REDIA-prev1 Cohort - Follow-up of the participants to an intervention controlled trial for the primary prevention of type-2 diabetes mellitus and metabolic syndrome on Reunion Island

Head :FIANU Adrian, CENTRE D'INVESTIGATION CLINIQUE DE LA RÉUNION (CIC 1410) INSERM / CHU
FAVIER François, CENTRE D'INVESTIGATION CLINIQUE DE LA RÉUNION (CIC 1410) INSERM / CHU

Last update : 06/02/2025 | Version : 5 | ID : 20903

General

Identification

Detailed name	Follow-up of the participants to an intervention controlled trial for the primary prevention of type-2 diabetes mellitus and metabolic syndrome on Reunion Island
Sign or acronym	REDIA-prev1 Cohort
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	Accord CNIL : 01/08/2001 ; CPP SOOM III : 2010/56 ; ID RCB : 2010-A00432-37 ; AFSSAPS : B100595-70

General Aspects

Medical area	Endocrinology and metabolism
Study in connection with Covid-19	No
Pathology (details)	Type-2 diabetes mellitus risk factors, metabolic syndrom
Health determinants	Lifestyle and behavior Nutrition
Keywords	adiposity, lifestyle intervention, vulnerable population, physical activity, glycemic status, quasi-experimentation, diet, community approach, primary prevention, post-trial follow-up study, long-term effectiveness, transferability.

Scientific investigator(s) (Contact)

Name of the director	FIANU
Surname	Adrian

Address	CIC de La Réunion CHU Sud BP350 97448 SAINT PIERRE Cedex
Phone	+ 33 (0)2 62 35 90 00
Email	adrian.fianu@chu-reunion.fr
Unit	CENTRE D'INVESTIGATION CLINIQUE DE LA RÉUNION (CIC 1410) INSERM / CHU
Organization	CHU de La Réunion
Name of the director	FAVIER
Surname	François
Address	CIC de La Réunion CHU Sud BP350 97448 SAINT PIERRE Cedex
Phone	+ 33 (0)2 62 35 90 00
Email	francois.favier@chu-reunion.fr
Unit	CENTRE D'INVESTIGATION CLINIQUE DE LA RÉUNION (CIC 1410) INSERM / CHU
Organization	CHU de La Réunion

Collaborations

Participation in projects, networks and consortia	Yes
Details	Research team: Team EQUITY from the CERPOP (UMR1295, joint research unit INSERM-Université Paul Sabatier), at Toulouse

Funding

Funding status	Public
Details	INSERM, CHR, INPES. The work focused on the transferability analysis of the REDIA-prev1 intervention was supported by the National Agency for Research (ANR-11-INEG-0003 "EVALISS"), the Reunion CHU and CIC 1410.

Governance of the database

Sponsor(s) or organisation(s) responsible	INSERM - Institut National de la Santé et de la Recherche Médicale

Organisation status	Public
Presence of scientific or steering committees	No
Labelling and database evaluation	A inter CIC's Audit was conducted by the INSERM Institut thématique Santé Publique Pôle Recherche Clinique in 2011 November.

Additional contact

Main features

Type of database

Type of database	Study databases
Study databases (details)	Cohort study
Database recruitment is carried out by an intermediary	A population file
Database recruitment is is made on the basis of:	Another treatment or procedure
Database recruitment is carried out as part of an interventional study	Yes
Details	Performed at group level (clusters)
Additional information regarding sample selection.	At inclusion: non-probabilist sampling of subjects screened at home. For high-risk subjects: selection by restriction of eligibility. At follow-up: all incuded subjects were eligible to follow-up, except those living outside Reunion Island or having a serious disability conducting to real difficulties to collect data.

Database objective

Main objective	Primary objective: to evaluate the long-term effectiveness of an intervention promoting a healthy diet and the practice of a moderate regular physical activity, on body weight and adiposity (waist circumference, fat mass), in Type-2 diabetes mellitus (T2DM) high-risk young adults. Secondary objectives: - To compare body weight change and adiposity change between groups (intervention versus control) in the entire cohort including all screened

	persons (with high-risk status or not). - To compare diet and physical activity reported at follow-up, between groups, then according to the intervention adherence. - To compare incidence of screened glycemic impairments between groups and according to the baseline risk level. - To describe change in knowledge and beliefs on both T2DM and obesity (KABP).
Inclusion criteria	The target population eligible to the lifestyle intervention trial was composed of men and women (non-pregnant), aged 18-40, with no serious illness (e.g., diabetes, cardiovascular disease, cancer) nor disability (incompatible with physical activity practice), living in the studied districts, and screened at home as high-risk subjects. This high-risk status was based on a combination of T2DM risk factors: overall obesity (BMI >= 30 kg/m²), or central adiposity (waist circumference >= 100 cm for men, >= 90 cm for women), or overweight status (BMI between 25 and 30 kg/m²) associated with at least one other T2DM risk factor *. * High blood pressure treated or detected (>= 140/90 mm Hg), elevated glycated hemoglobin (HbA1c between 5.5% and 6.0%), family history of diabetes at first degree, and for women, having a child weighting more than 4 kg at birth and /or an history of gestational diabetes. Screened subjects without high-risk status were thus not obese (and if overweight with no other T2DM risk factors from those listed above). These collateral persons had been included in the follow-up process besides the high-risk subjects, but they did not participate to the long-term effectiveness evaluation analysis (primary objective of this research). All subjects were screened as non-diabetic based on glycated hemoglobin (HbA1c) measure < 6.0%
Population type	
Age	Adulthood (19 to 24 years)

	Adulthood (25 to 44 years)
Population covered	General population
Pathology	
Gender	Male Woman
Geography area	Local
French regions covered by the database	La Réunion
Detail of the geography area	Geographical coverage: two groups of inhabitants, each one selected within a vulnerable district (defined by low SES) from the municipality of Saint-Pierre (on Reunion Island), Basse-Terre / JoliFond (intervention group) and Ravine des Cabris (control group).

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	08/2001
Date of last collection (YYYY or MM/YYYY)	04/2011

Size of the database

Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	At inclusion:- 1251 screened persons. - 445 high-risk persons. *- 806 collateral persons screened without "high-risk" status. * The short-term effectiveness of the lifestype intervention was evaluate on a total of 439 high-risk subjects (see: Favier et al. Rev Med Ass Maladie 2005). However, six non eligible persons had participated to the intervention: 4 collateral individuals (without high-risk status), plus two high-risk individuals aged 41 and 45 respectively. Although these participants were excluded from the short-term effectiveness analysis according to population selection criteria, we decided to include them in the follow-up process and to classified them in the intervention group to follow the intention-to-treat principle in the analysis of the long-term effectiveness of the lifestyle intervention, leading to 445 high-risk subjects

	included in the REDIA-prev1 Cohort Study.
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Declarative data Biological data Administrative data
Clinical data (detail)	Medical registration
Details of collected clinical data	In-home screening of T2DM risk factors. Anthropometric measurements: body weight, height (for body mass index calculation), waist circumference, fat mass by impedancemetry (TANITA). Blood pressure measurements (x2). Data collection on personal history, diabetes familial history and lifestyle.
Declarative data (detail)	Face to face interview
Details of collected declarative data	In-home survey. Diet: assessment conducted by trained investigators using a 7-days food consumption questionnaire with food portion size estimated by a photo album. Data on diet history since intervention completion were also collected. Physical activity: assessment conducted by trained investigators using a questionnaire derived from the Baecke model (45 items on physical activity at work, at home, during sport and leisure, for specific scores calculation). Data on physical activity history since intervention completion were also collected. Knowledge and beliefs on both T2DM and obesity: risk factors, consequences on health and prevention means.
Biological data (detail)	Fasting required: lipid (total cholesterol, HDL cholesterol, triglycerides), glucose balance (including HbA1c) and insulinaemic. Urine test (proteinuria, microalbuminuria).
Administrative data (detail)	Personal data: gender, date of birth, marital status and occupation, education, last occupation by parents and spouse. Collective data: household size (number of persons residing there).
Presence of a biobank	No
Health parameters studied	Health event/morbidity Others

Other (detail)	Body weight, nutritional status (body mass index), adiposity (waist circumference, fat mass), glycemic status and others components of metabolic syndrome, reported behaviors, knowledges and beliefs on health.

Procedures

Data collection method	Home-visit # 1: medical examination by a research-skilled nurse (approximate duration = 30 min). Home-visit # 2: within a few days to a few weeks after the first visit, survey on history of lifestyle since trial completion, and knowledge related to health, by a dietician monitoring (60 min duration).
Classifications used	BMI: body mass index WHO cut-off for adults. Items of the physical activity questionnaire of Baecke et al. Am J Clin Nutr 1982. Food consumption: estimation of food servings photo album INSERM E3N team. PCS (professions and professional categories): INSEE nomenclature.
Quality procedure(s) used	Recalling of subjects for follow-up visits, information on personal data use. - Monitoring by a clinical research associate selected by the sponsor: after the first subject's inclusion, regularly according to the follow-up implementation and the observed protocol's deviations, at the end of the study. - Audit / inspection: at each step of the study and until 15 years after study completion. A inter CIC's Audit was conducted by the INSERM Institut thématique Santé Publique Pôle Recherche Clinique in 2011 November. - Use of a consistency query: at the time of data entry. - Missing data management: when necessary, use of subject contact for data completion in the closest timeframe. - Data management implementation before statistical analysis.
Participant monitoring	Yes
Monitoring procedures	Monitoring by contact with the participant (mail, e-mail, telephone etc.)
Details on monitoring of participants	Research timeframe: inclusion between August 2001 and October 2002, trial competion between March and July 2003, post-intervention follow-up between October 2010 and April 2011.
Followed pathology	E66 - Obesity
	E11 - Type 2 diabetes mellitus

Links to administrative sources	No

Promotion and access

Promotion

Link to the document	C10-06_proto_VF_autorisée_28mai10.pdf
Description	Protocol research of the REDIA-prev1 Cohort Study (2010-2011): document in French
Link to the document	Article AM.pdf
Description	Results of the intervention controlled trial (2001-2003): Publication in French
Link to the document	doi:10.1371/journal.pone.0146095
Description	Publication of the follow-up results on nine-year changes from inclusion in adiposity : body weight, body mass index, and waist circumference
Link to the document	DOI: 10.3917/spub.174.0525
Description	Description of the REDIA-prev1 intervention and analysis of its transferability using the 'key functions/implementation/context' approach (FIC).

Access

Presence of document that lists variables and coding procedures	No
Terms of data access (charter for data provision, format of data, availability delay)	To define.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only