Sensory gating and trait anxiety in people with psychotic symptoms.

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Do patients with (recent onset, medicated) psychotic disorder (PDM), in persons at ultra high risk for later psychosis (UHR), in patients with schizophrenia who do not use anti-psychotics anymore (PDUM) report higher levels of trait anxiety (...

Ethical review	Approved WMO
Status	Pending
Health condition type	Schizophrenia and other psychotic disorders
Study type	Observational invasive

Summary

ID

NL-OMON36333

Source
ToetsingOnline

Brief title
Sensory gating and trait anxiety in people with psychotic symptoms.

Condition

- Schizophrenia and other psychotic disorders

Synonym
mental disorder with hallucinations and delusions, psychotic disorder

Research involving
Human

Sponsors and support

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

Intervention

Keyword: PPI, psychotic symptoms, sensory gating, trait anxiety

Outcome measures

Primary outcome

Trait anxiety is measured by self-rating lists STAI DY and BIS/ BAS. Sensory motor gating is measured by Pre Pulse Inhibition of the Acoustic Startle Reflex recorded by electro myograhpic recordings of the orbicularis oculi muscle through dermal electrodes.

Secondary outcome

Possible influence of age, hormonal cycle in females, medication and smoking behaviour are assessed through demographic information list that participants are requested to fill in. Female hormonal influences are also measured by levels of estradiol and progestron determined from bloodsample.

Study description

Background summary

Impairment in information processing is a central problem in patients with schizophrenia. Dysfunction in sensory motor gating is considered an operational measure of information processing. In patients with schizophrenia, dysfunction in sensory motor gating has been frequently described in terms of a breakdown of an attentional filter and as impaired selective attention. Impairments in sensory filters are found in patients with schizophrenia as well as in their non-affected siblings and in persons with prodromal symptoms (Braff et al. 1978, 1992; Dawson et al. 1993, Grillon et al. 1992; Kumari et al, 2005; Quednow et al., 2008). In human subjects, sensory motor gating is usually studied using the eye-blink response of the startle reflex. The contraction of the eye muscle on a loud auditory, visual/ tactile stimulus (the startle reflex) is recorded by an electric myograph through dermal electrodes. When the startling stimulus is preceded by a relatively weak (non-startling) tone, a normal diminishing of the intensity of the startle response, called prepulse

inhibition (PPI) is expected.
Interest in the prodromal stage of schizophrenia, the period directly preceding the onset of psychosis, has undergone dramatic increase over the past decade. The prodromal stage can be defined as the stage of schizophrenia that begins with the first changes in behaviour and lasts up until the onset of the first psychotic episode (McGorry et al., 1995). The prodromal period can be characterized by various mental state features, including non-specific symptoms such as depressed mood and anxiety as well as sub-threshold or attenuated psychotic symptoms (Yung AR and McGorry, 1996). Presence of certain *basic symptoms*, like subjective disturbance of attention, thinking, perception, speech and motor action, have also been described (Yung et al., 2003). One important aspect of the prodrome is that it is a period in which intervention could occur if it would be recognised prospectively. The retrospective term *prodromal* therefore cannot appropriately be used in prospective investigations. After all, it is only after someone has a full-blown psychosis one can say with certainty that the symptoms were prodromal. Instead of putatively prodromal the subjects are referred to as ultra high risk (UHR).
Research using PPI has shown that sensory motor gating is affected by several modulating factors such as sex, age, smoking, psychotic symptoms and anti-psychotic medication. (Swerdlow et al, 1995; Kumari, Checkley and Gray, 1996; Dawson et al.; 2000; Kumari, Soni and Sharma, 2001; Kumari, Aasen and Sharma, 2004; Kumari et al., 2010). Some findings in the literature also suggest that emotionional state or trait may similarly affect PPI. (Corr, Tynan and Kumari, 2002; Ludwig et al., 2002).
For people who have unpleasant and threatening experiences like psychotic symptoms it is normal to respond with anxiety. However several studies showed that the tendency to react with anxiety, (defined as high-trait anxiety/ neuroticism) is related to the severity of psychotic symptoms in healthy controls, people who later became psychotic and in patients with schizophrenia. (van Os & Jones, 2001; Goodwin, Fergusson & Horwood, 2003; Camisa et al., 2005;).
A number of lines of evidence point to a role for emotion in sensory motor gating (Swerdlow et al, 1994, Ludewig et al., 2002, Corr, Tynan and Kumari, 2002; Franklin et al., 2009) For example Swerdlow et al. (1994) and Hoenig et al. (2005) found that patients with obsessive-compulsive disorder show weaker PPI than normal individuals. Ludewig et al. (2002) found a negative relationship between trait anxiety and PPI in persons with a panic disorder. Knowledge about the relationship between the proneness to worry and experience anxiety (as measured with STAI-DY and BIS/BAS) and sensory motor gating (as measured with PPI) in both people at UHR as in patients diagnosed with a psychotic disorder may be of use in understanding dysfunction in sensory motor gating in complex disorders like schizophrenia.

Study objective

Do patients with (recent onset, medicated) psychotic disorder (PDM), in persons at ultra high risk for later psychosis (UHR), in patients with schizophrenia

who do not use anti-psychotics anymore (PDUM) report higher levels of trait anxiety (measured by STAI-DY and BIS/BAS) compared to controls with no family history for psychosis? Is trait anxiety associated with dysfunction in sensory motor gating, measured by prepulse inhibition of the acoustic startle reflex in these groups? Is antipsychotic medication of influence on the relation between trait anxiety and PPI? Does the relationship between trait anxiety and PPI differ between man and women. The answer to this question may give more insight into differential symptomatology and its relationship to measures of attentional function in subgroups of patients (at ultra high risk of) a psychotic disorder. When subgroups with high trait anxiety related to PPI disturbances are found, the next step could be to study interventions aimed at these specific problems.

Study design

This is a cross sectional study consisting of 3 independent samples. The first sample consist of males and females at ultra high risk for developing a psychosis (UHR). UHR subjects are defined as persons who have had no previous psychotic episode for more than one week. In addition, each subject had to fall into one or more of the following groups: 1. Familial risk plus reduced functioning: Individuals with a DSM-IV schizotypal personality disorder or a first-degree relative with a history of any DSM-IV psychotic disorder and a change in mental state or functioning in the individual leading to a reduction of 30 percent or more on the Global Assessment of Functioning (GAF) Scale. A *best estimate* derived from an independent interview with the subject and a close relative, mostly one of the parents, defines the initial baseline of functioning. 2. Attenuated psychotic symptoms: Presence of at least one of the ultra high risk symptoms as assessed with the Structured Interview for Prodromal Symptoms (SIPS) (18). The SIPS is a comprehensive diagnostic tool designed specifically for the assessment of the whole spectrum of prodromal signs and symptoms. The scale is composed of 19 items (5 positive, 6 negative, 4 disorganization, 4 general symptoms) each of which is given a score of 0 to six according to defined criteria. A score between 3 and 5 on the positive symptoms indicates attenuated psychotic symptoms and a score of 6 indicates a psychotic state. These symptoms should occur at least several times a week and should have been present for at least one week. 3. Brief, limited or intermittent psychotic symptoms (BLIPS): a score of six on one of the positive items of the SIPS, with duration of less than one week and spontaneous remission. 4. Basic symptoms: At least two self-perceived deficiencies of cognition or perception: basic symptoms assessed with the Bonn Scale for the Assessment of Basic Symptoms - Prediction List (BSABS-P) (19). The BSABS-P contains 17 selected self-perceived disturbances in cognition and perception that were found to be predictive for a transition to psychosis over a 10 year period. Each basic symptom is given a score of 0 to 6 according to frequency of occurrence. A score of 3 or more on at least 2 of the first 9 items also indicates an UHR state and makes the subject eligible for the study.
The second sample consists of patients with a recently developed psychotic

disorder. The third sample consists of healthy controls with no family history of psychosis who are recruited for this study.

Study burden and risks

Participants will be informed about the procedure. It will be mentioned that the startling tone is usually experienced as unpleasant but not painful. A headphone, connected to the PPI program on the computer, will be applied on the head of the participant. The skin around the right eye is cleaned with alcohol 70%. Two electrodes will be attached to the skin around the right eye (on the eye muscle) with stickers. Another electrode is placed on the bone behind the right ear. To inform participants they will hear the background noise and the startling tone for a brief moment before the start of the trial. Participants are asked to sit at ease, to look out of the window to the wall in opposite of the test room for the duration of the test. For 12 minutes participants will hear alternately the background noise and the startling tone. After the PPI procedure the participants are requested to fill in self-rating lists (demographic information, information about hormonal cycle in females, STAI DY, BIS/BAS)); the self rating lists will take about 15 minutes. Via venapunction a bloodsample of 7 ml will be collected.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

a. Persons who have had no previous psychotic episode for more than one week and spontaneous remission. In addition, each person falls into one or more of the following groups: 1. Familial risk plus reduced functioning: leading to a reduction of 30 percent or more on the Global Assessment of Functioning (GAF) Scale. 2. Attenuated psychotic symptoms: Presence of at least one of the ultra high risk symptoms as assessed with the Structured Interview for Prodromal Symptoms (SIPS): a score between 3 and 5 on the positive symptoms indicates attenuated psychotic symptoms and a score of 6 indicates a psychotic state. age 18-30
b. patients with a recently developed psychotic disorder, age 18-30
c. participants with no family history of psychosis , age 18-30

Exclusion criteria

exclusion criteria for controls: family history for psychosis.
Psychotic symptoms due to an organic etiological factor.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2010

Enrollment:	120
Type:	Anticipated

Ethics review

Approved WMO Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL31373.018.10