Prognostic factors for quality of life in patients with severe personality disorders.
Influence of psychotic features and failures in social cognition after one and two years.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Psychiatric disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON43521

Source
ToetsingOnline

Brief title
Prognostic factors in severe personality disorders.

Condition

- Psychiatric disorders NEC

Synonym
personality disorders

Research involving

Human

Sponsors and support

Primary sponsor: Parnassia (Den Haag)
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: prognostic factors, psychotic features, severe personality disorder, social cognition

Outcome measures

Primary outcome

Quality of life by means of the World Health Organization Quality of Life

Assessment BREF

Secondary outcome

Total costs of mental health

The Trimbos and Institute for Medical Technology Assessment Questionnaire on

Costs Associated with Psychiatric Illness and reference list for guidelines for

healthcare costs are used to assess direct and indirect costs. Quality-Adjusted

Life Year (QALY) is used as measure for life expectancy in number of years

corrected by quality of life (Short Form 12). One Qualy means one year in good

health. To conduct a costeffectiveness analysis the total extra costs before

onset of treatment are divided by the number of extra QALY*s in comparance to

the situation before treatment.

Structured Clinical Interview for DSM-IV axis II personality disorders

Mini International Neuropsychiatric Interview Plus

Costs Associated with Psychiatric Illness (TiC-P verkorte versie)

Questionnaire for Psychotic Experiences (QPE)

Korte Klachten Lijst / OQ45

Severity Indices of Personality Problems

Dissociative Experiences Scale

Jeugd Trauma Vragenlijst

Deel 3 Posttraumatic Diagnostic Scale

Hinting Task paradigm

Amsterdam Neuropsychological Tasks (ANT) - Identifying facial emotions subtest

WAIS III - Picture arrangement subtest

Davos Assessment of Cognitive Biases Scale (DACOBS)

Continuous Performance Test

Brief Cognitive Assessment Tool for Schizophrenia (including trail making test

B, digit symbol and verbal fluency test)

Study description

Background summary

Patients with personality disorders experience a variety of problems concerning self esteem, temperament and social relations. Consequently, quality of life (QoL) of these patients is low and societal costs are high. Depression, anxiety and substance abuse often co-occur, as do psychotic symptoms which are usually associated with multiple diagnoses and more severe childhood trauma. However, patients with psychotic features and substance abuse were generally excluded from studies, and (social) cognitive disturbances that are expected to co-occur with psychotic features, have not been explored as a predictive factor so far.
It was commonly assumed that diagnoses of personality disorders are lifetime, however, these diagnoses are not static. Symptoms fade, increase or transcend into different psychiatric disorders, such as bipolar disorder or schizophrenia. The literature does not provide sufficient information to be

able to predict who will have a bad prognosis.
Therefore, patients cannot be properly informed about their prognosis and it is difficult to compose the appropriate patient based treatment.

Study objective

The primary objective of this study is to get insight into the course of personality disorders in order to be better able to inform patients about their prognosis. We aim to identify factors associated with lower QoL and higher societal and medical costs in order to identify patients with these prognostic features in an early stage. and may become a focus of treatment for patients with severe personality disorders?

Study design

In this observational longitudinal study, data will be gathered at three points in time, namely at baseline, 1 and 2 years thereafter, in order to monitor the course of symptoms during the first 2 years after admission. At every time point, all participants will be subjected to structured and semi-structured standardized questionnaires and self-report questionnaires. Data regarding cognitive functioning will be collected at baseline and two years after admission.

Location
The study will be performed at the department of Personality Disorders, PsyQ, The Hague, the Netherlands.

Statistical methods
With the aims of Statistical Package for the Social Sciences, version 20.0, data will be analysed. Quality of life and total costs of healthcare are the dependent valuables; possible predictive valuables will be used as covariates. As these valuables can vary with change of time, multilevel-analysis will be used as statistical method for continuous valuables of quality of life and health care costs.

Study burden and risks

The collection of the data with questionnaires and cognitive tasks cost time. For some patients questions regarding childhood trauma might be a burden. During and at the end of the visits the investigator will inquire if the patient has questions or increase of symptoms. If necessary an extra appointment will be offered, or a caregiver will be consulted.

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 personality disorder diagnosed with the Structured Clinical Interview for DSM-IV axis 2 personality disorders
-Age 18 years or older
-Written informed consent of the patient

Exclusion criteria

-Participants that cannot read, speak or understand Dutch

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2016
Enrollment:	231
Type:	Anticipated

Ethics review

Approved WMO

Date:	22-08-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL56118.058.16