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# Implementing a nurse-led safety planning intervention in emergency departments to prevent suicide reattempts: a stepped-wedge randomized controlled trial protocol (French multicentre randomized controlled trial with a stepped-wedge design)

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## Abstract

Suicide prevention is a worldwide challenge, and an emergency department (ED) visit is a key moment to prevent subsequent suicide risk. Previous studies reported the effectiveness of safety plan interventions (SPI), which are recommended by the suicide prevention resource centre and various health ministries. The safety plan encompasses a range of strategies to prevent and manage suicidal thoughts and actions. Our study (PROTECT) aims to evaluate the effectiveness of the SPI before patient discharged after suicide attempt by nurses and other health care professionals in the ED. Secondly, we will examine the implementation of the intervention among healthcare professionals and patients. The primary outcome is the reduction of suicidal behavior at six months, including suicide reattempts and death by suicide, after the index suicide attempt in patients who received the SPI compared to those who received the practices as usual. The effectiveness of the SPI will be evaluated through a multicenter stepped-wedge cluster randomized controlled trial. 2,387 people who have attempted suicide will be identified in 20 EDs and will first be observed during a control phase. The control group (observation phase) is defined by the administration of usual practices, which include the suicidal recontact program (Vigilans) combined with specialized follow-up tailored to each patient. Initially, the research teams will train emergency professionals in the use of the SPI (transition phase). Finally, an intervention phase will be activated during which the SPI will be implemented in addition to practices as usual. PROTECT is the first study to largely evaluate the effectiveness of the SPI and is the first ongoing study with a large number of included participants and participating centres. Significant findings may aid in the adoption of novel nursing care approaches to prevent suicide reattempts in the ED. The present trial has been registered on the ClinicalTrials.gov database (NCT05609487) since 8 November 2022.

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## Background

Suicide prevention is a worldwide challenge that is part of a global action plan for mental health [1]. The suicide mortality rate in the world is estimated at 9.2/100,000 (World Bank data), causing the death of 703,000 people each year by suicide. In Europe, the rate of mortality by suicide is even higher (11.3/100,000). The 12-month prevalence of suicide attempts worldwide, although variable from region to region, is estimated to be between 2.1% and 0.3%, with the World Health Organization presupposing that for every 1 suicide death, 20 suicide attempts are likely made.

Many studies [2] have indicated that suicidal reattempt is a very frequent occurrence: 16% to 34% of people reattempt suicide in the two years following an initial suicide attempt (SA). The year following an SA is identified as a higher risk period of death by suicide [3], especially in the first month following the attempt. SAs are characterized by nonfatal suicidal behaviour and self-inflicted injury with a desire to end one's life that does not result in death (World Health Organization). Another definition of a SA from the 5th Diagnostic and Statistical Manual of Mental Disorders (DSM-5) defines it as behaviour that the individual undertakes with some intention to die. It is pertinent to highlight the growing interest in the phenomenon of deliberate self-harm, which encompasses actions without the intent to end one's life [4]. This interest is driven by evidence suggesting a 30-fold increase in risk of death by suicide [5] among those engaging in this behaviour. The distinction between the act and the suicidal intention is considered to be challenging [6, 7].

A meta-analysis [8] based on randomized controlled trials for the prevention of deaths by suicide identified brief interventions and contact as the best interventions to significantly reduce suicide deaths. In 2012, in the United States, a safety plan intervention (SPI) part of brief interventions and contact, was developed by B. Stanley and G. Brown [9]. The SPI is a hierarchical list of coping strategies and sources of support [9], co-constructed with the patient, that can be used to mitigate a suicidal crisis. It is deployed in 6 points in an increasing sequence that the person can use autonomously from the first signs of a potential suicidal crisis: 1) identification of the personal prodromes of the suicidal crisis; 2) identification of internal coping strategies to distract from suicidal thinking; 3) soliciting of a social network of distraction (friends, family, places); 4) soliciting of a social network of support during suicidal crisis; 5) identification of professional/services care resources; 6) restriction of access to the suicidal means by securing of the environment. The last point concerns the reason for living.

The SPI is co-constructed by a trained professional and the person who is in suicidal crisis. This tool showed high acceptance among US veterans [10], 93% of whom agreed to receive the SPI (n = 471), and its usefulness has been recognized by those involved. An initial study [11] on the quality of the SPI showed a correlation between the quality of completion and the reduction in frequency of emergency department (ED) visits prior to the SA. The effectiveness of the SPI was demonstrated [12] for the first time in a comparative study involving American veterans. These results showed a 45% decrease in suicidal behaviour (SA and interrupted attempts) at six months with the use of the SPI compared to usual care. Furthermore, a meta-analysis [13] on the effectiveness of the SPI, based on 6 studies including a total of 3,536 subjects support the use of SPI.

In a recent systematic review based on 26 articles Ferguson et al. (2022) [14] demonstrated that the SPI is a valuable indicated intervention for general adult and veteran populations. A number of positive associations were identified in relation to the use of the SPI. These included improvements in suicidal ideation and behaviour, a reduction in depression and feelings of hopelessness, a reduction in hospital admissions and an improvement in adherence to treatment.

Using the SPI is recommended for healthcare organizations in the United Kingdom by the National Institute for Health Care Excellence [15] and in the United States by the National Action Alliance for Suicide Prevention [16].

The involvement of frontline nurses in the assessment of suicidal crisis has been documented in different countries. Since 2016, the Irish Health Service Executive has set up a "Suicide Crisis Assessment Nurse" [17] intervention to facilitate care pathways and the overall management of patients in suicidal crisis, with the first encouraging results on care access. England [18] and Japan [19] use nursing interventions in their suicide prevention policies. Finally, a systematic review on nurses' commitment to suicide prevention [20] focuses on the patient relationship [21–25] and communication skills.

The quantity of suicides in France has experienced a consistent decline since 2000, with a decrease of almost 33.5% (CépiDc Inserm). However, despite all its efforts, France still has a rate of 13.4/100,000, which is higher than the European and world rates. A total of 8,932 people died by suicide in 2020 (CépiDc Inserm) in France. Implementing national strategies is recommended both internationally by the World Health Organization and nationally in France through the mental health action plan (2018). The principal measure concerns the context of the ED, including suicide prevention strategies with

the VigilanS program [26]. This program (Table 1) was founded in 2015 [27, 28], and aims to prevent suicidal reattempts through a multimodal monitoring strategy [29, 30] and the implementation of brief interventions and contact. Five years later, the French population was able to access a national suicide prevention helpline [31].

Analysis [32] of two French national registries of approximately 136,000 people indicated an increased risk of reattempt in the first year following the initial SA, which was estimated to be 12.4%. Seventy-five percent of people who attempted suicide reattempt the act within 6 months, and 63% of deaths by suicide occur during the same period [32]. The majority of people (60%) who attempt suicide are managed at the acute phase in the ED in France [33]. The discharge process from the ED after an SA is a key moment for the implementation of procedures to prevent subsequent suicide risk [34].

At least 6 studies have been published on the effectiveness of the SPI in the general population [12, 35–39]. Recently, a Spanish team led by Beatriz Rodriguez Vega built an effectiveness-implementation hybrid design (NCT:04230434) with a recruitment target of 58 subjects. To date, PROTECT is the first multicentre study of SPI in France. Internationally, it stands out due to its large number of ED participants and the high number of subjects included.

The current literature on the effectiveness of the SPI is sparse and has some limitations. The original study conducted by Stanley et al. (2018) [12] have limitations in quality and quantity. The groups were unequal in size, not randomized, and had a high proportion of men. The meta-analysis of Nuij et al. [13] compared a control group (n = 1,440) with an intervention group (n = 2,096), with a low number of SA events in both groups (n = 348). All 6 studies had limitations, as only one had a low risk of bias. Finally, an analysis of the funnel plot suggested publication bias, which means that studies reporting no positive effect of the SPI may have remained unpublished.

Preventing suicide reattempts represents a significant global challenge. It has been demonstrated that brief interventions, and particulary the SPI, have a strong case for protecting suicidal individuals from reiteration. Its utilisation, particularly by nurses, has already convinced healthcare organisations of its efficacy. In the French context, where there is a robust commitment to suicide prevention, the efficacy and acceptability of the SPI remain unproven and necessitate a comprehensive multicentre study before it can be endorsed for implementation.

**Table 1** The VigilanS program

| The VIGILANS program: |
| --- |
| VigilanS is a suicide reattempt prevention program that uses a multimodal monitoring strategy including telephone recontacts and postcard mailings by nurses and psychologists. It is proposed that people who have attempted suicide and are leaving an ED and should be included in the process. It is based on three key components: |
| 1- A resource card is delivered to the people who have attempted suicide that provides the number of a help line that is available during working hours (9 am-6 pm) and that provides contact with a helper (professionals trained in dealing with suicidal crises and telephone regulation) who will be able to respond to the person in the event of a reappearance of suicidal thoughts and to direct them. |
| 2- The person's care network (physicians, psychologists, treating psychiatrists, home nurses, etc.) is solicited by sending a letter informing them of the system and the individual's inclusion. A special hot line is also established for them to facilitate connections with the caregivers. |
| 3- Finally, telephone recontacts are conducted during the first month after discharge from the ED and then at 6 months. These recontacts are made by health care professionals trained in the management of suicidal crisis. |

### Objective of the study

The main objective of the study is to evaluate the effectiveness of a pre-discharge nurse-administered in the ED SPI in reducing suicidal behavior, including suicide reattempts and death by suicide (composite criteria), six months after the initial suicide attempt in patients enrolled in the VigilanS programme. We will therefore compare the suicidal behavior rates of patients receiving both the SPI and the VigilanS programme (intervention group) with those of patients receiving the VigilanS programme alone (control group in practices as usual).

Secondary objectives are 1) to evaluate the implementation of the procedure; 1.1) to measure the quality of completion and the duration of the SPI at 1 month and 6 months; and 1.2) to measure the acceptability of the SPI by healthcare professionals (from the ED and VigilanS) and by the people concerned; 2) to reduce the recurrence of suicidal behaviour at 1 month; 3) to promote adherence care at 1 month and 6 months; 4) to reduce the use of EDs at 1 and 6 months for a suicidal crisis.

## Method

### Study design

The reporting of the study is guided by the SPIRIT guidelines [40] and Consolidated Standards of Reporting Trials extension for the stepped-wedge cluster randomized trial [41]. The PROTECT study (implementation of an SPI by the ED nurse to prevent suicidal behavior) is a multicentred stepped-wedge randomized trial. The study is based on five groups (i.e., clusters) composed of 1 to 3 VigilanS centres to compose clusters with similar inclusion capacities. For each VigilanS centre, 1 or 4 EDs are 'included', for a total of 11 VigilanS centres and 20 EDs (Fig. 1). The list of participating centres can be found as additional material. PROTECT compares the effectiveness of usual care alone versus usual care associated with SPI.

All groups will have a control phase, and depending on a randomization list, they will be progressively transferred to an intervention phase after undergoing

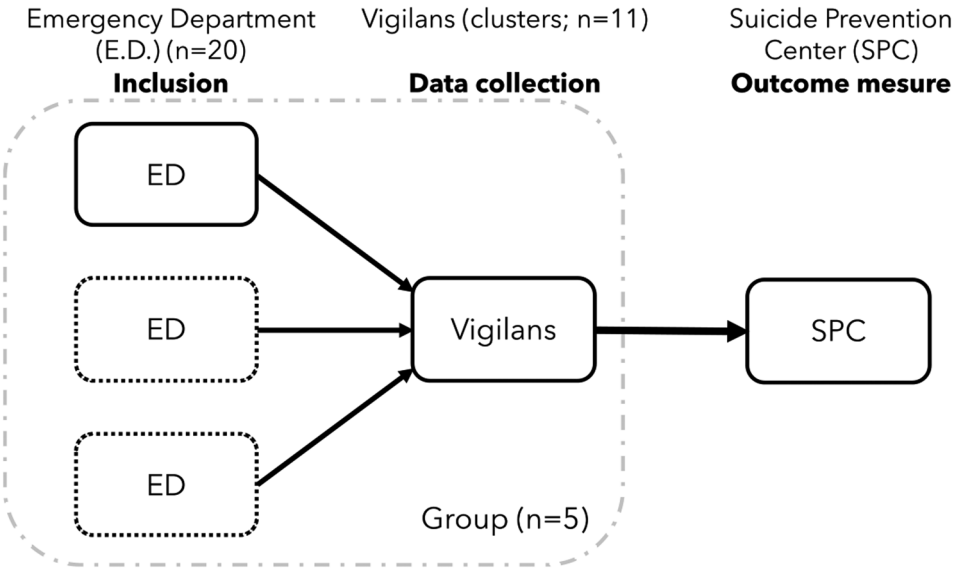


**Fig. 1** Study outline (ED: Emergency Department; SPC: Suicide Prevention Center)

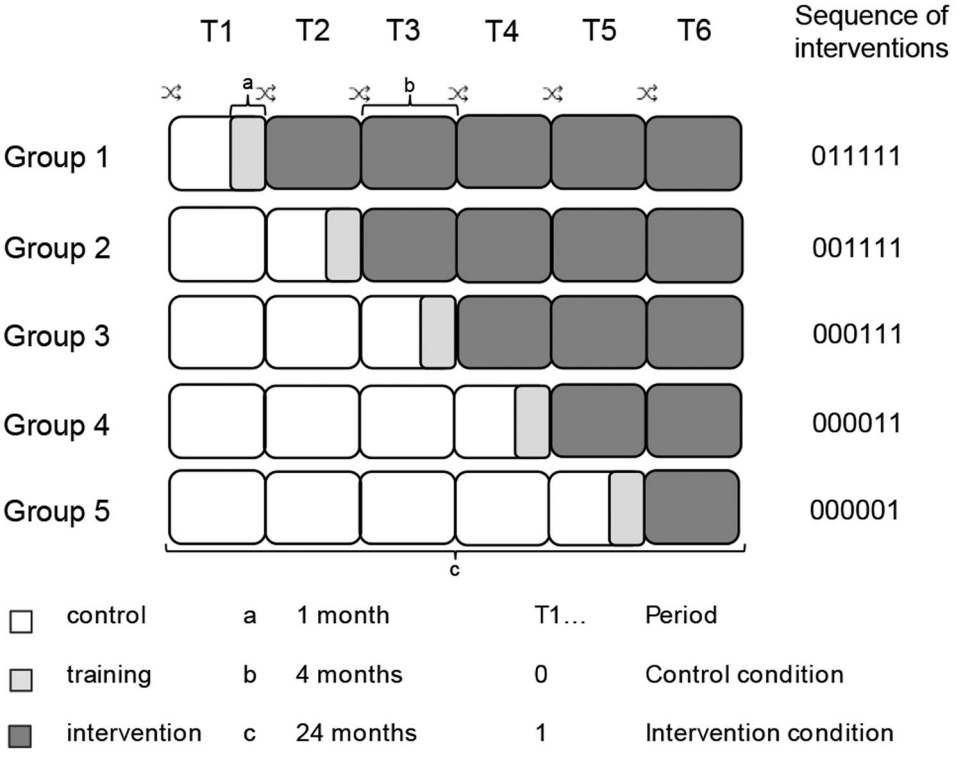


**Fig. 2** Stepped-wedge design of the PROTECT study

a transition period (Fig. 2). Overall, six periods of four months are defined, with the first period being a control phase for all groups.

Randomization of the clusters will be conducted independently by the biostatisticians.

Each group will be composed of 1 to 3 VigilanS centres and 1 to 5 emergency departments. Each period (T1, T2, T3, T4, T5 and T6) takes 4 months, for a total duration of 24 months.

***Control phase (observation)***

The control group will be composed of patients engaging in usual care. During this observation phase, all EDs will manage patients in suicidal crisis as usual, which means that they will propose to all eligible patients to be

managed by "psychiatrist" nurses or psychiatrists who received a short training. The nurse will usually takes part in the patient's consultation with the psychiatrist. The elements of the consultation constitute keys information's useful for drafting the SPI. The usual care is described by the French National Strategy of Suicide Prevention, including the VigilanS program for maintaining contact with the people who have attempted suicide.

#### *Transition phase with training (duration: one month)*

The training phase acts as a transition period for a group of clusters to the intervention phase. One month is considered sufficient time to organize the trainings and give the professionals time to try out the SPI in real care situations before starting the intervention phase. All clusters will be trained by two nurses trained in suicide prevention, one of whom (study coordinator) has over ten years' experience in suicidology and has been a trainer in suicide prevention for over 10 years. The training period will be three and a half hours in duration. This training will be based on 1) the recommendations of the authors of the SPI [42]; 2) a literature review on the best methods for the training of healthcare professionals in the use of the SPI; and 3) elements of the grey literature. This training module was tested with healthcare professionals not participating in the study to improve the pedagogical facilitation of the module.

This training module is developed in 3 sequences:

1) Theoretical elements on suicidal crisis
2) The scientific rationale for the SPI and recommendations for co-constructing each SPI item will be outlined and supported with examples.
3) There will be time for exchanges with the learners on a regular basis, who will finish their training with two role plays based on real situations in practice.

Finally, there will be an evaluation of satisfaction with the training, attitudes and self-efficacy.

Our objective is to train 50% of health professionals in-person. In order to enhance the implementation of the training, an e-learning module will be integrated specifically for those unable to attend in-person training. The online training will be conducted during working hours at a designated location, lasting one hour. This is used in response to the frequent turnover of health professionals in EDs.

#### *Intervention phase*

After the transition phase during which the teams will be trained, the intervention phase will take place in addition to the usual care.

At the time of the discharge consultation and inclusion in VigilanS, if the patient is eligible, he or she will be offered an opportunity to participate in the study. If he or she accepts, the patient will co-construct the SPI with a trained health professional (nurses, nurse practitioners, physicians, medical student, psychologist).

According to the Quick Guide of the SPI [43] the first step is a clinical tool in which the clinician must demonstrate a capacity for listening, empathy, and engagement with the patient. The key word is co-construction, which favours the development and appropriation of the tool by the user. The co-construction of the SPI is one of the last actions implemented by the care team. It takes place at the end of the consultation. The clinician refers to the content of the consultation to enrich the SP. The clinician advises the patient in the construction of the plan.

The 6 steps of the SP are completed one by one. The number of answers is limited for each item. Some items of the SP may not be answered, but the completion of the SP takes place over time, and the patient can update it independently after the first draft. The patient can also update it with a trained clinician.

The drafting of the SP takes 20 to 40 minutes and will be completed as part of the study at the time of discharge from the emergency room and after the usual care (including VigilanS). The intervention requires an office equipped with a computer and an internet connection. In the context of the study, the drafting of the SP will be completed on a dedicated web page (https://monplansecurite.fr). A free and eponymous smartphone application can be used. The use of the web page facilitates a quick and easy way to find the SP. The web application generates the tool in different formats (Excel, pdf, .mps). The .mps format allows the plan to be downloaded directly onto the patient's smartphone application at the end of the consultation. This allows the patient to always have the SP with him or her. The .pdf format allows the SP to be easily shared via the patient's email address or sent to health partners. Finally, the SP in an Excel format, set up specifically for the study, will be sent concomitantly with the patient's inclusion in VigilanS to the VigilanS secretariat, where the Excel file will be uploaded into the e-crf.

### Primary outcome

The primary outcome measure of the study is suicidal behavior, including suicidal reattempt or death by suicide, at 6 months (composite criteria) after the initial suicide attempt, measured by the Columbia Suicide Severity Rating Scale (C-SSRS) [44]. The C-SSRS is a recognized scale [45] that is widely used internationally in suicidology studies. Its use is validated by phone [46].

The primary outcome will be monitored via a standardized telephone interview conducted by a trained nurse, independent of the inclusion circuit and the VigilanS program. This measure will be centralized in the Suicide Prevention Center (Bron) at the Vinatier Hospital, blinded

to the control or intervention groups (Fig. 1). Number of deaths by suicide at 6 months will be collected by cross-referencing data from VigilanS or by call with health professionals, general practitioner, or person contact. In the event of a subject lost to follow-up without data on vital status, civil status registers (INSEE database (Institut National de la statistique et des études économiques)) will be queried. It is for this purpose that the year of birth is collected at inclusion.

#### Secondary outcome

- Suicidal behavior at 1 month will be determined by a standardized phone call in the same way as the primary outcome, using the C-SSRS scale (Fig. 1).
- Commitment to care at 1 and 6 months will be assessed with a standardized phone call (Fig. 1), with many criteria for adherence to care:
    - Engagement in care will be assessed by asking the participant if he or she went to the care initiated in the ED. If the appointment has not taken place at the time of the call, the intention to attend will be assessed. We will also ask about appointments with the general practitioner or mental health specialist (psychologist, psychiatrist, or specialist nurse) or if the patient has been hospitalized for mental health reasons. Finally, calls made by the patient to 3114 and VigilanS will be collected from the patient.
- Number and frequency of ED visits by the patient for a suicidal crisis at 1 and 6 months will be determined, as measured by the study participant during the standardized call at 1 and 6 months.
    - The frequency of ED visits due to a suicidal crisis will be measured through a verbal response from the patient during the call.

#### Follow-up measures

The outcomes of the study will be collected by phone at 1 and 6 months after patient inclusion. If there is no response to the first call, a maximum of three calls will be performed. To limit the risk of missing data and loss to follow-up, a family or friend will also be contacted in a second phase, with a maximum of two attempted calls. To facilitate a better telephone response from the participants in the study, patients will be informed in advance of the call through two text messages establishing the contact. In the case of patients lost to follow-up at 6 months, despite a call to a contact person, the vital status of patients will be measured.

As part of the usual VigilanS care program, mortality data are only partially available through feedback from family members and health professionals (family, general practitioner, person contact). In addition to the mortality data collected in the field, the INSEE database based on civil status certificate [47] will be queried to verify the vital status of participants. We will query the database at 9 months for patients who have been lost to follow-up with the aim of determining their vital status.

All study data will be collected in an electronic case report form available online. The initial data will be recorded by the VigilanS secretary, who will be trained in data recording. Data from calls at 1 and 6 months will be recorded by a clinical research nurse.

#### Eligibility criteria

Participating VigilanS centres were selected after responding positively to a call for participation in the study addressed to several centres in France. The eligibility criteria were as follows: being an active centre with a care team and a secretariat. Second, VigilanS identified the EDs with which they usually collaborate. We selected only those EDs with a psychiatric crisis care team based in the ED and with a nurse specialized in mental health consultations. Then, we asked for their agreement to participate in the study. Finally, their recruitment capacity and feasibility in terms of staff resources were considered before they were included as partner centres. We also anticipated the possibility that some centres may not be able to open by identifying so-called "rescue" centres. All centres participating in the study received training in the study protocol for at least 50% (and up to 100%) of their staff. Each coinvestigator in the study was able to attest to a certificate of the *International Conference on Harmonization Guidelines Good Clinical Practice E6* (R2).

#### Population

All adults admitted to an ED for an SA (including interrupted or abandoned) will be offered to participate at the time of the discharge consultation and after inclusion in VigilanS. They will receive free, comprehensive information about the PROTECT study (aims, methods of assessment) from a health care professional trained in the study protocol. After a short period of reflection, written consent from the participant will be required by the professional. This consent will be archived for quality control purposes.

#### Recruitment

The inclusion of patients will be performed at the ED by a trained nurse at the time of the patient's discharge. After the provision of information about the voluntary nature of the study, the written consent of the patient will be collected. The data collection in the electronic case report

form will be performed at the VigilanS secretary concurrently with the collection of data for daily care. Participation in the study does not prohibit inclusion in a second research protocol.

The inclusion criteria are as follows: 1) over 18 years of age, 2) seen in the ED for a suicide attempt crisis that occurred less than 48 hours prior, 3) have been treated in the ED for no more than 72 hours (including a stay in a short-term unit), 4) have been discharged home, 5) have agreed to be part of the VigilanS program, 6) have social security coverage, and 7) be fluent in French.

The exclusion criteria are as follows: 1) declining to be included in the VigilanS program; 2) being hospitalized for more than 72 hours in the immediate aftermath of the SA; 3) receiving intensive home care hospitalization including home visits in the weeks following discharge and repeat during the first month with the main reason for psychiatric care; and 4) being under special protection, being pregnant, being hospitalized without consent, or being deprived of one's liberty (French legislative framework).

### Sample size

Under the hypothesis of a percentage of suicidal behavior, including suicidal reattempt and death by suicide (composite criteria) at six months of 20% [2, 3, 32, 48] without intervention and 12% with intervention (relative improvement of 40% [12, 13]), with a two-sided alpha level of 5%, a total of 720 patients would provide a power of 90% for the statistical comparison. With a conservative intracluster correlation of 0.2, 11 clusters, 5 groups of clusters and 25% of patients lost to follow-up at 6 months [26, 49], a total of 2387 patients will be needed. The number of inclusions for each cluster is calculated in proportion to the active files of the services.

The period of recruitment will be 24 months, corresponding to 100 inclusions per month spread over the 11 centres grouped into 5 equitable groups of 1 to 3 clusters (coinvestigating centre + attached ED). Each cluster will have 6 periods of 4 months for recruitment, i.e., 9 to 10 inclusions per month per cluster.

### Data analysis

The primary outcome will be compared between the two strategies in the intent-to-treat population (control in usual care and intervention with the SPI) using a mixed logistic regression model. The model will consider, as a fixed effect, the strategy (control or intervention) and the condition of a first SA or not. This model will consider, as a random effect, a random intercept per VigilanS centre, as well as a random intercept by ED nested in the VigilanS centre level.

The effect of the intervention will be quantified by an odds ratio with the 95% confidence interval and will be tested by a Wald test. A time effect will be accounted for by introducing a "period" variable into the model. An interaction between the effect of the intervention and the random intercept by VigilanS centre may be added to quantify any heterogeneity in the benefit of the intervention between VigilanS centres. In addition, a sensitivity analysis of the primary outcome will be performed in the per protocol population, excluding from the intervention group patients who did not actually use the SPI.

The same approach will be used to analyse the results at 1 month, as well as death by suicide only at 6 months.

### Monitoring

Monitoring of data from included patients will be based on a sample of approximately 10% of participants (n = 240) selected at random from the participating centres. This visit, conducted by the study promoter (Le Vinatier), will enable compliance with the study protocol and procedures to be checked, as well as the quality of the data collected in the e-crf (accuracy, missing data, coherence of the data with the "parent" data).

## Discussion

The present study could provide additional evidence by using a robust method. Indeed, the study is national and offers a representative population of twenty EDs all over France. The methodological choice of a high level of evidence using an stepped-wedge design allows the activation of the centres to be randomized while limiting the risks of contamination bias. In addition, the implementation of SPI training by the research team has many advantages, such as the standardization of SPI use and the possibility of training several members of the same team on site, who will be able to use the tool quickly.

### Limitations of the literature and strengths of PROTECT

One of the limitations is the lack of comparability of the populations before and after the implementation of the intervention (SPI). Those patients who declined to participate in the SPI would not be included during the intervention phase. Moreover, Gamarra's [11] demonstrated a positive correlation between the quality of the SPI and a reduction in the number of psychiatric hospitalisations. It is possible that refusal may be correlated with an increased risk of suicidal reiteration. Furthermore, the instrument is designed to encourage the implementation of care practices by making the SPI systematic. It is anticipated that the occurrence of refusal of the SPI will be relatively uncommon in the event of standardised care. In order to limit the rejection of the SPI, we use the training time to describe the factors that favour its acceptance. In particular, the evidence of the instrument's effectiveness ([12, 13], the acceptability data [50–52] and finally, the comprehensive approach described by the authors [9] of

the instrument tend to favour its acceptance. The establishment of an anonymous and non-mandatory register of the reasons for refusal to participate in the study will, to a certain extent, provide insight into the reasons for these refusals. Finally, the descriptive data collected will allow us to accurately describe the population included and, if necessary, adjust the statistical models if there is an imbalance.

A second limitation of the study concerns the exclusion criteria, which precluded the recruitment of patients undergoing intensive home care hospitalization, including home visits. It can be reasonably assumed that patients with higher psychiatric care needs than the usual patients included in Vigilans were excluded from the study. The feasibility of recruiting these subjects was assessed as being limited due to the highly heterogeneous nature of access to psychiatric care for these patients.

It is also necessary to mention that French legislation restricts our capacity to recruit individuals who are pregnant, under special protection, hospitalized without consent or deprived of liberty. Apart from the regulatory context, people with these characteristics are not the target of the intervention studied. This should not affect the generalisability of the findings. In fact, they develop in different care contexts (care pathway and alternative care resource).

Nevertheless, there is a risk of attempted suicide among these populations, as is the case with individuals incarcerated [53] and pregnant women [54]. Should the results of this study yield positive outcomes, it would be recommended that further efficacy studies be conducted with these populations in mind.

It should be noted that, due to circumstances beyond our control, the co-investigator centres selected were the very first centres to benefit from the implementation of Vigilans. It is likely that these pioneering centres have more experience in treating suicidal crises. Therefore, generalising the results of the study to other, less experienced centres may have certain limitations. It is also interesting to note the diversity of the participating centres, some of which are located in large hospitals (e.g. university hospitals) and others in more modest hospitals (e.g. general hospitals). However, the size of the hospital does not correlate with the Vigilans inclusion rate. Vigilans centres monitor the inclusion rate of the Vigilans active file (penetrance rate), although this is sometimes approximate.

The stepped-wedge provides an ethical advantage in the implementation of the intervention, as each centre is its own control group, and each centre will benefit from participating in the study. The successive activation of the centres offers a reasonable time to implement the action. Finally, the heterogeneity of the results of the centres will be evaluated by a before-and-after measure.

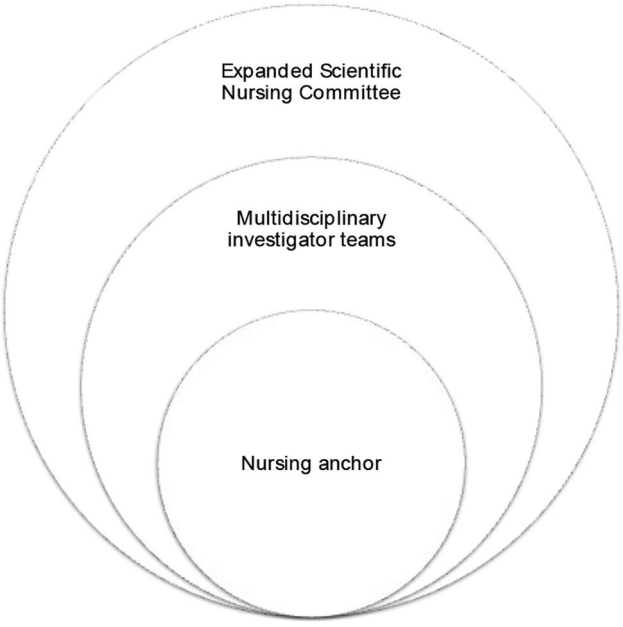


**Fig. 3** Implemented strategies

## Challenges and solutions

### *Implementing the protocol*

In addition to the worldwide deficit of nurses [55] there has been a profound crisis in the ED after the major COVID-19 epidemic. In this context, to facilitate the implementation of the study, we draw on an already existing link between EDs and VigilanS care services. In fact, in the usual care setting, inclusion in VigilanS is mainly based on EDs. To promote this collaboration in the context of care, meetings are organized regularly. The teams are familiar with each other, and the existing links will be useful for collaboration on the protocol.

To improve the participation of investigators identified in the centres (EDs + VigilanS), we implemented three strategies that operate at three complementary levels (Fig. 3). First, we proposed that nurses and advanced practice nurses take on the role of investigator (n = 13) to involve their colleagues. The professions of the investigators in the 31 centres (VigilanS and EDs) are distributed as follows: nurse & advanced practice nurse: 13; psychiatrist: 13; psychologist: 4; health executive: 1. To mobilize the team at a second level, we identified "multidisciplinary investigator teams" of three health professionals at each centre. This trio of doctor-health manager-nurse offers a complementary view, and each professional has different levers specific to each function to complete the study. Finally, on a third level, we have established an "expanded scientific nursing committee", made up of specialists in suicidal crises (emergency or VigilanS) nurse science in EDs, and an expert patient. This committee meets regularly to monitor the progress of the

protocol and advise us on the progress of the study in the workplace.

#### *Ethical considerations*

One of the ethical challenges of the trial is to ensure the safety of patients in the control phase. To achieve this, the first inclusion criterion is that patients should be under the usual care (Vigilans). In this way, patients will benefit from a program to prevent suicidal reattempt. The estimated loss of chance of not benefiting from the SPI for patients in the control phase is considered acceptable given the current effectiveness of Vigilans. In addition, the calls during the trial are made by a nurse trained in suicide crisis management who had completed a placement with the Vigilans and 3114 teams. We have also established links between these two supports to ensure that they can provide support in the event of a patient experiencing an acute crisis. A procedure allows the research nurse to immediately refer patients to the Vigilans and 3114 teams in their area.

#### *Promoting access to training for ED professionals*

The current deficit of health professionals adds to the difficulty of access to training for ED professionals. Indeed, the continuous influx of consultants complicates the organization of teamwork and access to training. The short format (3 hours) of the training should facilitate access. More over a complementary e-learning modality is currently developed, is based on the same guidelines as face-to-face training but without role play. It should facilitate the implementation of the SPI in the departments, bypassing organizational constraints. E-learning is complementary to traditional classroom-based training and cannot replace it.

#### *Limiting data loss*

One concern of the research team is the necessity for strict vigilance regarding the feasibility of this protocol. In fact, the frequent lack of time in the ED and the unfamiliarity of health professionals with research represent a significant risk of data loss.

We consider that the actions taken as part of the study should be as simple and succinct as possible. The data collected is therefore limited to the information strictly necessary for the study. In addition, these data are cross-referenced with the data already entered in the usual care (VigilanS), so there is no information specific to the study to identify in addition. The centralized assessment at the SPC, the use of an e-crf and SMS reminders should help to limit data loss.

#### *Stepped-wedge design justification and constraints*

Several points justify the use of a stepped-wedge design: First, the nature of the studied intervention concerns the improvement of care practices [56]. In the case of individual randomization, it would not be appropriate for health professionals trained in SPI to provide it to some people and not to others. The feasibility of the study is facilitated by the successive deployment of the intervention, which offers better conditions for organizing training sessions. Moreover, implementing the tool in all the centres in a random order ensures greater acceptability because all the centres will play an active role in the study, which also reduces the risk of contamination between centres. Last, the high level of evidence provided through an stepped-wedge design is [57], making it possible to compare each centre (before/after) to explore the heterogeneity of the results. Finally, it will be possible to analyse the "time effect" to study changes over the course of the study.

We anticipate that the multidisciplinary investigative team at the centres and the motivation of the teams to use the tools will facilitate the implementation of the intervention phase of the study.

We learned from the literature that recruitment is difficult in this type of study design. However, a literature review [58] of 35 studies shows that 69% (n = 24/35) of stepped-wedge studies achieve their recruitment targets, but almost as many exceed their inclusion targets (n = 23/35). Studies that do not manage to recruit enough (n = 12/35) achieve a recruitment rate between 50 and 99.6% in the vast majority of cases.

The recruitment capacity of the centres is considered excellent, especially as the number of people included in the VigilanS program has increased since it was lauched in 2015, with approximatively 30,000 to 35,000 inclusions per year in 2022 and 2023. We are exposed to a major risk of over recruitment. To regulate this risk, the e-crf always displays the number of inclusions for each centre, which will allow centres that have completed their quotas to be put on pause. In addition, an automatic e-mail alert will be set up when the number of inclusions will about to be achieved.

The PROTECT study will evaluate the effectiveness of the SPI principally used by ED nurses using a multicentred stepped-wedge randomized trial. The conclusions of this study should make it possible to propose a tool used in daily practice by emergency service nurses to reduce suicidal behaviour. The study will contribute to consolidating patient safety in addition to the care currently used in the EDs.

### Relevance to clinical practice

The PROTECT multicentred study benefits participants by providing strategies for managing suicidal crises as soon as they leave the emergency room while reinforcing their empowerment. The SPI is a complementary care strategy between the different care settings in the patient's journey. The results of the study will contribute

to the development and validation of new care guidelines using the SPI on a routine basis. The delivery of face-to-face training by the research team is a factor favouring the implementation of new care strategies. The implementation of the SPI by the nurse should allow the persons concerned to better identify their own and social resources but also to identify the request for care outside the emergency context, thus limiting the use of unexpected care in the ED. It is hoped that the daily practices of allied health professionals will be improved. Indeed, if the expected results are confirmed, the generalization of this SPI will provide an additional tool for suicide prevention, which can be used daily by emergency care nurses and in suicide prevention units.

### Dissemination policy

The final results of the study will be published in international scientific journals. Oral presentations will be submitted to national and international conferences. The results of the study will also be disseminated to the general public and in non-scientific (professionals) journals.

## Supplementary information

The online version contains supplementary material available at https://doi.org/10.1186/s12912-025-03121-w.

Supplementary Material 1

Supplementary Material 2

Supplementary Material 3

Supplementary Material 4

Supplementary Material 5

Supplementary Material 6

Supplementary Material 7

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**Author contributions**

BC, JH, MV, EP, EL and FS contributed to the conception and design of the PROTECT program. Project monitoring participation: Study Group. BC wrote the first draft of the manuscript. JH, FS wrote the sections of the manuscript. AV, MV, EL JH, FS and LS critically reviewed manuscript. EL and EP supervised and approved the submission manuscript. All authors contributed to manuscript revision, read, and approved the submitted version.

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**Data availability**

The materials that support the study are available in the supplementary material of this article. The Stanley-Brown Safety Plan is copyrighted by Barbara Stanley, PhD & Gregory K. Brown, PhD (2008, 2021). Individual use of the Stanley-Brown Safety Plan form is permitted. Written permission from the authors is required for any changes to this form or use of this form in the

electronic medical record. Additional resources are available from http://www.suicidesafetyplan.com.

## Declarations

### Ethical approval and consent to participate

The study, sponsored by the "Le Vinatier", will be conducted in accordance with the recommendations provided in the current version of the Declaration of Helsinki. This study was approved by the ethics committee *Comité de protection des personnes Sud Ouest et Outre mer 1*- (registration number: 2022-A00163-40). The reference methodology MR001 (framework for the processing of health data in interventional research) will be respected in the implementation of the study. Information and written consent from the participant will be required by the professional. This consent will be archived for quality control purposes. An authorization from the *Commission Nationale de l'Informatique et des Libertés* (CNIL) has been obtained (number 923012v2 for the collection of nominative data and the telephone numbers of patients and persons contact. The data will be archived 15 years after the completion or interruption of the research. The study was preregistered at clinicaltrials.gov, first registered on 8 November 2022 (https://clinicaltrials.gov registration number: NCT05609487). All important protocol modifications (e.g., changes to eligibility criteria, outcomes, analyses) will be communicated to relevant parties (coinvestigators, trial registries, regulators).

### Consent for publication

Not applicable.

### Competing interests

The authors declare no competing interests.


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## Publisher's Note