Experience sampling for detection of early clinical changes during dose reduction of antipsychotics in patients with a psychotic disorder

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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-OMON48652

Source
ToetsingOnline

Brief title
experience sampling during dose reduction of antipsychotics

Condition

- Schizophrenia and other psychotic disorders

Synonym
psychotic disorder; psychosis

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Eindhoven (Eindhoven)

Source(s) of monetary or material Support: zonMW,GGzE

Intervention

Keyword: antipsychotics, dose reduction, experience sampling method, monitoring

Outcome measures

Primary outcome

Momentary mental states and behaviour in terms of psychotic experiences,

subjective well-being (positive affect, negative affect, physical well-being),

social interactions, sleep, cognition, dopamine super-sensitivity and negative

symptoms in the context of daily life.

Secondary outcome

Clinical symptoms, mental health and functioning, recovery, physical

complaints/side effects, quality of life

Study description

Background summary

In 2013, there were 290.000 users of antipsychotic medication in the Netherlands. The multidisciplinary guideline Schizophrenia recommends to aim at treatment with the lowest effective dose of antipsychotic medication. Often, the prescribed dose is higher than necessary, with negative consequences for health, motivation and functioning. While there is a knowledge gap in the domain of antipsychotics use and its consequences, research with the ultimate goal of improving quality of life for people with psychotic illness by responsible medication use and (dis)continuation is necessary. Many antipsychotic medication trials have been conducted, but this has not resulted in guidelines for the optimal dose for the individual so far. There is evidence that dose optimization of antipsychotic medication has a positive effect on subjective wellbeing. Personalized dose-optimization is predicated on the assumption that the average appropriate dose is not necessarily the optimal dose for the individual. Therefore, N=1 trials to self-manage functional outcome by titrating dose changes are necessary. The experience sampling method (ESM) offers opportunities for intensive monitoring of symptoms during

discontinuation of antipsychotics because intensive sampling of daily life experiences allows for the detection of early changes in affective and mental states. This may contribute to responsible medication use and dose reduction/(dis)continuation.

Study objective

The aim of the study is to gain insight, based on 30 N=1 trials, into whether intensive ESM monitoring can be used to evaluate the consequences of dose reduction of antipsychotic medication by detecting meaningful within-subject changes in daily life mental states that occur during and after dose reduction. The present study also aims to determine the clinical effects of dose reduction of antipsychotic medication under longitudinal ESM self-monitoring by meta-analyzing these 30 N=1 trials to investigate group-level trends in the effects of dose reduction.

Study design

Single-case trials.

Study burden and risks

Participation entails that patients will receive extra questionnaires at baseline, after dose reduction, and at four follow-up moments over a total time period of approximately four years to evaluate the effects of antipsychotic dose reduction under intensive monitoring with the PsyMate app. Participants will also be asked to engage in additional monitoring with the PsyMate app at the three yearly follow-ups to evaluate the long term effects of dose reduction on daily mental states and behaviour.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

1. The participant has a diagnosis of a psychotic disorder.
2. Psychotic symptoms are in remission for at least three months for first episode psychosis and at least six months for multiple episode psychosis.
3. Age 16-65 years.
4. The participant understands the study and is able to provide written informed consent.
5. The participant is not participating in a medication study.
6. The participant is currently using antipsychotic medication and participant and his/her treating clinician agree to discontinuation/dose reduction. Patients with depot medication can also participate.
7. Sufficient command of the Dutch language.
8. Sufficient vision to read the questions in the PsyMate app and sufficient hearing to hear the PsyMate signals.

Exclusion criteria

Exclusion criteria are kept as few as possible. Only when the safety of the participant is at risk, exclusion will follow.
Patients will be excluded from the trial if patients are not in remission (at least 3 months for first episode patients and at least 6 months for multiple episodes) .

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-03-2019
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	14-11-2018
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	28-08-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL66325.068.18