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Randomised controlled trial for evaluating the prescribing impact of information meetings led by pharmacists and of new information formats in general practice in Italy: INFANT 1

Submission date
21/05/2007

Recruitment status
No longer recruiting

Registration date
07/06/2007

Overall study status
Completed

Last Edited
29/07/2015

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

Study website
http://www.ceveas.it/ceveas/ceveas/spaziofarmaci/farmacistafacilitatore/progetto1/Root.aspx

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
FARM59NWKF

Study information

Scientific Title
Randomised controlled trial for evaluating the prescribing impact of information meetings led by pharmacists and of new information formats in general practice in Italy: INFANT 1

Acronym
INFANT 1 (INformazione sui FArmaci e Nuove Terapie)

Study objectives
Information meetings with small groups of physicians (Primary Care Groups [PCGs] in Emilia-Romagna and Friuli Venezia Giulia), led by pharmacists and organised by Local Health Authorities within a large scale independent information program involving local General Practitioners (GPs), can be effective in changing physicians' prescribing behaviour.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Between November 2006 and March 2007, the protocol was sent to the Local Ethics Committees (LEC) of the Health Authorities involved. Most of the LEC have already approved the protocol (Parma, Reggio Emilia, Modena, Bologna, Forlì, ASL n° 2 Isontina, Trieste, ASL n° 5 Bassa Friulana), some specifying that it was unnecessary to analyse it formally since no ethical problems arise in carrying out a randomisation differentiating the kind of information actively discussed during the outreach visits.

Study design
Randomised controlled trial: the unit of randomisation will be PCGs in Emilia-Romagna and Friuli Venezia Giulia

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied

Information to physicians

Interventions
Both the intervention and control groups will have information meetings led by a pharmacist on one specific topic versus another topic, both supported by a drug bulletin developed ad hoc. The prescription of drug A will be compared in physicians randomised to receiving information on topic A versus those who received information on topic B (i.e., not receiving information on topic A) and vice versa.

The information meetings will last two to three hours.

The process described above will be repeated a second time with different topics, so that the number of comparisons and indicators is doubled and more qualitative and quantitative data are available.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Difference (%) in NHS prescription of drugs under scrutiny (expressed as Defined Daily Dose [DDD] per thousand inhabitants/day), comparing those who have/ have not received the specific information. Prescriptions within six months after the intervention will be evaluated.

Secondary outcome measures
1. Difference in the % of patients who were prescribed the specific drug(s)
2. Difference in the % of patients who were prescribed the specific drug(s) for the first time (in the previous 12 months)
3. Difference in expenditure for the specific drug (per 1000 patients/day)
4. Differences in the main and secondary outcomes in each of the regions involved
5. Differences in the main and secondary outcomes according to the number of assisted population in the related PCG
6. Differences in the main and secondary outcomes according to the terziles of physicians age
7. Adjusted difference in prescribed DDD per 1000 patients/day according to a statistical model, considering as possible covariates:
7.1. Overall prescription in DDD per 1000 patients day at baseline
7.2. Number of physicians in the specific PCGs
7.3. Number of assisted population
7.4. Region (Emilia-Romagna or Friuli Venezia Giulia)
7.5. Geographical location (mountain, hill, plain, urban centre according to definitions given by the Italian Statistics Institute)
7.6. Age distribution of assisted population (in quartiles)
7.7. % females in the assisted population
7.8. Physician age
7.9. Total physician drug expenditure (excluding drugs under scrutiny)
7.10. % assisted population with polyprescription (greater than or equal to three drugs of different classes)
7.11. Number of new prescriptions (in the last 12 months)
7.12. Month of evaluation

7.13. Participation to the information meetings
7.14. % exact answers to the questionnaire testing knowledge
8. Difference in the variability (expressed as standard deviations) of prescription of drugs under scrutiny within PCGs
9. Difference in knowledge (measured through the number of correct answers to a specific questionnaire)
10. Difference in attitudes (measured through the answers to a specific anonymous questionnaire)

Prescriptions within six months after the intervention will be evaluated.

Overall study start date
15/03/2007

Completion date
23/12/2007

Eligibility

Key inclusion criteria
PCGs are defined as small groups, ranging from about 10 to 20 General Practitioners (GPs) and assisting about 8,000 to 25,000 people in a defined area. A general rule is to include PCGs with less than or equal to 20 physicians.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
150 PCGs

Key exclusion criteria
PCGs with more than 20 physicians (not a strict criterion, but justification will be needed).

Date of first enrolment
15/03/2007

Date of final enrolment
23/12/2007

Locations

Countries of recruitment
Italy

Study participating centre
Viale Muratori 201
Modena
Italy
41100

Sponsor information

Organisation
Italian Drug Agency (Agenzia Italiana del Farmaco [AIFA])

Sponsor details
Via della Sierra Nevada, 60
Rome
Italy
00144

Sponsor type
Government

Website
http://www.agenziafarmaco.it

ROR
https://ror.org/01ttmqc18

Funder(s)

Funder type
Government

Funder Name
Italian Drug Agency (Agenzia Italiana del Farmaco [AIFA]) - operates within the Italian National Health Service

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	17/10/2014		Yes	No