Suicidal ideation Assessment: Fluctuation monitoring with Ecological momentary assessment

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

Summary

ID

NL-OMON52614

Source
ToetsingOnline

Brief title
SAFE

Condition

- Suicidal and self-injurious behaviours NEC

Synonym
suicide

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: NWO Research Talent Grant

Intervention

Keyword: actigraphy, mobile phone assessments, suicide ideation

Outcome measures

Primary outcome

The primary outcome measure is self-reported suicidal ideation, as measured with EMA.

The primary predictors include self-reported sleep parameters (sleep quality/quantity), mood (positive/negative), cognitions (hopelessness, burdensomeness, loneliness, optimism), stressful events, social interaction (/isolation), and substance use/coping strategies, as measured with EMA; and objective sleep parameters (incl. total sleep time, sleep onset latency, sleep efficiency, wake after sleep onset), as measured with actigraphy.

Secondary outcome

The following self report measures will be assessed at the beginning and at the end of the cohort study.

1. suicidal ideation
2. depressive symptoms
3. anxiety symptoms
4. quality of life
5. sleep problems
6. cognitive reactivity
7. anger expression
8. borderline personality traits

Acceptability of EMA will also be tested: agreement to participate, compliance rates, and attrition (operationalized as the number and percentage of individuals who agree to participate in the study/ valid EMA observations/ individuals who complete the study) and study burden questions (self-report).

Study description

Background summary

Suicide is a major cause of death worldwide, and overall, it costs approximately 800,000 lives annually (WHO, 2017). Although multiple predictors of suicidal ideation and behavior have been identified (including depression, hopelessness, stress), they are non-specific and often chronic risk factors that do not assist the identification of those most at risk in real world settings. Consequently, suicide is notoriously difficult to predict. Due to the limitations of the current common approach of assessing suicidal ideation and its risk factors at infrequent time points and over long periods of time, little is known about the short-term temporal correlates of suicidal thought. Less than 1% of suicide research has focused on a time range of a month or less. Hence, while this is the most crucial period for the decision-making process of clinicians, we know very little about it. Although we know that suicidal ideation may fluctuate abruptly, we do not yet know: What influences these short-term (daily and even hourly) fluctuations? Under which circumstances are suicidal thoughts more or less prominent?
Research assessing these fluctuations is needed for better understanding and prediction of suicidal ideation, and real-time methodologies (ecological momentary assessment, EMA; and actigraphy) are optimally suited for these purposes.

Study objective

This is the first study to combine both objective and subjective daily measures (EMA and actigraphy) to assess fluctuations in suicidal ideation, in real time and in natural settings. The aims of the study are
(1) to examine how momentary risk and protective factors (sleep, mood, cognitions, stressful events, social interactions, substance use/coping strategies) lead to increases or decreases in suicidal ideation in the short term,
(2) to assess the long-term fluctuation of suicidal ideation and identify proximal predictors for increased/decreased suicidal ideation (weekly for one year)

(3) to assess the acceptability of electronic symptom self-monitoring (EMA) in individuals with suicidal ideation.

Study design

A longitudinal cohort study

Study burden and risks

No adverse effects are expected, and participant safety will be monitored throughout the study.
A potential risk of the study is that participants get sensitized by the questions (EMA) about suicidal thoughts. If this occurs they can contact the investigator and can stop the study immediately. Participants are informed about this risk at the start of the study. Prior studies have shown good acceptability and no reactivity of assessments (EMA) in suicidal participants (Husky et al., 2014).
A potential benefit of the study is that, following the assessment period, the participants will be offered the option of receiving a summary report of their data that they can also share with their therapist if currently in treatment. This information can be insightful for the individual and potentially beneficial for their treatment. Such symptom self-monitoring is increasingly used in mental health care, and can help mental health professionals obtain more detailed information about the patient*s functioning, and help them identify high- and low-risk conditions that are specific for the individual.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. A history of a suicide attempt or severe ideation in the past 12 months (>=3 Columbia-Suicide Severity Rating Scale, or >=2 if symptoms present in the past 2 months).
2. Aged 18 years or older.
3. Adequate proficiency of both written and spoken Dutch or English.
4. Possession/use of an Android or iOS compatible mobile phone.
5. Willingness to participate in a 1-year longitudinal study.

Exclusion criteria

1. Current diagnosis of Bipolar disorder, a Psychotic disorder, or (severe) Substance dependence (DSM-5 criteria).
2. Intellectual impairment, dementia or a physical impairment that may prevent the participant from adequately following the study procedures.

Participants in need of immediate support or treatment will be referred before enrolment in the study.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-08-2020
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	24-04-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	13-05-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	05-07-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL71510.058.19

Study results

Results posted: 13-09-2024

First publication
13-09-2024