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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 2

Submission date
23/05/2007

Recruitment status
No longer recruiting

Registration date
07/06/2007

Overall study status
Completed

Last Edited
04/01/2021

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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 2

Acronym
INFANT 2 (INformazione sui FArmaci e Nuove Terapie)

Study objectives
Information meetings with single physicians, 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. Some of the LEC have already approved the protocol (Olbia, Carbonia, Sassari, Nuoro), 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 single physicians in Sardinia.

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

Three groups of single physicians will be provided with one of the following:
1. One information meeting led by a pharmacist and supported by a bulletin developed ad hoc
2. One information meeting led by a pharmacist and supported by information already available (e.g., from the Italian translation of Medical Letter, or the Drug and Therapeutics Bulletin [DTB], etc)
3. No intervention

The information meetings will last half to one hour.

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. Difference in NHS prescription of drugs under scrutiny (expressed as DDD per thousand inhabitants/day), comparing those who have received the traditional versus enriched format, and any information versus no information
5. Differences in the main and secondary outcomes according to the number of assisted population in the related PCG
6. Adjusted difference in prescribed DDD per 1000 patients/day according to a statistical model, considering as possible covariates:
6.1. Overall prescription in DDD per 1000 patients day at baseline
6.2. Number of assisted population
6.3. Geographical location (mountain, hill, plain, urban centre according to definitions given by the Italian Statistics Institute)
6.4. Age distribution of assisted population (in quartiles)
6.5. % females in the assisted population
6.6. Physician age
6.7. Total physician drug expenditure (excluding drugs under scrutiny)
6.8. % assisted population with polyprescription (greater than or equal to three drugs of different classes)
6.9. Number of new prescriptions (in the last 12 months)
6.10. Month of evaluation
6.11. Participation to the information meetings

6.12. % exact answers to the questionnaire testing knowledge
7. Difference in knowledge (measured through the number of correct answers to a specific questionnaire)
8. 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
15/02/2008

Eligibility

Key inclusion criteria
All GPs are eligible, provided that their Local Health Authority has an organised system for tracking their prescriptions made within the Italian National Heath Service (NHS) till the 5th Anatomic Therapeutic Chemical (ATC) level, in order to evaluate these prescriptions and to provide doctors with feedback.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
900 GPs

Key exclusion criteria
No exclusion criteria.

Date of first enrolment
15/03/2007

Date of final enrolment
15/02/2008

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
ROMA
Italy
144

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?
Protocol article	protocol	28/09/2007	04/01/2021	Yes	No