

PRISM - Multidisciplinary care of the metabolic syndrome during spa therapy

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General	
Identification	
Detailed name	Multidisciplinary care of the metabolic syndrome during spa therapy
Sign or acronym	PRISM
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CCTI-RS 08.076bis, CNIL 908160
General Aspects	
Medical area	Endocrinology and metabolism
Health determinants	Lifestyle and behavior Medicine Nutrition
Keywords	Metabolic syndrome, spa therapy, multidisciplinary care, balneology, department of pharmacology, pharmacoepidemiology, cohort, Bordeaux
Scientific investigator(s) (Contact)	
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Unit	Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen
Organization	Université Bordeaux

Collaborations

Funding

Funding status Mixed

Details Association Française pour la Recherche Thermale - AFRETh (soutien inconditionnel) dans le cadre de l'Appel d'Offre 2007

Governance of the database

Sponsor(s) or organisation(s) responsible Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen

Organisation status Public

Additional contact

Main features

Type of database

Type of database Study databases

Study databases (details) Longitudinal study (except cohorts)

Database recruitment is carried out by an intermediary A selection of health institutions and services

Database recruitment is made on the basis of: Another treatment or procedure

Database recruitment is carried out as part of an interventional study No

Additional information regarding sample selection. Spa physicians proposed the study to non-diabetic patients initiating spa therapy between July 2008 and December 2009 and presenting with metabolic syndrome. Patients fulfilling the inclusion criteria and agreeing to participate were included. Those whose general practitioner agreed to participate were followed for 1 year without any further intervention.

Database objective

Main objective The main objective of this study was to determine the maximal effect of multidisciplinary management initiated during spa therapy on metabolic syndrome at one year.

Inclusion criteria	<p>Patient presenting a metabolic syndrome according to the criteria of the NCEP-ATP III (at least three of the following criteria: waist circumference > 102 cm for men and 88 cm for women, triglycerides ? 1.5 g/l, HDL-Cholestérol < 0.4 g/l for men and 0.5 g/l for women, fasting glycaemia ? 1.10 g/l, blood pressure ? 130/85 mmHg 130/85); greater than 18 years old; patient having a BMI < 40; patient having a fasting glycaemia < 1.26 g/l; patient who can be followed during the study period; patient able to understand the protocol and complete the questionnaire; patient initiating spa therapy for "metabolic disease" (alone or with a second indication); patient accepting to participate in the study.</p>
Population type	
Age	<p>Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years) Great age (80 years and more)</p>
Population covered	Sick population
Gender	<p>Male Woman</p>
Geography area	National
Detail of the geography area	Patients initiating spa therapy at Eugénie les Bains
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2008
Date of last 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	145 patients inclus dont 97 patients suivis pendant 1 an
Data	

Database activity	Data collection completed
Type of data collected	Clinical data Declarative data Administrative data
Clinical data (detail)	Direct physical measures Medical registration
Declarative data (detail)	Paper self-questionnaire Face to face interview Phone interview
Administrative data (detail)	Name, first name, home address, email address, phone number, general practitioner address
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)	Medical/paramedical consultation Medicines consumption
Other (detail)	Dietary evaluation (questionnaire Nutrition Alimentation)
Procedures	
Data collection method	The inclusion data were collected by the thermal team (thermal physician, dietician, psychologist) and from the patient (paper questionnaire). During the follow-up at 6 and 12 months, the data were collected by the coordinating centre from the patients and their general practitioners.
Participant monitoring	Yes
Details on monitoring of participants	The patients included by the thermal physicians were also seen by a dietician and a nurse to fill-out two questionnaires. They participated in multidisciplinary care programme associated with the hydrotherapy. Those whose general practitioner agreed to participate were contacted again at 6 and 12 months to complete a telephone questionnaire (SF36 quality of life evaluation, physical activity, perceived health status, dietary evaluation). In parallel, general practitioners were also contacted at 6 and 12 months to fill-out a medical questionnaire (vital status, clinical examination, cardiovascular

events, biological examinations and medicinal treatments).

Links to administrative sources	No
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Promotion and access

Promotion

Link to the document	http://tinyurl.com/Pubmed-PRISME
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Description	List of publications in Pubmed
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Access

Terms of data access (charter for data provision, format of data, availability delay)	A study report was delivered to the AFRETh after validation by the study Steering committee experts. Ownership of study data is the subject of an agreement between the University of Bordeaux Segalen and the AFRETh. Terms for third-party access to the database are to be defined.
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Access to aggregated data	Access on specific project only
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Access to individual data	Access on specific project only
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