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Adverse events analysis as an educational tool to improve patient safety culture in primary care: an experimental study

Submission date 31/12/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 07/02/2011	**Overall study status** Completed	
Last Edited 12/02/2020	**Condition category** Other	

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
The adverse events analysis as an educational tool to improve patient safety culture between family physicians in primary care: an experimental unifactorial controlled randomised multicentre trial

Study objectives
1. The registry of adverse events is a teaching tool that has a positive impact on patient safety culture in the Family and Community Medicine teaching units of Galicia
2. The Hospital Survey on Patient Safety Culture (SOPS) is valid for use in primary health care services

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of Clinical Research of Galicia approved on the 30th September 2008 (ref: 2008/268)

Study design
Experimental unifactorial controlled randomised multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Patient safety culture

Interventions
Residents and their respective tutor (tutor-resident pair) in teaching units on Family and Community Medicine throughout Galicia will be invited to participate. Tutor-resident pairs that agree to participate will be sent the Hospital Survey on Patient Safety Culture. Then, tutor-resident pair will be assigned to each group - either intervention or control - through simple random sampling.

The intervention group will receive specific training to record the adverse effects found in patients under their care, with subsequent feedback, after receiving instruction on the process. No action will be taken in the control group. After the intervention has ended, the survey will once again be provided to all participants.

Intervention group:
1. One training workshops will be conducted in each of the 7 areas included (except in Lugo where 2 will be given). Each workshop will last 2 hours.
2. Professionals in the tutor-resident pairs in the intervention group will record adverse events for 15 days.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The dependent variable will be patient safety culture as measured by the Hospital Survey on Patient Safety Culture (SOPS). The independent or explanatory variable will be participation in the intervention - training workshops, recording of adverse events in daily work and reception of feedback.

First round SOPS (3-6 months) and second round SOPS (9-12 months).

Secondary outcome measures
Reliability (internal consistency, repeatability), validity (content, criteria, construct) and change sensitivity (size of effect, paired t) of the Hospital Survey on Patient Safety Culture

First round SOPS (3-6 months) and second round SOPS (9-12 months).

Overall study start date
01/01/2009

Completion date
31/12/2010

Eligibility

Key inclusion criteria
Tutors and residents in Family and Community Medicine in last year of studies in Galicia, Spain

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
27 tutor-resident pairs in each group (108 in total)

Total final enrolment
138

Key exclusion criteria
Unwilling to participate

Date of first enrolment
01/01/2009

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
Spain

Study participating centre
Rosalía de Castro, 21-23
Vigo
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36201

Sponsor information

Organisation
Department of Health of Galicia (Spain)

Sponsor details
Edificio Administrativo de San Lázaro
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Sponsor type
Government

Website
http://www.sergas.es

ROR
https://ror.org/0181xnw06

Funder(s)

Funder type
Government

Funder Name
Department of Health of Galicia (Spain) (ref: PS08/43)

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	18/01/2019	12/02/2020	Yes	No