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

Last update : 05/12/2015 | Version : 1 | ID : 8543

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 ?140 mmHg, diastolic pressure ? 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_gnrale._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