Experience sampling tijdens dosisreductie van antipsychotica

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23844

Source
NTR

Brief title
N1AP

Health condition

psychosis

Sponsors and support

Primary sponsor: GGzE
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

Main study parameters/endpoints are ESM measures of:
1. Psychotic experiences
2. Subjective wellbeing (positive affect, negative affect, physical well-being)
3. Social functioning
4. Cognition

5. Sleep
6. Dopamine super-sensitivity (indicator of risk for psychotic relapse)
7. Negative symptoms

Secondary outcome

1. Symptom severity as assessed with the Positive and Negative Symptom Scale (PANSS; (Kay et al., 1987))
2. Mental health and functioning as assessed with the OQ-45 (Lambert et al., 2004) or HoNOS
3. Recovery as assessed with the Recovery Assessment Schedule – Domains and Stages (RAS-DS; (Hancock et al., 2016))
4. Physical complaints/side effects as assessed with the Somatic miniscreen (SmS; (de Ruiter, 2015)) and SHRS
5. Quality of life as assessed with the MANSA (van Nieuwenhuizen et al., 2000) or KIDSCREEN-27 (The KIDSCREEN Group Europe, 2004).

Study description

Background summary

Rationale: 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.
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 aggregated-level trends in the effects of dose reduction.

Study design: Single-case trials.
Study population: Participants with a psychotic disorder (n=30), aged 16-65 years, who are in stable remission (first episode patients: minimally three months in remission, multiple episode patients: minimally six months in remission) and who have a clinical indication to reduce the dose of or discontinue their antipsychotic medication.
Intervention: Thirty patients will use an e-health application (self-monitoring app 'PsyMate') based on the experience sampling method (ESM) to evaluate consequences of reduction of antipsychotic medication on changes in momentary 1) psychotic experiences, 2) subjective well-being, 3) social functioning, 4) cognition, 5) sleep, 6) dopamine super-sensitivity, and (7) negative symptoms.
During the two-week baseline period, the dose reduction phase (approximately 12 weeks, depending on the dose reduction scheme that the treating physician has described), the two-weeks post-reduction, monthly follow-ups (7 days per month for a period of six months after dose reduction) and yearly follow-ups (in a three-year period), ESM will be completed daily, at eight semi-random moments during the day.
Main study parameters/endpoints: Primary study parameters are 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 study parameters include symptom severity, mental health and functioning, recovery, physical complaints/side effects, and quality of life.

Study objective

We hypothesize that the subjective well-being of individual patients will show improvement after dose reduction compared with baseline, that is, patients will experience more positive affect, less negative affect and higher physical well-being during the flow of daily life. Social functioning and cognition of individual patients are also expected to improve. That is, patients will engage more in social activities, appraise these activities as more positive, and feel more able to concentrate in daily life. Dose reduction can be a risk for patients with dopamine super-sensitivity. Therefore, dopamine super-sensitivity will be closely monitored as well.

Study design

During the two-week baseline period, ESM will be completed daily, at eight semi-random moments during the day. Baseline assessment will also consist of the PANSS and OQ-45 or HoNOS. Additional questionnaires consist of the MANSA or KIDSCREEN-27, RAS-DS, somatic miniscreen, SHRS, CTQ-s, CIDI substance use, collection of demographic information, and a treatment inventory.
During the dose reduction phase (approximately 12 weeks, depending on the dose reduction scheme that the treating physician has described), the participant will engage in ESM self-monitoring, filling in the PsyMate for a minimum of five days a week. The trained clinician views the feedback together with the participant (as described in the next paragraph) in feedback sessions. During the first four weeks, these sessions take place weekly. After these initial four weeks, these sessions will take place once every two weeks.

After the dose reduction phase, the patient will continue with the ESM self-monitoring for two weeks (minimally five days a week), at the end of which the feedback in the web application is again discussed with the patient. During this session, PANSS, OQ-45 or HoNOS, MANSA or KIDSCREEN-27, RAS-DS, treatment inventory, SmS, and SHRS, CTQ-SF, and CIDI substance use will be assessed. Additionally, participants' opinion about the feedback procedure will be evaluated at the post-reduction assessment as well.
During the monthly follow-ups (7 days per month for a period of six months after dose reduction), ESM will be completed daily, at eight semi-random moments during the day. These monthly follow-ups also include seven consecutive days of ESM monitoring beforehand on which feedback is provided. After these six months, we will again administer the PANSS, OQ-45 or HoNOS, MANSA or KIDSCREEN-27, RAS-DS, treatment inventory, SmS, SHRS, and CIDI substance use.
During the yearly follow-ups (in a three-year period), we will administer the PANSS, OQ-45 or HoNOS, RAS-DS, MANSA or KIDSCREEN-27, SmS, SHRS, CIDI substance use, and the treatment inventory. Before each yearly assessment, we will ask participants to engage in ESM monitoring for 14 consecutive days. The ESM data will be discussed with the participant (similar to the feedback sessions during the dose reduction phase).

Intervention

Thirty patients will use an e-health application (self-monitoring app 'PsyMate') based on the experience sampling method (ESM) to evaluate consequences of reduction of antipsychotic medication on changes in momentary 1) psychotic experiences, 2) subjective well-being, 3) social functioning, 4) cognition, 5) sleep, 6) dopamine super-sensitivity, and (7) negative symptoms.

Contacts

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Eligibility criteria

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 with comorbidity, drug- and alcohol abuse or low IQ will be able to participate, so that the sample will reflect the general population of patients with psychosis and the study's outcomes will be generalizable.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2019
Enrollment:	30

Type: Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion
Date: 19-12-2018

Application type: First submission

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
NTR-new	NL7434
NTR-old	NTR7676
Other	NL66325.068/METC18-007 : METC aZM/UM

Study results