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Comparing the effects of mindfulness-based cognitive therapy and psychoeducational therapy on symptomatology and neurophysiological correlates of adult attention deficit hyperactivity disorder (ADHD)

Submission date
29/06/2012

Recruitment status
No longer recruiting

Registration date
31/07/2012

Overall study status
Completed

Last Edited
20/11/2019

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] 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 mental disorder with symptoms including inattentiveness, hyperactivity and impulsiveness. The symptoms usually improve with age, but many adults continue to experience problems. This study focuses on the effects of two types of psychotherapy for the treatment of adult ADHD. The goal is to assess the effectiveness of a mindfulness-based psychotherapy and compare it to the effectiveness of a psychoeducative psychotherapy.

Who can participate?
Patients aged 18 to 65 with ADHD

What does the study involve?
During the first week of the study, participants complete questionnaires assessing their ADHD symptoms and undergo MRI scans. Over the course of next 8 weeks, participants are randomly allocated to take part in either weekly mindfulness-based psychotherapy or weekly psychoeducative group therapy. After 8 weeks participants complete the questionnaires and undergo MRI scans again. Participants are followed up again after 8 months.

What are the possible benefits and risks of participating?
Potential benefits include the positive effects of psychotherapy specifically for ADHD. Possible risks include side effects of psychotherapy, such as added stress in confronting their symptoms.

Where is the study run from?
University Hospital of Freiburg (Germany)

When is study starting and how long is it expected to run for?
September 2012 to September 2013

Who is funding the study?
University Hospital of Freiburg (Germany)

Who is the main contact?
Dr Alexandra Philipsen

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Study information

Scientific Title
Comparing the effects of mindfulness-based cognitive therapy and psychoeducational therapy on symptomatology and neurophysiological correlates of adult ADHD: a randomized controlled trial

Study objectives
1. Participants in mindfulness-based group psychotherapy for adult ADHD (Zylowska et al., 2008) will show a decrease in the severity of their ADHD symptomatology after treatment in comparison with ADHD symptomatology before treatment.
2. Participants in psychoeducative group therapy for adult ADHD (DAmelio, Retz, Philipsen, & Rösler, 2009) will show a decrease in the severity of their ADHD symptomatology after treatment in comparison with ADHD symptomatology before treatment.
3. Participants in mindfulness-based group psychotherapy for adult ADHD (Zylowska et al., 2008) and participants in psychoeducative group therapy (DAmelio, Retz, Philipsen & Rösler, 2009) will not differ from one another before study treatment with regard to their ADHD symptatomology. After the therapy, participants in mindfulness-based group therapy (Zylowska et. al 2008) will show a greater decrease in the severity of their ADHD symptomatology in comparison with participants in psychoeducative group therapy (DAmelio, Retz, Philipsen & Rösler, 2009).
4. Participants in mindfulness-based group psychotherapy for adult ADHD (Zylowska et al, 2008) and participants in psychoeducative group psychotherapy will not differ from one another

regarding the activation of the caudate nucleus during a Go/no-go task before treatment. After treatment, participants in mindfulness-based group psychotherapy for adult ADHD (Zylowska et al., 2008) will show higher activation in the caudate nucleus during a Go/no-go task in comparison with participants in psychoeducative group psychotherapy (DAmelio, Retz, Philipsen & Rösler, 2009).
5. Participants in mindfulness-based group psychotherapy for adult ADHD (Zylowska et al., 2008) and participants in psychoeducative group psychotherapy (DAmelio, Retz, Philipsen & Rösler, 2009) will not differ from one another before the study treatment in regards to the activation of the default-mode network. After the therapy, participants in mindfulness-based group psychotherapy for adult ADHD (Zylowska et al., 2008) will show lower activation of the default-mode network during the task in comparison with participants in psychoeducative group psychotherapy (DAmelio, Retz, Philipsen & Rösler, 2009).
6. Participants in mindfulness-based group psychotherapy for adult ADHD by Zylowska et al. (2008) will show higher mindfulness scores after the study treatment in comparison to mindfulness scores before the beginning of the study treatment.
7. Participants in psychoeducative group psychotherapy by DAmelio, Retz, Philipsen & Rösler (2009) will not differ before and after the study treatment with regards to self-assessed mindfulness scores.
8. Participants in mindfulness-based group psychotherapy for adult ADHD (Zylowska et al., 2008) and participants in psychoeducative group psychotherapy (DAmelio, Retz, Philipsen & Rösler, 2009) will not differ from each other before the study treatment with regards to their self-assessed mindfulness. After the therapy, the participants in mindfulness-based group psychotherapy for adult ADHD (Zylowska et al., 2008) will show higher self-assessed mindfulness scores than participants in psychoeducative group psychotherapy (DAmelio, Retz, Philipsen & Rösler, 2009).
9. Participants in mindfulness-based group psychotherapy for adult ADHD by Zylowska et al. (2008) will show lower general psychopathology after the study treatment than before the study treatment.
10. Participants in psychoeducative group psychotherapy for adult ADHD by DAmelio, Retz, Philipsen & Rösler (2009) will show lower general psychopathology after treatment than before the study treatment.
11. Participants in mindfulness-based group psychotherapy for adult ADHD (Zylowska et al., 2008) and participants in psychoeducative group psychotherapy (DAmelio, Retz, Philipsen & Rösler, 2009) will not differ from each other before the study treatment with regards to the characteristic of their general psychopathology. After the therapy the participants in mindfulness-based group psychotherapy for adult ADHD (Zylowska et al., 2008) will show lower general psychopathology than participants in psychoeducative group psychotherapy (DAmelio, Retz, Philipsen & Rösler, 2009).
12. Participants in mindfulness-based group psychotherapy for adult ADHD by Zylowska et al. (2008) will show higher quality of life after study treatment than before study treatment.
13. Participants in psychoeducative group psychotherapy for adult ADHD by DAmelio, Retz, Philipsen &Rösler (2009) will show higher quality of life after study treatment than before study treatment.
14. Participants in mindfulness-based group psychotherapy for adult ADHD (Zylowska et al., 2008) and participants in psychoeducative group psychotherapy (DAmelio, Retz, Philipsen & Rösler, 2009) will not differ from each other before the study treatment with regards to self-assessed quality of life. After the therapy the participants in mindfulness-based group psychotherapy for adult ADHD (Zylowska et al., 2008) will show higher self-assessed quality of life than participants in psychoeducative group psychotherapy (DAmelio, Retz, Philipsen & Rösler, 2009).
15. Participants in mindfulness-based group psychotherapy for adult ADHD by Zylowska et al. (2008) will show lower severity of depression after study treatment than before study

treatment.
16. Participants in psychoeducative group psychotherapy for adult ADHD by DAmelio, Retz, Philipsen &Rösler (2009) will show lower severity of depression after study treatment than before study treatment.
17. Participants in mindfulness-based group psychotherapy for adult ADHD (Zylowska et al., 2008) and participants in psychoeducative group psychotherapy (DAmelio, Retz, Philipsen & Rösler, 2009) will not differ from each other before the study treatment with regards to severity of depression. After the therapy the participants in mindfulness-based group psychotherapy for adult ADHD (Zylowska et al., 2008) will show lower severity of depression than participants in psychoeducative group psychotherapy (DAmelio, Retz, Philipsen & Rösler, 2009).
18. Participants in mindfulness-based group psychotherapy for adult ADHD by Zylowska et al. (2008) will show lower nicotine dependence after study treatment than before study treatment.
19. Participants in psychoeducative group psychotherapy for adult ADHD by DAmelio, Retz, Philipsen & Rösler (2009) will show lower nicotine dependence after study treatment than before study treatment.
20. Participants in mindfulness-based group psychotherapy for adult ADHD (Zylowska et al., 2008) and participants in psychoeducative group psychotherapy (DAmelio, Retz, Philipsen & Rösler, 2009) will not differ from each other before the study treatment with regards to nicotine dependence. After the therapy the participants in mindfulness-based group psychotherapy for adult ADHD (Zylowska et al., 2008) will show lower nicotine dependence than participants in psychoeducative group psychotherapy (DAmelio, Retz, Philipsen & Rösler, 2009).
21. Participants in mindfulness-based group psychotherapy for adult ADHD by Zylowska et al. (2008) will show lower caffeine consumption after study treatment than before study treatment.
22. Participants in psychoeducative group psychotherapy for adult ADHD by DAmelio, Retz, Philipsen &Rösler (2009) will show lower caffeine consumption after study treatment than before study treatment.
23. Participants in mindfulness-based group psychotherapy for adult ADHD (Zylowska et al., 2008) and participants in psychoeducative group psychotherapy (DAmelio, Retz, Philipsen & Rösler, 2009) will not differ from each other before the study treatment with regards to caffeine consumption. After the therapy the participants in mindfulness-based group psychotherapy for adult ADHD (Zylowska et al., 2008) will show lower caffeine consumption than participants in psychoeducative group psychotherapy (DAmelio, Retz, Philipsen & Rösler, 2009).
24. Participants in mindfulness-based group psychotherapy for adult ADHD by Zylowska et al. (2008) will show a lesser degree of behavioral addiction after study treatment than before study treatment.
25. Participants in psychoeducative group psychotherapy for adult ADHD by DAmelio, Retz, Philipsen &Rösler (2009) will show a lesser degree of behavioral addiction after study treatment than before study treatment.
26. Participants in mindfulness-based group psychotherapy for adult ADHD (Zylowska et al., 2008) and participants in psychoeducative group psychotherapy (DAmelio, Retz, Philipsen & Rösler, 2009) will not differ from each other before the study treatment with regards to behavioral addiction. After the therapy the participants in mindfulness-based group psychotherapy for adult ADHD (Zylowska et al., 2008) will show lesser degree of behavioral addiction than participants in psychoeducative group psychotherapy (DAmelio, Retz, Philipsen & Rösler, 2009).

Ethics approval required
Old ethics approval format

Ethics approval(s)

Ethics commission of the Albert-Ludwigs-University Freiburg (Ethik-Kommision of the Albert-Ludwigs-Universität Freiburg), 18/06/2012, ref: 240/12

Primary study design
Interventional

Study design
Randomized 2x3 factorial design investigators blind to patient group membership

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Adult attention deficit hyperactivity disorder (ADHD)

Interventions
Intervention 1: Mindfulness-based group psychotherapy for adult ADHD
Duration: 8 weekly meetings, lasting 2.5 hours each

Intervention 2: Psychoeducative group psychotherapy for adult ADHD
Duration: 8 weekly meetings, lasting 2.5 hours each

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. ADHD symptomatology, measured using Conners Adult ADHD Rating Scale-Observer [Inattention Scale (A) and Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) ADHD- Overall Symptoms (G)] in week 0, week 8, and month 8
2. Neurobiological correlates: activity in caudate nucleus measured using functional magnetic resonance imaging (fMRI) in week 0, week 8, and month 8

Key secondary outcome(s)
1. Severity of depression, measured using Beck Depression Inventory II in week 0, week 8, and month 8
2. General psychopathology, measured using Symptom Check List- 90- revised in week 0, week 8, and month 8
3. Quality of life, measured using the German version of Short-Form 36 questionnaire in week 0, week 8, and month 8
4. Mindfulness, measured using the Five-Facet Mindfulness Questionnaire in week 0, week 8, and month 8
5. Nicotine dependence, measured using Fagerström Nicotine Dependence Test in week 0, week 8, and month 8
6. Caffeine consumption, recorded through single item in blind external assessment in week 0, week 8, and month 8
7. Extent of behavioral addiction, recorded through single item in blind external assessment in week 0, week 8, and month 8

Completion date
15/09/2013

Eligibility

Key inclusion criteria
1. Men and women
2. First language German or comparable level
3. At least 18 years old, at most 65 years old
4. Diagnosed with ADHD (through a doctor or psychologist)
5. Wender Utah Rating Scale (WURS)-Score of at least 30
6. Subjects consent in written form
7. Unlimited legal competency

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
81

Key exclusion criteria
1. Following diagnoses: schizophrenia, bipolar disorder, antisocial personality disorder, borderline personality disorder, pervasive developmental disorder/autism, Tourette syndrome, alcohol or drug addiction (misuse, abuse)
2. Suicidality or self-harm
3. Body-Mass Index under 19
4. Pregnancy (first trimester)
5. Metallic implants in body
6. Tattoos
7. Claustrophobia (ICD 10 F40.2)
8. Past or current presence of neurological disease: stroke, epilepsy, dementia
9. Current taking methylphenidate and/or other stimulants
10. Participation in other psychotherapy during the 3 months prior to study treatment
11. Evidence of below-average intelligence measured using the Multiple choice vocabulary intelligence test (Mehrfachwahl-Wortschatz-Intelligenztest) (MWT-B)
12. Patient incapable of acting under law

Date of first enrolment

15/09/2012

Date of final enrolment
15/09/2013

Locations

Countries of recruitment
Germany

Study participating centre
Universitätsklinikum Freiburg
Freiburg
Germany
79104

Sponsor information

Organisation
University Hospital of Freiburg (Universitätsklinikum Freiburg) (Germany)

ROR
https://ror.org/03vzbgh69

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital of Freiburg (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	fMRI results	01/07/2018	26/02/2019	Yes	No
Results article	results	01/06/2018	26/02/2019	Yes	No
Results article	fMRI results	25/01/2019	20/11/2019	Yes	No