Effectiveness of Mindfulness Based Cognitive Therapy in adults with high-functioning autism

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Answering four research questions:• Do adults with ASD report less complaints of depression after the mindfulness training when compared to prior the training?• Do adults with ASD have significant deviant patterns in neurometric data including EEG...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Developmental disorders NEC
Study type	Interventional

Summary

ID

NL-OMON32624

Source
ToetsingOnline

Brief title
mindfulness and autism

Condition

- Developmental disorders NEC

Synonym
autism, autism spectrum disorder

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Eindhoven (Eindhoven)
Source(s) of monetary or material Support: ZonMW (aangevraagd)

Intervention

Keyword: Autism, Mindfulness, Neurometry, Treatment

Outcome measures

Primary outcome

Depressive complaints: SCL-90 scores

Sensory processing:AASP scores

mindfulness skills: FFMQ scores

interpersonal functioning and functioning in society : OQ-45 scores

neurometric measures:

* quantitative EEG (qEEG); spectral parameters; coherence measures

* Event Related Potentials measures: latency/amplitude N2/P3 components

* neuropsychological measures (reaction times, error rates etc.)

* autonomous nervous system measures (heart rate variability, electrodermal

activity)

Secondary outcome

N/A

Study description

Background summary

Adults with autism spectrum disorder (ASD) experience often and much psychological problems in social life. This frequently leads to depressive symptoms. Moreover, adult ASD patients often suffer from sensory overload. To date, no scientific studies have been published on how to adequately treat these serious problems in ASD patients. However, there is literature that indicates that Mindfulness treatment can achieve positive results in other patient groups suffering from depression. The current project aims at evaluating the effect of Mindfulness Based Cognitive Therapy (MBCT) in adult

ASD patients. For this purpose, neuropsychological tests and questionaires will be used as well as measurement of neurometric variables such as quantitative EEG (qEEG) measures, Event Related Potentials, heart rate variability and electrodermal activity. As reference, the same measurements will be done in a control group of neurotypical volunteers.

Study objective

Answering four research questions:
• Do adults with ASD report less complaints of depression after the mindfulness training when compared to prior the training?
• Do adults with ASD have significant deviant patterns in neurometric data including EEG during rest and during task performance and ERPs when compared to an age-matched neurotypical control group
• Are adults with ASD less oversensitive to sensory stimuli after MBCT training when compared to prior the training
• Do adults with ASD show less deviant neurometic characteristics after the mindfulness training when compared to prior the training.

Study design

This is a cross-over study where three patient groups, each comprising of 15 participants undergo the same protocol:
1) a baseline measurement/recording (M0)
2) a second measurement/recording (M1)
3) start of the MBCT directly after M1
4) MBCT during 9 weeks
5) third measurement/recording after end of the training (M2)
Start of the protocol for each of the patient groups is 9 weeks apart from each other.
In addition, the measurement/recording protocol is applied in a healthy controls group of 15 age and gender matched volunteers at the beginning of the project.

Intervention

individual weekly MBCT sessions (2 hrs). Client has to excercise at least 6 days/wk

Study burden and risks

Risks: not applicable

All treatment groups:
* questionaires: reference (null) recording: 1 hour; pre-recording: 1 hour; final recording: 1 hour

* training MBCT: 9 weekly sessions; each 2.5 hours
* home exercises MBCT: 9 weeks, 6 days/week, 1 hour /day

Additional burden for participants in the extended protocol (incl neurometry):
* initial recording: 1 hour neurometric recordings
* effect recording: 1 hour neurometric recordings

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Treatment groups meet DSM-IV/TR and ADI-R criteria for autistic disorder or Asperger disorder. Age 18-60. WAIS-III IQ score >85. Suffer from depressive complaints and/or sensory over-excitability

Control group: matched on gender and age.

Exclusion criteria

Treatment group: no comorbid neuropsychiatric disorders such as substance abuse, epilepsy, neuropathologies
Control group: no known neuropsychiatric disorders such as depression, addiction, epilepsy, neuropathology; use of psycho-active medication.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-01-2010
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	28-10-2010
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL29437.097.09