

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

Submission date 07/06/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 15/06/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 11/07/2019	Condition category Other	<input type="checkbox"/> 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

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

Study type(s)

Treatment

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(s)

Rate of total notifications per month

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

Funder(s)

Funder type

University/education

Funder Name

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

Results and Publications

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