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Evaluation of a multifaceted implementation strategy of three Clinical Practice Guidelines on cardiovascular risks in primary health care in the Basque Country

Submission date
13/01/2009

Recruitment status
No longer recruiting

Registration date
30/04/2009

Overall study status
Completed

Last Edited
13/02/2018

Condition category
Circulatory System

[_] Prospectively registered
[X] 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
CTGPC1

Study information

Scientific Title
Evaluation of a multifaceted implementation strategy of three Clinical Practice Guidelines on cardiovascular risks in primary health care in the Basque Country: a cluster randomised trial

Acronym
CLUES

Study objectives
An implementation strategy that includes interactive presentations, a web platform and workshops with reminders is more effective than the usual strategy in the Basque Health Service.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee for Clinical Research, Euskadi (Comité Etico de Investigación Clínica de Euskadi) (CEIC-C), 25/07/2008

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Cardiovascular risk, hypertension, diabetes, dyslipemia

Interventions
Control group (usual intervention): guidelines sent by post, electronic dissemination, presentations in health centres, limited number of workshops.

Experimental group (multifaceted intervention): usual intervention plus Clinical Practice Guidelines (CPG) website, feedback on performance data, specific workshops and reminders.

Intervention will last for 12 weeks, with reminders at 6 and 12 months from the beginning of the intervention. Total duration of follow up is 18 months from the beginning of the intervention.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Hypertension:
1.1. Percentage of patients monitored over the study period (blood pressure and blood analysis registered)
2. Dyslipemia:
2.1. Percentage of patients (women >44 of age and men >39) whose coronary risk has been calculated during the study period
2.2. Percentage of patients with new statin prescription whose coronary risk was calculated during the previous year
3. Diabetes:
3.1. Percentage of patients with HbA1c determination during the study period

All primary and secondary outcome measures will be assessed at the end of the study period, i. e., 18 months after initiation of intervention.

Secondary outcome measures
1. Hypertension:
1.1. Systolic blood pressure (SBP), diastolic blood pressure (DBP)
1.2. Percentage of patients with good blood pressure control (<140 mmHg/90 mmHg)
1.3. Percentage of patients with high blood pressure (>140/90 mmHg) being treated with only one drug

1.4. Percentage of patients treated with an angiotensin II receptor blocker (ARB-II)
2. Dyslipemia:
2.1. Patients with coronary heart disease treated with statins

All primary and secondary outcome measures will be assessed at the end of the study period, i. e., 18 months after initiation of intervention.

Overall study start date
01/01/2009

Completion date
30/06/2010

Eligibility

Key inclusion criteria
Primary care units from two health districts (family physicians and nurses). Data will be taken from the computerised clinical records of all diabetics, hypertensive patients and general patients, who have attended the health centre over the last year for whatever reason.

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
43 health units, 400 family physicians, 380 nurses

Key exclusion criteria
Units, physicians and nurses who refuse to take part in the study

Date of first enrolment
01/01/2009

Date of final enrolment
30/06/2010

Locations

Countries of recruitment
Spain

Study participating centre

Osakidetza-Servicio Vasco de Salud (Basque Health Service)
Hernani
Spain
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Sponsor information

Organisation
Ministry of Health (Spain)

Sponsor details
c/o Pablo Rivero
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Sponsor type
Government

Website
http://www.msc.es

Organisation
Health Technology Assessment Service (Servicio de Evaluación de Tecnologías Sanitarias [OSTEBA])

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c/o José Asua Asurmendi
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Sponsor type
Other

Website
http://www.osanet.euskadi.net/osteba/es

Organisation
Ministry of Health

Sponsor details

Sponsor type
Government

Website
http://www.msssi.gob.es/

ROR
https://ror.org/00y6q9n79

Funder(s)

Funder type
Government

Funder Name
Ministry of Health (Spain)

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	24/10/2013		Yes	No
Results article	results	08/02/2018		Yes	No