Continuous Assessment for Suicide Prevention And Research (CASPAR): a feasibility study of smartphone-based safety-planning and self-monitoring for suicidal patients in mental health care

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Suicidal and self-injurious behaviours NEC
Study type	Interventional

Summary

ID

NL-OMON46684

Source
ToetsingOnline

Brief title
CASPAR

Condition

- Suicidal and self-injurious behaviours NEC

Synonym
Suicidal ideation

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: EMA / ecological momentary assessment, eMental health, Practice-based research, Suicide prevention

Outcome measures

Primary outcome

The primary objective is to test the feasibility of the safety planning and

self-monitoring tools. Feasibility endpoints are defined in terms of uptake,

patient satisfaction and usability.

Secondary outcome

Secondary outcomes are the mental health variables measured by the EMA items.

These variables include anxiety, belongingness, (brooding) rumination,

burdensomeness, fear of dying, coping, defeat, depression, entrapment, future

thinking, impulsiveness, resilience and suicidal ideation (see also

attachment).

Study description

Background summary

Suicidal behaviour often occurs outside treatment hours, resulting in completed suicides, crisis interventions and hospital admissions. Smartphone-based safety planning and self-monitoring could provide tools for patients to avoid situations of high risk, organise support in times of suicidal crisis, and avoid relapse.

Study objective

The primary objective is pilot-implementation of smartphone-based safety planning and real-time self-monitoring for patients with recurrent depression and suicide risk in mental health care.
For the secondary objectives we will analyse the real-time monitoring data, in order to (a) empirically validate hypothesised psychological processes and stages of suicide pathways, (b) identify individual pathways to suicidal behaviour, and (c) profile types of suicidal individuals.

Study design

This feasibility study is a single cohort design among patients of three mental health centres. There will be three measurement points: T0 (baseline), T1 (1 month after T0) and T2 (3 months after T0). We consider this study to be an adaptive design, which means that the apps that we investigate will be improved based on patient feedback when possible and, therefore, may slightly change during the study.

Intervention

We will add two mobile apps to the regular treatment of patients. We will only look at the feasibility of the implementation and we do not have a therapeutic meaning. The CASPAR study is therefore a feasibility study and not a standard implementation study.
- Electronic safety planning is the electronic form of the existing, regular safety plan.
- Electronic self-monitoring is the electronic form of registration of symptoms of patients.

Study burden and risks

This study will point out whether mobile safety planning and self-monitoring are useful additions to treating depressed patients with suicidal ideation. It can be expected that at least some patients will benefit from these tools. Furthermore, the secondary analyses might provide valuable data on the psychological processes that coincide with suicidality. The added risk can be considered to be minimal. Our study protocol interferes minimally with the normal treatment. Dutch suicide prevention guidelines recommend safety planning with mental health care patients who are at risk of engaging in suicidal behaviour. Many participating patients will already have a safety plan and the only difference is that it will be electronic instead of on paper.
Self-monitoring is comparable with keeping a mood diary, which is often used in treatment. An extensive literature review shows that there is no evidence that intensive assessment of suicidal ideation could lead to more suicidal ideation or suicidal behaviour. Moreover, previous studies on EMA of suicidal ideation have also shown no adverse effects.

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

- Age * 18 years
- Outpatients or day-care patients
- Recurrent depressive disorder or dysthymia
- Severe suicidal ideation
- Understanding written Dutch
- Smartphone that runs either Android or iOS

Exclusion criteria

- Severe psychotic symptoms

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-03-2019
Enrollment:	81
Type:	Actual

Ethics review

Approved WMO

Date:	09-08-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL62795.029.17