Plan Overview

A Data Management Plan created using CORA.eiNa DMP

Title: Evaluation of a Telephone Follow-up Programme for the Prevention of Suicidal Behaviour in Adults after a Suicide Attempt: Randomised Clinical Trial in the Multicentre SURVIVE Study.

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Project abstract:

Introduction. Suicide is a universal, complex and multifaceted health problem, among the leading causes of preventable death worldwide, and is therefore a priority for public health systems.
Objectives. The current research project aims to (1) synthesise the published evidence on the efficacy of synchronous, non-face-to-face suicide prevention interventions; and (2) empirically test a telephone follow-up intervention for patients discharged from the emergency department of Spanish public health care centres.
Method. We will conduct a systematic review and meta-analysis, and a multicentre randomised controlled clinical trial, publishing at least 2 original research articles in high-impact scientific journals.
Results. The data collected will allow us to provide evidence-based recommendations to prevent suicidal behaviour; to improve the understanding of suicidal behaviour at national level; and to foster in academic and professional context a critical analysis in E-Mental Health, Prevention and Epidemiology of Neuropsychiatric Diseases.
Discussion. Telemental suicide prevention is an emerging field. The lack of replication of studies, through randomised controlled trials with structured protocols, is an important gap in the literature and opens up new lines of research.

Start date: 01-10-2021

End date: 29-01-2029

Evaluation of a Telephone Follow-up Programme for the Prevention of Suicidal Behaviour in Adults after a Suicide Attempt: Randomised Clinical Trial in the Multicentre SURVIVE Study.

About your research

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Working title for the thesis

Evaluation of a Telephone Follow-up Programme for the Prevention of Suicidal Behaviour in Adults after a Suicide Attempt: Randomised Clinical Trial in the Multicentre SURVIVE Study.

Describe your research

Suicide is a global public health issue. The current study examines the efficacy of synchronous and remote interventions through a systematic review and a randomised controlled trial (RCT) of secondary prevention programme for suicide attempts in Spain. It aims to enhance the understanding of suicide and promote research in E-Mental Health, prevention, and epidemiology.

Duration of your research

Start date: 01-10-2021
End date: 29-01-2029

Linked project

SUicide PReVention and InterVEntion (SURVIVE): cohort study and nested randomized controlled trials of secondary prevention programs for suicide attempts

Funding

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About this data management plan

Creation date

01-03-2021

Last update

16-06-2025

Version and date

Version 1.0, 16-06-2025

Sensitive/personal data

- I will work with personal data [see point 2]

1. Data collection

1.1 Will you use existing data during your research? If not, indicate the origin of the data you are going to use

- Your own data or data from the research group in which you participate
- Publicly available databases/files

1.2 Data description

Data description:
We generate primary data related to suicide prevention interventions. The primary variables include: (a) subsequent suicide attempts and/or suicide mortality at 12 months; (b) time elapsed between the initial suicide attempt and the repetition of suicidal behaviour; and (c) adherence to the telephone intervention programme.
We follow established protocols and standards in the field of suicide prevention research, including those outlined by the World Health Organisation (WHO) and relevant national health guidelines. The study uses validated clinical assessment tools and structured follow-up protocols to ensure data accuracy and reliability.
If we reuse third-party data, we ensure that we have obtained the necessary permissions and comply with all applicable terms and conditions. We strictly follow confidentiality and ethical considerations in accordance with the General Data Protection Regulation (GDPR) and institutional research ethics policies.

1.3 Data type and formats

Type of data:
Clinical assessments include data from structured clinical interviews and self-reports. Data are collected using quantitative measures. For data collection and analysis, we use:

- Electronic Forms for structured data entry
- Secure database management systems for data storage and processing (ePro platform for clinical trials and spreadsheets)
- Statistical software such as SPSS, R, or Stata for quantitative analyses
- Telephone communication platforms to administer the intervention

Longevity of the file formats:
To ensure that data is easily accessible and remains usable over time, we adhere to the following principles:

- Use of open standards: Where possible, we store data in open and widely used file formats to ensure long-term readability and accessibility (CSV, PDF, TXT, .sav).
- Software and code: We use standard statistical and data management software, ensuring that data is processed in a way that other researchers can easily access, analyse and share it.
- Data preservation: We store all data in secure institutional repositories that meet data retention standards to ensure long-term access. In addition, we take steps to ensure that data is backed up regularly and that data is stored in multiple locations to prevent loss.

1.4 Specify the data volume

- 30-50 GB

2. Data storage and security

2.1 Specify any restrictions (commercial, ethical or confidentiality) that may affect your data

- Legal obligations: protection of personal data (LOPDGDD, RGPD...) [see 4.1]
- Ethical restrictions [see 4.1]
- Formal security standards

2.2 Major data security risks

1. Accidental Deletion or Corruption of Data

- **Risk**: Data may be accidentally deleted, overwritten, or corrupted due to human error or software malfunctions.
- **Consequences**: Loss of critical research information, delays in analysis, and potential gaps in findings.
- **Mitigation Measures**:
  - Regular **automated backups**.
  - Version control and restricted editing permissions.
  - Use of **cloud-based storage** with recovery options.
  - **Treatment of missing values**.

2. Data Theft

- **Risk**: Unauthorised access by individuals outside the research team.
- **Consequences**: Potential ethical and legal issues.
- **Mitigation Measures**:
  - **Restricted access** using password-protected databases.
  - Training researchers on **cybersecurity best practices**.

By addressing these risks, the study ensures research integrity, protects participant confidentiality, and maintains compliance with ethical and legal requirements.

2.3 Measures to be taken to reduce the risk of data loss

- Access restrictions
- Data processing
- Pseudonymization
- Regular backups

2.4 Where will you store your data?

- Cloud service (e.g., Dropbox)
- In the university network
- In the network of your department or research group

Data will be deposited in the CORA Repositorio de Datos de Investigación (CORA RDR), if possible. A specific DOI will be provided for each dataset generated.

3. Data documentation

3.1 Name and structure of the files and the folders

The data files and folders follow a structured and standardised naming convention to ensure consistency, easy retrieval, and proper version control.

Folder Structure:

The project directory is organised as follows:

SURVIVE_Project/ *(Main project folder)*
01_Raw_Data/ *(Original, unprocessed data files – read-only)*
02_Cleaned_Data/ *(Processed and formatted datasets for analysis)*
03_Analyses/ *(Statistical scripts, code, and results)*
04_Documentation/ *(Data dictionaries, codebooks, protocols, metadata)*
05_Publications/ *(Manuscripts, reports, and supplementary materials)*
06_Backups/ *(Regularly saved copies of critical data files)*

File Naming Convention:

Each file name follows a structured format to ensure clarity:

[StudyPhase]*[Dataset]*[Date].ext

Examples:

- Raw_SURVIVE_20250310.csv *(Raw sociodemographic dataset collected on 10th March 2025)*
- Analysis_SURVIVE_20250501.R *(Statistical script analysing PHQ-9 and GAD-7 scores, created on 1st May 2025)*
- Documentation_Codebook_v1.2.xlsx *(Updated codebook detailing variables and measures, version 1.2)*

This structured approach ensures **data integrity, accessibility, and traceability** throughout the study.

3.2 Version control

- Making a copy of the script in which the data is processed
- Version number and date in the file or folder name

Version Control:

- File versions are indicated using **v1, v2, v3.**
- Outdated files are moved to an **Archive** folder instead of being deleted.

Data Deletion Protocol:

- **Accidental Deletion:** Regular automated backups ensure that lost data can be recovered.
- **Intentional Deletion:** If data must be permanently removed, a record is kept in an **Archive** folder.

The structured approach ensures accurate tracking of changes, minimises errors, and prevents data loss.

3.3 Which metadata standards do you intend to use?

- Generic metadata schema (e.g., Dublin Core)

A metadata file will be created to facilitate easy identification and retrieval of the datasets. The **Dublin Core** metadata standard will be used to describe the datasets, ensuring enhanced interoperability, clarity, and long-term accessibility of the data.

Metadata Documentation

The following Dublin Core elements are recorded for each dataset:

- **Title**: Dataset name (e.g., Raw_SURVIVE_20250310_v1.csv)
- **Creator**: Author(s)
- **Subject**: Brief description of the dataset and its purpose
- **Description**: Detailed explanation of the dataset, variables, and methodology
- **Publisher**: Institution responsible for the data
- **Contributor**: Other personnel involved in data collection and processing
- **Date**: Date of creation and updates
- **Type**: Dataset format (e.g., .csv, .xlsx)
- **Format**: File structure
- **Identifier**: Dataset DOI (if applicable)
- **Source**: Origin of the data (e.g., clinical assessments, surveys)
- **Language**: Language of the dataset
- **Relation**: Links to related datasets or publications
- **Coverage**: Geographic and temporal scope of the data
- **Rights**: CC BY 4.0

Metadata Storage

- A **README file** accompanies each dataset, containing the Dublin Core metadata elements.
- A **Codebook** (in .xlsx or .pdf format) provides additional details on variables, coding, and missing values.

4. Access, share and reuse the data

4.1 Do you have any restrictions on data sharing as regards the existing regulation (General Data Protection Regulations) or others (ethics, commercial, security, intellectual property, or copyright)?

- **General Data Protection Regulation (GDPR)** : The dataset must comply with GDPR guidelines. Anonymisation will be implemented.
- **Ethical Approval**: Data sharing is subject to approval by the relevant ethical review boards.
- **Intellectual Property and Copyright**: Intellectual property rights must be respected.

4.2 Who are the potential users of your data and how are they going to find them?

Potential users of the data include researchers, healthcare providers, and policy makers.
To distribute the data and make it accessible:

- **Data Repositories**: Data will be deposited in the CORA Repositorio de Datos de Investigación (CORA RDR), if possible. The data will be shared through the academic data repositories **DDD-UAB (Depòsit Digital de Documents de la UAB)** , available at https://ddd.uab.cat/
- **Conference Publications**.
- **Academic Journals**.

4.3 Specify the licenses that you will apply to the data to enable maximum reuse

Creative Commons C BY 4.0 licences, if possible, in accordance with UAB recommendations for research data.

5. Deposit and conservation of the data

5.1 What criteria will you use when selecting the data for long-term preservation?

- Data linked to a publication
- Type of data (raw, processed) and ease of generation

5.2 How long do you intend to preserve the data?

The centre, the researcher and the sponsor will keep the data collected for the study according to the legal periods established in the regulations. The sponsor and the investigator for at least 10 years after the end of the study (according to clinical trial regulations) and the centre for as long as necessary to provide adequate care (according to clinical record regulations).

5.3 In which repository will you store your data?

- Institutional repository

Planned Research Outputs

Dataset - "Replication Data for: Effect of synchronous remote-based interventions on suicidal behaviours: systematic review and meta-analysis"

This dataset comprises the data extracted from the articles incorporated in a systematic review and meta-analysis. For more information, please refer to the study protocol: "Effect of synchronous remote-based interventions on suicidal behaviours: protocol for a systematic review and meta-analysis" Comendador L, et al. BMJ Open 2023;13:e075116. doi:10.1136/bmjopen-2023-075116. Data are presented in the following categories: a) general characteristics of the study (authors, date of publication, setting and geographic location, research design, sample size, participant sociodemographic and baseline characteristics), b) intervention and control group details (type of intervention or control group, sample sizes, follow-up time, dropout rates), c) outcomes (descriptive and comparative statistical indexes of efficacy and effectiveness, assessment measures, and procedures), and d) limitations reported by study authors. It consists of 1) a csv-file containing information and extracted data of studies selected; 2) a csv-file containing the risk of bias analysis of the studies selected; 3) a csv-file containing the abbreviations and their explanations as used in the other csv-files.

Dataset - "Replication Data for: Effect of telephone-based interventions on suicidal behaviours"

This dataset comprises the data extracted from the project « ***SUicide PReVention and InterVEntion (SURVIVE): cohort study and nested randomized controlled trials of secondary prevention programs for suicide attempts***» a multicentre cohort study with nested randomised controlled trials (RCTs) in Spanish population.

Planned research output details

Title	Type	Anticipated release date	Initial access level	Intended repository(ies)	Anticipated file size	License	Metadata standard(s)	May contain sensitive data?	May contain PII?
Replication Data for: Effect of synchronous remote ...	Dataset	2025-02-09	Open	CORA. Repositori de Dades de Recerca	40 MB	Creative Commons Attribution 4.0 International	Dublin Core	No	No
Replication Data for: Effect of telephone-based in ...	Dataset	2026-01-01	Open	CORA. Repositori de Dades de Recerca		Creative Commons Attribution 4.0 International	Dublin Core	Yes	Yes