A digital companion for ecological momentary assessment and prevention of suicide: A case series on the use of the *emma* app

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Abstract

Background: Many suicide risk factors have been identified, but traditional clinical methods do not allow the accurate prediction of suicide behaviors. To face this challenge, we developed *emma*, an app for Ecological Momentary Assessment/Intervention (EMA/EMI) and prediction of suicide risk in high risk patients.

Objective: We wanted to test the feasibility of implementing this mHealth-based suicide risk assessment and prevention tool and its impact in subjects at high risk of suicide in real world conditions.

Methods: The EMMA Study is an ongoing longitudinal interventional multicenter trial in which patients at high-risk for suicide (n=100) use *emma* for 6 months. During this period, they complete four EMA types (daily, weekly, monthly, spontaneous) and may use EMI modules. Participants undergo clinical assessment at month 0, 1, 3 and 6 after inclusion.

Results: Among the 43 patients already recruited in the EMMA Study, 14 participants had completed the follow-up. Their data were analyzed to evaluate *emma* implementation and impact on suicide risk management. EMA completion rates were extremely heterogeneous among the 14 participants with a sharp decrease over time. The completion rates of the weekly EMA (25% to 87.5%) were higher than for the daily EMA (0% to 53.3%). Most patients (n=10/14) answered the EMA questionnaires spontaneously. Similarly, the *Safety Plan Modules* use was very heterogeneous (2 to 75 times). Specifically, 11 patients used the *Call Module* (1 to 29 times), designed by our team to help them to get in touch with healthcare professionals and/or relatives during a crisis. All patients used the *Breathing Space Module* and 8 the *Emotion Regulation Module* (1 to 46 times). The diversity of patient profiles and use of the EMA and EMI modules proposed by *emma* was highlighted by three case reports.

Conclusions: These preliminary results suggest that it is possible and acceptable to collect longitudinal fine-grained contextualized data (EMA) and to offer personalized intervention (EMI) in real time to people at high risk of suicide. Patients have different clinical and digital profiles and needs that require a highly scalable, interactive and customizable app. To become a complementary tool for suicide prevention, *emma* should be integrated in the existing emergency procedures.

Trial Registration: ClinicalTrials.gov NCT03410381, <https://clinicaltrials.gov/ct2/show/NCT03410381>.

Key words: Suicide, Ecological Momentary Assessment, Prediction, Prevention, Mobile health (mHealth), Case reports, Ecological Momentary Intervention.

BACKGROUND

Context

According to the World Health Organization (WHO) suicide is the cause of one million deaths per year (nearly 2% of all deaths worldwide), and should increase to 1.5 million by 2020 [1,2]. The WHO recognizes suicide prevention as a public health priority [1]. History of suicide attempts is the most important risk factor of suicide death in the general population, and is present in about 40% of suicides [3,4]. Patients who come to the emergency department (ED) following a suicide attempt present an extremely high risk of suicide in the short term [5–7].

People at risk of suicide often do not seek help and do not remain connected to the health service after an attempt [8]. Access to mental healthcare is inversely correlated with the suicide rate [9]. It is reported that less than half of patients at risk of suicide are in contact with the health system, including mental health services [10], partly because they think they will "get on by themselves" [11]. Access to care is hindered by attitudinal (e.g., no hope or trust in treatments, stigma, shame, previous contact with psychiatry [12], refusal or avoidance of help, "help-negation") and structural barriers (e.g., financial, geographical, and issues with healthcare access, etc.) [13] 14]. It can be hypothesized that factors and traits of vulnerability to suicidal behavior (impulsivity, hostility, decision-making anomalies correlated with interpersonal problems, emotional dysregulation, hypersensitivity to social rejection, reduced perception of social support, despair) facilitate and amplify these difficulties of access and adherence to care.

Ecological Momentary Assessment

Often, suicidal risk is exacerbated when patients are in their natural environment, far from the healthcare system, in their daily life [15]. Therefore, real-time emotional, behavioral and psychological assessments could improve the identification of high-risk individuals who require rapid interventions. Ecological Momentary Assessment (EMA), also commonly defined as experience sampling method, allows collecting longitudinal fine-grained data as they occur in the real world. It gives an accurate picture of the patient's symptoms [16], and reduces the impact of self-report response bias, thus leading to a better appreciation of the temporal dynamics of suicide risk [17]. Davidson et al. regretted that this method has been fairly neglected in suicidology [18]. Indeed, only ten studies have used real-time monitoring to assess suicidal thoughts [19], although compliance with daily life repeated assessments is high across populations with different suicide and suicidal ideation risks [20]. Moreover, no iatrogenic effect related to repeated assessments of suicidal ideation was found [20–22], and several studies even suggested potential benefits. According to Davidson et al [18], patients may feel less hopeless by following their suicidal ideation changes over time. Other studies suggested that EMA could decrease suicidal ideation [21,23].

Typically, suicidal ideation is episodic, with a quick onset [24] and short duration (shorter than an hour) [25]. Suicidal thoughts vary dramatically among individuals [19], and fluctuating or persistent suicidal thoughts are associated with the risk of different suicidal behavior types [25]. Currently, suicidal thoughts are intermittently assessed at intervals that can go from weeks to years [26], and suicidal thoughts "in the wild" cannot be observed and monitored [24] because they can vary within few hours [24,27,28]. Furthermore, suicide attempts can occur in response to a rapid increase in suicidal thoughts within a very short time (one day) [15,24,29]. These observations highlight the importance of not relying on intermittent assessments of suicidal ideation for clinical decision-making (such as hospital discharge) [24,30]. Mobile health (mHealth) interventions are a promising way to assess these fluctuations in real time.

Ecological Momentary Intervention for suicide prevention

The safety plan intervention [42] is one of the recommended strategies in suicide prevention guidelines [43], and is considered as a therapeutic intervention on its own [44]. At the ED, patients with suicidal ideation and clinicians identify the warning signs and write together a personalized crisis plan that can be used at times of crisis [44]. The Zero Suicide Model [45] recommends this evidence-

based best practice brief intervention that allows reducing lethal means, promoting brief problem solving and coping skills, increasing social support, and identifying emergency contacts to use during a suicide crisis.

Digital tools could increase the effectiveness of these prevention strategies. Indeed, apps are affordable and ubiquitous, and can be used in any situation, particularly during a crisis [46]. The WHO recommends them for people at risk of suicide [1] because they offer new opportunities to overcome some of the help-seeking barriers [14,47–49], and enhance safety planning [43] in response to dynamic suicidal processes in real-time [24].

Hypothesis and aims

We hypothesized that it is possible to assess and prevent suicidal behaviors in real time in high-risk patients using digital tools. To test this hypothesis, we developed *emma*, an app to monitor the psychological, emotional and social fluctuations of patients in their daily life. In addition to EMA, the app includes also interactive and customized EMI modules for suicide prevention. This app is currently tested in an on-going trial (EMMA study). Here, we performed a descriptive analysis of selected patients at high risk of suicide to obtain insights into the feasibility of implementing a mHealth-based suicide risk assessment and prevention procedure in real life conditions.

Objectives

The main objective of the present study was to assess the feasibility of implementing a mHealth-based tool to assess and prevent suicidal behaviors in real life conditions in a sample of individuals at high risk of suicide.

The secondary objectives were:

- To describe typical user profiles of the *emma* app;
- To describe relevant qualitative elements from the interviews of participants who completed the 6-month study.

METHODS/DESIGN

Study design

The EMMA project includes two successive clinical studies:

- Step 1 (EMMA Study): Building a suicide predictive algorithm based on the EMA data supplied by high-risk patients (n=100) through the *emma* app
- Step 2: Validation of the algorithm effectiveness in a larger sample (n=500).

The EMMA Study is an on-going prospective longitudinal interventional multicenter trial (involving four French university hospitals in Montpellier, Lille, Brest, and Créteil) completed by a qualitative study. The protocol was registered in the Clinical Trials Registry (ClinicalTrials.gov; number: NCT03410381, 18/01/2018), was authorized by the French Health Ministry (ANSM, 30/11/2017), and approved by the Est IV Ethical Committee for the Protection of Patients (10/10/2017).

Participants

The EMMA Study plans to recruit 100 patients from EDs and mental health departments. Patients are included after a suicide attempt (<8 days) and/or if they had suicide ideation (IDSC-30 scale score ≥ 2). The other inclusion criteria are: aged 18 years or older, signature of the informed consent, and possession of a smartphone (iOS or Android). Exclusion criteria are: refusing to participate, under guardianship, protected by law, deprived of liberty, not affiliated to a social security system, in a period of exclusion from other trials, and unable to understand the study.

Procedure

At inclusion, a psychiatrist performs the first interview to ensure that the patient meets the eligibility criteria and to obtain the informed written consent. Four clinical assessments are conducted, at inclusion and at month 1, 3 and 6. Clinical data are collected by:

1) Hetero-evaluation: presence of psychopathology (Mini-International Neuropsychiatric Interview & Structured Clinical Interview, MINI [61]), depression intensity (Inventory of Depressive Symptomatology, IDS [62]), and suicidal spectrum (Columbia–Suicide Severity Rating Scale, C-SSRS [63]; Risk-Rescue Rating Scale, RRRS [64]; Risk Rescue and Suicidal Ideation Scale, SIS [65]).

2) Self-assessment questionnaires: depression (Quick Inventory of Depressive Symptomatology, QIDS [62]); childhood abuse (Childhood Trauma Questionnaire-Short Form, CTQ-SF [66]); loneliness [67], social isolation [68], attachment [69], and hopelessness (Beck Hopelessness Scale, BHS, [70]); impulsivity [71] and emotion regulation (Difficulties in Emotion Regulation Scale, DERS [72]); Interpersonal Needs Questionnaire [73]; reasons for living (RFL [74]); Meaning in Life [75], and quality of life (SF-36 [76]).

Satisfaction concerning the app is evaluated in three distinct ways: i) questionnaire about the usefulness and satisfaction of the app administered every month via *emma*, ii) standardized self-administered questionnaire (Mobile App Rating Scale, MARS [81]) at the end of the study, and iii) qualitative semi-structured interview about the participant's subjective experience.

At inclusion, a member of the research team helps patients to install, configure and personalize the app. Patients are asked to use *emma* for 6 months. Data collected during the assessments made by clinicians as well as data and metadata resulting from *emma* use are encrypted and stored in a secure server. All these data will be used to develop the algorithm to predict suicidal risk (Figure 1). Considering the crucial issue of health data privacy and security, multi-level technical and organizational safeguards were put in place. The app is secured by a password, as requested by the co-designer patients, and data are anonymized, encrypted, and stored in a secure server to prevent unauthorized data disclosure or breach, as recommended by European General Data Protection Regulation (GDPR).

Figure 1. Visual description of the study

Outcome Measures

The principal outcome measure of this study was the quantitative description of the app use: completion of the EMA questionnaires and use of EMI modules.

The secondary outcome measures were:

- Quantitative description and app use timeline in few selected patients to illustrate different users' profiles;
- Qualitative analysis of selected interviews of participants who completed the 6-month follow-up.

Emma design

Emma is a smartphone app we developed for the assessment, prevention, and ultimately prediction of suicidal behaviors. It was designed by integrating evidence-based suicide prevention strategies

and recommendations for the development of apps in the field of mental health [50,51]. *Emma* design was based on theoretical literature data and on the practical data obtained by our research team by testing the available suicide-related apps. *Emma* was developed for Android and iOS for wide usage.

Emma was conceived using a participatory design approach that included patients with suicidal thoughts/behaviors as equal partners of our professional multidisciplinary team (researchers, psychiatrists, psychologists, sociologists, computer scientists, engineers and data scientists) from start to finish [52,53]. This ensured that *emma* meets scientific and technical standards [54] as well as the patients' needs [55–57]. To this aim an user-involving methodology based on focus groups [58] was implemented. Early in the development process, the involved patients stressed the importance of having a secured password to open the app, and contributed to the choice of the name "*emma*" that they wanted to be not stigmatizing, and without any mention of psychiatry or suicide. A group of co-designer patients (n=5) and clinical staff (n=5) tested extensively the app for 3 months, and their feedback was taken into account in an iterative way by the developers at the Laboratory of Informatics, Robotics and Microelectronics of Montpellier (LIRMM) to improve the app. This allowed ensuring that the notifications asking to fill in the EMA questionnaires were not leading to interruption/disruption in the users' daily activities in order to maximize *emma* acceptability, use [56], and validity [59].

***Emma* contents**

Emma allows patients to define and personalize their own safety plan based on the steps defined by Stanley and Brown [42], and was designed to be used as a self-help tool for suicidal crisis management. Patients are invited to identify: A) their warning signs (e.g., negative feelings and problematic behaviors); B) their individualized coping strategies (e.g., "Breathing Space": audio awareness guide made specifically for *emma* by a psychiatrist expert in suicidal behavior); C) their distraction activities (e.g., favorite places and activities, libraries of music and pictures that are known to help with emotional regulation [46] and to connect with the patient's reasons for living); D) their social support (e.g., collating the contact details of the patient's social network, mental health professionals, and other crisis resources). This module promotes connectedness, a major protective factor in suicide prevention [47].

Emma does not include advices to make the environment safe in order to avoid any risk related to the cognitive availability of access to lethal means that could potentially encourage risky behaviors [60].

To improve treatment access and adherence, drug management and therapy session reminders are proposed by the app, and the patient may fill in a diary.

As recommended, an app section provides information (text and video) on how *emma* was designed, how to use it, how to contact the team, and on the legal notice that specifies the secure data storage. Examples of *emma* screens are shown in Figure 2.

Figure 2. *Emma* screenshots

Emma proposes four brief EMA types: three scheduled evaluations at pre-determined frequencies (daily, weekly, and monthly), and one spontaneous assessment (Figure 3). We defined alarm thresholds on the basis of the patient's answer to critical questions that lead to the automatic suggestion of adapted EMI modules (Figure 4). For each EMI module, the app presents a list of suggestions (their content and order can be changed). Modules are designed to be adaptable to the user's state, needs, and strategies.

Figure 3. EMA types proposed by *emma*

Figure 4. Algorithm for automatic EMI triggering according to the EMA answer thresholds

RESULTS

1. Baseline assessment

From May 2018 to March 2019, 43 patients at risk for suicide (recent attempters or current ideators) were selected for the EMMA study at EDs and post-emergency departments, and 38 (88%) agreed to participate. Five patients refused because they considered the study duration (6 months) too long. The present analysis included the 14 patients who have already completed the study (Figure 5). Their sociodemographic and clinical data are reported in Table 1 and 2, respectively. These first *emma* users were mostly women (n=12/14), with an mean age of 34 years (18-57 years). All participants presented at least one mental disorder, according to the DSM-5 criteria, and most of them more than one (up to five comorbid disorders); 43% were recent suicide attempters (≤ 8 days), and they all had severe suicidal ideation (average C-SSRS score: 22/25, range: 15 to 25).

During the study, four patients were admitted to the ED (suicide ideation and/or suicide attempt) 1 to 3 times, and one patient made a suicide attempt without ED admission (Supplemental Table). Two patients left before the first follow-up visit (one was excluded because she was restrained, and the other one withdrew from the study).

Figure 5. Flowchart of patients' selection

Table 1. Sociodemographic data

Patient	Sex	Age	Marital status	Number of children	Cohabitation	Professional situation
1	Female	24	Single	0	Lives alone	Working (stable)
2	Female	18	Single	0	With family	Student/Training
3	Female	27	In a relationship	0	Lives alone	Volunteer
4	Female	33	In a relationship	2	With family	Working (stable)
5	Female	40	In a relationship	2	With family	Working (precarious)
6	Female	46	Separated	3	Non-family cohabitation	Without activity, at home
7	Female	30	Single	0	Lives alone	Disability
8	Male	48	In a relationship	2	With family	Sick leave
9	Female	57	Separated	4	With family	Disability
10	Female	48	In a relationship	2	With family	Sick leave
11	Female	21	In a relationship	0	Non-family cohabitation	Student/Training
12	Female	23	Single	0	Lives alone	Student/Training
13	Male	18	Single	0	With family	Student/Training

14	Female	48	Separated	1	Lives alone	Working (stable)
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Table 2. Clinical data

Patient	Current diagnoses	DSM-5	Borderline personality	Suicidal risk in the near future according to the DSM-5	Suicidal ideation intensity*	Number of suicide attempts	Characteristics of severe/violent suicide attempt**	Family history of suicide attempt	Family history of suicide
1	Major depressive disorder			Yes	22	2		No	No
2	Major depressive disorder Agoraphobia Social phobia Anorexia		Yes	Yes	25	2		No	No
3	Major depressive disorder Agoraphobia Social phobia Bulimia		Yes	No	25	30	Violent (n=2) Severe (n=1)	Yes	No
4	Major depressive disorder			Yes	25	2		Yes	No
5	Major depressive disorder Severe alcohol and substance-related disorder Bulimia Bipolar disorder II			No	23	1		Yes	Yes
6	Major depressive disorder Severe alcohol-related disorder			Yes	15	2		No	No
7	Major depressive disorder Generalized anxiety disorder Bipolar disorder I			Yes	25	55	Violent (n=15)	No	No
8	Major depressive disorder Social phobia Severe alcohol-related disorder Generalized anxiety disorder Bipolar disorder I			No	25	1		Yes	No
9	Major depressive disorder Agoraphobia Post traumatic disorder Bipolar disorder II			Yes	25	8	Severe (n=1)	No	No
10	Major depressive disorder			Yes	24	1		Unknown	Yes
11	Generalized anxiety disorder			Yes	16	1		Yes	No
12	Major depressive disorder Agoraphobia Social phobia Bulimia			Yes	19	0		Yes	Yes
13	Major depressive disorder Social phobia Generalized anxiety disorder		Yes	Yes	20	3		No	No
14	Major depressive			No	18	1		No	No

* sums of items 7 to 11 of the C-SSRS, scores from 0 to 25.

** Violent suicide attempt was defined by the method violence: weapons, hanging, jumping from a height, traffic, drowning, or immolation.
Severe suicide attempt: suicide attempt requiring hospitalization in intensive care unit.

2. Principal outcome

The completion rates were higher for the weekly than daily EMAs (25% to 87.5%, and 0% to 53.3%, respectively). Moreover, they were extremely heterogeneous among participants with a sharp decrease over time. Most patients (n=10/14) filled in the questionnaires spontaneously at times of crisis (from 1 to 39 times).

Similarly, use of the *Safety Plan Modules* (EMI) varied among patients (2 to 75 times). Most patients (n=11) used the *Call Module* (1 to 29 times) to get in touch with the healthcare system and/or family and friends during a crisis. Most patients (n=10) called the SAMU (French national emergency medical assistance service available 24/7; 1 to 15 times), 8 their relatives (1 to 7 times), and 7 their ED (1 to 7 times). About half of the patients (n=8) used one of the *Emotion Regulation Modules* (1 to 46 times). Specifically, eight listened to the *Breathing Space Module* (1 to 5 times), while only four looked at *Pictures* (1 to 41 times), and two listened to *Music* (2 and 7 times).

3. User profiles

Three users are described in detail to better illustrate the different *emma* uses. These patients were chosen to reflect the diversity of patients' clinical profiles and of *emma* use (i.e., completion rate of the scheduled EMAs and use of the *Safety Plan Modules*).

Patient 7

Patient 7 is a 30-year-old single woman living alone, without children, unemployed and benefiting from the disability living allowance for adults (Table 1). At inclusion, she had major depressive disorder, generalized anxiety disorder, and bipolar disorder I, according to the DSM-5. She had 55 previous suicide attempts of which 15 violent, and a maximal suicidal ideation intensity at inclusion (C-SSRS score of 25/25) (Table 2). Therefore, she was at very high risk, and the period following hospitalization is known to be particularly at risk of recurrence, as confirmed by her three admissions to the ED during the study period (Figure 6). The first admission for suicidal ideation occurred just after her hospital discharge. She presented maximal suicidal ideation intensity that was ecologically assessed via *emma*, and she used the *Call Module* just before ED admission, and an *Emotion Regulation Module* just after. Two months later, in addition to the scheduled EMA, she filled in the questionnaires spontaneously several times with very high suicidal ideation scores. These spontaneous self-assessments were immediately followed by the use of the *Call Module* with a sharp decrease in suicidal ideation. Nevertheless, suicidal ideation rapidly increased again, leading to a new admission to the ED. About a month later, despite the lower suicidal ideation score at the spontaneous self-assessment and the use of the *Emotion Regulation Module*, she was admitted to the ED for an aborted suicide attempt by hanging.

During the study period, Patient 7 completed 66 EMA self-assessments. Specifically, she completed only 4.4% of the scheduled daily questionnaires due to technical problems (notifications not received), and about 75% of the weekly questionnaires, and she frequently filled in the questionnaires in a spontaneous way (39 times), particularly at specific times (without frequency decrease during the study period). She often used the *Call Module* (29 times), particularly to contact the SAMU (15 times), followed by the ED (7 times) and relatives (7 times). She also looked at *Pictures* (41 times) and listened to the *Breathing Space Module* (5 times).

A qualitative longitudinal analysis showed that the EMA made via the app allowed capturing suicidal ideation fluctuations that were not highlighted by the clinical follow-up visits (Figure 6). It also showed a regular use of the safety plan modules (at least one module per month) the frequency of which increased at specific times. For instance, in July the high intensity of suicidal ideation evaluated ecologically by *emma* corresponded to an increased use of the *Call Module*. December was

characterized by many spontaneous EMA completions, lower suicidal intensity, and frequent use of the *Emotion Regulation Module*. This suggests that *emma* alarm thresholds triggered EMIs adapted to her condition severity.

Patient 9

Patient 9 is a 57-year-old single woman living with her four children. She is unemployed with a disability living allowance for adults (Table 1). At inclusion, she had major depressive disorder, agoraphobia, post-traumatic disorder, and bipolar disorder II, according to the DSM-5. At the first clinical evaluation, suicidal ideation intensity was very high (C-SSRS score of 25/25) with suicide risk in the near future. She already committed eight suicide attempts, including one severe (Table 2). During the study, the clinician reported a decrease in suicidal thoughts at the 1-month follow-up visit, and then absence of suicidal thoughts at the 3- and 6-month visits.

Patient 9 filled in rarely the daily EMAs (10%), but she completed 81.2% of the weekly EMAs, and filled in EMAs spontaneously 29 times. She completed 100% of the monthly questionnaires about her perception, experience and satisfaction about *emma* use. The longitudinal qualitative analysis (Figure 6) showed that from month 2 after inclusion, both the self-assessments made with *emma* and the hetero-assessments made during the visits did not detect any suicidal idea. Patient 9 used her safety plan only once at the very beginning of the study, when she still had suicidal thoughts.

Patient 10

Patient 10 is a 48-year-old woman, living with her husband and their two children. When included in the study she was on sick leave (Table 1). She had major depressive disorder and suicidal risk in the near future, according to the DSM-5, and very high suicidal ideation intensity (C-SSRS score of 24/25). She reported one suicide attempt and family history of suicide (Table 2). Patient 10's suicidal ideation decreased at the 1- and 3-month follow-up visits, but was higher again at the 6-month visit.

Patient 10 never filled in questionnaires spontaneously, only once the daily EMAs, and not often the weekly EMAs (35%). She completed only one monthly questionnaire about her *emma* experience. She used her safety plan several times, mainly to call her relatives (3 times), the SAMU (3 times), and the ED (2 times). She also listened to the *Breathing Space Module* (3 times).

Patient 10 reported suicidal thoughts via *emma* only during a brief period (in October and early November) and at that occasion she used the *Emotion Regulation Module*, also only once (Figure 6). Self-assessment may have helped her to become aware of her condition and use the tools *emma* offers to regulate her emotions. This patient used the *Call Module* twice: immediately after her inclusion in the study, in August, when she had severe suicidal thoughts and suicide risk, and then at the end of November (no suicidal thought reported via *emma* at that time). Therefore, the app seems to be useful at times of crisis, even when patients do not complete the scheduled questionnaires.

Figure 6. Case reports, Patients 7, 9, and 10.

4. Qualitative study

The first qualitative feedbacks from the participants collected during the qualitative study (semi-directive interviews) were very positive. They emphasized the support and the connectedness dimensions allowed by the app. During the co-design process, patients proposed to give the app a female name to personify it. The first users interviewed seemed to appreciate this, as stressed by a patient: *“emma is like having a companion”*.

This “digital companion” seemed to help reducing the feeling of loneliness: *“We have the feeling that we are not alone, that the software supports us”*. Moreover, this support comes at a critical time, after hospital discharge. To our knowledge, this period at very high suicide risk [19], when patients may experience painful loneliness in contrast to the time in hospital where they are followed by the healthcare team 24 hours per day, has not been much studied. *“Thanks to emma, I did not feel alone”*

when I left the hospital. I know emma less than my relatives, but I can tell her more". Emma also appeared to be a support, autonomy, and empowerment tool by helping people to use their own resources: "emma is an appointment with oneself. It is the memory of the patient: I know who to call." This empowerment was facilitated by the possibility to personalize the app: *"It is important that we can each fill in the things that affect us and the things that impact us because we are all different and it allows targeting everyone specifically; it is good because it helps us deep down"*. These first qualitative interviews highlighted the interest of the co-design process that enabled patients to appropriate the digital tool.

Discussion

EMMA is an on-going study designed to develop a mHealth-based prediction algorithm for suicide prevention. The present report describes quantitatively and qualitatively the *emma* app use by the first 14 patients included in the study. Moreover, the in-depth analysis of its use by three patients brings more insights into the app use timeline, and how it might be integrated in the routine care. These descriptive results indicated that this type of digital tool could be accepted and used by patients at high risk of suicide. The study participation rate (88%) was very good compared with other studies. For example, Hallensleben et al reported that 46.7% of inpatients with unipolar depression agreed to complete EMA [30]. As the EMMA Study plans to include 100 patients who will use the app for 6 months, a larger number of patients will perform EMA over a longer period of time compared with all previous studies [19].

Our analysis showed a heterogeneous use and engagement with the *emma* app, most often an under-use relative to our expectations. This could be interpreted as a poor adherence to the app [77,78], and was partly caused by technical problems experienced by the first participants (e.g., notifications did not appear at the beginning of the study). Besides the simple quantitative measure of the app use, it was important also to evaluate the users' subjective experience [79]. As recommended [80], our evaluation was based on a mixed-method approach that combined: 1) automatically recorded metadata on *emma* use, 2) questionnaires on the app usefulness and satisfaction administered via the app and at the end of the protocol (MARS), and 3) a qualitative semi-structured interview on the participants' experiential and subjective experience at the end of the study. This should allow identifying different user profiles, and developing tailored prevention strategies [44].

The app was designed to strengthen the patients' connection to their natural support network (family, friends...) and also to the healthcare system, particularly through the *Call Module* promoting help-seeking at times of crisis. The connectedness philosophy implemented in *emma* is considered a strong protective factor for suicidal behaviors [82,83]. *Emma* does not replace the patients' relational supports, but increases them. This is important because it is thought that subjectively perceived and effectively received social supports [84] improve mental and physical well-being [85]. *Emma* has the potential to act on the quality of patients' social ties and their social pain that seems to be involved in suicidal crises [87]. During the first qualitative interviews, patients expressed the importance to feel supported by the software, to have the opportunity to "*talk to emma*" as a companion, to tell her things they would not dare to say to their relatives, to protect them and/or out of fear of the stigma that their confidences could generate.

For *emma* design, data from the scientific literature and the wishes and experiences of patient-users were integrated. The app specifically targets suicidal behavior and proposes an interactive and proactive content that is an effective prevention strategy [8,88–90]. Despite this scientific evidence, a recent literature review [60] identified very few suicide-specific apps (24) with safety planning (14) and that directly allow the user to seek support (13). Moreover, potentially harmful content that

encourages self-harm and suicide [26] was identified, and many of the existing apps for suicide prevention have not been scientifically validated [48,60]. During the design phase, a patient indicated that he thought three apps were needed: "*When we are doing well, not well, and not well at all*". Therefore, *emma* was designed to be as adaptable as possible. The tailored adjustment of the technology-delivered program is also in line with evidence-based recommendations for mental health: "*the app can recommend specific solutions to each user's specific problems*" [46].

While the co-design methodology is recommended [52,53] and constitutes a guarantee to develop a tool adapted to the users' needs, it requires a lot of rigor and benevolence. It seemed essential to us to consult patients very early and at all stages of this project through focus groups for the app design, then feedback from patients during prototype testing, and finally through qualitative interviews with *emma* user patients. However, as patients with suicidal behavior are a high-risk population, it is important to ensure that their participation in research respects the safety principle. Therefore, we put in place a trust-based exchange framework that was flexible enough to adapt to fluctuations in their condition. When carefully implemented, the participation of patients as partners can be a factor of empowerment and self-esteem restoration [91], as confirmed throughout this study.

In summary, *emma* is a unique opportunity, by integrating in the patient's life, to monitor with a fine granularity the emotional, psychological, social and physiological dimensions involved in suicidal ideas and behaviors and their contextualized interactions. Our preliminary results with an encouraging patient acceptance rate highlight the great inter- and intra-individual diversity of app usage patterns (EMA questionnaires completion rate and/or *Safety Plan Modules* use). Patients have different clinical and digital profiles and needs that require a highly scalable, interactive and customizable app.

Currently *emma* allows the active collection of the subjective state self-assessed by the user. However, we would like to complete it with a seamless [51,92] *in situ* collection of objective data, particularly on connectedness indicators that have been evaluated only in few studies related to suicide [19]. Therefore, we plan to implement digital phenotyping/footprinting [15,93,94] in the app to collect all metadata on phone use (number, duration, direction of calls and sms) and activity on social media because they appear to be a very promising field of exploration and intervention in suicidology (Notredame in press).

Conclusion

Data on immediate and long-term risk of suicide are extremely sparse and based on measures with poor temporal resolution [95,96]. *Emma* is a great opportunity to capture the dynamics of suicidal ideas [44], and their translation into action in a contextualized way that allows a much more nuanced view of variables over time [18]. We hope that this digital tool will lead to scientific and clinical advances, and will allow identifying high-risk periods, and predicting the imminent risk, which is extremely challenging at the moment [27]. These fine-grained digital assessments and predictive mHealth-based interventions are promising tools for suicide prevention [57], because they represent an unprecedented opportunity to act at multiple levels through targeted, scalable and contextualized micro-interventions [98]. They might allow proposing just-in-time adaptive interventions (JITAI), defined by Nahum-Shani [99] as the *right support* (e.g., type, intensity) *at the right time* [26]. The challenge is now to integrate such digital interventions in the existing healthcare systems [54]. For instance, *emma* could be integrated in the ED procedures and become a complementary healthcare tool. In the patient's pocket, *emma* could provide individualized support when needed. The app could improve coordination among the different services (ED, crisis centers, hospital services, outpatient services, and general practitioners). However, the smooth and optimal integration of such digital tools in patient care requires the healthcare professionals' support. Indeed, they should not perceive these tools as disruptive elements in their daily clinical practice [32,104], but as helps to improve the therapeutic relationship within a well-defined ethical social and legal framework.

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Acknowledgments

First, we would like to thank Christine, Patrice, Romane, Jonathan, Astate, and Claire, the co-designer patients who improved *emma*! We would like to thank Dr. Déborah Ducasse for her contribution that greatly enriched the app content and Kathlyne Dupuis-Maurin for her unfailing involvement in this research. Thanks to the NERB team: Luc Mallet, Sirenia Lizbeth Mondragón-González and Karim N'Diaye for his creative help.

This study would not have been possible without the support of the FondaMental Chair for the prevention of suicidal behavior created by the FondaMental Foundation, led by Professor Philippe Courtet and supported by *SNCF*, *SNCF réseau*, and *SNCF mobilité*.

This innovative project received the Marcel Dassault Research Award for Research on Mental Illnesses in 2014. Finally, we would like to thank the Clinea and OC Santé Clinics for their support.

Supplemental Table. Adverse events during the follow-up

Patient	Number of suicide attempts	Aborted suicide attempts	Number of emergency department visits	Premature study stop
1			1 (road accident)	
2	1 (voluntary drug ingestion) 1 (bladed weapon)		2 (suicide attempts)	Exclusion (deprived of liberty) before visit 1
3			3 (suicidal ideation)	
4				
5				
6				
7		1 (hanging)	3 (suicidal ideation)	
8				
9				
10				
11				
12	1 (voluntary drug ingestion)			
13				
14				Withdrawal before visit 1