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BMJ Open Smartphone-based Ecological Momentary Intervention for secondary prevention of suicidal thoughts and behaviour: protocol for the SmartCrisis V.2.0 randomised clinical trial

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ABSTRACT

Introduction Suicide is one of the leading public health issues worldwide. Mobile health can help us to combat suicide through monitoring and treatment. The SmartCrisis V.2.0 randomised clinical trial aims to evaluate the effectiveness of a smartphone-based Ecological Momentary Intervention to prevent suicidal thoughts and behaviour.

Methods and analysis The SmartCrisis V.2.0 study is a randomised clinical trial with two parallel groups, conducted among patients with a history of suicidal behaviour treated at five sites in France and Spain. The intervention group will be monitored using Ecological Momentary Assessment (EMA) and will receive an Ecological Momentary Intervention called 'SmartSafe' in addition to their treatment as usual (TAU). TAU will consist of mental health follow-up of the patient (scheduled appointments with a psychiatrist) in an outpatient Suicide Prevention programme, with predetermined clinical appointments according to the Brief Intervention Contact recommendations (1, 2, 4, 7 and 11 weeks and 4, 6, 9 and 12 months). The control group would receive TAU and be monitored using EMA.

Ethics and dissemination This study has been approved by the Ethics Committee of the University Hospital Fundación Jiménez Díaz. It is expected that, in the near future, our mobile health intervention and monitoring system can be implemented in routine clinical practice. Results will be disseminated through peer-reviewed journals and psychiatric congresses. Reference number EC005-21_FJD. Participants gave informed consent to participate in the study before taking part.

Trial registration number NCT04775160.

INTRODUCTION

Suicide is a major public health issue. Despite this, in recent decades and in most countries, no substantial decline in mortality by suicide has been observed. In 2018, suicide caused 1 344 552 Years of Potential Life Lost in the USA, almost as many as COVID-19 caused

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study stands out for its innovation, as there is no clinical trial with results that combines Ecological Momentary Assessment (EMA) with Ecological Momentary Intervention (EMI) to create an automatic risk detection system integrated into a digital tool.
- ⇒ Similarly, passive monitoring has never been combined with EMI-type interventions.
- ⇒ One of the limitations of this study is the possibility of missing data due to a drop in compliance with EMA questions. Sample size calculation has been performed taking into account missing data.
- ⇒ Another limitation is the impossibility of implementing the intervention in people who do not own a personal smartphone. Although smartphone ownership has increased dramatically in recent years, it does not reach every sector in the population. Patients who do not own a smartphone will still be referred to our suicide prevention programme. We hope that this limitation will be attenuated as the adoption of new technologies in society increases.

in 2020.¹ Annual suicide deaths worldwide are estimated at over 800 000, while suicide attempts (SAs) are 20 times more frequent.² Spain has a yearly suicide rate of 7.9 per 100 000 inhabitants,³ while France has a suicide rate of 12.1 per 100 000 inhabitants.⁴

Also, suicidal ideation (SI) is estimated to affect 2% of the population.⁵ SI and SAs, which jointly receive the name of Suicidal Thoughts and Behaviours (STB), increase the risk of death by suicide, impair people's quality of life and result in high healthcare costs.^{6 7} A key aspect to prevent death by suicide is implementing secondary prevention strategies. Secondary prevention consists of acting in the early stages of a disease to prevent its progression; in this case, focusing



on people with a history of SI or behaviour with the aim of preventing death by suicide.⁸

The search for new and more valid risk markers for STB has hardly progressed in the last decades.⁹ Predominantly, there is a gap in identifying precipitating risk factors,¹⁰ since prospectively investigating a rare event on an individual scale such as an SA is methodologically problematic. New technologies can help us to focus on individuals rather than just groups in a methodologically feasible way to integrate bottom-up and top-down approaches. In particular, among other advantages, there is the possibility of implementing smartphone-based real-time monitoring.¹¹

Ecological Momentary Assessment (EMA) is one of the most common types of smartphone-based monitoring. Active EMA involves asking daily questions, resulting in real-time responses in the patient's usual environment.¹² EMA reduces recall bias, respects ecological validity and facilitates the real-time simultaneous collection of information from multiple media. In the field of suicidal behaviour, EMA provides a more accurate picture of the emotional and cognitive context in which SI appears, offering us the opportunity to identify its immediate predictors.¹³

Passive monitoring—also called passive or non-intrusive EMA—involves using the mobile phone's native sensors to collect information such as physical activity, mobility or sleep, which can be helpful as proxy factors for mental state. The combination of active and passive monitoring produces valuable information to characterise people's behaviour, giving rise to what is known as an individual's digital phenotype.¹⁴

Furthermore, passive EMA, when designed well, requires nothing from the patient but to live their life as usual, which can increase the acceptability of monitoring, and counteract the so-called 'EMA fatigue', which leads patients to stop answering EMA questions.¹⁵

A considerable number of studies have applied EMA technology to suicide research.^{11 16–23} In contrast, passive EMA has been used scarcely in suicidology.^{11 16}

A further step is to exploit EMA's potential to design digital therapeutic tools, providing continuous support in the patient's usual environment. This therapeutic approach is known as Ecological Momentary Intervention (EMI).^{24 25} EMIs can be a useful add-on to traditional treatment, thanks to their 24-hour availability, low cost and the possibility of continuing follow-up in a non-presential manner.²⁵ The latter is becoming particularly important given the situation caused by the COVID-19 pandemic.²⁶ Mobile health also brings us closer to a participatory model in which patients are involved in their treatment.²⁷

Some studies have explored the effectiveness of EMI on suicidal behaviour, showing good acceptability and a reduction in SI after the intervention.^{28–30}

Another possibility is to combine these two modalities offered by mobile technology: monitoring—EMA—and intervention—EMI. In this way, systems could monitor suicide risk and automatically launch an EMI if a high

risk is detected. To our knowledge, a case series³¹ and a clinical trial protocol³² have considered the combination of EMA with EMI.

Smartphone passive monitoring for suicide risk detection is an up-and-coming area that has not yet received sufficient attention in the scientific literature.³³

The SmartCrisis V.2.0 randomised clinical trial aims to evaluate the feasibility and effectiveness of the Ecological Momentary Intervention (EMI) 'SmartSafe' combined with smartphone-based monitoring to prevent STB in patients at high risk of suicide.

Our main hypotheses are that the SmartSafe intervention will be feasible and effective in reducing STB in patients at high risk of suicide. Table 1 outlines the specific objectives and hypotheses of our study.

METHODS AND ANALYSIS

Setting and design

SmartCrisis V.2.0 is a randomised clinical trial with two parallel groups. The intervention group will receive an EMI called SmartSafe, will be monitored using EMA and *will receive* their treatment as usual (TAU). TAU will consist of psychiatric follow-up (scheduled appointments with their psychiatrist) in an outpatient mental health clinic with scheduled clinical reviews based on the Brief Intervention and Contact (BIC) recommendations.³⁴ The control group will receive TAU and will be monitored using EMA.

Sample

Our sample will consist of patients with a history of recent STB attended at the emergency rooms (ERs) of either one of these five locations: University Hospital Fundación Jiménez Díaz (Madrid, Spain), Rey Juan Carlos Hospital (Móstoles, Spain) and General Hospital of Villalba (Villalba, Spain), Centre Hospitalier Universitaire Montpellier (Montpellier, France) or Nîmes University Hospital (Nîmes, France).

Inclusion criteria:

1. Being 18 years of age or older.
2. Presenting with an SA or an emergency referral for SI in the past month. At the time of evaluation in the ER, the attending psychiatrist will administer the Columbia Suicide Severity Rating Scale (CSSRS)³⁵ to determine eligibility—see details on Procedure section.
3. Being able to understand and sign the informed consent form.
4. Being fluent in Spanish.
5. Owning a smartphone with internet access and iOS or Android operating system.

Exclusion criteria:

1. Refusal to instal the mobile application.
2. Inability to understand and sign the informed consent form for any reason.
3. Institutionalised or incarcerated patients, without access to regular mobile phone use.
4. Having participated in the SmartCrisis V.1.0 study.

Table 1 Objectives and hypotheses of the SmartCrisis V.2.0 project

| Area | Objective | Hypothesis |
|----------------------------------|---|---|
| Effectiveness: prevention of STB | To test the effectiveness of the SmartSafe intervention for preventing STB in patients at high risk of suicide | The intervention group will experience a significant reduction in suicide ideation measured with the CSSRS. This reduction will be greater than in the control group. The intervention group will experience a significant reduction in n° of SAs. This reduction will be greater than in the control group. |
| Effectiveness: quality of life | To test the effectiveness of the SmartSafe intervention for improving quality of life in patients at high risk of suicide | The intervention group will experience a significant improvement in quality of life measured with the SLDS. This improvement will be greater than in the control group. |
| Effectiveness: functionality | To test the effectiveness of the SmartSafe intervention for improving functionality in patients at high risk of suicide | The intervention group will experience a significant improvement in functionality measured with the WHODAS 2.0. This improvement will be greater than in the control group. |
| Feasibility: participation | To test the feasibility of the SmartCrisis project in terms of participation, retention, and compliance with EMA questions | Both groups will present participation rates over 75% |
| Feasibility: retention | | Retention will be significantly greater in the intervention group than in the control group |
| Feasibility: compliance | | Compliance with EMA questions will be significantly greater in the intervention group than in the control group |
| Acceptability | To test the acceptability of the SmartCrisis project in terms of satisfaction with the SmartSafe intervention and with the EMA monitoring | The intervention group will obtain significantly higher scores in the satisfaction survey than the control group. |
| Prediction | To test the accuracy of the eB2 and MEMind monitoring systems to predict clinical suicidal events (suicide attempts, emergency referral for suicide ideation and non-suicidal self-injury). | Alterations in normal behavioural patterns detected with eB2 and psychiatric symptoms detected with MEMind will correlate with clinical suicidal events |

CSSRS, Columbia Suicide Severity Rating Scale; EMA, Ecological Momentary Assessment; SA, suicide attempt; SLDS, Satisfaction with Life Domains Scale; WHODAS 2.0, World Health Organization Disability Assessment Schedule 2.

We will accept participants with any diagnosis and any kind of previous treatment (including no treatment).

Sample size calculation

Sample size calculation was performed using G*Power software, V.3.1. Based on previous clinical trials exploring the ability of interventions to reduce SI in the mid-term,³⁶ we estimated a target sample size enough to have 80% power to detect between-group differences of 6–7 points on the SI subscale of the CSSRS³⁵ (25% decrease in the intensity of SI in the intervention group). The alpha error was set at 5% and the power at 80%. We assumed a dropout rate of 20% and a randomisation imbalance of 10%. With these settings, we estimated that we needed a total of 220 participants, 110 in each arm.

Patient and public involvement

Before starting the clinical trial, a pilot will be conducted, in approximately 40 patients. The aim of this pilot is to detect any technical—software, hardware, servers, etc— or human failure—that is, errors made by the staff—in time, as well as to know what our patients think of the intervention, to optimise it as much as possible before

the start of the clinical trial. Patients will be asked what they found most useful, what improvements they would make to the application, and to what extent they would be willing to recommend it to their family or friends. This kind of studies have been performed with other EMIs, such as Crisis Care, EMMA or MyPlan, with sample sizes ranging from 14 to 40 patients³⁷. All of them will receive the SmartSafe EMI and be monitored using active and passive EMA. These patients will not be part of the final analysis. After 3 months of follow-up, when all participants have had time to try out the application, a focus group will be held between the research team, the attending clinicians and the patients in order to get their opinion on the intervention and to identify possible technical and human failures that could be improved before starting the clinical trial.

Procedure

At inclusion (ie, at the index event), the attending psychiatrist will check the patients' eligibility by checking inclusion criteria and by administering the CSSRS.³⁵ We will consider that patients meet the criteria for SI if they score

≥4—active SI with some intent to act—in the CSSRS SI subscale. We will consider that an SA has occurred when the patient meets the criteria for ‘actual SA’ in the CSSRS suicidal behaviour subscale. Additionally, the CSSRS will be administered at every follow-up visit.

After checking the patients’ eligibility, the attending psychiatrist will explain the project in detail and invite patients to participate. If patients agree to participate, they will be asked to sign the informed consent, after which they will be randomly assigned to the intervention group (EMI+EMA+TAU) or the control group (EMA+TAU) using a mixed block randomisation scheme generated with NQuery software. Allocation ratio will be 1:1.

After enrolment, participants will undergo a baseline interview, which will be divided into two parts: the first part will be carried out by attending psychiatrist who will further assess the characteristics of the SA using the Brief Suicide Questionnaire (BSQ),³⁸ and set up the MEmind application—which administers EMI and EMA—with the participant. One of the interventions—the digital safety plan—is fully customisable. It will be set up by the clinicians following the patients’ preferences, and patients will be able to further customise the plan at home if they wish to do so. The second part of the interview will be performed by a trained research assistant, blind to the patient’s assigned arm, who will instal the eB2 application and administer the standardised questionnaires described in the ‘non-digital measures’ section and in [table 2](#).

Patients will be followed up for 1 year, with face-to-face research visits—carried out by the research assistant—at 6 months and at the end of the study, and phone follow-ups—also by the research assistant—at 3 months and 9 months. All questionnaires will be completed through the MEmind website.

The piloting is expected to take place between June and December 2021. Recruitment is expected to commence in January 2022 and to be completed by June 2023. Data collection will take place from 2022 to 2024. Data analysis will take place from 2022 to 2024. We expect to publish partial results by the end of 2022 and final results by early 2025.

[Figure 1](#) illustrates the recruitment, randomisation and follow-up processes.

Non-digital measures

Assessments will be carried out by attending psychiatrists and research assistants, all of them previously trained. All questionnaires will be completed on the MEmind website, which allows for easy completion and immediate uploading to databases.

Some of the main tools used will be the following:

- ▶ The BSQ³⁸ will be administered by the attending psychiatrist to characterise the index event that motivated inclusion in the study (SA or emergency referral for SI). It includes questions on lethality, method and surrounding circumstances of the attempt and life-time history of suicidal behaviour.

- ▶ The CSSRS scale³⁵ will be administered by the attending psychiatrist at inclusion to determine eligibility. Additionally, the CSSRS will be administered by the research assistant at every follow-up visit to detect the occurrence of a new suicidal event.
- ▶ The research assistant will also verify SAs and possible death through digital medical records, which integrates information on ER visits, hospitalisations and visits to specialist consultations. If a patient cannot be located, and there is no information in their record, we will contact the patient’s family telephone number. We will also request access to the Spanish register of deaths and causes of death of the ‘Instituto Nacional de Estadística’ (National Statistics Institute) and its French counterpart, the ‘Institut national de la statistique et des études économiques’ (National Institute of Statistics and Economic Studies).

At the 6-month follow-up visit, patients will complete a previously used qualitative satisfaction survey³⁹ referring to each of the applications used (MEmind and eB2) and the face-to-face assessments. The rest of the questionnaires used are shown in [table 2](#)^{35 38–53}

Digital monitoring

Two EMA modalities will be used: active using the MEmind app⁵⁴ and passive using the eB2 app.⁵⁵

The MEmind app

The MEmind app asks short daily questions that appear on the mobile screen. Each day, a prompt will appear containing 2–4 random questions—four questions during the first 2 months, as this is the period with the higher risk of suicide reattempt⁵⁶; two questions afterwards—will be asked at random times (respecting sleep hours: from 9:00 to 21:00) from the pool of 34 questions that make up the questionnaire, which is based on the Salzburg Suicide Process Questionnaire,⁵⁷ the Patient Health Questionnaire-9,⁵⁸ the Positive and Negative Affect Schedule,⁵⁹ the Interpersonal Needs Questionnaire⁶⁰ and previous EMA studies.^{17 19 22 23}

The EMA questions belong to four categories:

- ▶ Suicidality: 5 questions.
- ▶ Non-suicidal self-injury: 2 questions.
- ▶ Affect: 9 questions.
- ▶ Interpersonal experiences: 11 questions.
- ▶ Sleep: 4 questions.
- ▶ Eating: 3 questions.
- ▶ Appetite: 7 questions.

[Table 2](#) shows the complete list of EMA questions.

The Evidence-Based Behavior (eB2) mobile app

The evidence-based behavior (eB2) app runs in the background and does not require user intervention. It collects real-time information from the patient’s mobile phone (location, mobility, smartphone usage and sleep), stores it and downloads it to a server. All the information collected from the phone is transformed with a hash function. This

Table 2 Ecological Momentary Assessment (EMA) questionnaire

| Area | Variable | Question | Minimum value | Maximum value | Scoring | Source |
|--|--------------------------|---|-----------------------------------|--------------------------------------|---------|---|
| Suicidality (5 questions) | Passive SI | My wish to live is | No wish to die | Maximum wish to die | 1–7 | SSPQ ³⁶ |
| | | My wish to live is | No wish to live | Maximum wish to live | 1–7 | |
| | | Do you have thoughts that you would be better off dead or of hurting yourself in some way? | Not at all | Nearly every day | 0–3 | PHQ-9 ³⁷ |
| Active SI | | How intense is your desire to kill yourself right now? | Absent/no desire | Extremely intense | 0–5 | Based on prior EMA studies ^{15,20} |
| | | How able are you to keep yourself safe right now? | I definitely can keep myself safe | I definitely cannot keep myself safe | 1–5 | |
| Non-suicidal self-injury (2 questions) | Non-suicidal self-injury | At any point in the last 24 hours, did you harm yourself on purpose without the intention to die? | Yes | No | Y/N | Based on prior EMA studies ¹⁷ |
| | | Since the last prompt, have you felt an urge or wanted to harm or injure yourself on purpose, without wanting to die? | Not at all | Extremely | 1–5 | Based on prior EMA studies ²¹ |
| Affect (6 questions) | Psychological pain | I feel psychological pain | No pain | Maximum pain | 1–7 | SSPQ ³⁶ |
| | Stress | I feel stressed out today (with pressure, overwhelmed) | No stress | Maximum stress | 1–7 | |
| | Restlessness | I feel restless (agitated), with the need to keep moving | No restlessness | Maximum restlessness | 1–7 | |
| | Hopelessness | I feel full of hope | No hope | Maximum hope | 1–7 | |
| | Anger towards self | I feel hatred or anger towards myself | No hatred | Maximum hatred | 1–7 | |
| | Anger towards others | I feel hatred or anger towards others | No hatred | Maximum hatred | 1–7 | |
| | Anxiety | At this moment I feel nervous | Very slightly or not at all | Extremely | 1–5 | PANA ³⁸ |
| | Depression | At this moment I feel sad | Very slightly or not at all | Extremely | 1–5 | |
| | Happiness | At this moment I feel happy | Very slightly or not at all | Extremely | 1–5 | |

Continued

Table 2 Continued

| Area | Variable | Question | Minimum value | Maximum value | Scoring | Source |
|---|--|--|--------------------------|-----------------------------|---------|--|
| Interpersonal experiences (11 questions) | Thwarted belongingness | I wish there was a trusted person with whom I can talk about all my personal issues | Not at all | Absolutely | 1-7 | SSPQ ³⁶ |
| | Thwarted belongingness | I feel like an outsider | Not at all | Absolutely | 1-7 | |
| | Lack of recognition | I wish I received more recognition and love from others | Not at all | Absolutely | 1-7 | |
| | Lack of independence | I have the impression that important people around me want to decide for me what I should think and do | Not at all | Absolutely | 1-7 | |
| Criticism | | Since the last prompt have you felt insulted or criticised? | Not at all | Extremely | 1-5 | Based on prior EMA studies ²¹ |
| | Thwarted belongingness | Since the last prompt have you felt rejected, abandoned, excluded, or left out? | Not at all | Extremely | 1-5 | |
| Perceived burdensomeness | | I believe I'm contributing to the well-being of my family/friends | Not at all | Absolutely | 1-7 | SSPQ ³⁶ |
| | | I believe I'm contributing to the well-being of the people around me | Not at all | Absolutely | 1-7 | |
| | Thwarted belongingness | I feel disconnected from other people | Not at all | Absolutely | 1-7 | |
| Perceived burdensomeness | | I feel like a burden to others | Not at all true for me | Very true for me | 1-7 | INQ ³⁹ |
| | | I feel useless | Not at all true for me | Very true for me | 1-7 | |
| Sleep (4 questions) | Sleep maintenance | Last night I had trouble staying asleep | None | Very severe | 0-4 | SSPQ ³⁶ |
| | Sleep-derived quality of life | Others think that sleep problems affect my quality of life | Not at all | Absolutely | 1-7 | |
| | Sleep dissatisfaction | Today I am satisfied with my sleep | Very unsatisfied | Very satisfied | 1-7 | |
| | Sleep-derived interference with daily activity | My sleep problems are interfering with my daily activity | Not at all | Very much | 0-4 | |
| Eating (3 questions) | Appetite | In the last few days, I have been hungry. | Never | All the time | 0-4 | SSPQ ³⁶ |
| | Taste | In the last days when I eat, the food tastes. | Very bad | Very good | 0-4 | |
| | Number of meals | In the last few days, I usually do. | Less than one meal a day | More than three meals a day | 0-4 | |
| INQ, Interpersonal Needs Questionnaire; PANAS, Positive and Negative Affect Schedule; PHQ-9, Patient Health Questionnaire-9; SI, suicidal ideation; SSPQ, Salzburg Suicide Process Questionnaire. | | | | | | |

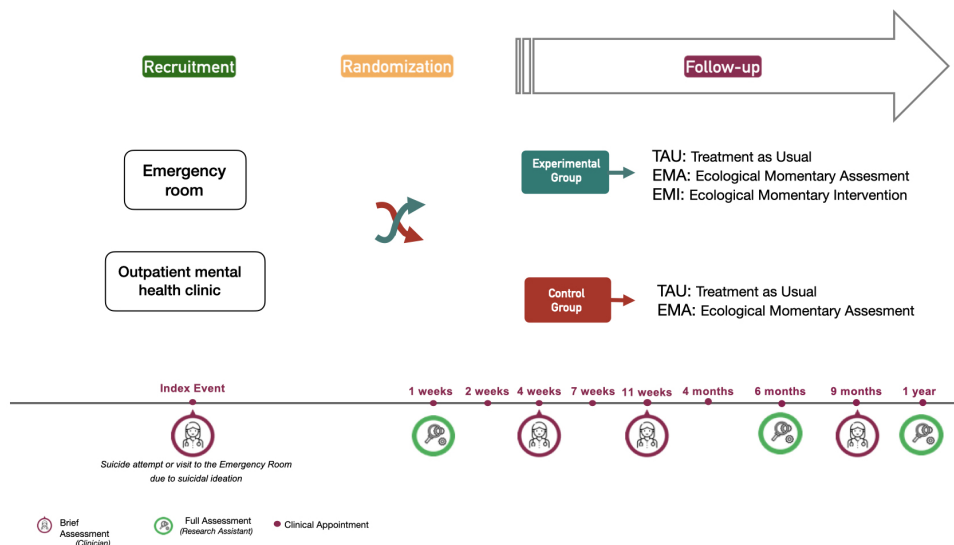


Figure 1 Recruitment, randomisation and follow-up process.

hash function makes it impossible to know the original data but allows the analysis of behavioural patterns.

Other digital assessments

In addition to the smartphone-based monitoring, another two digital assessments will be carried out:

Digital intervention

The SmartSafe EMI is contained in the MEmind app and consists of three modules: a Safety plan, an Enhanced contact via app (app-EC) intervention and a toolbox with different exercises (Mental Toolbox).

Safety plan: a safety plan consists of a set of personalised coping strategies that the patient can use in a suicidal crisis.⁶¹ It should be set up with the assistance of clinical staff. Our safety plan is based on the Safety Planning Intervention developed by Stanley and Brown,⁶¹ adapted to a digital environment. The safety plan will benefit from smartphones' advantages, including the possibility to call their loved ones, show videos with relaxation techniques, activate prerecorded messages, lead to websites with health resources or put the patient in contact with the emergency services.

The safety plan has the following elements, all of which are customisable:

1. **Warning signs:** this is a list of symptoms of signs that may alert the patient that a suicidal crisis is about to take place. For instance: insomnia in the past few days.
2. **Internal coping strategies:** What can I do on my own to get better? For instance: a video with relaxation techniques.
3. **External coping strategies:** these are distraction strategies, such as going for a stroll or going to watch a movie.
4. **Personal contacts:** family or friends who can help us. Phone contacts can be imported and directly accessed through the app.

5. **Professional contacts:** institutions and professionals that can provide help. Phones or web links can be imported. Also, a link to a Maps application showing the fastest route to the nearest Emergency Room or Mental Health Clinic can be uploaded to the app.
6. **Safe environment:** tips for keeping the environment free of lethal means.
7. **Reasons for living:** the most important reason for staying alive. Here, the patient can, for instance, upload the photo of a loved one.

Enhanced contact via app (app-EC): This intervention is inspired by the SIAM (Suicide intervention assisted by messages) project,⁶² based on the pioneering intervention proposed by Motto and Bostrom.⁶³ Throughout the follow-up, personalised messages will be sent via the MEmind app to patients and announced via push notifications on the phone screen. The message will inquire patients about their mental well-being and inform them of the means to request preferential or urgent care. We will send different text messages to each patient 48 hours after discharge, day 8, day 15 and monthly from months 1 to 12.

Mental toolbox: the mental toolbox includes videos with relaxation techniques—deep breathing and meditation, behavioural activation exercises—self-monitoring of activities and activity scheduling and structuring—metacognition training exercises and mentalisation exercises.

Any side effect or discomfort that patients may experience during the research will be registered.

During the scheduled appointments, patients will have the opportunity to discuss the safety plan with the attending psychiatrist, who will assist them in performing further customisations and keeping the plan up to date.

Non-digital intervention

All patients, regardless of their group —Intervention or Control— will receive TAU, consisting of a scheduled mental health follow-up at an Outpatient Mental Health Clinic. TAU will consist of scheduled clinical reviews based on BIC recommendations adapted to a follow-up of 12 months instead of the original 18 months (1, 2, 4, 7 and 11 weeks, and 4, 6, 9 and 12 months).³⁴ The BIC intervention has shown to significantly lower the odds for suicide (OR=0.20, 95% CI 0.09 to 0.42).⁶⁴ The need for psychopharmacological treatment and the treatment chosen in each case will be decided by the attending psychiatrist based on the individual needs of each patient.

Outcomes

Two comparisons will be made after the intervention: before/after comparison, and comparison between the intervention group and the control group, regarding the primary and secondary outcomes mentioned below.

Our primary outcome will be reduction of SI, measured with the CSSRS (severity and intensity subscales).

Our secondary outcomes will be:

- ▶ Improvement in symptoms, quality of life and functionality measured by standardised questionnaires.
- ▶ Reduction of STB, measured as a clinical event (death by suicide, SAs, ER visit for SI).
- ▶ Reduction of EMA-measured active SI—thoughts about taking one's life—and passive SI—that is, wish to die.
- ▶ Correlation between clinically observed suicidal events and active and passive EMA-detected crises. For active EMA, crisis will be defined as extreme scores in the SI questions. For passive EMA, crisis will be defined as changes in the previously detected usual behavioural patterns—sleep, physical activity and smartphone use—for each patients—15 days of use are required to determine such patterns.
- ▶ Acceptability measured by user satisfaction.
- ▶ Feasibility measured by participation rate, retention rate and compliance with EMA questions.

Safety protocol

To safeguard the well-being of our patients, we will implement a suicide risk safety protocol: the CSSRS will be administered to all patients at every measurement point. On detecting an alarming level of SI severity (threshold established at CSSRS score ≥ 4), their attending psychiatrist will be informed, and patients will be offered to go to the ER. Also, as part of the EMI intervention, extreme values of SI detected by EMA will activate the safety plan contained in the application, which will implement different strategies to contain suicide risk, as explained in the section Digital intervention.

Statistical analysis

Traditional statistical analyses will be performed using SPSS V.24.0 statistical software. To compare SI

at baseline with SI at the end of follow-up (CSSRS score), we will use paired samples t tests. To compare the improvement in SI after follow-up between the intervention group and the control group, we will use an independent samples t-test.

Survival curves (time to a new suicidal event) will be calculated using the Kaplan-Meier test. The intervention group's survival curves and the control group will be compared using the log rank test. To assess the project's feasibility, participation rate, retention and percentage of EMA questions answered will be calculated.

Binary logistic regression will be used to explore the correlation between the study variables, obtaining crude ORs and age-adjusted and sex-adjusted ORs. A multivariate regression model will also be built to assess the unique strength of the association of the variables. Cox regression analysis will be performed to explore variables associated with survival time (time until next event). All tests will be two-tailed, with a significance level of $p < 0.05$ and 95% CIs.

In addition to the traditional analyses, with the Signal Theory Department of the Carlos III University's support, unsupervised analyses will be carried out using machine learning techniques to create behavioural models and patient activity profiles from data collected through active and passive EMA.

ETHICS AND DISSEMINATION

Study approval

This study has been approved by the Ethics Committee of the University Hospital Fundación Jiménez Díaz. The research will be conducted following the World Medical Association's Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects.⁶⁵

No data that could lead to the identification of participants will be published. Each participant will receive a code with which he/she will be identified throughout the study. All patients must give their written informed consent to participate in the study. It will be stressed that participation is voluntary and that they may revoke consent and leave the study at any time if they wish to do so. There is no cost or financial compensation for participating in this study.

The protocol for this study has been registered in ClinicalTrials.gov.

Dissemination plans

Suicide is a major but potentially preventable health problem.⁶⁶ Smartphone-based monitoring and intervention can help us in the management and prevention of STB. The SmartCrisis V.2.0 study aims to provide a smartphone-based intervention for the management of suicidal crisis that complements the traditional therapeutic approach.

We expect our project to be well accepted by participants, which will be reflected in high satisfaction survey scores. We also expect that participants in the study will experience a significant reduction in SI and that this reduction will be more significant than that experienced by the control group. Finally, it is hoped that the MEmind and eB2 mobile applications can be implemented in everyday clinical practice in the near future.

Our study results will be analysed and used to write a number of manuscripts, which will be submitted to peer-reviewed journals. Both significant and non-significant results will be presented, whether they show the effectiveness of the intervention or not. We will also present the results of our research at psychiatry conferences and other forums for the dissemination of knowledge.

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Contributors EB-G, MLB, AP-S, PC, SB, M-MP-R, JL-C, AA and the MEmind study group conceived and designed the SmartCrisis 2.0 study. AP-S and MLB wrote the first draft of the study protocol. Their co-authors made significant revisions. All authors contributed significantly to the manuscript's drafting and revision and approved the final revision of the manuscript.

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