

# 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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Unit	U 897 - Département de Médecine Générale
Organization	Université de
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	<p>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.</p> <p>Secondary objectives:</p> <ul style="list-style-type: none"> <li>- 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);</li> <li>- To compare morbidity and mortality in the 3 groups;</li> <li>- To compare the impact of individual or collective action against standard follow-up;</li> <li>- To compare the results of individual action to collective action;</li> <li>- To analyse the psychosocial profile of respondents to either method;</li> <li>- To identify factors justifying the choice of either method or association;</li> <li>- To describe and compare the quality of life of patients in the 3 groups.</li> </ul>
Inclusion criteria	<p>Inclusion criteria:</p> <ul style="list-style-type: none"> <li>- Men over 50 and women over 60 years old (&lt;75 years old);</li> <li>- Individuals with essential arterial hypertension (systolic pressure <math>\geq</math>140 mmHg, diastolic pressure <math>\geq</math> 90 mmHg);</li> <li>- With another risk factor: smoking, diabetes, dyslipidemia (i.e., at least 3 cardiovascular risk factors);</li> <li>- No history of cardiovascular accident (primary prevention).</li> </ul>

#### 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)
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Population covered	General population
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Gender	Male Woman
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Geography area	Regional
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French regions covered by the database	Aquitaine Limousin Poitou-Charentes
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Detail of the geography area	Aquitaine
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### Data collection

#### Dates

Date of first collection (YYYY or MM/YYYY)	2009
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#### Size of the database

Size of the database (number of individuals)	< 500 individuals
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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.
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### Data

Database activity	Current data collection
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Type of data collected	Clinical data Declarative data Biological data
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Clinical data (detail)	Direct physical measures
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## 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.
<b>Procedures</b>	
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
<b>Promotion and access</b>	
<b>Promotion</b>	
Link to the document	<a href="http://www.researchgate.net/publication/233842679_Education_thrapeutique_du_patient_en_mdecine_g_nrale._Ltude_ETHICCAR_faisabilit_et_valuation_chez_le_patient_risque_cardiovasculaire">http://www.researchgate.net/publication/233842679_Education_thrapeutique_du_patient_en_mdecine_g_nrale._Ltude_ETHICCAR_faisabilit_et_valuation_chez_le_patient_risque_cardiovasculaire</a>
<b>Access</b>	
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

