

ETHICCAR - Case-Control Study on Individual and Collective Therapeutic Education for At-Risk Cardiovascular Patients in General Medicine

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General

Identification

Detailed name Case-Control Study on Individual and Collective Therapeutic Education for At-Risk Cardiovascular Patients in General Medicine

Sign or acronym ETHICCAR

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation CNIL approval no. 908457 received 02/11/2009 - CCTIRS favourable opinion received 18/04/2008.

General Aspects

Medical area Cardiology
Psychology and psychiatry

Health determinants Addictions
Lifestyle and behavior
Nutrition
Social and psychosocial factors

Keywords therapeutic, individual, collective, profile, psychosocial, cardiovascular risk, nutrition, alcohol, tobacco, physical activity

Scientific investigator(s) (Contact)

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Collaborations

Funding

Funding status	Public
Details	URCAM Aquitaine (FNPEIS), Regional Public Health Bodies, HAS, INPES.

Governance of the database

Sponsor(s) or organisation(s) responsible Université de Bordeaux

Organisation status Public

Sponsor(s) or organisation(s) responsible INSERM

Organisation status Public

Additional contact

Main features

Type of database

Type of database	Study databases
Study databases (details)	Case control study

Database recruitment is carried out by an intermediary

A selection of health care professionals

Database recruitment is carried out as part of an interventional study

Yes

Details

Performed at group level (clusters)

Additional information regarding sample selection.

102 general practitioners, with an average of 3 patients for each, were randomly selected across 6 clusters in Aquitaine (Carto Santé URCAM). Patients are selected as such: first 3 patients eligible for the study who agreed to participate (patient register kept).

Database objective

Main objective

To assesses the impact of therapeutic education on reducing the risk and/or cardiovascular morbidity and mortality for hypertensive patients compared to regular follow-up.

Secondary objectives:

- To describe the development of cardiovascular risk score in the three groups over 5 years: individual education, collective education and control group (regular follow-up);
- To compare morbidity and mortality in the 3 groups;
- To compare the impact of individual or collective action against standard follow-up;
- To compare the results of individual action to collective action;
- To analyse the psychosocial profile of respondents to either method;
- To identify factors justifying the choice of either method or association;
- To describe and compare the quality of life of patients in the 3 groups.

Inclusion criteria

Inclusion criteria:

- Men over 50 and women over 60 years old (<75 years old);
- Individuals with essential arterial hypertension (systolic pressure \geq 140 mmHg, diastolic pressure \geq 90 mmHg);
- With another risk factor: smoking, diabetes, dyslipidemia (i.e., at least 3 cardiovascular risk factors);
- No history of cardiovascular accident (primary prevention).

- Exclusion criteria:
- Previous history of cardiovascular accident;
 - Secondary arterial hypertension;
 - Type 1 diabetes;
 - Short-term life-threatening disease;
 - Social or cultural situation making educational process impossible;
 - Cannot be monitored for at least two years;
 - Patient included in another study that could affect treatment (cohort study, therapeutic trial, etc.).

Population type

Age
Adulthood (45 to 64 years)
Elderly (65 to 79 years)

Population covered
General population

Gender
Male
Woman

Geography area
Regional

French regions covered by the database
Aquitaine Limousin Poitou-Charentes

Detail of the geography area
Aquitaine

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)
2009

Size of the database

Size of the database (number of individuals)
< 500 individuals

Details of the number of individuals
188 patients included: 66 in the collective action group, 68 in the individual action group and 54 in the control group.

Data

Database activity
Current data collection

Type of data collected
Clinical data
Declarative data
Biological data

Clinical data (detail)
Direct physical measures

Medical registration

Details of collected clinical data	Cardiovascular events, Body Mass Index, echocardiography.
Declarative data (detail)	Face to face interview
Details of collected declarative data	Medical questionnaire: smoking, alcohol, physical activity, medication, quality of life.
Biological data (detail)	--
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services Quality of life/health perception Others
Care consumption (detail)	Medicines consumption
Other (detail)	Cardiovascular risk score.
Procedures	
Data collection method	D0, D0 + 6 months, D0 + 12 months, D0 + 24 months, D0 + 36 months, D0 + 48 months, D0 + 60 months.
Participant monitoring	Yes
Links to administrative sources	No
Promotion and access	
Promotion	
Link to the document	http://www.researchgate.net/publication/233842679_Education_thrapeutique_du_patient_en_mdecine_g_nrale._Ltude_ETHICCAR_faisabilit_et_valuation_chez_le_patient_risque_cardiovasculaire
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Contact the scientist in charge.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only

