved to compensate for the memory problems (modification of the environment), the use of reminders, lists or calendars to foster memory (technical aids), errorless learning to avoid incorrect recall (specific interventions), and/or mnemonics (strategic interventions). These different approaches can be categorized as restoring or re-training of functions, compensating by the use of internal/external strategies, environmental modifications, and/or pharmacological treatment (Cicerone et al., 2006).

The choice of intervention(s) and approach for each patient should be guided by the individuals' cognitive profile, activities the person used to engage in before the injury, and personal goals (Bayley et al., 2014). Further, the multitude of factors like diminished self-awareness (Prigatano & Altman, 1990), psychological and/or emotional distress (Hart et al., 2012), and the broader context of the individuals' life (Wilson, 2008), needs to be taken into consideration. Severe impairments will often need an approach emphasizing external strategies and environmental modifications, because the extent of the cognitive impairments makes it difficult for the individual to apply compensatory strategies.

The efficacy of cognitive rehabilitation has been examined in several evidence-based reviews that have addressed attention, vision and visuospatial functioning, language and communication, memory, executive functioning, and comprehensive integrated neuropsychological rehabilitation. Clinical recommendations have been developed for cognitive rehabilitation interventions for adults with TBI and stroke (Cicerone et al., 2000; Cicerone et al., 2005; Cicerone et al., 2011; Rees et al., 2007), for children and adolescents with ABI (Laatsch et al., 2007; Limond & Leeke, 2005), and for other medical conditions affecting cognitive function (Langenbahn, Ashman, Cantor, & Trott, 2013). The INCOG guidelines for cognitive rehabilitation following TBI were published recently (Bayley et al., 2014), presenting evidence-based recommendations for adults with moderate to severe TBI in all relevant phases of care. They cover assessment and intervention for post-traumatic amnesia (Ponsford, Janzen, et al., 2014), attention deficits (Ponsford, Bayley, et al., 2014), memory impairments (Velikonja et al., 2014), cognitive communication disorders (Togher et al., 2014), and executive dysfunction (Tate et al., 2014). Of particular interest, the guidelines include a clinical decision algorithm and criteria for auditing practice, providing the clinician with hands-on tools for navigating and choosing interventions suited for each patient.

The effectiveness of cognitive rehabilitation is well documented within some domains, and has resulted in clinical guidelines. Of particular interest for this thesis are evidence-based guidelines for treatment of EFs.

1.4.2 Cognitive rehabilitation of executive functions

In their latest review (Cicerone et al., 2011), a total of 19 studies were identified that addressed interventions for ED, including training in metacognitive strategies to increase awareness. The authors classified only 3 of the studies as a class I (RCT), while the remaining 16 provided "weaker" evidence in terms of being non-randomized cohort studies (class II), or studies without concurrent controls (class III). Metacognitive strategy training, including self-monitoring and self-regulation, was recommended as practice standard following TBI, in accord with the conclusions in another review of interventions for executive functions after TBI (Kennedy et al., 2008; Zoccolotti et al., 2011).

Although these reviews vary in the criteria used to include and exclude studies and/or research design, there is substantial overlap in the primary studies included and the recommendations made. In an updated review, Tate and colleagues (2014, p. 343) provided 4 recommendations for rehabilitation of executive impairments following TBI:

1. Metacognitive strategy instruction should be used for difficulties with problem-solving, planning and organization, focusing on everyday problems and functional outcomes. The approach is optimal when the patient is aware of the need to use a strategy and able to identify when and in what context the strategy should be applied. Training in self-monitoring and incorporation of feedback into future performance are common strategies across all included studies.
2. Strategies to improve the capacity to analyze and synthesize information should be used for impaired reasoning skills.

3. Corrective feedback, delivered within the context of a multicontextual program, should be used for impaired self-awareness.
4. Group-based interventions may be considered for remediation of executive and problem-solving deficits.

Although some studies have documented benefits of pharmacological treatment for behavioral (Wheaton, Mathias, & Vink, 2011; Whyte et al., 2004), and attention deficits and post-acute recovery of consciousness after TBI (Giacino et al., 2012), there are no practice standards for pharmacological treatment of impaired EF (Cicerone et al., 2006).

Regarding recommendations for attention and information processing speed, INCOG (Ponsford, Bayley, et al., 2014) emphasizes metacognitive strategy training focusing on everyday activities, dual-task training, environmental modifications, and cognitive behavioral therapy. Finally, the integration of internal and external compensatory strategies for rehabilitation of memory impairments, based on considerations of functional relevance and important patient characteristics, are recommended (Velikonja et al., 2014).

In summary, an evidence-based intervention addressing ED in daily life, should thus emphasize metacognitive strategy instructions and the use of compensatory strategies, aim at improving daily life functioning, and possibly be administered in groups.

1.4.3 Metacognitive strategy training

There are considerable differences between interventions addressing ED regarding theoretical framework, methodology, organization of- and amount of training, and outcome measures applied (Cicerone et al., 2011; Tate et al., 2014; Zoccolotti et al., 2011). Still, most convey compensatory strategies aimed at facilitating adaptation to disability rather than to restore executive capacities, and intend to generalize to a variety of situations (Haskins et al., 2011). To exemplify, three well-recognized studies aiming at improving EF in daily life for patients with TBI at least one year post injury will be presented, emphasizing emotional regulation and problem-solving (Rath et al., 2003), holistic rehabilitation and community integration (Cicerone et al., 2008), and executive dysfunction and attention (Cantor et al., 2014).

Rath and colleagues (2003) evaluated the efficacy of a 48 hour intervention addressing problem-solving deficits after TBI (n=32), compared to “conventional” neuropsychological treatment (n=28), in a RCT. The problem-solving intervention consisted of two parts; twelve 2-hour sessions practicing problem-orientation, followed by twelve 2-hour sessions training problem-solving skills. The problem-orientation aimed at removing impediments (reduced emotional self-regulation) to promote the effective use of the problem-solving skills, facilitate motivation, and increase the feeling of self-efficacy, applying techniques from Cognitive Behavioral Therapy (CBT) (Beck, 1976). Problem definition, generation of ideas, decision making, and implementation and verification constituted the framework for the problem-solving part (D'Zurilla & Goldfried, 1971). The problem-solving group improved on test measures of EF, self-appraisal of problem-solving, emotional regulation, and performance in role played scenarios involving problem-solving. All improvements were maintained at six-month follow-up.

The Intensive Cognitive Rehabilitation Program (Cicerone et al., 2008) was based on principles of comprehensive holistic neuropsychological rehabilitation (Ben-Yishay & Daniles-Zide, 2000; Ben-Yishay & Gold, 1990), and consisted of a total of 240 hours distributed over 16 weeks. The intervention emphasized the integration of cognitive deficits, emotional difficulties, interpersonal behaviors, and functional skills, and included both group and individual therapy. The program was divided into four phases; 1) group process and cohesion, the use of feedback, and strategies for attention, 2) acquisition and practice of strategies for each participant's problem areas and goals, 3) independent application and carryover of compensatory strategies, and 4) generalization of strategies to everyday functioning, positive acceptance of role limitations, and transition to the community. The effectiveness of the intervention (n=34) was evaluated in a RCT comparing it with standard neurorehabilitation (n=34) consisting of individual, discipline-specific therapies. All participants had suffered a TBI. Participants in the Intensive Cognitive Rehabilitation Intervention showed greater improvements of self-reported community integration, QoL, and self-efficacy, while no differences were seen between the groups regarding neuropsychological test performance (Cicerone et al., 2008).

The Short-Term Executive Plus Intervention for Executive Dysfunction (Gordon, Cantor, Ashman, & Brown, 2006) is based on three theoretical and empirical assumptions: a) ED includes problem-solving deficits, b) problem-solving is supported or thwarted by emotion, and c) EF, problem-solving, emotional regulation, and learning are mediated by attention. The 108 hours intervention was evaluated as a waitlist controlled trial, and included 98 participants with TBI. The program consisted of four components; training in problem-solving, emotional regulation, attention, and the use of external aids, provided in both groups and individual sessions. Significant improvements were found on neuropsychological measures of EF, and self-reported problem-solving. However, no beneficial effects were detected regarding emotional regulation, affective distress, or quality of life (QOL) (Cantor et al., 2014).

In summary, these interventions conceptually follow an approach paralleling the structure of executive functioning: a) the creation of an internal plan to reach a desired goal, b) the execution of a response/sequence of responses, c) the comparison of the plan with the outcome by feedback, and d) the consequent modification of the plan (Haskins et al., 2011). Furthermore, they are organized in a stepwise approach, and involve some kind of problem solving, "stop-and-think" training, and goal management in daily life, the latter constituting the core of Goal Management training (GMT), which was applied in the present study.

1.5 Goal Management Training

Goal Management Training (GMT) is the metacognitive intervention employed in this study. It is a structured, interactive, manual-based metacognitive strategy intervention, originally developed for TBI patients with ED (Levine et al., 2000; Robertson, 1996). Goal Management Training promotes a mindful approach to complex real-life tasks, training patients to periodically *stop* ongoing behavior to monitor and adjust goals (Levine et al., 2011). The intervention heavily emphasizes discussions of the patients' own experiences, practical demonstrations, and homework. The intervention was originally based on Duncan's theory of goal-neglect (Duncan et al., 1996), while later developments of GMT have further stressed the importance of sustained attention, WM, arousal and the use of cueing techniques (Robertson & Levine, 2013). The intervention also incorporates problem-solving components similar to other problem-solving interventions (Cantor et al., 2014; Rath et al., 2003; Von Cramon, Matthes-von Cramon, & Mai, 1991), although it has been argued that GMT is less focused on how to solve a problem and more focused on the process of determining which problem that ought be solved (Stubberud, 2014).

1.5.1 Goal neglect as a cause of dysexecutive behavior

Duncan's (1996) theory of "goal neglect" emphasized how impaired construction and use of goal lists are an important cause of dysexecutive behavior. Goal neglect is defined as "*the disregard of a task requirement even though it has been understood and remembered"* (Duncan et al., 1996, p. 294). In other words, it is as though the neglected requirement slips the subject's mind, and the knowledge of a failure produces no active attempt to correct it. Further, the theory emphasizes the distinction between controlled and automatic processing, and argues that eliciting conditions for goal neglect include novelty, weak error feedback, and/or multiple concurrent task requirements. The individuals' actual control of action is a result of the "competition" between these three candidates (Duncan et al., 1996). In GMT, the participants own "slip-ups" in daily life activities are discussed, and different tasks are practiced to illustrate how automatic processing can overrule the intended behavior and goals as people enter the "autopilot" mode. Goals in daily life activities often include a number of sub-activities (sub-goals). Techniques for defining goals, how to break down overarching goals into sub-goals are therefore emphasized. Thus, the primary objective of GMT is to train patients to *actively* stop ongoing behavior by verbal self-instruction, in order to define goal hierarchies, and monitor ongoing performance (Levine et al., 2011).

1.5.2 The importance of sustained attention and working memory in Goal Management Training

In line with current theories on the role of the frontal lobes in attention (Stuss, 2011), recent versions of GMT have increasingly emphasized the importance of sustained and controlled attention. They introduced more mindfulness tasks to attempt to address underlying attentional deficits, because sustained attention is required to actively maintain neural representations of goals in WM (Levine et al., 2011; Robertson & Levine, 2013). When the attention system is compromised, habits and/or environmental triggers may oppose and displace higher-order goals. This can result in more stimulus-driven, cue-dependent or distracted behavior (Fernandez-Duque, Baird, & Posner, 2000; Levine et al., 2011). In the training, WM is conceptualized as a "mental blackboard", where the current information (e.g. goals) is easily replaced by new information. Thus, the patients are trained to check the "mental blackboard" regularly, to ensure that current behavior supports their actual goals, underscored by a strong focus on inhibitory control.

1.5.3 Arousal and cueing as prerequisites for executive functions

The capacity of the nervous system to allocate processing resources selectively to a particular stimulus is a key mechanism in experience-dependent plasticity (Blake, Heiser, Caywood, & Merzenich, 2006), and requires an adequate level of arousal (Coull, 1995; Smith, 1996). Deficits in arousal or regulation of arousal, which is common after brain injury (Baumann, Werth, Stocker, Ludwig, & Bassetti, 2008), can contribute to attentional and high-level executive deficits (Coull, 1995; Greene, Bellgrove, Gill, & Robertson, 2009; Smith, 1996). Robertson, Mattingley, Rorden, and Driver (1998) showed that left spatial neglect in patients with right hemisphere strokes could be abolished for a very brief period of time, by exposing the patients to a moderately loud, unexpected tone. In another study (Robertson, Tegner, Tham, Lo, & Nimmo-Smith, 1995), they showed that similar patients could learn to “self-alert” and improve both the neglect and their sustained attention. Arousal and attention can thus be manipulated by external and internal alerts.

External alerts (tones) combined with metacognitive strategy training has been associated with improved goal attainment (Manly, Hawkins, Evans, Woldt, & Robertson, 2002). Ten patients performed a complex task under conditions with and without external cueing. The cuing condition consisted of exposure to random brief auditory tones, and the patients were instructed to stop and consider their overall goal when they heard the tones. In fact, in the cued condition, the patients performed comparably to the control group, which consisted of age and IQ matched subjects without brain damage. External cueing has also been shown to enhance management of current and future goals (Fish et al., 2007). These studies thus suggest that content-free cueing can increase arousal, and contribute to drawing attention back to relevant goals. In GMT, the internalization of such cues is promoted through training of a self-cueing process to stop ongoing behavior in order to define goal hierarchies and monitor performance (Levine et al., 2011). By embedding the techniques for sustained attention and cueing in a larger metacognitive intervention, GMT is hypothesized to address impairments in both fundamental (attention and arousal) and higher-order (EF) processes, to improve EF in daily life (Robertson & Levine, 2013).

In recent studies of GMT (Novakovic-Agopian et al., 2011; Stubberud, Langenbahn, Levine, Stanghelle, & Schanke, 2013), mindfulness techniques (Kabat-Zinn, 1990; Segal, Willams, & Teasdale, 2002) have been implemented to aid the development of the skill of repetitively bringing one's mind to the present, in order to better monitor ongoing behavior, goal states, and the correspondence between them (Robertson & Levine, 2013). In a review investigating whether mindfulness training improves cognitive abilities, the authors suggested that early phases of mindfulness training addressing focused attention, could be associated with significant improvements in selective and executive attention (Chiesa et al., 2011). Still, carefulness is necessitated regarding the conclusions due to methodological limitations and mixed findings. The INCOG group concluded that mindfulness-based meditation techniques are not recommended for remediation of attention deficits after TBI outside of a research protocol, due to lack of demonstrated efficacy (Ponsford, Bayley, et al., 2014).

1.5.4 Goal Management Training studies

Goal Management Training is among the most extensively studied metacognitive approaches for ED (Krasny-Pacini, Chevignard, & Evans, 2014). It has been evaluated both with regard to the effectiveness of the inherent principles/model ("proof-of-principles studies"), and as a comprehensive rehabilitation intervention ("rehabilitation studies"). In the first RCT evaluation of the principles of GMT (Levine et al., 2000), 30 patients with ABI were randomly assigned to brief trials (i.e. one hour) of GMT or motor skills training. Only GMT was associated with significant improvement on three paper-and-pencil simulations of real-life tasks in terms of error reduction. Furthermore, GMT was also associated with increased time to task completion, indicating increased care and attention. The evaluation also included a case study of a post-encephalitic patient, showing improvement in meal preparation abilities following GMT, assessed by naturalistic observation and self-reports measures.

Several studies have provided empirical support for GMT in various adult populations; ABI (Chen et al., 2011; Fish et al., 2007; Grant, Ponsford, & Bennett, 2012; Levine et al., 2011; Novakovic-Agopian et al., 2011; Spikman, Boelen, Lamberts, Brouwer, & Fasotti, 2010; Waid-Ebbs et al., 2014), healthy elderly (Levine et al., 2007; van Hooren et al., 2007), spina bifida (Stubberud et al., 2013), attention deficit/hyperactivity disorder (ADHD) (In de Braek, Dijkstra, Ponds, & Jolles, 2012), addiction (Alfonso, Caracuel, Delgado-Pastor, & Verdejo-Garcia, 2011), and intensive care unit survivors (Jackson et al., 2011). Case studies have further demonstrated beneficial effects associated with GMT in diagnoses as diverse as focal cerebellar damage (Schweizer et al., 2008) and schizophrenia (Levaux et al., 2012).

Studies of GMT for patients with ABI have reported improved sustained and executive attention measured by neuropsychological measures (error reduction, planning and time allocation) (Levine et al., 2000; Levine et al., 2011; Metzler-Baddeley & Jones, 2010; Novakovic-Agopian et al., 2011; Schweizer et al., 2008), and reduction of ED in daily life as measured by self-report and/or neuropsychological measures (Miotto, Evans, de Lucia, & Scaff, 2009; Spikman et al., 2010). Neuroimaging studies have suggested that GMT results in functional changes in brain networks supporting sustained attention, hypothesized to lead to functional improvements that generalize to broader domains of goal-directed behaviors (Chen et al., 2011; Robertson & Levine, 2013).

However, previous GMT studies of ABI patients have some important methodological limitations. Novakovic-Agopian et al. (2011) applied a crossover design, rendering long-term follow-up of the sixteen ABI patients impossible. Other studies have combined GMT with other interventions such as problem solving therapy (Miotto et al., 2009) or multifaceted treatment (Spikman et al., 2010), making it difficult to isolate the unique effects of GMT. Several studies have used a case-study design (Levine et al., 2000; Metzler-Baddeley & Jones, 2010; Schweizer et al., 2008), or included small samples with only partial randomization (Levine et al., 2011). Although some group-based GMT studies (Levine et al., 2011; Loya et al., 2017; Novakovic-Agopian et al., 2011) have reported follow-up analyses for more than three months post-intervention, the evidence for long-term effects is very limited. Some of the studies (Levine et al., 2011; Novakovic-Agopian et al., 2011; Spikman et al., 2010) included an active control group, but the methodological limitations described above restrict the conclusions that can be drawn. Furthermore, these studies included small and/or mixed disease/injury etiologies with coarse, if any, description of the anatomical localization and volume of lesions. The efficacy of GMT assessed by neuropsychological measures and self-reported questionnaires of EF in daily life, is presented in **Paper I**.

It has been suggested that interventions combining GMT with other interventions like external cueing, problem-solving, and/or goal-setting, are more effective in ameliorating ED, than GMT stand-alone interventions (Krasny-Pacini et al., 2014). Spikman et al.

(2010) conducted a large multicenter RCT including seventy-five ABI patients, comparing their multifaceted treatment of ED intervention, relying heavily on GMT (Levine et al., 2000) and problem solving therapy (PST) (von Cramon & Matthes-von Cramon, 1994), with computerized cognitive function training. The intervention was associated with significant improvement of EF in daily life at six month follow-up compared to the control condition, in terms of social roles resumed, goals attained, and the Executive Secretarial Task (Lamberts, Evans, & Spikman, 2010) that simulates a job assessment procedure. Of interest, they reported no differences regarding life satisfaction and subjective well-being.

Although a number of studies have provided evidence that emotional self-regulation is a critical component of metacognitive strategy training (Cantor et al., 2014; D'Zurilla, 2001; D'Zurilla & Goldfried, 1971; Rath et al., 2003), the traditional GMT protocol primarily addresses cognitive ED (Stubberud, Langenbahn, Levine, Stanghelle, & Schanke, 2014). However, the basic steps of GMT (to stop behavior, check and monitor performance relative to current goals), have the potential to augment emotional regulation skills as well. Cicerone and colleagues noted that metacognitive training targeting self-regulation was associated with improved self-efficacy, and the ability to manage residual cognitive and emotional symptoms (Cicerone et al., 2008). Thus, an emotional regulation module combining the GMT algorithm and CBT techniques was developed and added to the intervention in this study. The efficacy of GMT on emotional regulation, psychological distress, and QoL, is presented in **Paper II**.

The ability to resume activities and participate in the community, has been described as the ultimate end-goal of rehabilitation (Peterson, 2005). Therefore, cognitive rehabilitation interventions should aim at impacting real-life functioning (Cicerone, 2012; Cicerone et al., 2008), to enable people with disabilities to function optimally in their environments (Wilson, 2008). Impact on- and transfer to everyday functioning for ABI-patients after GMT has been reported by patient self-report (Levine et al., 2007; Novakovic-Agopian et al., 2011), and by close relative-report (Miotto et al., 2009; Schweizer et al., 2008; Spikman et al., 2010). Generalization effects and transfer to daily life activities are explored and discussed in **Papers I-II**.

Despite the increasing number of studies associating GMT with significant improvement of EF for patients with ABI, the knowledge of the characteristics of those who might benefit the most from GMT is sparse (Krasny-Pacini et al., 2014). These questions are important to the rehabilitation field, as more evidence-based knowledge is needed to guide the clinicians in matching the individual patients' needs and the best suitable interventions at the right time (Bayley et al., 2014). Spikman et al. (2013) reported that pre-treatment deficits in emotion recognition, a crucial aspect of social cognition, affected learning of the compensatory strategy for ED negatively (Spikman et al., 2010). Interestingly, pre-treatment executive dysfunction assessed by neuropsychological tests did not. Bertens and colleagues´ (2016) exploratory study investigated moderators (for whom and under what conditions) and mediators (mechanisms of treatment effects) of outcome after GMT. They compared standard GMT (van Hooren et al., 2007) and "errorless" GMT. The latter referred to a highly structured approach where the tasks steps were trained using errorless learning techniques, to prevent the errors that commonly occur during task learning. Higher age was found to moderate better everyday task performance after conventional GMT, and higher IQ moderated better performance after errorless GMT. Furthermore, higher EF scores after training predicted improved everyday task performance across both interventions by mediating treatment outcome. As this study is the only one so far to explore predictors of GMT-treatment efficacy, the present study sought to add to the knowledge base by exploring predictors of outcome after GMT (**Paper III**).

To summarize, GMT is recommended as a metacognitive strategy intervention for ED. Still, the previous GMT-studies had a number of methodological weaknesses. The present study addressed the majority of these, as it was conducted as a RCT with an active control group, included the largest sample so far (by study start in 2012), had long-term follow-up, blinded assessments at all time-points, and radiological injury descriptions.

2. AIMS OF THE STUDY

The main aim of this randomized controlled trial was to determine the efficacy of GMT combined with external cuing and a module for emotional regulation, as a group-based metacognitive intervention for ED in adults with ABI in the chronic phase. The secondary aim was to identify possible predictors of treatment outcome.

2.1 Paper I, Goal Management Training in improving cognitive aspects of EF

In the first paper, the objective was to investigate the efficacy of GMT in improving cognitive aspects of EF, as assessed by neuropsychological test measures and self-report questionnaires of EF in daily life.

2.2 Paper II, Goal Management Training in improving emotional regulation, psychological functioning, and quality of life

In the second paper, the aim was to investigate whether GMT was associated with improved emotional regulation, psychological functioning, and quality of life, as measured by improved functioning and/or reduced symptom load on self-report questionnaires.

2.3 Paper III, moderators, mediators, and nonspecific predictors of executive functioning after Goal Management Training

In the third paper, the aim was to explore moderators, mediators, and nonspecific predictors of executive functioning after cognitive rehabilitation, investigating the variables' general contribution to cognitive rehabilitation interventions and possible GMT specific predictors.

3. METHODS

3.1 Procedures

A total of 178 patients with ABI were requested to participate. An information letter was sent to 153 former patients at Sunnaas Rehabilitation hospital, with a verified ABI and a documented history of ED. Twenty-three persons additionally requested more information about the study following a presentation in a user organization's magazine. Finally, two persons were recruited through their primary physician, after having been referred to Sunnaas rehabilitation hospital. To be included, the participants had to have a confirmed non-progressive ABI, be minimum 6 months post-injury, experience on-going ED (by self-report and neuropsychological assessment), and be within the age ranging from 18-67 years. Major psychiatric disorders, on-going substance abuse, neurodegenerative disorders, and severe cognitive problems (IQ < 80) interfering with the capacity to participate in the program, were set as exclusion criteria.

Ninety persons provided written informed consent, and underwent a comprehensive custom-made telephone based screening interview examining medical, cognitive, and psychological issues for assessment of eligibility. Six did not meet the inclusion criteria; one had too extensive cognitive impairments to participate, 2 were considered not to experience ED, and 3 were excluded to preserve a conservative criterion regarding the documentation of the ABI. Nine persons subsequently reconsidered participation after receiving information about the study, and 5 were not able to participate due to work or family issues. Thus, the final sample consisted of 70 participants. After being enrolled in the study, an appointment for baseline evaluation including neuropsychological assessment and questionnaires (duration approximately 4 hours) was made (see Figure 1, Consort Diagram) (Schulz, Altman, & Moher, 2010).

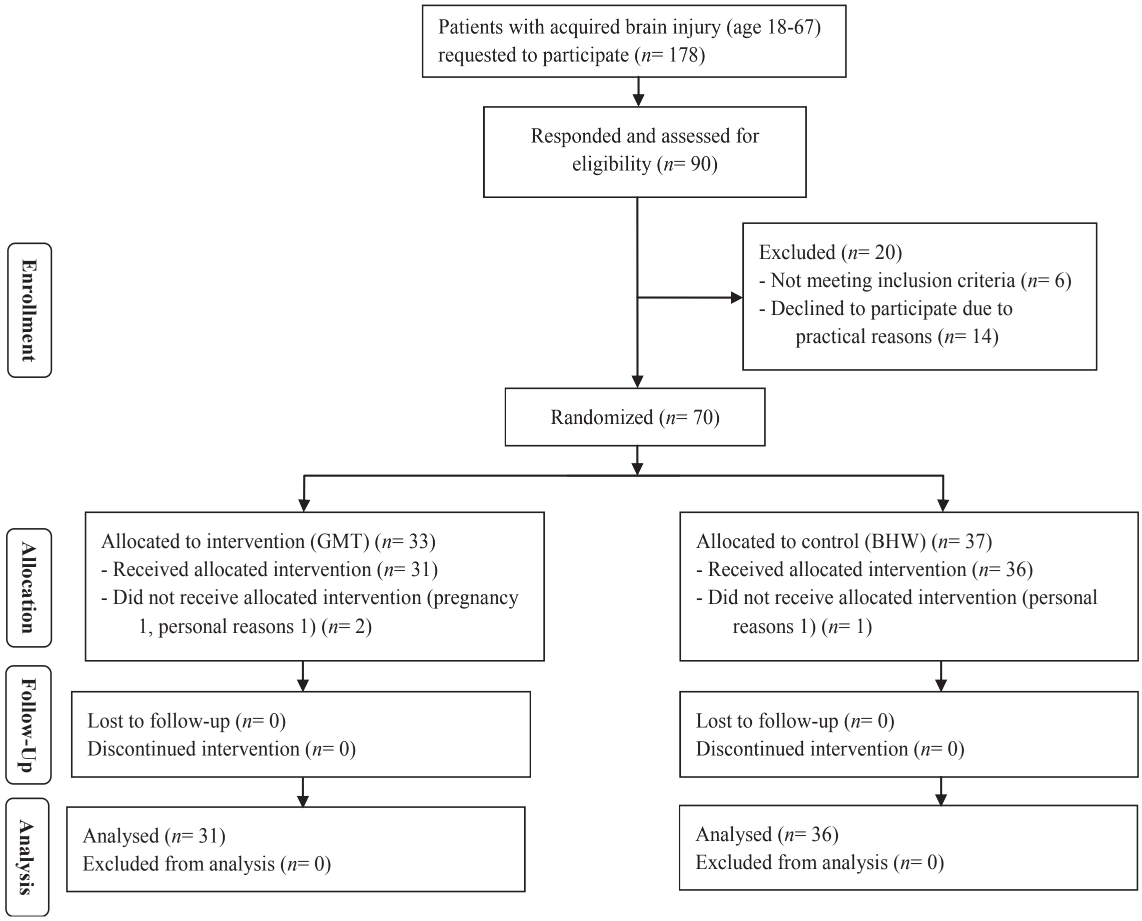

Figure 1. Consort diagram

3.2 Randomization and blinding

A power analysis based on prior research on the efficacy of GMT in adults with ABI (Levine et al., 2000; Levine et al., 2011) and Spina Bifida (Stubberud et al., 2013), where moderate to large effect sizes were reported, indicated that having 30 participants in each group with an expected effect size of d=.65 provided a statistical power of .80 (Cohen, 1988). The study aimed to include 80 participants, with 40 in each group. Hence, even with a dropout rate of 20%, the sample size was considered satisfactory. Therefore, 40 A's (GMT) and 40 B's (BHW) were drawn from a lot and put in enclosed envelopes. The person responsible for the randomization procedure was not involved in the study, and the groups were not stratified or matched by any characteristics. After baseline assessment, an envelope was drawn for each participant, determining group allocation. Thirty-three participants were assigned to GMT, and 37 to BHW. Groups of 5-7 participants were established, resulting in 5 GMT and 7 BHW groups.

The participants were informed that the study investigated two different approaches to cognitive training of EF; one specific and one more general. They were not informed of the randomization outcome, thus participants were blinded to their group allocation. None of the groups ever met each other. Both interventions were denoted as cognitive training of EF, regardless of group membership. Since the study lasted for more than 18 months, with several groups running in parallel, there was a risk that staff at the hospital and the participants by accident could reveal the randomization. Everyone was therefore asked not to share the specific content of the training outside their group or on social media, except close family. To the investigators´ knowledge, this did not happen.

3.3 Participants

A slight majority of the 70 participants were males (38/52.9%). TBI was the dominant cause of injury (45/64.3%), followed by CVA (15/21.5%), tumor (6/8.6%), anoxic brain injury (2/2.9%), meningitis (1/1.4%), and encephalitis (1/1.4%). Age ranged from 19-66 years (*M*= 42.9; *SD* =13), mean length of education was 13.4 years (*SD*=2.4), and mean time since injury was 97.4 months (Range 10-575 months, *SD* = 112.4). About one quarter (19/27%) was employed or studying, 28 (40%) were on sick-leave or received different kinds of vocational services, and the remaining 23 (32.8%) were on disability pension. Thirty-nine (55.8%) were married or lived with a partner, 21 (30%) were single, 5 (7.1%) divorced, and 5 (7.1%) in a stable relationship. Sixty-eight of the participants were Caucasian, one was African, and one was Asian. Both of the latter came to Norway as refugees, had lived in Norway for at least five years, and were fluent in Norwegian.

The total sample was classified as having mild to moderate cognitive impairments, performing within 1 *SD* from the normative mean on the majority of the neuropsychological measures at baseline (see **Paper I** for details). Regarding self-reported everyday EF, the participants on average had mild to moderate problems with an average Global Executive Index *T*-score of 64.7 (*SD* 9,7) on the Behavior Rating Inventory of Executive Function-Adult (BRIEF-A; Roth, Isquith, & Gioia, 2005), moderate dysexecutive symptoms with a mean score of 29.2 (*SD* 12.4) on the Dysexecutive Questionnaire (DEX; Bennett, Ong, & Ponsford, 2005; Burgess, Alderman, Wilson, Evans, & Emslie, 1996), and moderate cognitive failures with a mean score of 49.1 (*SD* 14.3) on the Cognitive Failures Questionnaire (CFQ;

Broadbent, Cooper, FitzGerald, & Parkes, 1982). On average, the participants scored just below clinical threshold for psychological distress, with a mean total score of 22.4 (*SD* 15.3) on the Hopkins Symptoms Checklist-25 (HSCL-25; Derogatis, Lipman, Rickels, Uhlenhuth, & Covi, 1974; Ravndal & Amundsen, 2010).

Documentation of structural brain injury by Magnetic Resonance Imaging (MRI) or Computer Tomography (CT) scans at the time of onset was collected for 69 (98.6%) of the participants. One injury was verified by clinical neurological and neuropsychological examination. At study baseline (T1), new MRI scans were obtained for 61 of the participants. Fifty-six (80.0%) MRI scans were obtained as part of the baseline assessment using a 3 Tesla scanner (Achieva 3.0T, Philips Medical System Best, The Netherlands) at the Intervention Centre at Oslo University Hospital. For five (7.1%) participants, MRI scans conducted within the last two years were collected from other hospitals. Nine (12.9%) participants could not perform MRI due to various medical reasons, e.g. medical implants. All scans were interpreted by an experienced radiologist (author PKH, **Paper I**). Overall, 45 (64.3%) of the participants had at least one verifiable lesion at the time of inclusion. The frontal lobes were the most frequent cortical location of damage (25/35.7%), followed by temporal (14/20.0%), and parietal lobe damage (10/14.3%). Thirty-five (50.0%) of the total sample had signs of brain atrophy. The patients refrained from participation in other cognitive rehabilitation programs while taking part in the study. A more detailed description of the sample's demographic, medical, and cognitive characteristics is presented in **Papers I – II**.

3.4 Interventions

The intervention protocols were based on a Norwegian translation and adaptation of Levine and colleagues' (2011) protocols for GMT (Stubberud et al., 2013) and BHW (Tornås, 2016). Both interventions were administered according to a manualized script, with accompanying PowerPoint slides and participant workbooks.

The two interventions were matched regarding amount of group training, educational material, homework, and therapist contact. The eight two-hour modules were distributed over four days, thus the participants received two modules in one day every second week. All modules followed a fixed framework; introduction to key-concepts, practical exercises, discussion of examples from the participants' daily life, and recapitulation of the key topics. All the group sessions were led by a clinical neuropsychologist (PhD candidate and first author of **papers I-III**: ST), with assistance of a skilled co-therapist (clinical neuropsychologist, advanced psychology student, or rehabilitation nurse). Following the fourth session, all participants received a daily text-message stating "STOP" (a key instruction in GMT), for the remaining duration of treatment (28 per participant), to cue goal management in their daily contexts. The cuing time was between 9 am and 5 pm, and changed every second or third day to prevent habituation. Although both interventions were standardized and delivered in groups, the approach was also personalized and individualized. Through interactive discussions, tasks and homework assignments, the individuals' personal experiences, challenges and goals were heavily emphasized.

3.4.1 Goal Management Training

The primary objective of GMT is to train patients *"to stop ongoing behavior in order to define goals and monitor performance"* (Levine et al., 2011, p. 2). Over nine sessions this is achieved by introducing, practicing and rehearsing the following algorithm: Stop behavior, define goal, list the steps, learn the steps, do the task and check performance (see Figure 2).

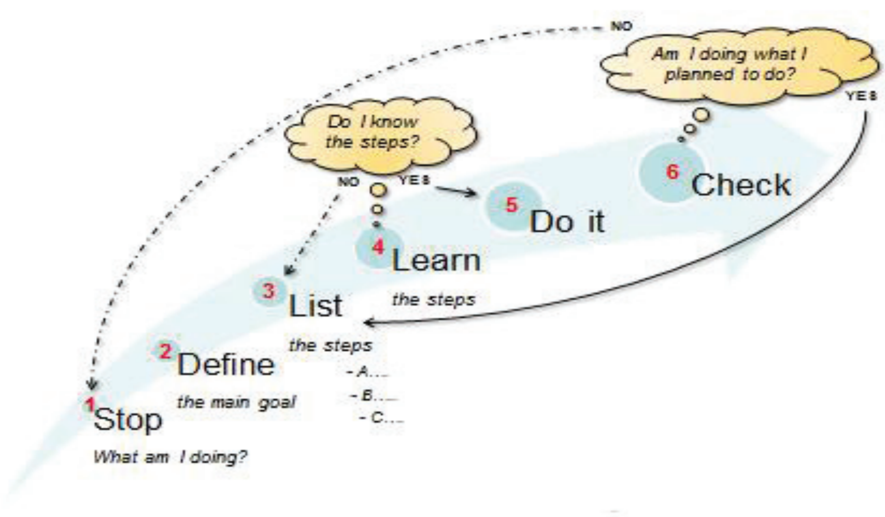

Figure 2. Schematic presentation of the steps in Goal Management Training

In this study, the nine original GMT-modules (Levine et al., 2011) were merged into seven, carefully addressing all core concepts of GMT and maintaining the same order (Tornås, 2016). The new emotional regulation module was administered as module number 7, resulting in a GMT protocol of 8 modules of 2 hours´ duration each. Some minor adjustments to the GMT protocol (Levine et al., 2011) were made through personal communication with Professor Levine (see Table 1 for a schematic description of the content in the GMT and BHW modules).

Module one gave an overall introduction to the intervention, and an introduction of the group and the therapists. The concepts present- and absentmindedness were introduced, along with the importance and role of goals in carrying out everyday activities. The "slip-ups" everyone can experience from time to time while performing activities where used as a means to illustrate absentmindedness. In *module two*, the main objective was to discuss factors that increase the probability of absentminded errors, and how present mindedness can help counteract them. A mindfulness task (body scan) was practiced to explore and support present mindedness. *Module three* addressed the "autopilot", as an operationalization of how overlearned action-patterns turn into habitual responding, and might result in "slip-ups". "STOP" was introduced as a means to stop the "autopilot", as a momentary suspension of ongoing activity to access current goals. A new mindfulness task (breath focus) was introduced, to address and improve awareness towards the current actions and the goal of the activity, through promoting focus on the present (Kabat-Zinn, 1990). Working-memory was operationalized as a mental blackboard, and the "location" to look-up goals. Thus, the participants rehearsed checking their mental blackboard, to compare the current actions performed to the intended goal.

Module four introduced the limits of WM, in terms of content and time. The participants explored how the current content (like a goal) of WM, can easily and rapidly be exchanged with new content. Thus, the importance of actively defining and stating the goal was emphasized. In *module five*, the importance of decision making, especially in situations with conflicting goals, and the accompanying emotional reactions that might be experienced, was addressed. The usefulness of to-do-lists was discussed, and the participants practiced methods of dividing "overwhelming" goals into sub-goals, and how to prioritize the different sub-goals to achieve the main goal, like when planning a vacation or a party. *Module six* summarized the "STOP-STATE-SPLIT" cycle. After this, the new *module seven* for emotional regulation was introduced. Core concepts from CBT were introduced, emphasizing the mutual relationship between thoughts, situations and emotions (Beck & Alford, 2009), and how negative self-talk can become "automatic" and interfere with goal-achievement. Negative self-talk and feelings were discussed as internal "alarm-signals" to "STOP", and to apply mindfulness-exercises in order to enhance awareness of the ongoing situation and goals. Examples from daily-life were used to explore the concepts. The final and *eighth module* introduced the importance of stopping ongoing activity to CHECK if current actions matched the goal to be achieved. The training ended with a summary of the intervention: STOP-STATE-SPLIT-CHECK.

The intervention aimed to increase the patients´ understanding of their own goal management strategies, providing a vocabulary to describe the problems, and a set of techniques to help compensate for them. Thus, the individuals' real-life ED was addressed through discussions, practical demonstrations and home-assignments. As an example, the homework-assignments for emotional regulation included logging of automatic thoughts and an examination of the relationship between situations, thoughts, and accompanying emotions.

3.4.2 Brain Health Workshop

The BHW protocol was matched to GMT with respect to the number of modules, amount of therapist contact, and quantity of educational material, homework, and group participation (Levine et al., 2011). Thus, the nine original BHW sessions were delivered over eight sessions, and some of the original reading assignments were replaced with comparable Norwegian information-booklets. The BHW comprises educational materials and various lifestyle interventions that are typically part of psycho-educative programs delivered at brain injury rehabilitation programs (Becker et al., 2014). The sessions addressed brain function and dysfunction, brain plasticity, and cognitive functions like memory, EF, and attention. Regarding lifestyle interventions, stress, physical exercise, sleep, nutrition, and energy management were given particular attention. Within-session activities and homework included reading assignments, brain-games and puzzles, testing of acquired knowledge, and practical exercises like keeping a sleep log (see Table 1).

Table 1. Description of the modules and objectives in GMT and BHW

Training day		GMT objectives	In-session tasks	BHW objectives	In-session tasks
1	Module 1	1. Introduction, Present and absent mindedness:, Goals in daily life.	Clapping task Present-mindedness 1	1. Introduction, Brain anatomy and cognition, Etiology	Visual perception
	Module 2	2. Slip-ups, Absentmindedness, Probability of slip-ups, Present-mindedness	Clapping task Present-mindedness 2 Body scan task	2. Neuroplasticity, Brain damage and assessment, Brain plasticity	Mental training
	Home-work	Record daily slips. Practice daily present-mindedness and present-mindedness 2. Do the Body scan task.		Reading assignments: Acquired brain injury and neuroplasticity. Do Brain puzzles.	
2	Module 3	3. The Automatic Pilot, The Mental Blackboard, Errors in daily life, WM, "STOP!" to check the mental blackboard	Card dealing Clapping task with STOP! Present mindedness 3	3. Memory I, Review, The importance of memory, Types of memory, Memory processes	Brain jeopardy
	Module 4	4. Define and State your goal, Activate WM, STOP!-STATE goal	Complex task I Complex task II	4. Memory II: Memory and the brain, Loss of Memory	Memory challenges
	Home-work	Practice Daily STOP and present mindedness 2. Do the Body scan task. Practice daily present-mindedness 3		Reading assignment memory. Do Brain puzzles.	
3	Module 5	5. Making decisions, Competing goals, Emotional reaction to competing goals, To-Do Lists in the "STOP"-STATE	Complex task with STOP Present-mindedness task and to-do-list	5. What is Executive functioning and attention? How may these functions break down	Problem solving
	Module 6	6. Splitting tasks into sub-tasks, Defining goals that require splitting, Organizing goal hierarchies, STOP!-STATE-SPLIT cycle	Splitting tasks into sub-tasks Wedding task	6. Lifestyle, neuroplasticity and recovery, Stress and brain function, Sleep and brain function	Sleep quality assessment
	Module 7	7. Emotional regulation (Thoughts, situations and emotions), Automatic thoughts and present-mindedness, Managing emotional situations	Thoughts and actions influence feelings Clapping task with negative feedback	7. Fatigue, Nutrition and brain function, Physical exercise and brain function	
	Home-work	Log STOP-STATE-SPLIT scenarios. Practice daily present-mindedness task 3. Do the Catalogue Tasks I and II. Log automatic thoughts, situation and feelings		Reading assignments: executive functions, attention, sleep, stress, physical training and nutrition. Problem-solving tasks, Sleep Log and exercises for sleep hygiene.	
4	Module 8	8. Check (STOP!), Recognizing errors in STOP!-STATE-SPLIT cycle, Using "STOP" to monitor output. Summary	Clapping task with STOP! by participants	8. Review. Summary of the intervention	Brain jeopardy

3.5 Assessments methods: Neuropsychological tests and questionnaires

The participants underwent a neuropsychological examination at baseline (T1), immediately after the end of the interventions (T2), and at six-month follow-up (T3). The examination included neuropsychological tests and questionnaires, administered by clinical neuropsychologists or experienced test technicians. The assessors were blinded for group allocation at all assessment points. In addition, a custom-made survey assessing patient satisfaction with the practical arrangements, the group, the therapists, and the interventions, was applied at T2 and T3. This was done to examine any differences with regard to how the interventions were carried out and experienced.

The following tests were included to describe cognitive functioning at baseline (T1): Full scale verbal and performance IQ was calculated with the Wechsler Abbreviated Scale of Intelligence (WASI; Wechsler, 1999), WM with Digit Span from the Wechsler Adult Intelligence Scale III (WAIS III; Wechsler 1997), visuospatial attention and memory with the Brief Visuospatial Memory Test - Revised (BVMT-R; Benedict, 1997), and verbal learning and memory with the California Verbal Learning Test - II, Standard Form (CVLT-II; Delis, 2000).

In **Paper I,** neuropsychological outcome measures included Conners' Continuous Performance Test II (CPT-II; Conners, 2000), Colour-Word Interference Test (CWIT), Verbal Fluency Test (VFT), the Tower Test, and the Trail Making Test (TMT) from the Delis-Kaplan Executive Function System (D-KEFS; Delis, Kaplan, & Kramer, 2001). The Hotel Task (Manly et al., 2002) and the UCSD Performance-Based Skills Assessment (UPSA; Patterson, Goldman, McKibbin, Hughs, & Jeste, 2001) were also included to assess "real-life" multitasking situations, to increase the ecological validity of test measures. Measures of EF in daily living included index and subscale scores from the BRIEF-A (Gioia, Isquith, Guy, & Kenworthy, 2000), along with total scores from the CFQ (Broadbent et al., 1982), and the DEX (Burgess et al., 1996).

Primary outcome measures for emotional regulation in **Paper II** included The Brain Injury Rehabilitation Trust Regulation of Emotions Questionnaire (BREQ; Cattran et al., 2011), the Emotional Control subscale (BRIEF-A), the "Emotional Regulation factor" from BRIEF-A (Donders & Strong, 2016), and the subscales "Positive Affect" and "Negative affect" from DEX. Secondary outcome measures included the HSCL-25 (Derogatis et al., 1974) to assess psychological distress, and Quality Of Life after Brain Injury (QOLIBRI; von Steinbüchel, Petersen, Bullinger, & Force, 2005) for quality-of-life ratings. Motor speed (TMT5), a cognitive domain often affected by ABI, but not targeted by the interventions, was included as a marker of non-specific change in **Papers I and II**.

Paper III addressed predictors of outcome in terms of cognitive executive complaints, emotional dysregulation, and psychological distress. The following variables were included as candidate moderators: demographic and medical variables (age, sex, time since injury, lesion etiology, and localization of brain injury), general intellectual capacity (WASI), and neuropsychological measures for verbal recall (CVLT-II), strategic planning (the Tower Test), and attention (inhibition CPT-II/CWIT3, sustained attention CPT-II, and shifting CWIT4). In addition, self-reported EF in daily life (BRIEF-A and DEX), cognitive functioning (CFQ), emotional regulation (BREQ), and psychological distress (HSCL-25) were examined as potential moderators. Six-month follow-up scores on the same neuropsychological tests, self-reported cognitive and executive function, emotional regulation, and psychological distress were explored as potential mediators. A more detailed description of the neuropsychological measures and self-report questionnaires that were included in each paper can be found in **Papers I-III.** See Table 2 for an overall summary of the measures applied in each study.

Table 2. Baseline (T1), post intervention (T2), and six-month follow-up (T3) measures.

Measures	**Article**	**T1**	**T2**	**T3**
Neuropsychological measures				
WAIS	I,II,III	X		
Digit Span	I,II	X		
CVLT II	I,II,III	X	X	X
BVMT-R	I,II	X		
TMT	I,II	X	X	X
CPT II	I,II,III	X	X	X
VFT	I,III	X	X	X
CWIT 3	I,II,III	X	X	X
CWIT 4	I,II,III	X	X	X
The Tower Test	I,II,III	X	X	X
The Hotel Test	I	X	X	X
The UPSA	I	X	X	X
Questionnaires				
BRIEF-A	I,II,III	X	X	X
DEX	I,II,III	X	X	X
CFQ	I,III	X	X	X
BREQ	II,III	X	X	X
HCSL-25	I,II,III	X	X	X
QOLIBRI	II	X	X	X

3.6 Statistical analysis

Data were analyzed with Statistical Package for the Social Sciences version 21 for Windows. Descriptive statistics were performed for demographic, medical, and questionnaire variables. In **Papers I and II,** between-group differences were analyzed using *t*-tests for continuous variables and Chi-square for dichotomous variables. A general linear model (GLM) with repeated measures analysis of variance (RM ANOVA) was used to examine group-related treatment effects, with Group (GMT, BHW) as between-subjects factor, and Time (T1, T2, T3) as within-subjects factor. Analyses used the intention-to-treat principle, and included all randomized subjects, regardless of whether they completed treatment (**Papers I-III**). *T*-tests were used to explore change within groups (T1-T2, T1-T3). In **Papers I-III,** effect-size statistics were provided with partial eta-squared for ANOVA and eta-squared (η^2) for *t*-tests, interpreting $\eta^2<.06$ as small, .06-.14 as medium, and >.14 as large effects (Cohen, 1988).

A conservative significance value of <.01 was applied, due to numerous comparisons. Findings in the p<.01-.05 range were interpreted as tendencies. In **Paper II,** the Holm-Bonferroni procedure was applied to control for the family-wise error rate. Furthermore, in subsequent *post-hoc analyses* in the GMT-group, a linear regression analysis was used, with pre-scores (T1) predicting follow-up scores (T3). Standardized residual scores for the outcome variables were used to represent change over time, and the standardized scores were correlated (Pearson two-tailed test), to evaluate covariation of treatment effects.

In **Paper III**, composite outcome measures were established by factor analysis of the six-month follow-up subscale scores of the following measures: BRIEF-A, DEX, and the total score from the BREQ. The subscales for depression and anxiety from HSCL-25 were also added to the factor-analysis, to examine possible overlap between emotion regulation and psychological distress. The examination of eigenvalues and scree plots suggested retaining three factors; emotional dysregulation, cognitive executive complaints, and psychological distress. The subscale scores included in each factor were summarized to a total T-score for each of the three factors, where a low total-score indicated less, and a high score represented more symptoms. See **Paper III** for further details on the results of the factor analysis.

Candidate predictor variables (moderators, mediators, and nonspecific predictors) were examined using univariate GLM. The three outcome measures (factors) were in turn entered as the dependent variable, with baseline values of the outcome factor, the possible predictor (grand mean centered), treatment group (GMT or BHW), and predictor-by-treatment group interaction entered as independent variables. Post hoc general linear models were used to investigate the nature of significant predictors or interaction terms (Kraemer, Wilson, Fairburn, & Agras, 2002).

In accordance with Kraemer et al. (2002), the baseline variables (including demographic information) were classified as nonspecific predictors in case of a significant main effect on outcome, and as a moderator in case of a significant interaction effect between the variable and the treatment group. Post treatment (six-month follow-up) variables that significantly correlated with treatment(s) were classified as potential mediators if a main effect or an interaction effect was significant. This statistical approach is similar to the study of Bertens, Fasotti, Boelen, and Kessels (2016), and was discussed and confirmed through personal communication with Bertens.

3.7 Ethical considerations

The study was approved by the Regional Committee for Medical Research Ethics (2012/1436), South-Eastern Norway, and conducted in accordance with the Helsinki Declaration (Williams, 2015). Written informed consent was obtained from all participants, after they had been presented to a detailed written description of the study. In addition, several participants were given a thorough oral description of the study.

Since the majority of the participants were recruited from the rehabilitation hospital that provided their primary rehabilitation services, actions were taken to ensure that the subjects understood the difference between using the hospitals' clinical services and participating in the study. This ethical challenge is often referred to as the "therapeutic misconception" (Henderson et al., 2007). The written information related to participation in the study clearly separated the study from the regular clinical services. Professional language and expressions were exchanged with simple language wherever possible. Furthermore, the participants were encouraged to convey any questions they might have. Finally, all subjects were informed that they at any time and without any explanation could withdraw from the study, without any consequences for access to future clinical care and/or rehabilitation. Three participants withdrew from the study, two subjects assigned to GMT after completing the second and fourth module respectively, and one subject after completing the fourth module of BHW. The subjects were thoroughly informed about the MRI examination, and that they could still participate in the clinical trial if they declined or were not able to do the MRI.

Conducting a RCT raises an ethical challenge related to providing patients with the best possible treatment. All participants were therefore informed that the study investigated two different approaches to cognitive rehabilitation of EF. They were furthermore informed that those who received the control intervention would be offered the active treatment condition after study completion, given that it proved efficient.

None of the participants were former patients of the primary investigator (ST) or any of the other administrators/members of the research group. One participant expressed concerns regarding depressive thoughts during baseline assessment, and was offered three sessions of psychological support before participating. Two participants needed follow-up services, and were referred to psychological outpatient services after six - month follow-up. A brief neuropsychological report was written for every participant after completion of the six-month follow-up assessments. This report, together with oral information, was offered to all participants upon request.

3.8 Treatment fidelity and adherence

All group sessions were led by an experienced neuropsychologist (ST) and a skilled co-therapist (rehabilitation nurse, neuropsychologist or advanced psychology-student). Both interventions (GMT & BHW) were administered according to a script with corresponding PowerPoint-slides and participant workbooks. To ensure that the interventions were delivered consistently, the protocols were rehearsed repeatedly within the research group; the co-therapist had a copy of the scripts, and was instructed to add-in if something by mistake was left out in the sessions.

In order to maximize treatment adherence, a number of actions were taken; participants with long travelling distances and/or fatigue were offered to stay the night before training at the hospital, breaks were introduced according to participants´ needs, all participants were reminded the day before training, and scheduling was adjusted as far as possible to accommodate practical issues. Missed attendance was minimal, as only one participant in the BHW-group missed 2 sessions.

4. RESULTS / SUMMARY OF PAPERS

4.1 Paper I

Rehabilitation of executive functions in patients with chronic acquired brain injury with Goal Management Training, external cuing and emotional regulation: A randomized controlled trial.

Background: ED is a common consequence of ABI, causing significant disability in daily life. This RCT investigated the efficacy of GMT combined with external cueing and a module for emotional regulation in improving EF in patients with chronic ABI, compared to a psycho-educative active control condition (BHW). GMT was hypothesized to be associated with improvement in executive- and sustained attention post-intervention, measured by self-report questionnaires and neuropsychological tests.

Methods: Seventy patients with a verified ABI and ED were randomly allocated to GMT (n = 33) or BHW (n = 37). Neuropsychological tests and self-reported questionnaires of EF were administered at baseline, post-intervention, and at six-month follow-up, with all assessors being blinded to group allocation.

Results: Self-report measures of EF indicated significant improvement of everyday EF in the GMT group, most prominent at six-month follow-up. Improvement for both groups was observed on the majority of the neuropsychological tests, but improved performance for executive attention was most prominent in the GMT group.

Conclusions: GMT combined with external cueing is an effective intervention for ameliorating ED in daily life in patients with chronic ABI, even years post injury. The strongest effects observed six-month post-treatment, suggest that strategies learned in GMT were applied and consolidated in everyday life.

4.2 Paper II

Goal Management Training combined with external cuing as a means to improve emotional regulation, psychological functioning, and quality of life in patients with acquired brain injury: A randomized controlled trial

Background: Emotional dysregulation and psychological distress are common sequelae following ABI, causing significant disability in daily life. This RCT investigated the efficacy of GMT, including external cuing and an emotional regulation module in improving emotional regulation, psychological functioning, and QOL in the chronic phase of ABI. GMT was hypothesized to be associated with self-reported improvement of emotional regulation, psychological distress and QoL.

Methods: Seventy persons with ABI and resulting ED (64% TBI; 52% males; mean age 43 ± 13 years; mean time since injury 8.1 ± 9.4 years) participated, receiving either eight sessions of GMT or a psychoeducative control condition (BHW) in groups. Emotional regulation, psychological distress and QoL were assessed by self-report.

Results: Findings indicated beneficial effects of GMT on emotional regulation skills in everyday life and in QOL six-month post-treatment. No intervention effects on measures of psychological distress were observed.

Conclusion: GMT including a module on emotion regulation seems to be a promising intervention for improving emotional regulation following ABI in the chronic phase.

4.3 Paper III

Moderators, mediators, and nonspecific predictors of treatment after cognitive rehabilitation of executive functions in a randomized controlled trial

Objective: Knowledge about which patient characteristics predict outcome following interventions for EF is limited. This study explored possible predictors of EF after cognitive rehabilitation in a RCT, comparing GMT with an active control-intervention (BHW), in patients with chronic ABI.

Methods: Seventy patients with ED were randomly allocated to GMT (n=33) or BHW (n=37). Outcome measures assessing key aspects of EF were established by factor analysis, resulting in three factors; cognitive executive complaints, emotional dysregulation, and psychological distress.

Results: Higher age and IQ emerged as nonspecific predictors. WM and planning moderated or mediated outcomes. Inhibitory control emerged as a GMT-specific mediator. Irrespective of intervention type, higher levels of self-reported symptoms predicted less benefit on one or more of the outcomes.

Conclusions: The majority of treatment effects were unspecific to group membership, probably underscoring the variables' general contribution to cognitive rehabilitation efficacy. In line with the theoretical underpinnings of GMT, changes in inhibitory control were GMT-specific. Interventions targeting specific cognitive domains, such as attention or WM, need to take into account the patients' overall cognitive and emotional self-perceived functioning.

5. DISCUSSION

5.1 Summary of main findings

The main aim of this study was to investigate the efficacy of the metacognitive strategy intervention GMT on improvement of EF in patients with ABI in the chronic phase, compared to an active psycho-educative control treatment (BHW). The efficacy of GMT in augmenting emotional regulation skills, improving QoL, and alleviating emotional distress was also investigated. Treatment efficacy of ED, transfer and generalization to everyday life and activities is addressed in **Papers I-II.** In **Paper III**, the second main aim of the study was explored, by investigating predictors of treatment outcome.

The main findings were fourfold, with the strongest effects being reported at six-month follow-up, suggesting transfer and consolidation of treatment effects to everyday life:

1. Compared to the control intervention (BHW), GMT is an effective intervention for improving EF in everyday life, as measured by self-report.
2. The principles of GMT are promising for addressing emotional dysregulation.
3. Error reduction on attentionally demanding tasks was observed following GMT and not BHW, suggesting GMT-specific effects on executive attention.
4. The majority of the identified predictors were unspecific to the interventions. Improved inhibitory control post-training mediated GMT-specific treatment outcome.

5.2 Discussion of main findings

5.2.1 Self-reported improvement of executive functioning in everyday life

The overall goal of cognitive rehabilitation is to enable people with disabilities due to neurological insult to function optimally in their environments (Wilson, 2008). Generalization and transfer to everyday activities and new situations is therefore a critical aspect of clinical interventions (Wilson et al., 2009). The “ultimate test” for a strategy intervention should be the possible transference used in a number of daily life situations (Tate et al., 2014), beyond what could be practiced and rehearsed as part of the training.

Relevant to the concepts of generalization and transfer are measures for EF in everyday life. In **Paper I**, GMT-associated self-reported improvement of EF in daily life was documented in all applied questionnaires; behavioral regulation and metacognition (BRIEF-A), reduced ED in daily life (DEX), and less cognitive failures (CFQ). The greatest improvements and largest effect sizes being evident at six month follow-up indicate that the participants continued to use the acquired strategies, established new habits, and consolidated these in everyday life, in line with previous findings (Novakovic-Agopian et al., 2011; Spikman et al., 2010). This line of reasoning is underscored by the observations that a number of GMT participants, both during the training and at six-month follow-up, spontaneously shared examples of how they experienced better control of their "mind" when carrying out daily life activities. The key issue reported was that making "STOP!" a habit prevented their usual "mind-wandering". Several participants also told how the external cueing (the text message STOP!) received during the training helped them to keep up with the training, and acted as a reminder of the necessity to STOP! A key signature of GMT is the emphasis on how behavior is often governed in "autopilot mode", and that environmental triggers can result in numerous "slip-ups" when performing daily life activities. Therefore, GMT aims to improve EF in daily life by training the participants to periodically *stop* and *check* whether ongoing behavior is in accordance with the intended goal(s), through a mindful approach (Levine et al., 2011).

The greatest improvements of EF in daily life being evident at six-month follow-up, could also be related to positive changes in perceived self-efficacy over time, as discussed in **Papers I-III**. It has been suggested that metacognitive strategy-training targeting the patients' self-regulation of cognitive and emotional processes is associated with increased confidence in symptom management (Cicerone, 2012). Of interest, the active control-group reported some progress from baseline to post-intervention regarding ED, but then returned to baseline levels at six-month follow-up, possibly indicating initial nonspecific treatment effects.

5.2.2 Self-reported improvement of emotional regulation and psychological distress in everyday life

In **Paper II**, a significant improvement of emotional regulation in daily life was reported by the GMT group compared to the BHW group, again with the largest improvements at six-month follow-up. The emotional regulation module was the next-to-last module, introduced after all the steps in GMT had been discussed and rehearsed over a period of six weeks. The module introduced core concepts from CBT (Beck & Alford, 2009) in "GMT language", in conceptualizing negative self-talk as automatic thought-processes implying the need to STOP, and then application of the principles of GMT in order to redirect attention to "goal relevant thoughts". Despite GMT (Robertson & Levine, 2013) and CBT (Beck & Alford, 2009) having different theoretical and historical origins, both are characterized by being highly structured, introduced in a step-by-step approach, and with the aim of improving daily life functioning. The combination of GMT and CBT was thus believed a priori to be potentially appropriate, also justified by theoretical work that has highlighted problem-orientation as a necessary prerequisite for problem-solving (D'Zurilla, 2001; D'Zurilla & Goldfried, 1971).

Improvements of attentional control have been reported in a number of GMT studies (Levine et al., 2000; Levine et al., 2011; Miotto et al., 2009; Novakovic-Agopian et al., 2011; Tornås, 2016). The enhanced capacity for emotional regulation at six month follow-up could be seen as supporting the notion of a close relationship between attentional control and self-regulation (Petersen & Posner, 2012; Rueda, Posner, & Rothbart, 2004). As mindfulness-training has been associated with enhanced attentional control (Chiesa et al., 2011; Tang et al., 2007) and self-regulation (Kabat-Zinn, 1990), it is tempting to hypothesize that the extensive use of mindfulness exercises applied in the current version of GMT might also have contributed to this. The GMT study conducted by Novakovic-Agopian et al. (2011) also emphasized mindfulness training heavily, and reported improvements in the ability to stop and relax during stress, to refocus and to retain goal-relevant information in WM. In **Paper II,** the most notable changes in emotional regulation were related to improvements in inhibitory control assessed by the DEX subscale "Positive affect". Given that the factor structure of the DEX has been questioned (Chaytor et al., 2006; Simblett et al., 2012; Simblett & Bateman, 2011), these findings warrant cautious interpretation.

Based on reports from other GMT studies (Stubberud, Langenbahn, Levine, Stanghelle, & Schanke, 2015; van Hooren et al., 2007), a reduction in psychological distress was hypothesized to take place following GMT (**Paper II**). This was, however, not confirmed. Stubberud et al. (2015) conducted a RCT where GMT for people with spina bifida and associated ED (*n*=24) was compared to a wait list control group (*n*=14). They reported a significant reduction in anxiety and depression that lasted at least six-month post treatment. Similarly, van Hooren et al. (2007), who studied 69 healthy elderly in a RCT with wait list controls, reported less anxiety in the GMT group post-training, compared to the control group. However, the participants in the current study did not report a particularly high symptom load initially (Ravndal & Amundsen, 2010). Furthermore, in contrast to other comprehensive interventions (Ben-Yishay & Diller, 2011; Prigatano, 1999), the present study did not target individuals with psychological distress specifically.

It can be argued that neurogenic disturbances of emotional regulation are phenomenological distinct from psychological distress (Cisler, Olatunji, Feldner, & Forsyth, 2010). Still, a GMT-related association between improved emotional control (BRIEF-A) and reduced level of anxiety was reported in **Paper II**. Anxiety typically involves three domains; overt behavior, physiology, and cognitive appraisal (Beck, 1976; Mogg & Bradley, 1998; Zinbarg, 1998). All three domains were explicitly addressed in the emotional regulation module. Improvements of self-perceived emotional control and/or cognitive re-appraisal of situations, could thus represent a tool for understanding the mechanisms by which improved emotional regulation can contribute to reduce anxiety (Cisler et al., 2010). van Hooren et al. (2007) suggested that the GMT-related improved ability to structure activities and cope with cognitive impairments, was associated with the observed reduction in psychological distress. Another study demonstrated that improved attentional control was associated with reduced symptoms of anxiety and depression (Rueda et al., 2004), and it has been suggested that improved ability to direct attentional focus has implications for emotional functioning (Stubberud et al., 2015).

5.2.3 Improved executive functioning indexed by neuropsychological measures

Similarly to some of the previous GMT studies (Miotto et al., 2009; Spikman et al., 2010), a general trend towards improved neuropsychological functioning across the majority of tests from baseline to six-month follow-up, irrespective of intervention, was reported in **Paper I**. Still, other studies (Levine et al., 2000; Levine et al., 2011; Novakovic-Agopian et al., 2011) applying similar tests as this study, reported GMT-specific improvement on measures of sustained and executive attention. In their review of GMT in relation to ABI, Krasny-Pacini et al. (2014) noted that studies reporting an effect of GMT at the participation-level (e.g. questionnaires), have in general failed to detect a unique intervention effect at the impairment-level (e.g. tests), and vice versa. This observation could reflect the often weak relationship between a particular test measure and everyday behavior due to poor ecological validity (Burgess et al., 2006; Ready et al., 2001), different measurement levels (Lewis et al., 2011), the task impurity problem (Miyake & Friedman, 2012), and/or more test-specific issues like practise effects (Sohlberg, McLaughlin, Pavese, Heidrich, & Posner, 2000). Thus, traditional neuropsychological tests typically aim to assess cognitive functioning at the impairment level. They often provide adequate description of the individuals' capacity, but not necessarily their performance in real life tasks or activities (Burgess et al., 1998; Lewis et al., 2011; Manchester et al., 2004).

The Hotel test (Manly et al., 2002) was included In **Paper I**, as it mimics real-life multitasking situations, has demonstrated acceptable ecological validity and sensitivity in detecting ED in various disorders (Roca et al., 2010; Roca et al., 2008; Torralva et al., 2012). The UPSA, originally developed for studies of schizophrenia (Mausbach, Harvey, Goldman, Jeste, & Patterson, 2007; Patterson et al., 2001), was also included, as it targets "real-life" multitasking situations, by having the subjects role-play with the examiner in three different functional domains (communication, finance, and transportation). Both tests require that the participants make a plan, organize the materials, and remember the goals of the tasks, similar to EF in daily life and the aim of GMT (Levine et al., 2000). However, and surprisingly, the results showed unspecific treatment effects for both measures.

The findings of previous GMT studies that have applied the Hotel test are mixed. Stubberud et al. (2013) reported improved GMT-related performance, while Levine et al. (2011) observed that GMT-participants performed less consistent post-intervention. Other GMT studies have demonstrated positive effects on real-life analogue tasks (Levine et al., 2000; Levine et al., 2007; Miotto et al., 2009; Novakovic-Agopian et al., 2011). The results reported in **Paper I** probably reflect a combination of test-retest and non-specific treatment-effects. Several of the participants in both groups spontaneously commented that they remembered these two tests when conducting the post-intervention assessments, as they "stood out" compared to the other measures. Further, the average performance at baseline for both measures was close to the maximum score, leaving little room for further improvement, i.e. ceiling effects. Finally, with the inclusion of an active control group to control for non-specific treatment-effects, it is also reasonable to expect smaller treatment effects compared to observational studies.

However, as reported in **Paper I**, a notable pattern emerged; group by time interactions approached significance for reduction of errors on a number of tests in the GMT group. Therefore, a sum-score for all errors on neuropsychological tests (CPT-II omissions and commissions, TMT1-4, VFT1-3, and CWIT1-4, and rule violations in the Tower test) was calculated to explore possible treatment-related changes in errors. A tendency towards a significant time by group interaction was observed, and *t*-tests showed a significant reduction of errors for GMT from T1 toT3. This finding suggests improved inhibition of automatic responding (Levine et al., 2000; Levine et al., 2011; Miotto et al., 2009), a crucial component of GMT, and repeatedly rehearsed throughout the sessions by means of noticing attentional slips, stopping the auto-pilot, and improving present-mindedness. If so, these results are consistent with the theoretical assumptions that GMT targets executive attention (Robertson & Levine, 2013), and they are in line with the findings of Stubberud et al. (2013).

It is therefore suggested that improved inhibitory control can be seen as an important contribution to separate the nonspecific from the GMT-specific training effects, resulting in fewer but theoretically more important findings. In support of this notion, no changes were observed on the nonspecific control measure of motor speed.

5.2.4 Predictors of treatment effects

A major challenge for clinicians conducting cognitive rehabilitation is to adapt findings from group-based RCTs to individual patient decisions, i.e. implementing available evidence into clinical practice (Bayley et al., 2014). In general, current knowledge about which specific interventions work best for whom, when in the course of recovery, and under what conditions, is sparse (Cicerone et al., 2011). There is also a need for more knowledge about the specific patient characteristics that moderate the effect of treatments targeting EF in order to guide individualized clinical decision-making (Bertens et al., 2016).

In **Paper III,** potential moderators, mediators, and nonspecific predictors of ED in daily life following the two interventions were explored. Given the limited literature, the choice of predictors was guided by the Bertens et al. (2016) paper, and included medical and demographic characteristics, neuropsychological test performance, and self-reported cognitive-, executive-, emotional- and psychological functioning. For a detailed description of all the variables and the identified predictors, see **Paper III**. A general pattern was evident irrespective of group; more self-reported symptoms at six-month follow-up mediated higher symptom levels in the three outcome measures that were established (cognitive executive complaints, emotional dysregulation, and psychological distress). This could reflect the variables' contribution to cognitive rehabilitation interventions at a more general level, as in many other psychological interventions (Chorpita et al., 2011).

Of particular interest was the observation in both interventions that cognitive failures in everyday life not only mediated cognitive executive complaints, but also emotional and psychological functioning. In a similar way, higher levels of emotional dysregulation mediated more psychological distress. For the control group specifically, it was also observed that higher levels of psychological distress mediated higher scores for emotional dysregulation, and similarly, more cognitive failures and self-reported executive deficits mediated higher scores for psychological distress. It has been shown that lack of functional and cognitive recovery in TBI patients can be associated with worsening of mood over time, regardless of depression level after the first year (Hart et al., 2012). The results of the control group could therefore reflect the continuation of cognitive and executive symptoms, despite the effort to improve by participating in the psycho-educational intervention. The finding that poor planning performance emerged as a mediator of higher levels of psychological distress in both groups could also adhere with this hypothesis. It has been suggested that metacognitive training targeting improved self-regulation of both cognitive and emotional processes can lead to increased self-efficacy beliefs, specifically in the confidence in managing residual cognitive and emotional symptoms (Cicerone et al., 2008).

Furthermore, such improvements are directly related to positive outcomes, particularly patients' subjective well-being and life satisfaction (Cicerone, 2012), which could explain treatment effects also leading to improved psychological functioning and QoL. This line of reasoning is interesting in relation to **Paper II**, where a systematic trend towards enhanced QoL was observed for the GMT group, with the greatest improvements observed at six-month follow-up. Thus, improved QoL could reflect a global consequence of enhanced goal management in daily life. Of interest, Cicerone et al. (2004) showed that satisfaction with cognitive functioning contributed to post-treatment community integration. In summary this highlights the important role of the patients' overall self-perceived functioning, even when the aim is to target specific cognitive domains like attention or WM.

One GMT-specific mediator was observed; namely that improved inhibitory control of attention (CWIT3) after training mediated less psychological distress. In accord with this, the other inhibitory control measure (CPT-II, Commission errors) approached significance, whereas measures of sustained attention (CPT-II, Omission errors) and shifting (CWIT4) showed no mediating effects. Impaired inhibitory control has been suggested as a predictor of depression relapse in major depressive disorder (Schmid & Hammar, 2013). Previous studies have reported a favorable effect on measures for inhibition after GMT (Levine et al, 2011; Stubberud et al., 2013). It is therefore tempting to suggest that changes in inhibitory attentional control, underlying and supporting higher-order EF (Dams-O'Connor & Gordon, 2013; Robertson & Garavan, 2000), might be a possible mechanism through which GMT-effects are mediated. Attention underlies voluntary control of both thoughts and emotions (Posner & Rothbart, 2007), with the ability to inhibit irrelevant or interfering stimuli being at the core of attentional control. The GMT-intervention applied in this study, specifically addressed emotional functioning, which could have strengthened the association between attentional control and emotional regulation.

5.3 Methodological issues

Although the study had a number of strengths, countering many of the methodological challenges of previous GMT studies, some significant limitations should be noted.

5.3.1 Questionnaires

While applying questionnaire measures in addition to neuropsychological tests counters some of the issues related to ecological validity (Chan et al., 2008) and assessment of daily life EF, a number of factors can affect the accuracy and validity of these measurements. Thus, the strong reliance on self-report measures is a limitation. Reduced self-awareness, demand characteristics, cognitive deficits, social desirability bias, acquiescent responding and extreme responding, have been shown to affect the accuracy and validity of self-report (Cantor et al., 2014; Fischer, Trexler, & Gauggel, 2004; Hart, Whyte, Kim, & Vaccaro., 2005; Logan, Claar, & Scharff, 2008; McCambridge, de Bruin, & Witton, 2012; Prigatano & Altman, 1990). This might contribute to a tenuous relationship between self-report and "real life" activity-limitations.

In **Paper II**, the BREQ was expected to specifically measure emotional regulation. Still, the most significant results reported were associated with the DEX and the BRIEF-A - questionnaires considered measures of EF and not emotional regulation in particular. These findings could be seen as underscoring the close association between EF and emotional regulation (Dams-O'Connor & Gordon, 2013; Koole, 2009). Capturing problems of emotional regulation in formal assessments poses a methodological challenge, highlighting the need for assessment methods with good psychometric properties and ecological validity (Cattran et al., 2011; Zald & Andreotti, 2010). Information from significant others could have provided important additional information regarding EF in daily life. We originally aimed at including this, but a significant number of relatives dropped out at T2 and T3, despite reminders being sent at both time-points, leaving a very restricted sample.

5.3.2 Neuropsychological assessment

The applied neuropsychological tests were carefully chosen (**Paper I**), taking into account many of the challenges in assessing EF (Lewis et al., 2011), especially the issues of ecological validity and measurement levels (ICF). Therefore, particular attention was given to the Hotel test (Manly et al., 2002) and the UPSA (Mausbach et al., 2007), as these are considered to be more closely related to real life functioning. Given three administrations of these two tests in a year, the reported results probably reflect test-retest effects. Since EF is considered crucial in managing new situations, the lack of novel EF tests as outcome measures limits the possibility to assess possible generalization effects. Split-half administrations for some tests, e.g. the Tower test (Delis et al., 2001) could possibly have circumvented this to some extent.

Spikman et al. (2010) applied the Executive Secretarial Task (Lamberts et al., 2010) simulating a job assessment procedure at follow-up only, and reported higher scores being associated with GMT compared to the active control condition. However, the lack of pre-treatment measures warrants caution regarding follow-up treatment effects. The Multiple Errands Test (Dawson et al., 2009; Shallice & Burgess, 1991), requiring the subject to complete a number of everyday tasks in a real-world environment without breaking specific rules, could have been applied. The Multiple Errands Task is however very time-consuming, requires a lot of resources to conduct, and relies heavily on perceptual and spatial abilities (Lewis et al., 2011), and is therefore challenged by the task-impurity problem (Miyake & Friedman, 2012).

Valid neuropsychological test results are paramount to understand the consequences of ABI (Bigler, 2014). In order to evaluate performance validity, we inspected the scores on the forced-choice recognition condition of the CVLT-II, and the consistency in the neuropsychological profile for each participant, without identifying any special issues related to performance validity. Still, the confidence in the reported neuropsychological results in **Paper I – III** could have been improved by applying symptom validity tests such as the Test of Memory Malingering (Tombaugh, 1996).

5.3.3 Study design, statistical analysis and outcome measures

The GMT intervention applied in this study carefully addressed all the core concepts and in the same order as the standard GMT protocol (Levine et al., 2011). The implementation of a new module for emotional regulation and the use of external cuing, preclude the identification of the unique contributions of the original GMT-intervention. Furthermore, "Stop!" is a key concept in GMT, and the cuing therefore probably provided different connotations in the two groups. It should also be noted that some of the participants reported that the content was very comprehensive. One could consider extending the duration of the modules from two to three hours, distribute the content over more modules, or narrow down the content for some of the modules.

Despite being one of the largest study samples compared to other GMT studies, the sample size was relatively modest for the purpose of conducting predictor analyses, and also included a large number of variables. Mixed models analyses could have overcome some of these limitations, being particularly useful in settings where repeated measurements are done for the same individual, and being more robust regarding missing values (Field, 2013). Furthermore, the choice of candidate predictors in **Paper III** was exploratory, lacking strong specific a priori hypotheses. The suggested roles and implications of the reported variables as predictors of outcome need to be confirmed (and elaborated upon) in future studies.

Although the composite outcome measures applied in **Paper III** had internally high and distinct factor-loadings, their psychometric properties are not well known, and the factors were not totally independent of the candidate predictors. Future studies should be planned with an independent outcome measure embedded in the design, although the obstacle is a lack of baseline values, as noted. Capturing problems of and treatment-related changes in executive functioning constitutes a major methodological challenge in all treatment studies (Cicerone et al., 2006), including the current one.

The lack of objective measures of actual goal management in daily life (**Paper I-II**) makes it difficult to conclude whether the reported improvements relate to actual improvements or improved self-perceived mastery of daily activities (Cicerone, 2012). Therefore, measures for actual goal management could have been included. Including qualitative methods like in depth interviews could also provide additional information regarding the observed changes in EF and everyday life, and self-efficacy.

Although being conducted as a RCT with blinded assessors at all time-points, the inclusion of a non-intervention group could have improved the robustness of the results further, to disentangle the supposed non-specific training and/or intervention effects. This would on the other hand have been a very time-consuming design with unknown additional benefit. To explore long-term effects, a follow-up period for a year or more would be desirable. This was, however, not possible within the timeframes of the current PhD study, as it would have extended the period for data collection with one or two years.

Finally, although the participants refrained to participate in other cognitive rehabilitation programs during the study, other and unknown post-training factors might have influenced outcomes at six-month follow-up. Therefore, assessments to determine if improvements over time relate to the intervention or other post-training factors should have been included, for instance by mapping possible significant life events post-training to six-month follow-up.

5.3.3 Representativity

The majority of participants were recruited from a large specialized rehabilitation hospital, after receiving their primary rehabilitation at the same facility. This hospital typically provides services for persons with severe and moderate TBI, and younger CVA patients, thus not being representative for the ABI population in general. Furthermore, three other ABI etiologies tumor, anoxia/hypoxia, viral infections were included. As such, the study was conducted on a heterogeneous sample, however, quite similar to the majority of other studies on GMT following ABI. On the other hand, the main aim of the study was not to generalize findings to ABI-individuals in general. The study investigated GMT as an intervention targeting ED following documented ABI (of note, the frontal lobe being the most frequent cortical location of damage), conducted as a RCT, in patients with a documented ED (neuropsychological assessment and self-report). Although two individuals were less than one year post-injury (10 and 11 months) at study onset, the sample as a whole were considered to be in the chronic phase of ABI, with a mean time since injury of 97.4 months. The representativity and generalizability of the reported results must be interpreted within the limitations of the study group.

5.4 Clinical implications

From the perspective of the patients and their families, persistent problems with attention, inhibition, WM, initiative, planning, self-regulation, regulation of emotions, and goal-directed behavior can have devastating consequences for the individuals' ability to perform daily life activities and participate in society. Although ED symptoms usually are presented during post-acute rehabilitation, the accompanying consequences in the real-world often emerge across time, when the individual is back home, trying to re-engage in their daily life. Thus, there is a need for interventions targeting real-life functioning in a long term perspective.

From a health care professional perspective, ED is amongst the most challenging tasks for rehabilitation, simultaneously involving basic cognitive functions (like attention and WM), and the overarching cognitive processes determining goal-directed behavior and the orderly execution of daily life tasks and activities. Thus, evidence based interventions targeting ED are warranted.

Goal Management Training has proven efficient in alleviating ED in a number of studies. As a manualized intervention, it can be relatively easy implemented in clinical work compared to many other interventions that are of a more experimental nature. Further, comprising nine modules of two hours and addressing daily life functioning, this is considered a time-efficient intervention. However, it should be considered to explore more individualized based approaches, selecting modules tailored for individual patients or groups of patients. The GMT intervention applied in this study, incorporating emotional regulation, came out as a promising approach not only to address the cognitive aspects of EF, but taking on a more holistic perspective by including emotional regulation.

5.5 Implications for future research

The current study aimed to answer several research questions in the field, paving some paths for future research:

1. The current study (**Papers I-II**) did not investigate whether GMT is equally helpful for patients with TBI, CVA or other ABI related etiologies. In addition, the possible relationship between lesion location and EF outcome following GMT is not well understood.
2. Combining standard GMT with emotional regulation and external cueing (**Papers I-II)** precludes conclusions regarding the unique contributions of each treatment component. Therefore, conducting a RCT comparing different versions of GMT, similar to the study by Bertens, Kessels, Fiorenzato, Boelena, and Fasotti (2015), that compared standard GMT and errorless GMT, might be helpful. Dismantling studies are needed to understand which components have the strongest effect on particular outcomes.
3. Although **Paper III** aimed at enhancing the understanding of what patient characteristics predict treatment outcome following GMT, the findings and implications need further replication.
4. There is a need for future studies to investigate the relationship between emotional regulation, psychological distress and attentional control more closely, as addressed in **Paper II**. Such research could also include other measures of emotional regulation than self-report, such as data from collateral informants and patients' physiological responses to emotional challenges/stimuli. Measures of changes in self-efficacy could also be used to investigate it`s moderating effects.

6. CONCLUSIONS

Executive dysfunction is a common consequence of ABI, causing significant disability in daily life activities and participation. Hence, there is a great need for evidence-based interventions targeting improvement of ED following ABI. GMT is a practical, manualized metacognitive strategy intervention that addresses (cognitive) EF deficits through psycho-education, practical demonstrations and tasks, and mindfulness training. Since control of emotions also affects EF, a module for emotional regulation was developed and incorporated in the intervention. Finally, as external cueing has been associated with improved goal management, external cueing was included as part of the intervention.

The main aim of this RCT was to investigate the efficacy of GMT for ED in patients with ABI, compared to an active control group receiving the BHW intervention. A secondary aim was to investigate predictors of outcome. The study had a repeated-measures design across three time points, baseline, post intervention, and six-month follow-up. Neuropsychological tests and self-report questionnaires of EF, emotional regulation, psychological distress and QOL were administered to the participants at all three time points.

Overall, the results indicated that GMT participants showed significant improvements of EF and emotional regulation in daily life activities assessed by self-report measures, with the strongest findings observed at the six-month follow-up. Both interventions demonstrated improved scores on the neuropsychological tests, however, only the GMT group was associated with improved inhibitory control. In summary, these study results indicate that GMT administered as a group-based intervention, leads to long-term improvement of EF deficits following ABI in the chronic phase, and that the principles of GMT can be used to treat impaired emotional regulation.

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Papers I-III

Paper I

Paper II

Paper III