Using polygenic risk scoring in genetic counseling for mental illness: perception and added value (P-risk study)

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The objective of this study is to assess the added value of polygenic risk scoring in psychiatric genetic counseling for patients with serious mental illness (SMI) and their family members. The secondary objective of this study is to explore...

Ethical review	Not approved
Status	Will not start
Health condition type	Schizophrenia and other psychotic disorders
Study type	Observational invasive

Summary

ID

NL-OMON51018

Source
ToetsingOnline

Brief title
P-RISK

Condition

- Schizophrenia and other psychotic disorders

Synonym
bipolar disorder, psychosis, Schizophrenia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: GGNet,GGNet (Warnsveld)

Intervention

Keyword: Genetic counseling, Mental illness, PRS, Self stigma

Outcome measures

Primary outcome

To examine potential benefits of genetic counseling provided with PRS as compared to genetic counseling without PRS and to care as usual for people with serious mental illness (SMI) and their family members.

Secondary outcome

The secondary objective of this study is to explore attitudes of patients with SMI and their family members towards PRS. Third, we will explore knowledge and attitudes towards PRS in mental health professionals.

Study description

Background summary

Psychiatric disorders are highly prevalent and etiologically complex, with both genetic and environmental factors contributing to disease risk. This complex etiology often results in misunderstanding the cause of the disorder by patients and family members and overestimating the genetic contribution to the disorder. Genetic counseling helps people with mental illness and their family members by gaining more knowledge about the origins of their mental illness, correcting misconceptions, and promoting health-enhancing behaviors, leading to a sense of empowerment. Recently, polygenic risk scores (PRS) have gained increasing interest. Early findings suggest that PRS might allow for identification of individuals at-risk for psychiatric disorders, treatment optimization, and enhancement of prognostic accuracy. However, PRS is not yet implemented in clinical practice. The positive effect of genetic counseling could be further enhanced by providing even more individualized information using PRS.

Study objective

The objective of this study is to assess the added value of polygenic risk

scoring in psychiatric genetic counseling for patients with serious mental illness (SMI) and their family members. The secondary objective of this study is to explore attitudes of patients with SMI and their family members towards the calculation and provision of PRS. Third, we will explore knowledge and attitudes towards PRS in mental health professionals.

Study design

The study is designed as a mixed-methods, prospective, non-randomized three-arm pilot study. It is a monocenter study, with collaborating referring centers.

Intervention: For the quantitative study, one group receives personalized genetic counseling based on familial and medical history and clinical characteristics, one group receives personalized genetic counseling as mentioned above, provided with polygenic risk scoring, and one group receives care as usual. Allocation to a group is based on the preferences of each individual. For the qualitative study, an open, in-depth interview will be held, where participants can choose whether they want to participate or not.

Study burden and risks

Participants in the PRS-intervention group will have one blood sample drawn for DNA-extraction. This venipuncture entails the risk of a hematoma. We aim to minimize this risk by only allowing experienced personnel to perform the blood draw. No serious health risks are associated with this study.
Time investment is considered substantial. However, previous data on psychiatric genetic counselling report high participant satisfaction.
Participants will have a telephone screening of +-15 minutes, two face-to-face contacts of 30 to 60 minutes, and a telephone follow-up contact of +-30 minutes. Participants who choose to participate in the qualitative study, will receive an additional interview of 60-120 minutes. This may take place at the participant*s home if preferred, to minimize burden.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

To be eligible to participate in this study, a participant must meet all of the following criteria:
(1) The participant has been diagnosed with SMI, which is defined as having a psychosis spectrum disorder or bipolar disorder, or is a first-degree family member of a patient diagnosed with SMI.
(2) The participant is at least 16 years old;
(3) The participant must be able to speak and read the Dutch language;
(4) The participant must be mentally competent and have decisional capacity with regard to a decision in participating in the current study, which will be assessed by the (treating) physician.

Exclusion criteria

A potential participant who meets any of the following criteria will be excluded from participation in this study:
(1) The participant is admitted involuntary to a psychiatric unit in the context of a *crisismaatregel*;
(2) The participant was previously diagnosed with a clinically relevant genetic diagnosis;
(3) The experienced psychiatric episode was primarily substance-induced.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	110
Type:	Anticipated

Ethics review

Not approved

Date:	28-06-2021
Application type:	First submission
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	NL77163.041.21
Other	volgt