ISRCTN21681959 https://doi.org/10.1186/ISRCTN21681959

# 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please contact Mr Tim Tiemissen [t.tiemissen@karakter.com] for more information

## 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 measure
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.

### Secondary outcome measures
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

### Overall study start date
01/07/2010

### 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

### Age group
Other

### Sex
Both

### Target number of participants
30 per treatment condition, total 120

### 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
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6670 AC

# Sponsor information

**Organisation**
Karakter - Child and Adolescent Psychiatry (Netherlands)

**Sponsor details**
Horalaan 5
Ede
Netherlands
6717 LX

**Sponsor type**
Hospital/treatment centre

**Website**
http://www.karakter.com

**ROR**
https://ror.org/044jw3g30

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Karakter - Child and Adolescent Psychiatry (Netherlands)

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

## IPD sharing plan summary

Not provided at time of registration