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

Submission date	Recruitment status	[X] Prospectively registered
22/01/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
06/04/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/07/2010	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
III.04.1001

Study information

Scientific Title
Effective treatment of adolescents with aggression problems in clinical and non-clinical settings: a multicentre randomised treatment efficacy trial

Acronym
TOA

Study objectives
Primary:
To examine the comparative and combined effects of aggression replacement training (ART) and risperidone on aggressive behaviours among adolescents with aggression problems aged 12 - 21 years across clinical and non-clinical settings.

Secondary:
To examine how treatment response and non-responder profiles relate to contemporary dichotomised forms and correlates of aggressive behaviour (i.e. pro-active versus reactive, cognitive distortions), location where the treatment is offered.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Board CMO Arnhem/Nijmegen, pending approval as of 22/01/2010

Study design
Multicentre randomised treatment efficacy trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Aggression regulation problems

Interventions
Patients are randomised to one of three treatment groups:
1. 30 sessions of aggression replacement training (ART) over a period of 14 weeks
2. Risperidone daily doses from 0.5 to 2 mg
3. Combination of both treatments

Treatment:
In the treatment phase, subjects will receive 14 weeks of each of the treatment conditions. After the treatment phase assessment of quantity, typology and severity of aggressive behaviour is conducted again, as well as the secondary outcome variables regarding the social background and clinical symptoms, social skills, aggressive thoughts and thinking styles.

Follow up:
After a period of three months and again at six months follow up measurements are conducted relating to our primary hypothesis. Medication is continued during these 6 months. Participants which have not responded to either or both of the treatment conditions are offered other treatments or are referred to the health care services which suit the problems and demand of the participants at that time.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
A % decrease in severity and frequency of aggressive behaviour as observed on the MOAS, 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.

Key secondary outcome(s))
1. Impulsive-Premeditated Aggression Scale (IPAS) at pre-screening, and week 15
2. Clinical Global Impression 'Severity of Illness' (CGI-S) Scale at screening and week 15
3. REactive-PROactive Aggression Questionnaire (REPRO) (for parents, teachers, nurses or pedagogical workers) at screening and week 15
4. Instrument for Reactive and Proactive Aggression (IRPA) at screening and week 15
5. How I Think (HIT) questionnaire at screening and week 15
6. Social Support Questionnaire (SSQ) at screening and week 15
7. Socio-moral Reflection Objective Measure-Short Form (SROM-OSF) at screening and week 15
8. Inventory of callous-unemotional traits (ICU) at screening and week 15
9. Reactive-Proactive Aggression Questionnaire (RPQ) (for youths) at screening and week 15

Completion date
01/12/2011

Eligibility

Key inclusion criteria
1. Full scale intelligence quotient (IQ) at least 80; total IQ (TIQ) less than 75, verbal IQ (VIQ) at least 80
2. Minimal score on Modified Overt Aggression Scale (MOAS) of 5 on both initial screenings
3. Age lies between 12 and 21 years, either sex
4. (Psychiatric) medication free at beginning of the screening procedure
5. Minimal motivation among participant and family
6. Reading level of Avi 6 or 7

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria
1. Previous ART or risperidone (6 months)
2. Psychotic condition
3. Severe depression
4. Severe substance dependency
5. Suicidal tendencies
6. Pregnancy or lactation
7. Major medical problems
8. Epilepsy
9. Cardiovascular diseases
10. Regular medication which strongly interacts with risperidone
11. Unable to sign informed consent

Date of first enrolment
01/07/2010

Date of final enrolment
01/12/2011

Locations

Countries of recruitment
Netherlands

Study participating centre
Vluchtheuvellaan 6
Zetten
Netherlands
6670 AC

Sponsor information

Organisation
Karakter - Child and Adolescent Psychiatry (Netherlands)

ROR
https://ror.org/044jw3g30

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Karakter - Child and Adolescent Psychiatry (Netherlands)

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes