Auditory Verbal Hallucinations in Children and Adolescents

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Disturbances in thinking and perception
Study type	Observational non invasive

Summary

ID

NL-OMON41367

Source
ToetsingOnline

Brief title
AVH in Youth

Condition

- Disturbances in thinking and perception

Synonym
acoustic hallucinations, hearing voices

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: VIDI Prof. Dr. I.E.C. Sommer

Intervention

Keyword: adolescents, auditory, children, hallucinations

Outcome measures

Primary outcome

Main study end point is presence of AVH at follow-up.

Secondary outcome

Secondary endpoints are persistence of AVH and stress and dysfunction at

follow-up.

Study description

Background summary

Auditory verbal hallucinations (AVH) are common in children and adolescents among the general population. In the majority of children AVH are transient, but they can be associated with substantial suffering and problem behaviour. In most children, the AVH will disappear within a few years. However, the persistence of AVH is associated with lower cognitive abilities as well as the development into more severe psychiatric disorders. Currently, it is unclear which factors predict development and persistence of AVH and which factors determine associated suffering and dysfunction in youth with AVH.

Study objective

The major aim of this study is to reveal biological, psychological and social factors that predict development of AVH in youth. A second aim is to reveal which factors determine and predict percistence of AVH and associated distress and dysfunction in youngsters with AVH. Comparing children with AVH to their unaffected siblings provides the assessment of protecting factors against the development of hallucinations.

Study design

In this longitudinal observational study, assessment at baseline includes questionnaires, structured clinical interviewing, physical examination and neuropsychological tests. All participants will receive re-assessments one, three and five years after inclusion. Neuropsychocological tests will only be

assessed at baseline and at 5-year follow up.

Study burden and risks

All participating youngsters and their parents will be asked to fill in the questionnaires about the child and theirselves either at home or during the hospital visit, taking up to a total maximum of 55 minutes per child en 85 minutes for parents. Baseline and follow-up visits include screening for trauma and life events (15min.) and a general physical examination (5min.) for all children. Patients will also recieve an psychiatric evaluation (K-SADS 90min.) and assessment of AVH characteristics (PSYRATS 20min). Testing of neuropsychological functions (WISC or WAIS) will only be assessed at baseline and at five year follow up and will take up to 90 minutes. Participants may experience benefits from our study. We will perform a secure psychiatric en (neuro)psychological check-up. Children and their parents will obtain feedback on the results. If the results point out that an intervention is indicated, treatment will be arranged at our Voices Clinic without delay. All participants and their parents will be informed on the associated risks of drug abuse for these vulnerable children. For the comparison group, which consists of unaffected siblings, baseline and follow up assessment ensures early detection and, when indicated, treatment.
The results of the proposed study will enable the selection of those individuals with AVH at high risk for persistence of AVH and development of psychopathology. These individuals can be offered early intervention, while the youngsters with AVH without risk factors need not be bothered with hospital visits.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- between 8-18 years of age
- for the experimental group: auditory verbal hallucinations at least once a month
- provide written informed consent (by child and parents/care-takers)
- Dutch speaking
- IQ > 70

Exclusion criteria

Geen.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2014
Enrollment:	316
Type:	Actual

Ethics review

Approved WMO Date:	04-03-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	14-09-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL45710.041.13