# Persistence with pharmacological treatment in the specialist mental healthcare of patients with severe mental disorders (Persistence of treatment in mental patients)

**First published:** 12/12/2012

**Last updated:** 13/03/2025

Study Finalised

## Administrative details

**EU PAS number**

EUPAS3209

**Study ID**

3210

**DARWIN EU® study**

No

**Study countries**

Italy

**Study description**

PURPOSE: The aim of this study was to measure persistence with pharmacological treatment in the specialist mental healthcare of patients with schizophrenia, bipolar disorder, and unipolar depression in Lombardy, a region of 10 million inhabitants located in the northernmost part of Italy.METHODS: The data concerning psychiatric care used in this study were retrieved from the regional Psychiatric Information System, while information on drug treatment was retrieved from the regional administrative database. Time to lack of persistence with initial pharmacological treatment was the outcome measure.RESULTS: A total of 11,797 patients, followed in the specialist mental healthcare system, started a new pharmacological treatment for depression, schizophrenia, or bipolar disorder during 2007. Overall, 8,500 patients (72.1%) discontinued treatment during the 12 month follow-up, with a median duration of 101 days. Very similar discontinuation rates were observed in patients with unipolar depression, schizophrenia, and bipolar disorder. In the multivariate analysis, operational definitions of continuity and intensity of care were the most robust determinants of persistence with drug treatment in each of the three cohorts of psychiatric diagnoses.CONCLUSIONS: High rates of treatment discontinuation were found in a population of patients with severe mental disorders followed in the specialist mental healthcare system of an Italian region, with no differences among patients with unipolar major depression, schizophrenia, and bipolar disorder. These findings corroborate the notion that the problem of treatment discontinuation in psychiatric disorders is a factor related to the capacity of the mental health system to assure and maintain continuity and intensity of care.

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**Study status**

Finalised

## Research institutions and networks

# Institutions

## Centro Regionale di Farmacovigilanza (PhV Regional Centre of Lombardy, Italy), Regione Lombardia

Italy

**First published:** 09/02/2010

**Last updated:** 14/03/2018

Institution | Outdated | Other | ENCePP partner

## Centro Regionale di Farmacovigilanza (PhV Regional Centre of Lombardy, Italy), Regione Lombardia

Italy

**First published:** 09/02/2010

**Last updated:** 14/03/2018

Institution | Outdated | Other | ENCePP partner

## Pharmacology Unit - Veneto Pharmacovigilance Centre (Pharmacol UNIVR), University Hospital Verona

Italy

**First published:** 25/10/2022

**Last updated:** 13/03/2025

Institution | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

Institute of Psychiatry, University of Verona

Verona, Italy, Lecco Hospital Lecco, Italy

## Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Valentino Conti

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 01/01/2011

Actual: 01/01/2011

**Study start date**
Planned: 01/01/2011

Actual: 01/01/2011

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**Data analysis start date**
Planned: 01/06/2011

Actual: 01/06/2011

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**Date of final study report**
Planned: 01/03/2012

Actual: 01/03/2012

## Sources of funding

- Other

## More details on funding

Lombardy Region, University of Verona, Lecco Hospital

## Study protocol

persistence_protocol.pdf (544.54 KB)

## Regulatory

**Was the study required by a regulatory body?**

No

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

Not applicable

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To measure persistence with pharmacological treatment in the specialist mental healthcare of patients with schizophrenia, bipolar disorder, and unipolar depression in Lombardy, a region of 10 million inhabitants located in the northernmost part of Italy.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(N06A) ANTIDEPRESSANTS

ANTIDEPRESSANTS

(N05A) ANTIPSYCHOTICS

ANTIPSYCHOTICS

(N03A) ANTIEPILEPTICS

ANTIEPILEPTICS

## Population studied

**Short description of the study population**

Patients with schizophrenia, bipolar disorder, and unipolar depression in Lombardy who in an index period (January 1st to December 31st 2007) have received at least one psychiatric service and have one of the diagnoses of interest and have taken at least one prescription appropriate (antidepressants for depression, antipsychotics for schizophrenia, stabilizers medications/antipsychotics for bipolar disorder).

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**Age groups**

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)

- Adults (85 years and over)

**Estimated number of subjects**

11.797

## Study design details

**Outcomes**

Persitence with pharmacological treatment

**Data analysis plan**

Time to lack of persistence with initial pharmacological treatment was the outcome measure employed in this study. It was defined as a gap of at least 30 days between subsequent medication fills. The proportion of patients who were not persistent with drug treatment was calculated for the three cohorts of patients with depression, schizophrenia and bipolar disorder. Kaplan-Meier survival curves were used to examine time to treatment discontinuation. In order to identify potential determinants of discontinuation, three Cox regression models, one for each diagnostic cohort, were fitted, and adjusted hazard ratios with 95% confidence intervals were estimated according to level of exposure variables. The results were considered significant at $p<0.05$. Data management and statistical analysis were carried out using SAS statistical package(SAS Institute, Cary, NC), version 9.1, the PHREG procedurewas used to fit the Cox regression models.

## Documents

**Study results**

persistence_results.pdf (218.67 KB)

# Data management

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.

**Conflicts of interest of investigators**

persistence_Conflict_of_Interest_Form Conti.pdf (177.05 KB)

**Composition of steering group and observers**

Persistence Steering Group.pdf (161.2 KB)

# Data sources

**Data sources (types)**

Administrative healthcare records (e.g., claims)

Other

**Data sources (types), other**

Regional Psychiatric Information System, Regional Hospital Discharge Registry, Regional Prescription Database

# 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