Aggression Replacement Training (ART) for aggression-regulation disorders in adults: a randomized, controlled out-patient study

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The primary objective of the present study is to evaluate the effectiveness of the Aggression Replacement Training (ART) on aggression regulation disorder in a forensic psychiatric outpatient setting.A secondary objective is to examine how treatment...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Impulse control disorders NEC
Study type	Interventional

Summary

ID

NL-OMON35485

Source
ToetsingOnline

Brief title
Agression Replacement Training for adults

Condition

- Impulse control disorders NEC

Synonym
antisocial personality disorder, borderline personality 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, Aggression Replacement Training(ART)

Outcome measures

Primary outcome

The main outcome of aggressive behavior will be the score on the Overt Aggression Scale-Modified for Outpatient Use (MOAS) and Social Dysfunction and Aggression Scale (SDAS). The MOAS and SDAS will be completed by different relevant informants. A decrease of 50% on one of the questionnaires counts as a response to treatment, a decrease between 20-40% as a partial response and a decrease below 20% as a non response.

Secondary outcome

During the pre-screening, the MOAS will be completed to examine if the participant meets the inclusion criteria. To examine if the participant does meet the inclusion and does not meet the exclusion criteria the M.I.N.I., SCID-II, CIDI, PPI, EuropASI and NLV will be completed during the screening. For the baseline and follow-up measure of the interventions, the IOA will be conducted to measure social skills. The IPAS, RPQ, AQ, ZAV, SECS and PSAP will be used to measure the effect of the Anger Control Training. To assess the moral reasoning, the SRM-AV and HIT will be conducted. In addition, neurocognitive tasks will be conducted to include how responders and non-responders profiles relate to forms and correlates of aggressive behaviour.

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. Behavioral therapy like Aggression Replacement Training (ART) has been shown to be effective in the treatment of aggressive behavior in adolescents. However, little is known about the effectiveness of ART in adults. The efficacy of these interventions for aggression need to be examined in relation to specific types of aggressive behaviors (i.e. reactive vs. proactive).

Study objective

The primary objective of the present study is to evaluate the effectiveness of the Aggression Replacement Training (ART) on aggression regulation disorder in a forensic psychiatric outpatient setting.
A secondary objective is to examine how treatment responder and non-responder profiles relate to contemporary dichotomized forms and correlates of aggressive behavior (i.e. proactive vs. reactive).

Study design

Randomized controlled multi-centre treatment efficacy study among patients with aggression regulation disorder in a forensic psychiatric outpatient setting.

Intervention

Patients will be randomly assigned to an ART-intervention group and a control group. The intervention group receives 18 sessions of ART over a period of 18 to 19 weeks. The control group receives over the same period treatment as usual (i.e. individual contacts on a regular base that is not related to their aggression regulation disorder or other treatments). After the control group have completed this research, they will receive the ART. This data will not be collected

Study burden and risks

Burdens and risks for participation to this study have been kept to a minimum. Training (ART) will be given once a week during a 18 to 19 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. The experimental conditions are similar to clinical practice and the extent of burden for participants of the study is not significantly other than in clinical practice

except a few more questionnaires. Previous efficacy studies have pointed out that quality of life of aggressive individuals improves due to these interventions: less contacts with judicial services or reduction of convictions, inclusion in work trajectories.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Reinier Postlaan 10
6500 HB Nijmegen
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Reinier Postlaan 10
6500 HB Nijmegen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Meeting DSM-IV criteria for antisocial personality disorder, borderline personality disorder or the integrated research criteria for Intermittent Explosive Disorder (IED-IR):

Exclusion criteria

Lifetime history of (hypo)mania, schizophrenia, or delusional disorder

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-01-2012
Enrollment:	66
Type:	Anticipated

Ethics review

Approved WMO Date:	17-04-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-07-2012
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

ID: 25956
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL38040.091.11
OMON	NL-OMON25956