

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

Head :Gay Bernard, U 897 - Département de Médecine Générale  
Demeaux Jean-Louis, U 897 - Département de Médecine Générale

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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)

Name of the director Gay

Surname Bernard

Address Departement de Médecine Générale Université  
Bordeaux Segalen - Case 148 - 146 rue Léo Saignat  
33076 Bordeaux cedex

Phone +33 (0)5 57 57 12 77

Email	bernard.gay@u-bordeaux.fr
Unit	U 897 - Département de Médecine Générale
Organization	Université de
Name of the director	Demeaux
Surname	Jean-Louis
Address	Departement de Médecine Générale Université Bordeaux Segalen - Case 148 - 146 rue Léo Saignat 33076 Bordeaux cedex
Phone	+33 (0)5 57 57 12 77
Email	jean-louis.demeaux@u-bordeaux.fr
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

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.
<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

