Effective treatment of adolescents with aggression problems in clinical and non clinical settings

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Main: to examine the comparative and combined effects of aggression replacement training (ART) and Risperidone on aggressive behaviours among adolescents with aggression problems ages 14-21 across clinical and non clinical settingsSecondary: to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Psychiatric and behavioural symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON36647

Source
ToetsingOnline

Brief title
Treatment of Aggression / TOA

Condition

- Psychiatric and behavioural symptoms NEC
- Legal issues

Synonym
Aggressive behaviour among adolescents with externalising behaviour problems DSM-IV: Conduct disorder (314.9), Disruptive behavior disorder not otherwise specified (312.9) Intermittent explosive disorder (312.34), Oppositional defiant disorder (313.81)

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Aggression replacement training, overt aggression, proactive aggression, reactive aggression, risperidon, Treatment response profiles

Outcome measures

Primary outcome

A % decrease in severity and frequency of aggressive behaviour as observed on the Modified Overt Aggression scale, completed by at least two different informants at baseline and after the intervention period (including follow up measurements after three and six months. A decrease of 40% counts as a response to treatment, between 20-30% decrease as a partial response and a decrease below 20% as a non response.

Secondary outcome

We aim to compare the profiles of treatment responders, non-responders and drop outs in relation to across various contexts (schools, centre for Orthopsychiatry and residential youth care agency). Our main question of enquiry here is: what profiles regarding aggressive behaviour and correlates relating to aggressive behaviour can be found among responders and non responders?

It is hypothesised that non responder profiles to both treatment conditions show lower moral reasoning levels, higher levels of impulsiveness, pro active aggression, cognitive distortions relating to aggressive behaviour and

delinquency and higher levels of callous unemotional traits at baseline.

Study description

Background summary

The focus in efficacy studies of treatment of aggression problems has mostly been on recidivism rates of criminal acts in judicial terms (i.e. convictions) and not so much on changes in aggressive behaviour. Risperidone and Aggression replacement training (ART) have been found to be effective in numerous studies. However there is little to no knowledge of the comparative or combined effects of Risperidone and ART in relation to aggression among specific groups. The efficacy of these interventions for aggression need to be examined in relation to specific types of aggressive behaviours (i.e. impulsive vs. premeditated) and among both responders and non-responders in various settings: schools, outpatient, inpatient clinics and residential youth facilities. The present study aims that by including a relatively broad group of subjects and by conducting follow up measurements among responders and non responders, efficacy questions will be answered from a real world perspective.

Study objective

Main: to examine the comparative and combined effects of aggression replacement training (ART) and Risperidone on aggressive behaviours among adolescents with aggression problems ages 14-21 across clinical and non clinical settings
Secondary: to examine how treatment response and non responder profiles relate to contemporary dichotomized forms and correlates of aggressive behaviour (i.e. pro active vs. Reactive, cognitive distortions), location where the treatment is offered

Study design

Ranomized (open label) treatment efficacy design with three treatment condtions: ART, Risperidone and a combination of both

Intervention

One group receives 30 sessions of Aggression replacement training (ART) over a period of 15 weeks, another receives Risperidone daily doses from 0.5 to 2 mg. A third group receives a combination of both treatments. In the case that the demand outweighs the supply of the interventions at the study sites fourth Waitlist control condition is used at the sites for the duration of the treatment period. After which participants select one of the treatment

conditions they want to participate in.

Study burden and risks

Burdens and risks for participation to this study have been kept to a minimum. Most questionnaires are completed by parents or care givers, to avoid the participant being to burdened with this. Previous efficacy studies have pointed out that aggressive individuals quality of life improves due to these interventions: less contacts with judicial services or reduction of convictions, inclusion in work school trajectories. Blood samples and physical examination will only be applied to participants in the two treatment arms with medication according to international consensus before start of the medication and after three month of usage. A physical examination including taking a medical history takes place before start of medication including an electrocardiogram (if indicated). During the treatment phase physical examinations including heart rate, blood pressure, length, weight and waistline takes place every of the six visits and two times during the follow up phase. All efforts are according to international consensus and best clinical practise. Training (ART) will be given two times a week during a 15 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. During treatment phase no further questionnaires will be handed out. At the endpoint very few questionnaires will be repeated. All questionnaires are listed below. The experimental conditions are similar to clinical practise and the extent of burden for participants of the study is not significantly other than in clinical practise except a few more questionnaires

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Full scale IQ >= 80 ; PIQ >= 75 en VIQ >= 80.
-Minimal score on MOAS of 5 on both initial screenings
-Age lies between 12 and 18 years
-(Psychiatric) Medication free at beginning of the screening procedure.
-Minimal motivation among participant and family
-Reading level of Avi 6 or 7.
-Clinical diagnosis of 'Oppositional defiant disorder' or 'Conduct disorder'

Exclusion criteria

- Previous ART or Risperidone (6 months)
- Psychotic condition
- Severe depression
- Severe substance dependency
- Suicidal tendencies
- Pregnancy or lactation
- Major medical problems
- Epilepsy
- Cardiovascular diseases
- Regular medication which strongly interacts with Risperidone
- Unable to sign informed consent

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):	19-10-2011
Enrollment:	168
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	risperidone
Generic name:	risperidone
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	24-05-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date:	26-04-2012
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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2009-018239-95-NL
ISRCTN	ISRCTN21681959
CCMO	NL33231.091.10