Impact of the 2016 Nice terrorist attack on mental health service utilization in children and adolescents: Protocol for the PEDIMPACT Study

First published: 18/10/2021

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Study Planned

Administrative details

EU PAS number

EUPAS43738

Study ID

43739

DARWIN EU® study

No

Study countries

France

Study description

Introduction: The literature on mental healthcare use after a terror attack is relatively scarce. Moreover, several studies have highlighted the complexity of variations in patterns of care and psychotropic drug use after these attacks. The main objective of the PaEDiatric IMPact of terrorist AttaCks in general populaTion (PEDIMPACT) study is to evaluate the short- and middle-term impact in children and adolescents of the terror attack in Nice on July 14th, 2016 on use of mental health resources namely 1) use of psychotropic medications and 2) mental health-related hospitalizations and 3) outpatient visits. Methods and analysis: This is a population-based retrospective cohort study using data from the French National Health Data System (Système National des Données de Santé SNDS) collected from January 1, 2012, to 31 December 2021, in the pediatric population. We will conduct a quasi-experimental study using a monthly interrupted-time series analysis (based on mean-dispersion negative binomial regression models, segmented time series models and an autoregressive integrated moving average ARIMA models) to estimate the short- and middle-term impact on mental health service use in the Nice geographic region vs. three control regions, after the Nice truck-ramming attack. Ethics and dissemination: The study protocol will be submitted to the Institutional Review Board of Toulouse University Hospital and the National Ethics and Scientific Committee for approval. Results will be reported in accordance with the REporting of studies Conducted using Observational Routinely-collected health Data statement. They will be presented in national and international conferences and submitted to peer-reviewed journals.

Study status

Planned

Research institutions and networks

Institutions

Toulouse University Hospital

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Institution

Pharmacologie En Population cohorteS et biobanqueS

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Alexis Revet

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/09/2022

Study start date
Planned: 01/09/2022

Data analysis start date
Planned: 02/01/2023

Date of interim report, if expected
Planned: 01/06/2023

Date of final study report
Planned: 18/12/2023

Sources of funding

- Other

More details on funding

Grant submission in process, Grant submission in process

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Main study objective:

The main objective of the PaEDiatric IMPact of terrorist AttaCks in general populaTion (PEDIMPACT) Study is to evaluate the short- and middle-term impact in children and adolescents of the terror attack in Nice on July 14th, 2016 on use of mental health resources namely 1) use of psychotropic medications and 2) mental health-related hospitalizations and 3) outpatient visits.

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N05B) ANXIOLYTICS

ANXIOLYTICS

(N05A) ANTIPSYCHOTICS

ANTIPSYCHOTICS

(N06A) ANTIDEPRESSANTS

ANTIDEPRESSANTS

(N06BX) Other psychostimulants and nootropics

Other psychostimulants and nootropics

(N05AN) Lithium

Lithium

(N07A) PARASYMPATHOMIMETICS

PARASYMPATHOMIMETICS

Medical condition to be studied

Suicide attempt

Completed suicide

Population studied

Age groups

- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

Estimated number of subjects

100.000

Study design details

Outcomes

1) use of psychotropic medications and 2) mental health-related hospitalizations and 3) outpatient visits.

Data analysis plan

This is a population-based retrospective cohort study using data from the French National Health Data System (Système National des Données de Santé SNDS) collected from January 1, 2012, to 31 December 2021, in the pediatric population. We will conduct a quasi-experimental study using a monthly

interrupted-time series analysis (based on mean-dispersion negative binomial regression models, segmented time series models and an autoregressive integrated moving average ARIMA models) to estimate the short- and middle-term impact on mental health service use in the Nice geographic region vs. three control regions, after the Nice truck-ramming attack.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No