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Investigating the effects of goal management training as a possible intervention for adults with ADHD

Submission date
14/01/2021

Recruitment status
No longer recruiting

Registration date
18/01/2021

Overall study status
Completed

Last Edited
30/08/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims:
Attention-Deficit/Hyperactivity Disorder (ADHD) is a disorder characterized by difficulties of attention and various aspects of cognition which often has considerable negative consequences for those affected. As these negative consequences are believed to be related to reductions in inhibitory control (e.g. the ability to maintain goals in mind and to work towards these over time), we wish to examine whether Goal Management Training, an intervention aimed at strengthening inhibitory control, can reduce these difficulties among adults with ADHD.

Who can participate:
Interested individuals with a clinical diagnosis of ADHD and an age of 18 years or more may participate.

What does the study involve:
Participation involves taking part in a group-based intervention consisting of nine, weekly, two-hour sessions with approximately 15 - 20 minutes of daily homework between sessions. Furthermore, participants will be asked to undergo an assessment consisting of a clinical interview, neuropsychological tests, questionnaires, electrocardiogram and a computerized task of attention prior to, as well as immediately following and six months after completion of the intervention.

What are the possible benefits and risks of participating:
Participation does not involve any known risks. Possible benefits include an opportunity to learn strategies and techniques aimed at improving goal-attainment, as well as the opportunity to get to know and cooperate with other adults experiencing challenges similar to those you may have experienced yourself. Knowledge gained from the study may also contribute to the development of new treatment alternatives. Participation will involve spending time participating in the group sessions, doing homework as well as taking part in the assessments described above.

Where is the study run from?
The study will take place at the University of Bergen, Department of Biological and Medical Psychology (Norway)

When is the study starting and how long is it expected to run for?
May 2015 to January 2019

Who is funding the study?
The study is funded by the University of Bergen, the K.G. Jebsen Center for Neuropsychiatric Disorders, and the Norwegian National Research Network for ADHD.

Who is the main contact?
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Scientific

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Additional identifiers

Protocol serial number
2015/2325

Study information

Scientific Title
Goal Management Training (GMT) targeting cognitive regulatory abilities in adults with ADHD

Study objectives
Goal Management Training will improve executive functioning, specifically inhibitory control, in adults with ADHD. These effects will be , measured using performance-based measures, self- and informant-reports.
1. We expect that following GMT participants' inhibitory control specifically, and not other aspects of executive function such as working memory or flexibility of processing speed, will be improved
2. Following GMT participants will exhibit improvements in the attentional network responsible for conflict resolution as defined by the model of Posner et al. as this aspect of attention is closely related to inhibition
3. Improvements in executive functioning will be reflected in improved, self-reported self-regulation
4. Changes in self-regulation will be reflected in increased HRV

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/02/2016, Regional Ethics Committee (West) (Universitetet i Bergen, Det medisinske fakultet, Postboks 7804, 5020 Bergen, Norway; no telephone number provided; rek-vest@uib.no), ref: 2015/2325

Primary study design
Interventional

Study design
Single-centre interventional self-controlled design

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Attention-Deficit/Hyperactivity Disorder (ADHD) in adults

Interventions

Goal Management Training is a manualized, group-based intervention. This is an approach to cognitive rehabilitation aimed directly at improving inhibitory control and executive functioning by teaching strategies for improving attention and problem solving. The main focus in GMT is teaching patients how regularly stopping ongoing behavior (i.e. inhibitory control) to assess current goal hierarchies and their current performance may reduce difficulties related to poor executive functioning. To achieve this GMT introduces external cues during the performance of tasks and emphasizes the internalization of such stop-cues. Furthermore, components of mindfulness meditation are 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. Tasks used in GMT include both analogues to experimental tasks, and real-life examples from patients and therapists. GMT also includes a participant workbook which contains "homework" in the form of educational materials to repeat topics of psycho-education covered in the different sessions, sheets to log problematic and successful behavior between sessions, mindfulness exercises and analogues to real-life problem solving tasks.

Participants in the study will be assessed during the weeks prior to the intervention. Eligible participants will then receive the intervention in nine two-hour sessions. Sessions will be conducted on a weekly basis at the Department of Biological and Medical Psychology at the University of Bergen. The intervention is group-based, and groups will consist of a maximum of nine participants. In total 36 participants will be recruited. Further assessments will be conducted at the completion of the intervention and six months after completion.

Intervention Type
Behavioural

Primary outcome(s)
At baseline, within two weeks of completion of the intervention and six months after completion:
1. Inhibitory control measured using the third and fourth conditions of the Delis-Kaplan Executive Function System: Color-Word Interference Test
2. Inhibitory control measured using the Delis-Kaplan Executive Function System: Tower Test

Key secondary outcome(s)
Assessed at baseline, post-intervention and at follow-up six months after completion of the intervention:
1. ADHD symptoms measured with the Adult ADHD Self-Report Scale, 18 item version (ASRS)
2. Working memory capacity measured with the Letter-Number Sequencing task from the Wechsler Adult Intelligence Scale – 4th edition and the Spatial span from the Wechsler Memory Scale – 3rd edition
3. Processing speed measured with the fourth condition of the Delis-Kaplan Executive Function System: Trail Making Test
4. Attentional control measured with the Attention Network Test, revised version
5. An analogue to real-life problem solving measured using the Hotel task
6. Self-reported everyday executive functioning measured with the Behavior Rating Inventory of Executive Functions (BRIEF-A)
7. Self-reported everyday cognitive functioning measured with the Cognitive Failures Questionnaire (CFQ)
8. Emotional regulation and -distress measured with the Difficulties in Emotion Regulation Scale (DERS), Beck Depression Inventory II (BDI-II) and State-Trait Anxiety Inventory (STAI)
9. Motivational regulation measured with the Quick Delay Questionnaire (QDQ)

10. Quality of life measured with the Adult ADHD Quality of Life Questionnaire (AAQoL)
11. Heart rate variability measured with electrocardiography (ECG) in a resting condition. The Biopack system will be used to register heart rate and subsequently HRV will be analyzed with Kubios version 2.0

Completion date
06/01/2019

Eligibility

Key inclusion criteria
1. A clinical diagnosis of ADHD
2. Aged ≥18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
32

Key exclusion criteria
1. Current or lifetime psychotic disorder
2. Ongoing alcohol or substance use disorder
3. severe psychiatric illness (i.e. moderate to severe suicidality, severe depression, severe social anxiety preventing participation in group sessions)
4. Full scale intelligence quotient <80

Date of first enrolment
15/02/2017

Date of final enrolment
16/04/2018

Locations

Countries of recruitment
Norway

Study participating centre
University of Bergen
Department of Biological and Medical Psychology
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Sponsor information

Organisation
University of Bergen

ROR
https://ror.org/03zga2b32

Funder(s)

Funder type
University/education

Funder Name
Universitetet i Bergen

Alternative Name(s)
University of Bergen, University of Bergen, Norway, Universitas Bergensis, UiB

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Norway

Funder Name
K.G. Jebsen Centre for Neuropsychiatric Disorders

Funder Name
The Norwegian National Research Network for ADHD

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to limitations in the ethical approval stating that data are only approved for use by project members and registered collaborators.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		09/09/2021	14/01/2022	Yes	No
Results article		26/08/2022	30/08/2022	Yes	No
Protocol file			04/02/2021	No	No