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An educational intervention to improve adverse drug reactions reporting: a cluster-randomised trial among Portuguese physicians and pharmacists

Submission date
07/06/2006

Registration date
15/06/2006

Last Edited
11/07/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
An educational intervention to improve adverse drug reactions reporting: a cluster-randomised trial among Portuguese physicians and pharmacists

Study objectives
1. An educative intervention enhances the rate of reporting adverse drug reaction
2. An educative intervention enhances the quality of reporting, in terms of its relevance to the pharmacosurveillance system
3. Duration of the effect in terms of quantity and relevance could be more than one year

Ethics approval required
Old ethics approval format

Ethics approval(s)
In Portugal, educational interventions are not evaluated by ethical committees. In hospitals, it is the teaching committee that approves educational interventions. In communitarian pharmacies, we usually contact the pharmacist responsible by telephone.

Study design
Cluster-randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Under-reporting of adverse drug reactions

Interventions
We implemented a continuing medical education multifaceted intervention comprising of an outreach visit, reminder and report form. The main didactic material used for this purpose was a two-part presentation. The first part included definitions of pharmacosurveillance and adverse drug reaction, a number of international studies on morbidity and mortality, hospital admissions and the cost to health systems and patients, followed by the methods used in pharmacosurveillance and in spontaneous reporting systems in particular, explaining that underreporting constituted the system's principal limitation. The second part was designed to

change the five attitudes identified by the previous case-control study as being associated with underreporting, and for this section we created animated pictures that depicted a physicians daily work. Lastly, emphasis was laid on the fact that only five minutes was required to complete the report form. The control group clusters did not receive the intervention but, like those in the intervention group, did receive the briefing and standard training given by Portugal's northern pharmacovigilance unit.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Rate of total notifications per month

Secondary outcome measures
Rate of serious, unexpected, high-causality, and new-drug-related adverse drug reactions per month

Overall study start date
16/03/2004

Completion date
30/06/2005

Eligibility

Key inclusion criteria
All National Health System physicians working in the Northern Region of Portugal and all pharmacists working in the same geographical area.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
6,451 physicians and 1,433 pharmacists

Total final enrolment
1433

Key exclusion criteria
Physicians not involved in any clinical activity (e.g. engaged in administrative tasks, analysis, etc.); working in substance abuse and rehabilitation centers; working at the regional

pharmacosurveillance center or any department having a specific voluntary adverse drug reaction reporting program and physicians attached to specific hospitals (cancer, maternity, etc). Pharmacists working at the regional pharmacosurveillance center and attached to specific hospitals (cancer, maternity, etc).

Date of first enrolment
16/03/2004

Date of final enrolment
30/06/2005

Locations

Countries of recruitment
Portugal

Spain

Study participating centre
Dto. Medicina Preventiva
Santiago
Spain
15783

Sponsor information

Organisation
Educational Development Program for Portugal (Programa de Desenvolvimento Educativo para Portugal) (PRODEP) (Portugal)

Sponsor details
Rua de Xabregas 52
Lisboa
Portugal
1949-003

Sponsor type
University/education

Website
http://www.prodep.min-edu.pt

Funder(s)

Funder type
University/education

Funder Name
Educational Development Programme for Portugal (Programa de Desenvolvimento Educativo para Portugal) (PRODEP) (Portugal)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2008	11/07/2019	Yes	No