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Suicide prevention through innovative approaches in primary care

Submission date
14/04/2025

Recruitment status
Recruiting

Registration date
25/04/2025

Overall study status
Ongoing

Last Edited
25/04/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Suicide is one of the leading causes of death worldwide. The stigma associated with mental health and suicidal behavior significantly hinders prevention efforts. This study aims to enhance the capacity of primary healthcare professionals to identify, prevent, and address suicidal behavior in the context of Primary Care.

Who can participate?
Primary healthcare professionals working in the Balearic Islands primary health care centers (permanent staff and long-term substitution) will be recruited and randomly assigned to one of three groups: a control group and two intervention groups.

What does the study involve?
The intervention phase will last 3 months, followed by a 6-month follow-up, for a total study duration of 9 months. Intervention 1: Participants will receive an audit and feedback report, based on the previous 5-year real-world data from patients with suicidal behavior in the Balearic Islands. The report will include sociodemographic information, clinical characteristics, and patterns of healthcare service use. In addition, a targeted training session will be provided, focused on improving the detection and management of suicidal behavior. Intervention 2: This group will receive the same components as Intervention 1, with the addition of a mental health self-assessment completed by patients during their visit to the primary care provider. Results will be presented to the clinician in a simple visual format using a traffic light system, offering immediate feedback on the patient's mental health status. Control Group: Participants will continue with standard care practices without receiving any additional intervention.

What are the possible risks and benefits of participating?
No risks are expected from participation. However, the potential benefits are significant, including improved detection and management of suicidal behavior, which could ultimately contribute to saving lives.

Where is the study run from?
Balearic Islands, Spain. Primary Health Care Management.

When is the study starting and how long will it run?
The study began on May 1, 2024. The intervention will start on January 1, 2026, and will last 9 months. The study is expected to conclude on April 30, 2027.

Who is funding the study?
expediente PROSALUT 2023-26, de la Comunidad Autónoma de las Islas Baleares (Dirección General de Investigación en Salud, Formación y Acreditación) y puede ser objeto de cofinanciación, en un 60% con cargo al Programa FEDER 2021-2027 de las Islas Baleares (Spain)

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Suicide prevention through innovative approaches in primary care

Acronym
PROMESA

Study objectives
The combination of i) an audit & feedback strategy based on mental health indicators, suicidal behavior, and health service utilization, ii) a targeted formative training intervention for health care professionals, and iii) an additional intervention involving patient self-assessment of mental health in primary care, improves the ability of primary health care professionals to effectively identify, prevent and manage suicidal behavior in their primary health care clinical practice, compared to usual care.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 25/10/2023, Balearic Islands Ethics Committee (c/Calçat, 2A, 2n, Palma, 07011, Spain; +34971177378; ceic_ib@caib.es), ref: IB 5294/23PI

Study design
Phase II intervention study

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Inadequate management and detection of suicidal behaviour among primary healthcare professionals

Interventions
All primary healthcare professionals in the Balearic Islands will be invited to voluntarily participate in the study. Those who provide written informed consent will be randomly assigned

(1:1:1) to one of three groups: two intervention groups and one control group. The intervention will last for 3 months, followed by a 6-month follow-up period, resulting in a total follow-up duration of 9 months.

Intervention 1 consists of an audit and feedback providing each participating primary healthcare professional with a report based on 5-year data collected including indicators related to Balearic islands patients with suicidal behaviour, such as sociodemographic characteristics, clinical features, and patterns of healthcare service use. In addition, professionals in this group will receive a targeted training session specifically designed to improve the management and detection of suicidal behaviour.

Intervention 2 includes all components of Intervention 1, with the addition of a suicidal risk self-assessment completed by patients during their visit to the primary health care professional. The results of this self-assessment will be presented to the clinician in a simple visual format using a traffic light system, providing immediate feedback on the patient's mental health status.
The control group will continue with usual care practices without receiving any additional intervention.

Those who provide written informed consent will be randomly assigned (1:1:1) to one of the three groups using SPSS. The method will be simple random sampling. The unit of randomization will be the primary health care professional.

Intervention Type
Behavioural

Primary outcome(s)
Ability of primary healthcare professionals to effectively identify, prevent, and manage suicidal behaviour in primary care measured using ad-hoc questionnaires assessing knowledge of suicidal behaviour, the number of cases identified in clinical practice, and the number of referrals to specialized services within the public health system at the end of the intervention, and again at 3 and 6 months of follow-up.

Key secondary outcome(s))
The feasibility, viability, usefulness, and acceptability of the intervention. This will be evaluated by measuring the proportion of healthcare professionals who agree to participate, the completion rate of the training among those in the intervention groups, and the dropout rate. Additionally, participants' satisfaction, perceived acceptability, credibility, and impact of the intervention will be assessed through a self-administered questionnaire completed by the intervention group at the end of the intervention, and again at 3 and 6 months of follow-up.

Completion date
30/04/2027

Eligibility

Key inclusion criteria
Primary healthcare professionals in the Balearic Islands who works in a primary health care centre (permanent staff and long-term substitution), and agree to participate by signing informed consent.

Participant type(s)

Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
21 years

Upper age limit
80 years

Sex
All

Key exclusion criteria
Short-term substitute healthcare professionals

Date of first enrolment
01/01/2026

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
Spain

Study participating centre
Balearic Islands Health Service (IB-Salut)
Carrer de l'Escola Graduada, 3
Palma
Spain
07002

Sponsor information

Organisation
Primary Care Management of Mallorca (Gerencia de Atención Primaria de Mallorca)

Funder(s)

Funder type
Government

Funder Name
expediente PROSALUT 2023-26, de la Comunidad Autónoma de las Islas Baleares (Dirección General de Investigación en Salud, Formación y Acreditación) y puede ser objeto de cofinanciación, en un 60% con cargo al Programa FEDER 2021-2027 de las Islas Baleares

Results and Publications

Individual participant data (IPD) sharing plan
The datasets available during the study will be made available in public repository. The study will be published on Zenodo and will be publicly available. We anticipate its publication by May 2027. Additionally, the data will be anonymized.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes