

Goal Management Training (GMT) Targeting Cognitive Regulatory Abilities in Adults with ADHD

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1. Introduction

Attention-deficit/hyperactivity disorder (ADHD) is a lifespan disorder characterized by a persistent behavior pattern of inattention, hyperactivity, and impulsivity (American Psychiatric Association, 2013). It is one of the most prevalent mental health disorders both in childhood and in adult life (Kessler, Berglund, et al., 2005). An estimated prevalence of ADHD is 5-7% in childhood (Ullebø, Breivik, Gillberg, Lundervold, & Posserud, 2012), which tends to persist into adulthood for about 50% of those with ADHD in childhood (Lara et al., 2009). This underlines the importance of investigating possible treatment programs to ameliorate functional impairments associated with the disorder. The transition into adult life for individuals affected by ADHD seems to be especially challenging, as illustrated by a lifetime model of ADHD (Turgay et al., 2012) which shows that ADHD often leads to increased functional impairment during the transition into adulthood. This is related to higher external demands (i.e. in school, work, and social interactions) and the gradual removal of external support from caregivers, such as from parents and teachers. In line with this, findings indicate that those affected by ADHD symptoms in adult life have substantial functional impairments in domains such as work and social life compared to controls (Able, Johnston, Adler, & Swindle, 2007; Halmøy, Fasmer, Gillberg, & Haavik, 2009). ADHD among workers is shown to associate with an estimated average of 35 days of lost work performance annually (Kessler, Adler, Ames, Barkley, et al., 2005). This estimated absence represents 120 million days of annual lost work in the U.S. labor force, totaling an annual cost of US \$19.5 billion in lost human capital. Increased rates of ADHD have also been found in criminal offenders, and in patients with bipolar disorder ranges from 20-80% (Karaahmet et al., 2013; Young & Thome, 2011). Despite evidence suggesting that ADHD is a driver of poor outcome (Biederman et al., 2012), and one of the major public health problems in modern societies (R. A. Barkley, 2008), this has not been fully acknowledged by society and health and educational services.

The proposed research project focuses on treatment of cognitive regulatory functions, identified as a risk factor for the functional impairment observed in adults with ADHD (Halleland, Sørensen, Posserud, Haavik, & Lundervold, 2015), and by this follows the call for studies focusing on the treatment of mental health disorders in general (Hosman, Jane-Llopis, & Saxena, 2005). The proposed project is also in line with current policy regarding non-pharmacological treatment of mental health disorders (Helse- og omsorgsdepartementet, 2015)

1.1 Rationale

ADHD is associated with regulatory dysfunctions that tend to prevent those that are affected from succeeding academically and in work life (e.g. Biederman et al., 2004; Hallelund et al., 2015). Current treatment of ADHD is, to a large degree, based on pharmacotherapy and there is a need for increased knowledge about possible psychological interventions (NCCMH, 2009; Sonuga-Barke et al., 2013; Vidal-Estrada, Bosch-Munso, Nogueira-Morais, Casas-Brugue, & Ramos-Quiroga, 2012). Goal Management Training (GMT) is a non-pharmacological treatment targeting the cognitive part of regulatory abilities (inhibitory control and executive functions [EFs]; see Figure 1). GMT originates from a solid cognitive rehabilitation tradition (Evans, 2009) and is based on the theory of vigilant attention (Robertson & Garavan, 2000) and Duncan's (1986) theory of goal neglect. GMT has been found to successfully enhance cognitive regulatory abilities in disorders such as frontal lobe brain damage (Levine et al., 2011), polysubstance abuse (Alfonso, Caracul, Delgado-Pastor, & Verdejo-Garcia, 2011), and spina bifida (Stubberud, Langenbahn, Levine, Stanghelle, & Schanke, 2013). In the present project we will investigate whether GMT can enhance cognitive regulatory abilities in adults with ADHD, both with and without psychometrically defined executive function deficits (EFD; Doyle, Biederman, Seidman, Weber, & Faraone, 2000), and by this also enhance their quality of everyday life. The proposed project will consist of a pilot GMT study with outcome measures of cognitive regulatory abilities, sustained attention and heart rate variability (HRV; see Figure 1). Measures of quality of life, motivational and emotional regulation, as well as measures of anxiety symptoms and symptoms of mood disorders will also be included.

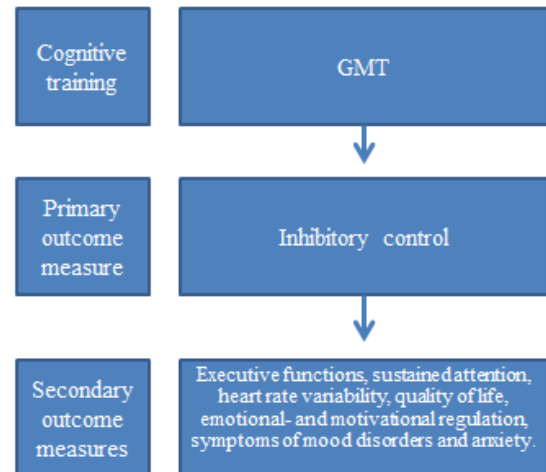


Figure 1

A diagram giving an overview of the outcome effect measures of GMT in this proposed project.

2. Background

2.1 ADHD and effects on executive functioning:

EFs have been defined as “general-purpose control mechanisms that modulate the operation of various cognitive sub-processes and thereby regulate the dynamics of human cognition” (Miyake et al., 2000, p. 50). As is apparent, EFs have a crucial role in activities of every-day life, predominantly related to self-regulation – where inhibitory control seems to be the most essential sub-function (Miyake & Friedman, 2012). Thus, impairments of EFs influence the quality and efficiency in social interactions, problem-solving, and goal attainment (Eslinger, Flaherty-Craig, & Chakara, 2013). Such impairments in cognitive regulatory functions, including inhibitory control, have been proposed as a core feature of ADHD (R.A. Barkley, 2010) and have been found to be associated with severe functional impairment in adults with ADHD (e.g. Hallelund et al., 2015).

Another cognitive dysfunction in ADHD is the high level of attentional lapses observed on performance-based measures (i.e. Antonini, Narad, Langberg, & Epstein, 2013; Gmehlin et al., 2014). This is assessed by measures of intraindividual variability in reaction times (IIVRT; for a review see Kuntsi & Klein, 2012). These attentional lapses make it challenging to sustain attention. Sustained attention facilitates the cognitive regulatory functions (Fan, McCandliss, Fossella, Flombaum, & Posner, 2005), and attentional lapses thereby disturb cognitive regulatory functioning in ADHD (Andrews-Hanna, Smallwood, &

Spreng, 2014). The high frequency of attentional lapses is further shown to correlate with a reduced ability to exhibit academic on-task behavior in ADHD (Antonini et al., 2013), to link with ADHD on genetic levels (Bellgrove, O'Connell, & Vance, 2008), and have also been found to be a better discriminator between ADHD and controls than other core EFs (Kuntsi, Oosterlaan, & Stevenson, 2001). This has led to hypotheses that the cognitive regulatory deficits in ADHD are not purely related to a problem of top-down regulation, but also a bottom-up problem in sustaining attention (Sonuga-Barke & Castellanos, 2007). This has recently been focused on as a problem following a high frequency of self-generative thoughts in individuals with ADHD (Andrews-Hanna et al., 2014), which leads to distraction from ongoing task behavior at work, at school and/or in leisure activities.

Regulatory abilities are typically measured with performance-based measures, but can also be measured on a psychophysiological level with HRV. HRV is an indirect measure of the ability to flexibly regulate cognition and emotions in accordance with contextual expectations, and is shown to correlate with inhibitory control and EFs (i.e. Park & Thayer, 2014; Thayer, Ahs, Fredrikson, Sollers, & Wager, 2012; Thayer & Friedman, 2002), also shown in children with ADHD (Desman, Petermann, & Hampel, 2008). Furthermore HRV has also been shown to correlate with sustained attention in children with ADHD (Börger et al., 1999).

2.2 Current treatment of ADHD

Current treatment of ADHD is to a large extent based on pharmacological approaches, which is illustrated by the following excerpt from the UK National Institute of Health and Clinical Excellence (NICE) guideline pertaining to diagnosis and management of ADHD in children, young people and adults; “Drug treatment is the first-line treatment for adults with ADHD with either moderate or severe levels of impairment. Methylphenidate is the first-line drug. *Psychological interventions without medication may be effective for some adults with moderate impairment, but there are insufficient data to support this recommendation.*” (NICE, 2008, pp. 29-30, *emphasis added*). A meta-analysis of non-pharmacological interventions for ADHD supports these conclusions, stating that there is a further need of evidence of efficacy before non-pharmacological treatments can be fully recommended as treatments for ADHD (Sonuga-Barke et al., 2013). The studies in this meta-analysis were based on children; however, the same is true for adults with ADHD, where controlled trials of non-pharmacological treatment options are scarce. In a review of psychological treatment of adults with ADHD, the authors call for more research exploring the differential effects of different psychological approaches (Vidal-Estrada et al., 2012). The complete guideline (NCCMH, 2009) also includes recommendations for the use of psychological treatment options in certain cases. Examples include cases where there are persisting functional impairments when undergoing pharmacological treatment, where patients choose not to undergo pharmacological treatment, are unresponsive or intolerant to such treatment or if there are residual impairments after pharmacological treatment. Based on these recommendations it is apparent that there is a need for scientifically proven non-pharmacological treatment options for ADHD and its associated impairments. Furthermore, the guidelines issue recommendations for research addressing questions about the effectiveness of non-pharmacological treatments and whether such approaches might have specific advantages over pharmacological alternatives in improving aspects of the lives of those affected. In our own group we have found that adult patients with ADHD report a wish for non-pharmacological treatment options (Solberg, in press).

Although there is abundant neuropsychological knowledge about ADHD (e.g. R. A. Barkley, 1997), this knowledge is not used on a regular basis in current treatment programs. One such possible approach to reducing the functional impairments suffered by those affected

by ADHD is addressing the deficits of cognitive regulatory functions (i.e., inhibitory control and EFs; Eslinger et al., 2013; Hallelund et al., 2015) .

2.3 GMT as a treatment approach to impairments associated with ADHD

GMT is an approach to cognitive rehabilitation aimed directly at improving inhibitory control and EFs by teaching strategies for improving attention and problem solving. The main focus of GMT is teaching patients to stop ongoing behavior (i.e., inhibitory control) to assess current goal hierarchies and their current performance in regards to these (Levine et al., 2011). To achieve this GMT introduces external cues during the performance of tasks and emphasizes the internalization of such stop-cues, furthermore mindfulness meditation (Kabat-Zinn, 1990) is incorporated to enhance or develop the ability for sustained attention (i.e. the ability to repeatedly adjust ones focus to the present and to the monitoring of current behavior, goals and the correspondence between these (Levine et al., 2011). Tasks used in GMT include both analogs to experimental tasks, and real-life examples from patients and therapists.

GMT has been shown to have a positive effect on measures of inhibitory control and EFs in a variety of diagnostic groups. These groups include, but are not limited to, people affected by frontal lobe brain damage (Levine et al., 2011), polysubstance abuse (Alfonso et al., 2011), and spina bifida (Stubberud et al., 2013). Results from a pilot study indicate that GMT may also have a positive effect on the same cognitive regulatory functions in adults with ADHD (In de Braek, Dijkstra, Ponds, & Jolles, 2012). Results indicate that GMT has a positive influence on measures closely related to tasks included in the training program (i.e. the Sustained Attention to Response Task; Levine et al., 2011) and tasks differing from those used as part of GMT but assumed to rely on the same underlying processes (i.e. the Tower test; Levine et al., 2011; Stubberud et al., 2013). Furthermore findings show effects on more general measures of functioning such as clinician rated improvement of cognitive functioning (In de Braek et al., 2012) and the Hotel Task (Stubberud et al., 2013). Results from self-report measures also indicate significant effects on daily life cognitive regulatory functions, lasting at least 6 months following GMT, suggesting transfer of intervention effects to functional performance in real-life (Stubberud et al., 2013).

With regards to current theoretical accounts of ADHD (i.e. Halperin & Schulz, 2006), GMT appears to be a highly suitable treatment option for the disorder as it aims at strengthening the ability of affected individuals to compensate for existing deficiencies by applying effortful and consciously guided executive processes. The findings of Halperin and colleagues (2008) can be interpreted to support that this is analogous to the processes underlying the differing outcomes for adult ADHD-persisters (i.e. individuals continuing to fulfill diagnostic criteria for ADHD) and ADHD-remitters (i.e. those individuals who no longer fulfill diagnostic criteria). The GMT addresses both enhancements of inhibitory control and EF and reduction of attentional lapses through mindfulness exercises, this multifaceted focus might also be a strength with regards to the large heterogeneity in deficits in diverse executive functions observed in ADHD.

GMT has so far been studied as a treatment of functional impairments associated with ADHD in only one pilot study of 15 adults with ADHD (i.e. In de Braek et al., 2012). As the authors of this study point out there is a need for further research applying GMT to larger groups, and for further attempts at separating the results of the intervention from that of a control condition. Prior results also indicate a need for evaluating the use of different outcome measures (e.g. measures of IIV and HRV) and for assessing effects on “everyday” functional impairments such as motivational- and emotional regulation. In de Braek et al. (2012) also note that qualitative information indicated that some participants experienced a large improvement, whereas others reported no improvement, and that efforts should be made to

distinguish these groups.

3. Research questions and main objectives of the present project

The main objective of the proposed project is to conduct a preliminary investigation of GMT as a group based treatment program for adults with ADHD. Although there are findings indicating that GMT has a positive effect on EFs in various diagnostic groups (e.g. Levine et al., 2011; Stubberud et al., 2013), the relevance of GMT to adults with ADHD still remains to be thoroughly investigated (In de Braek et al., 2012). The aim of the current pilot study is to address this lack of knowledge in preparation for a planned randomized, controlled trial. The main outcome measures of inhibitory control and executive functions together with sustained attention will be measured with a neuropsychological test battery, self- and informant-report measures, and psychophysiological with HRV.

Main Research questions:

1. Does GMT delivered to a group of adults with ADHD lead to improved EFs, particularly inhibition, measured through self- and informant-report and objective measures? And, is the effect of GMT comparable in groups of adults with ADHD with (i.e. at least one standard deviation below the mean score in the control group on two or more neuropsychological tests; Doyle et al., 2000) and without EFD?
2. How do changes in IIV associate with changes on outcome measures from neuropsychological tests and self-report measures of EFs?
3. Does GMT improve the participants experienced quality of life?
4. Does GMT have an effect on motivational- and emotional regulation, and the experience of symptoms of anxiety and depression, in adults with ADHD?
5. Will a possible effect of GMT on EFs also be reflected in a psychophysiological change as measured by HRV?

4 Materials and methods

The proposed study is a pilot on GMT in adults with ADHD ($n = 36$) originating from a larger, on-going multidisciplinary research project on adults with ADHD: “ADHD in adults; from clinical characterization to molecular mechanisms” at the University of Bergen (see Halleland et al., 2015 for a description of the recruitment process). All participants will be given active treatment as one of the aims of the study is to investigate whether GMT has an effect on EFs in adults with ADHD. Efforts will be made to include an equal number of participants with and without psychometrically defined EFD to allow for an investigation of whether the effects of GMT will differ between these groups. The number of participants is comparable to those included in earlier studies of GMT (Levine et al., 2011; Stubberud et al., 2013) where 19 and 38 participants, respectively, were included in the studies. A statistical power analysis (performed using G*Power) indicates acceptable power and, thus, a satisfactory sample size.

Inclusion criteria: Age > 18 years, confirmed ADHD diagnosis with or without EFD, reported executive problems as measured by the Quick Delay Questionnaire (QDQ; Clare, Helps, & Sonuga-Barke, 2010).

Exclusion criteria:

- Reported ongoing alcohol- or substance abuse.
- Current or lifetime psychotic disorder.
- IQ < 85

4.1 Procedure

A subgroup of the participants from the larger research project “ADHD in adults; from clinical characterization to molecular mechanisms” living in or around Bergen will be invited to participate. Based on a review of earlier neuropsychological testing conducted as part of their participation, and on a structured telephone interview, a total of 36 participants will be recruited. An assessment applying a battery of effect measures of inhibitory control, EF, sustained attention, emotional- and motivational regulation, quality of life, symptoms of depression and anxiety, symptoms of ADHD, and HRV will be conducted at baseline (T1), the majority of these measures will also be applied immediately after the treatment intervention (T2) and at follow-up 6 months post treatment.

The participants will be randomly assigned to one of six GMT groups; each group will consist of six participants. The randomization will be stratified, with stratification for age (above/below the mean age), gender (with males/females being distributed evenly among the groups), education (above/below the mean number of years) and presence or absence of EFD (50%/50%). The investigator responsible for randomization will not be involved in the training procedures.

Participants will receive an economic compensation of 1000 NOK at the completion of their participation for the time they have spent participating, to cover travel expenses and for any inconveniences incurred.

The GMT will be administered in nine two hours sessions with two sessions per week in accordance with the GMT research protocol. The main focus of the first session is on defining absentmindedness and the difference between this and mindfulness. The second session focuses on absentminded errors and the operationalization of these. The third session focuses on the mental “autopilot” or the performance of routine tasks with reduced mindfulness. Session four introduces strategies for regaining conscious control of activities by turning off the “autopilot”. Session five introduces the concept of the “mental blackboard” as a metaphor for working memory and strategies for enhancing awareness of ongoing behavior. Session six emphasizes the stating of goals as a method of activating goal representations. The emphasis in session seven is on decision making when dealing with competing goals, emotional reactions to competing goals, and to-do lists as a strategy for handling such situations. Session eight focuses on dividing goals into sub-goals. The final session, session nine, focuses on checking. That is, stopping or interrupting current ongoing behavior to assess progress or achievement.

4.2 Materials

Due to a lack of sensitivity in standardized neuropsychological test measures with regards to measuring executive deficits related to self-regulatory problems (Zald & Andreotti, 2010), and to investigate the generalization of effects of the treatment, a broad assessment will be conducted. The assessment battery will include both performance-based neuropsychological tests, analogs to complex everyday tasks, self-report and informant based questionnaires, and a measure of HRV. Authorized, Norwegian translations of all measures will be used. All measures have good psychometric properties.

Diagnostic assessment (Baseline T1)

1. A semi-structured diagnostic interview: The MINI PLUS (Sheehan et al., 2002)

Neuropsychological test measures (Baseline T1, outcome T2 and T3)

1. A general measure of intellectual capacity: Two subtests from the Wechsler Abbreviated Scale of Intelligence (WASI; Psychological Corporation, 1999).
2. Inhibitory control and intraindividual variability: Color Word Interference Test (D-KEFS; Delis, Kaplan, & Kramer, 2001) and the Attention Network Test, revised version (ANT-r; Fan et al., 2009).
3. Executive functions: Tower (D-KEFS; Delis et al., 2001) and the Hotel task (Manly, Hawkins, Evans, Woldt, & Robertson, 2002).
 - a. Working memory: Spatial Span Test and Letter-number Sequencing (Wechsler, 2003)
 - b. Processing speed: Trail Making Test (D-KEFS; Delis et al., 2001)

All measures, with the exception of the measure of intellectual capacity and ADHD symptom-measures, will be repeated at T2 and T3.

Self-report measures (baseline T1, outcome T2 and T3)

Executive functions:

1. Behavior Rating Inventory of Executive Function (BRIEF-A; Gioia, Isquith, Guy, & Kenworthy, 2000).
2. Cognitive Failures Questionnaire (CFQ; Broadbent, Cooper, FitzGerald, & Parkes, 1982).

Emotional regulation and –distress:

1. Difficulties in emotion regulation scale (DERS; Gratz & Roemer, 2004)
2. Mood Disorder Questionnaire (MDQ; Hirschfeld et al., 2000)
3. State-Trait Anxiety Inventory (STAI; Spielberger, 1985)

Motivational regulation:

1. Quick Delay Questionnaire (Clare et al., 2010). The QDQ will be used as a structured telephone interview at T1 as a screening measure for inclusion to the study.

Quality of life:

The Adult ADHD Quality of Life Questionnaire (AAQoL; Brod, Perwien, Adler, Spencer, & Johnston, 2005) *ADHD symptoms (T1 only):*

1. Adult ADHD Self-Report Scale (ASRS; Kessler, Adler, Ames, Demler, et al., 2005)
2. Wender Utah Rating Scale (WURS; Ward, Wender, & Reimherr, 1993)

Informant-report measures (baseline T1, outcome T2 and T3)

1. Behavior Rating Inventory of Executive Function (BRIEF-A; Gioia et al., 2000)

Psychophysiological measures (baseline T1, outcome T2 and T3)

1. ECG/Heart rate variability

4.3 Statistical analyses

Standardized data (z-scores) will be analyzed using a 2 x 3 mixed-design ANOVA that treats Group (ADHD with EFD, ADHD without EFD) as a between-subjects factor and Session (baseline, post-intervention, follow-up) as a within-subjects factor. Interpretation of the strength of experimental effects will be provided with effect size statistics. Analyses will be performed using the Statistical Package for the Social Sciences (SPSS) Version 22, with $p < 0.05$ as level of significance.

4.4 Ethics

The project will be conducted in accordance with guidelines listed by the Helsinki declaration and the Vancouver rules. If indications of serious illness or risk of such illness, for instance during the non-clinical ECG assessment or in the form of increased risk of suicidal behavior, are revealed as part during participation in the study the information will be forwarded to the participant's general practitioner with the participant's consent, or in more severe cases to the proper instances to the proper emergency services, to ensure that the patients receives appropriate treatment.

4.5. Resources, cooperation, and supervision

The project will be located at the Department of Biological and Medical Psychology, University of Bergen, and will be carried out as a cooperative project between researchers at the Department of Biological and Medical Psychology and the K. G. Jebsen Centre for Research on Neuropsychiatric disorders (<http://www.uib.no/kgj-npd/en>). Training in the intervention method (GMT) will be conducted in collaboration with Jan Stubberud, who wrote his doctoral thesis on the use of GMT in a group of Spina Bifida patients and who has also co-supervised a PhD-project investigating the use of GMT on patients with acquired brain injuries. Professor Jonathan Evans at the University of Glasgow, who is an international expert on the implementation of GMT on patient groups, will act as an adviser and supervise the design and implementation of this proposed pilot study.

4.6. Schedule and publishing

The study will be conducted in the period 01.2016-08.2017, and preparation of the results for publishing will commence on completion of data collection. The pilot study will be included in an application for a PhD-grant, and an article describing the findings is planned for publication in the first half of 2017.

4.7. Scientific and clinical importance

The study is part of the ongoing international research on GMT, and aims at increasing the knowledge on how persons with executive dysfunctions profit from systematic cognitive rehabilitation programs. The aim of the study is to gather information about the effects of GMT in a group of adults with or without EFD, information that will hopefully lead to improved treatment for adult patients with ADHD. If the expected positive effect of GMT is found, there are plans to conduct a randomized, controlled trial of GMT comparing it to dialectical behavior therapy and treatment as usual, possibly contributing to establishing evidence-based guidelines. The results from this study may be beneficial for other patient groups with executive dysfunction such as cerebral palsy, schizophrenia, brain injury and the elderly. This study will hopefully make a contribution to the current knowledge by providing information about the effects of GMT across subgroups of persons with ADHD, especially regarding aspects of executive dysfunction. The project is also in line with the increasing focus on non-pharmacological treatment of mental health disorders (Helse- og omsorgsdepartementet, 2015).

4.8. Financial support

There are no conflicting interests with industrial companies or commercialization of products in the study. The researchers receive no economic benefits from the project. The study is supported by the K.G. Jebsen Centre for Research on Neuropsychiatric Disorders, and is part of a PhD-application for Daniel A. Jensen.

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