The Correlations Between Fluctuations in Anxiety Symptoms and Heart Rate Variability in Patients With Panic Disorder Combined With Agoraphobia: Application of Time Series Analysis in Individual Treatment

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By achieving multiple measurements of ambulatory HRV and anxiety symptoms in one individual agoraphobia patient during a standard treatment at the University Center for Psychiatry (UCP), we will investigate how the bidirectional causal relations...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Anxiety disorders and symptoms
Study type	Observational non invasive

Summary

ID

NL-OMON37166

Source
ToetsingOnline

Brief title
Fluctuations in Agoraphobia

Condition

- Anxiety disorders and symptoms

Synonym
agoraphobia, fear of open spaces

Research involving

Human

Sponsors and support

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

Intervention

Keyword: Agoraphobia, Anxiety symptoms, Fluctiations, Heart rate variability

Outcome measures

Primary outcome

With regular time intervals, patients will be asked to fill out a ranking scale

on the following subjects in their diary;

- Anxiety

- Self-esteem

- The frequency of panic attacks and exposure (will only be asked at the end of

the day)

- With whom the patients were

- Where they were

- Stressful events (if applicable)

The physical activity and heart activity will be recorded by an accelerometer

and an ambulatory ECG device. The ECG device should be carried 24h a day for

two week in total: one week before and one week after the treatment.

Secondary outcome

not applicable

Study description

Background summary

Panic disorder is a common psychiatric disorder. The lifetime prevalence is 2.1% and 12-months prevalence is 1.2%, women are 1.5 to 3 times more affected then men, besides that panic disorders are responsible for 2,6% of all the absence of work. There seems to be a bimodal distribution of prevalence with age, one peak in late adolescence (15 - 19 years) and a second peak later in life (35 - 50 years) 5. Patients that develop a panic disorder during adolescence have an increased risk of acquiring a depressive disorder, other psychiatric comorbidity and even suicide.
Patients with a panic disorder present themselves with episodes of intense anxiety. These episodes are attended by physical symptoms such as chest aches, sweating and shortness of breath. Because most patients believe that these complaints are caused by heart failure (catastrophic cognitions), they often visit the emergency room.
Patients have multiple panic attacks a week; this causes the patient to worry about the future, when and where the next attack will occur. When this leads to phobic avoidance behaviour for situations that could possible provoke an attack, the patient has agoraphobia. Agoraphobia can lead to severe social restriction, because patients sometimes are too afraid to use public transport or even too afraid to leave the house3. This gives patients with agoraphobia three kinds of fear. First there is the panic attack itself. Second there is anticipation fear, in which the patients is afraid of a situation that is about to come. And the third kind of fear is when the patient is exposed to what he*s afraid of, called exposure. So on the one hand, there is the fear of a sudden panic attack, and on the other hand there is fear for when the next attack will be. This gives strong fluctuations in anxiety, with a lot of individual differences in these fluctuations.
Knowledge about the underlying mechanisms for the fluctuations in anxiety symptoms can contribute to the knowledge about the panic attack itself, but can also provide the foundation for new, different kind of treatments. A possible measure that has been related to both psychological as physical health complaints in panic disorder is heart rate variability (HRV).
HRV refers to the fluctuations in the time intervals between heartbeats. HRV is a common measure for vagal (main branch of the parasymathic nervous system) innervation of the heart but is also a marker for the capacity of emotional regulation. The ANS is subdivided in the sympathic (SNS) and parasympathic nervous system (PNS). During physical or psychological stress the activity of SNS becomes more dominant, producing a physiological arousal to help adapting to the physical or emotional needs. During periods of stability, the PNS takes over and maintains a lower degree of physiological arousal and makes the heart beat at a slower pace. The ease with which an individual can transition between different states of anxiety is dependent on the ability of the ANS to rapidly vary heart rate.

HRV is an independent risk factor for several somatic diseases, but is also related to psychiatric disorders, including panic disorder, agoraphobia and anxiety symptoms. Previous research has shown that a low HRV has been associated with high levels of stress, emotional tensions and an elevated state of anxiety. One explanation may be that the lack of flexibility of the autonomic nervous system may hinder an individual to produce an adequately responding to an environment that is constantly changing. This could enhance feelings of anxiety, and therefor may increase the risk for developing anxiety problems later in life. The relation between HRV and anxiety symptoms is bidirectional. Efferent output of the brain influences the cardiovascular regulation, and afferent output of the heart influences the brain. So in conclusion HRV serves as a marker for emotion regulation, and is regulated by emotions itself.

A recent study has shown that in adolescent girls, HRV predicted anxiety levels 2 years later, in boys no association was found. Previous research has shown that anxiety symptoms and HRV have the same anatomic basis, and genetic overlap has been suggested as well. However not all studies found these association. A possible explanation is that besides the fluctuations as described above, HRV can fluctuate between and in patients as well. Whether HRV increases the state of anxiety, or an increased state of anxiety decreases the HRV, or both are possibilities. But the amount of research to these findings in studies with an idiographic design is surprisingly low.

Study objective

By achieving multiple measurements of ambulatory HRV and anxiety symptoms in one individual agoraphobia patient during a standard treatment at the University Center for Psychiatry (UCP), we will investigate how the bidirectional causal relations between anxiety symptoms and HRV work. To achieve this we use intensive ambulatory measurements during the patients daily life
1. Will the daily reported anxiety symptoms decrease during the patients treatment?
2. Will an increase of HRV decrease anxiety symptoms or will a decrease in anxiety symptoms increase HRV?

Study design

The design of this study is idiographic, which means that instead of taking measurements in a group, the focus in this study will be on a large amount of measurements (>50) in one individual. Patients will be tracked while following their treatment (8 weeks) for panic disorder during their daily life. The total duration of the study is 10 weeks and will start one week prior to the treatment, and will continue until one week after. In the weeks prior and after the treatment an ECG-device is added. During the entire study patients must

wear an accelerometer and keep a diary, to document current anxiety symptoms and self-esteem, which is supposed to be filled out several times a day.

Study burden and risks

Except the intensity of the study, there no health risks or what so ever. The burdens consist out of, an inclusion interview (one hour), keeping a diary (x6 x 3x minutes a day prior and after treatment, during treatment x3 x 3x minutes a day), wear an accelerometer and wear an ambulatory monitoring device for two weeks in total: one week before, and one week after the treatment. The study period is 10 weeks. Benefits for the patients include, more insight in the patients pattern of anxiety symptoms, and person-specific factors that promote a good mood.

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

- Diagnosed with a panic disorder combined with agoraphobia as described in DSM-IV.
- Women between 18 and 50 years.
- Patients must be willing and capable to keep a diary and wear an accelerometer during their treatment.
- Patients must be willing and capable to wear an ECG device 24 hours a day for two separate weeks

Exclusion criteria

- Somatic and/or neurological disorders that restrict physical activity
- Patiënts that are diagnosed with psychiatric comorbidity
- Pregnancy
- Pacemaker, medication that influence the ECG

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	3
Type:	Anticipated

Ethics review

Approved WMO

Date:	15-10-2012
Application type:	First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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	NL41181.042.12