

Towards an individualized treatment of patients with disorders of aggression regulation; endophenotypes of aggressive behavior.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Personality disorders and disturbances in behaviour
Study type	Observational invasive

Summary

ID

NL-OMON38824

Source

ToetsingOnline

Brief title

Endophenotypes of Aggressive Behavior

Condition

- Personality disorders and disturbances in behaviour

Synonym

aggression regulation disorder, Intermittent Explosive Disorder

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: NWO

Intervention

Keyword: aggression, genetics, psychopathy, treatment responsiveness

Outcome measures

Primary outcome

The main outcome of aggressive behavior will be the score on the Modified Overt Aggression Scale for Outpatient Use (MOAS) and the Social Dysfunction and Aggression Scale (SDAS), which will be completed by the patient, and the Clinical Global Impression Scale for severity (CGI-s). Efficacy measures will be assessed at baseline, 6 and 12 weeks. A decrease of aggression of 50% on the MOAS and/or SDAS will be considered as a response to treatment, a decrease between 20% and 50% as a partial response and a decrease of less than 20% will be considered as a non response.

Secondary outcome

n.v.t.

Study description

Background summary

Inappropriate aggressive behavior poses a great burden on society and is the main reason for referral to a forensic psychiatric setting. Interventions based on principles of cognitive behavioral therapy (CBT) are the treatment of choice. Although CBT has been shown (moderate) effectiveness in the treatment of aggressive behavior in adolescents, little is known about the effectiveness in adults and it is clear to only a subgroup of patients benefits. The question is: what are the characteristics of those who are responsive to the therapy? Therefore, in the present study individual characteristics of patients with aggression regulation problems will be investigated and related to outcome of

therapy.

Study objective

Main: The primary objective of this study will be to discover patients* characteristics that predict the outcome of *Aggression Replacement Therapy*. Our main question of enquiry here is: what profiles regarding aggressive behavior and correlates relating to aggressive behavior can be found among responders and non responders? A profile will be based on the following variables of interest: type of aggression (proactive vs. reactive), psychological traumas in childhood and MAOA genotype.

Secondary: A secondary objective will be the evaluation of associations between type of aggression, psychological traumas in childhood, cognitive characteristics and MAOA, COMT and 5/HTTLPR genotypes within patients with aggression regulation disorders.

Study design

Cross-sectional treatment efficacy study among patients with aggression regulation disorders in a forensic psychiatric outpatient setting.

Study burden and risks

Burden has been kept to a minimum and no risks are involved in participation. Therapy will be given once a week during a 10/12 week treatment phase. All participants will be asked to fill in a number of questionnaires before treatment phase for the benefit of the main and secondary objectives. At the endpoint a number of questionnaires will be repeated. Previous efficacy studies have pointed out that quality of life of aggressive individuals improves due to this intervention: less contacts with judicial services or reduction of convictions, inclusion in work trajectories.

Contacts

Public

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Age 18-55 years
- Men and women
- Outpatient
- Meeting DSM-IV criteria for antisocial personality disorder, borderline personality disorder or the integrated research criteria for Intermittent Explosive Disorder (IED-IR):
 - Recurrent incidents of aggression manifest as either;
Verbal or physical aggression towards other people, animals, or property occurring twice weekly
on average for one month, or
 - Three episodes involving physical assault against other people or destruction of property over one-year period
 - The degree of aggressiveness expressed is grossly out of proportion to the provocation or any precipitating psychosocial stressors
 - The aggressive behavior is generally not premeditated (e.g., is impulsive) and is not committed in order to achieve some tangible objective (e.g., money, power, intimidation, etc.)
 - The aggressive behavior causes either marked distress in the individual or impairment in occupational or interpersonal functioning
 - The aggressive behavior is not better accounted for by another mental disorder (e.g., Major Depressive/Manic/Psychotic Disorder; ADHD); General Medical Condition (e.g., Head Trauma, Senile Dementia Alzheimer*s Type); or to the direct physiological effects of a substance
- Score on Overt Aggression Scale-Modified for Outpatient Use (MOAS) of ≥ 15 and/or a score of ≥ 5 on the Social Dysfunction Aggression Scale (SDAS)

Exclusion criteria

- Lifetime history of (hypo)mania, schizophrenia, or delusional disorder
- Current major depression
- Current alcohol or substance dependence
- Starting or changing pharmacotherapy relating to aggressive behavior

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 17-06-2013

Enrollment: 154

Type: Actual

Ethics review

Approved WMO

Date: 10-05-2013

Application type: First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date: 21-01-2014

Application type: Amendment

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL43642.091.13