

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 30/04/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/02/2018	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

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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

Agencia de Calidad del Sistema Nacional de Salud

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Sponsor type

Government

Website

<http://www.msc.es>

Organisation

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

Sponsor details

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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