Voices, Attachment and Trauma (VAT): a study on the recovery of people with severe mental illness

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

Summary

ID

NL-OMON52765

Source
ToetsingOnline

Brief title
The VAT study

Condition

- Schizophrenia and other psychotic disorders

Synonym
Psychosis, schizophrenia, stemmingsstoornissen

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Mood disorders, Psychosis, Recovery, Voices

Outcome measures

Primary outcome

The primary outcome measures are changes in clinical recovery (measured with the PANSS or HADS), functional recovery (housing/employment/studying from the autobiographical questionnaire) and personal recovery (measured with the Mental Health Confidence Scale and the Self Esteem Rating Scale).

Secondary outcome

Secundary parameters/outcome measures are the nature of the voices the participant hear (VOS), the changes and frequency in hearing of the voices (6 items of the PUVI) and how participants view themselves in relation to their voices (Social Comparison).

Other parameters are several factors related to recovery: general health (Rand-36), attachment (RAAS), cognitive insight (BCIS), response to major/traumatic events (TSQ), therapeutic alliance (WAV), self stigma (ISMI), physical activity (IPAQ, sleep (SCOPA-sleep) and loneliness (de Jong Gierveld).

Study description

Background summary

There are an estimated 218.000 people with a severe mental illness, the majority of which has a psychotic disorder. Additionally one in three Dutch people experience an anxiety or mood disorder at one moment in their life, of which a large proportion experience both at the same time. For a long time the

focus of treatment for these patients was to help the recover from the clinical symptoms. However, recently there has been more attention and recognition for a broader definition of recovery, where there is room for personal and functional recovery besides symptomatic recovery. There are many factors that influence the course of recovery. Several important factors and treatment outcmes of people with psychotic disorders are yearly monitored in the northern Netherlands with ROM-Phamous, a routine outcome monitoring program that has continued to develop this last decade. In its current state, ROM-Phamous does not accurately measure personal recovery. While there is plenty attention for clinical symptoms, use of prescribed drugs and physical health, ROM-Phamous measures few psychosocial factors. Previous research has provided insight into which psychosocial factors, such as trauma, attachmentstyle and empowerment, might be of importance. However, these studies were mostly cross-sectional, whereas we still know little about the course of these factors and how they interact with each other. It is therefore necessary that we research how all these different factors relate to one another, how they influence eacht other over time and how they are related to the different areas of recovery of people with a psychotic disorder.

Study objective

The VAT study aims to investigate which factors influence and predict the different areas of recovery. VAT also examines how the content of voices that patients hear should be mapped and registered. We examine whether these factors can predict changes in symptomatic, functional and personal recovery. Based on this we will provide recommendations for measurable constructs that should be included in annual ROM-Phamous screenings in the future. Its longitudinal design of the study allows VAT to map the course of several important recovery factors and to examine how they interact.

Study design

VAT is an observational cohort study.

Study burden and risks

Participants are measured three times with 6 months intervals. During these measures the examiner conducts a PANSS interview and the participants fill in self-report questionnaires. Participation to the study has no negative consequences. There is no intervention with expected effects. We have carefully considered the amount of variables and the completion-time of the questionnaires (on average 2 hours), to keep the burden on participants on an acceptable level. Participants can take a break anytime, interrupt the measure and continue another day or retract from the study. Questions about the consequences of a potentially traumatic event or the content of voices could potentially lead to an emotional respons. The measures will therefore be

conducted by a registered psychologist (GZ-psycholoog) in training to be a specialized Clinical Psychologist (Klinisch Psycholoog i.o.) or nurse practitioner in training to be a specialist, who can recognize these signals and are able to provide immediate care to the participant if necessary. By participating in the study, patients contribute to the knowledge needed to improve care for people with a psychotic disorder, including their own care and future. Considering this is unique information that only people with psychotic experiences can provide, it is not possible to conduct this study with healthy volunteers.

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

Inclusion criteria psychosis target group

1) There is a psychotic disorder according to the DSM-V; schizophrenia, schizophreniform, schizo-affective, schizotypal, delusional disorder, psychosis due to substance/medication use, psychotic disorder not otherwise defined and/or one of the following DSM-V codes 301. 22, 297.1, 298.8, 295.40, 295.90, 295.70, 293.81, 293.82, 293.89, 298.8, 298.9, 291.9, 292.9.
2) The patient is >= 18 years of age;
3) There is no crisis admission or admission to a closed ward;
4) The patient has sufficient command of the Dutch language.

Inclusion criteria for target group mood disorders
1) There is a bipolar disorder, anxiety or depression disorder according to the DSM-V;
2) The patient is >= 18 years of age;
3) There is no crisis admission or admission to a closed ward;
4) The patient has sufficient command of the Dutch language language.

Exclusion criteria

Exclusion criteria psychosis target group
1) There is a diagnosis other than schizophrenia spectrum and other related psychotic disorder according to the DSM-V.
2) The patient is < 18 years of age;
3) There is a crisis admission or admission to a closed ward;
4) The patient has insufficient command of the Dutch language.

Exclusion criteria mood disorder target group
1) There is a diagnosis other than bipolar disorder, anxiety or depression disorder according to the DSM-V.
2) The patient is < 18 years of age;
3) There is a crisis admission or admission to a closed ward;
4) The patient has insufficient command of the Dutch language.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-12-2018
Enrollment:	720
Type:	Actual

Ethics review

Approved WMO Date:	08-05-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	03-04-2023
Application type:	Amendment
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	NL64523.042.17