Optimization of pharmacological treatment in patients institutionalized in nursing homes in Catalonia. (OptPharma)

First published: 29/09/2023

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Study Ongoing

Administrative details

EU PAS number

EUPAS106748

Study ID

107868

DARWIN EU® study

No

Study countries

☐ Spain

Study description

A before-after study was performed without a control group. A multidisciplinary team was created in Catalonia, Spain, to intervene in nursing homes. This team combined general practitioners, nurses, social and administrative workers from primary care, clinicians and nurses assigned to the nursing homes, and a clinical pharmacologist. The intervention consisted of developing an improvement plan, reviewing the validity of prescriptions and medication plans in this population. The study population were all patients admitted to the 5 nursing homes intervened belonging to the North area of Barcelona. Patients were followed up from the intervention that began in June 2020 until approximately one year later or until death if prior. The inclusion criteria was institutionalized patients with public health coverage provided by CatSalut. The exclusion criteria were institutionalized patients with health coverage provided by other insurers, a short-term life expectancy, hospitalized during the intervention, who died or were discharged in the first month of review and who could not be reviewed due to lack of information. There was no formal sample size calculation since the analysis was done on all the reviewed patients, except those excluded. First, a detailed description of the clinical characteristics, chronic diseases and pharmacological treatments will be made. Also a descriptive analysis of incomplete data, interactions, duplications, contraindications and drugs deemed inappropriate or of doubtful efficacy. Secondly, a descriptive analysis of the number of drugs prescribed, withdrawn, added, and that were recommended to be withdrawn, changed or adequated will be made. Also a comparative analysis of changes in the number of drugs, use of absorbents and if recommendations were followed.

Study status

Ongoing

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Emilie Anderssen-Nordahl

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/10/2021

Actual: 15/10/2021

Study start date

Planned: 03/01/2022

Actual: 04/04/2022

Data analysis start date

Planned: 05/09/2022

Actual: 03/04/2023

Date of final study report

Planned: 01/05/2024

Sources of funding

- Other

More details on funding

Mutual Medical Scholarship 2022

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

Main study objective:

The main objectives of this study were to characterize institutionalized patients, systematically review their medication plans to detect potentially inappropriate medications, and to evaluate the impact of a multidisciplinary team intervention, with the inclusion of a clinical pharmacologist, on medication plans

in nursing homes in Catalonia.

Study Design

Non-interventional study design

Cross-sectional

Population studied

Age groups

- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

530

Study design details

Outcomes

The primary outcomes will be to describe the patients health-related problems, prescribed pharmacological treatments, a comparative analysis of changes in the number of drugs, use of absorbents and whether the recommendations were followed. The secondary outcomes will be a descriptive analysis of incomplete data, the risk of interactions, therapeutic duplications, contraindications, drugs of doubtful efficacy, inappropriate drugs, recommendations made, withdrawn and added drugs, the number of drugs

recommended to remove/change/adapt, along with the number of each one.

Data analysis plan

The data will be entered into a Research Electronic Data Capture (REDCap) platform. A quality analysis will be carried out prior to the descriptive and comparative analysis. The planned outcomes were the descriptive analysis according to clinical characteristics, chronic diseases and pharmacological treatments, the analysis of changes in the medication plan and the monitoring of proposals for changes. Continuous variables will be presented as means (standard deviation) or medians (interquartile range), and categorical variables as percentages. For the comparative analysis before-after post-intervention, we will carry out multiple comparisons.

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)

Electronic healthcare records (EHR)

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