Experience Sampling in patients and their partners at an emergency psychiatry service; a pilot study.

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The primary aim is to assess the feasibility of using PsyMate by emergency psychiatric patients and their partners. The secondary objective is to obtain observational data to design future ESM studies to be carried out within our department.

Ethical review	Approved WMO
Status	Pending
Health condition type	Suicidal and self-injurious behaviours NEC
Study type	Observational non invasive

Summary

ID

NL-OMON49413

Source
ToetsingOnline

Brief title
Experience Sampling in Emergency Psychiatry

Condition

- Suicidal and self-injurious behaviours NEC

Synonym
psychothology, suicidality

Research involving
Human

Sponsors and support

Primary sponsor: Arkin (Amsterdam)
Source(s) of monetary or material Support: Afdelingen onderzoek en opleiding psychiatrie Arkin

Intervention

Keyword: Ecological Momentary Evaluation, Experience Sampling, Suicide, System-oriented

Outcome measures

Primary outcome

Primary study parameters/ endpoints will be:

1)The number and percentage of participants completing the study;

2) the percentage of PsyMate beeps followed (i.e. questionnaires filled out)

per participant;

3) the participants* experiences with the PsyMate.

The secondary endpoints will be the outcomes on the test-battery, and daily ESM

questionnaires.

Secondary outcome

- psychiatric symptoms (as assessed by the brief psychiatric rating scale, BPRS

and the health of the nations outcomes scale, HONOS, mean +/- standard

deviation)

- relationship quality (as assessed by the relationship assessment scale, RAS,

mean +/ standard deviation)

- Quality of sleep (likert scale, mean +/- standard deviation)

- Positive affect (average of cheerful, satisfied, enthusiastic, relaxed)

(likert scale, mean +/- standard deviation)

- Negative affect (average of down, suspicious, guilty, irritated, lonely and

anxious) (likert scale, mean +/- standard deviation)

- View of self (likert scale, mean +/- standard deviation)

- (social) activities (percentage of time per option)

- Stress during activity (likert scale, mean +/- standard deviation)

General patient information will be reported as follows:

- Age (mean +/- standard deviation)

- Sex (number and % female)

- educational level (low * middle * high, number and percentage in each category);

- work (none / part-time / full-time, number and percentage in each category);

- participants with children (number and percentage)

- of participants with children: number of children (mean and standard deviation)

- past diagnosis (depression / bipolar disorder / schizophrenia / cluster a/b/c personality disorder, number and percentage of each category);

- current psychiatric condition (depression / bipolar disorder / schizophrenia / anxiety disorder / cluster a/b/c personality disorder, number and percentage of each category)

- current use of benzodiazepines / antidepressants / antipsychotics / mood stabilizer (number and percentage of each category);

- current psychotherapy (number and percentage).

Study description

Background summary

Patients are typically referred to the Psychiatric Emergency Service Amsterdam (SPA) because of a sudden start or increase of psychiatric symptoms resulting

in a risk of serious harm to the patient or his/her surroundings. The SPA aims to provide personalized treatment, and include and support the patients* social network.
Experience Sampling Method (ESM) strategies nudge patients to fill out questionnaires multiple times per day, to obtain information on mood, psychological complaints, activities, and social and environmental context. PsyMate is a smartphone-based ESM app specifically designed for psychiatric care and research.
Until now, ESM has not been used at the Psychiatric Emergency Service Amsterdam (SPA). We expect that use of PsyMate by patients and their partners at the SPA will be feasible. Also, we hypothesize that the resulting data could be used for scientific research and personalization of (network-oriented) treatment.

Study objective

The primary aim is to assess the feasibility of using PsyMate by emergency psychiatric patients and their partners. The secondary objective is to obtain observational data to design future ESM studies to be carried out within our department.

Study design

The current study is an observational pilot study.
Intervention (if applicable): All participants (patients and their partners) will use PsyMate four days per week for four weeks. On these days, they will fill out a morning questionnaire, an evening questionnaire and a repeating questionnaire. The morning questionnaire will cover sleep quality, the evening questionnaire general experiences during the day and with PsyMate. The repeating questionnaire will be filled out at semi-random moments and will cover positive and negative affect, psychiatric symptoms, time spent on (social) activities, stress during (social) activities, social and environmental context
Moreover, all participants will be subjected to a modest test battery at baseline and end-of-study (week 5). Questionnaires will evaluate general psychiatric symptoms, relationship quality between the patient and his/ her partner. At end-of-study, a questionnaire on the PsyMate user experiences will be filled out.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Based on previous studies and clinical experience, the risk of using PsyMate is regarded low. Burden mostly consists of repeatedly filling out the questionnaires, but previous studies indicate that the burden is low as well. This study does not offer financial rewards or

other specific incentives.

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

Population
15 patients who are referred to our department because of suicidal thoughts or behavior and accepted for out-patient treatment and their 15 live-in partners will be enrolled upon the start of treatment.

criteria for all 30 participants:
- To be mentally competent to decide about participating in the study
- Written informed consent has been provided
- Mastery of Dutch Language in speech and writing;

- In possession of an electronic device, e.g. smart-phone, i-pad, which supports the PsyMate app;
- Ability to use the PsyMate app and comply with the study protocol (clinical judgment treating physician).

Exclusion criteria

- Participation in another study that is ongoing at our department;
- Homelessness;
- Primary addiction problem

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):	01-01-2021
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	19-10-2020
Application type:	First submission
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	NL71906.068.20