PSY-coh 2 - French Cohort of People with Schizophrenia: Assessment of Different Stages of Illness Severity and Recovery

Head :Llorca Pierre-Michel
Fond Guillaume, Mondor University Hospital; AP-HP; DHU Pe-Psy; Créteil; Inserm U955 team 15, Fondation Fondamental
Leboyer Marion

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General

Identification

Detailed name	French Cohort of People with Schizophrenia: Assessment of Different Stages of Illness Severity and Recovery
Sign or acronym	PSY-coh 2
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	2014-A01188-39

General Aspects

Medical area	Psychology and psychiatry
Health determinants	Addictions Genetic Geography Healthcare system and access to health care services Iatrogenic Lifestyle and behavior Medicine Nutrition Occupation Social and psychosocial factors Others (specify)
Others (details)	Immunology, neuropsychology, pharmacology, metabolism, physical activity, depression, suicide, quality of life, adherence, insight
Keywords	rehabilitation, antipsychotic treatment response, health economics, vitamin D, compliance, staging, insight, adherence, inflammation, schizophrenia, comorbidity, progression, depression, suicide, employment, work, infection

Scientific investigator(s) (Contact)	
Name of the director	Llorca
Surname	Pierre-Michel
Address	CHU de Clermont-Ferrand Rue Montalembert 63003 Clermont Ferrand Cedex 3
Phone	+33 (0)6 68 10 22 58
Email	pmllorca@chu-clermontferrand.fr
Organization	Clermont-Ferrand University Hospital
Name of the director	Fond
Surname	Guillaume
Address	pavillon hartmann, 40 rue de Mesly, hôpital chenevier, 94000 creteil France
Email	guillaume.fond@gmail.com
Unit	Mondor University Hospital; AP-HP; DHU Pe-Psy; Créteil; Inserm U955 team 15, Fondation Fondamental
Name of the director	Leboyer
Surname	Marion
Address	Pavillon bourguignon, hôpital chenevier, 40 rue de Mesly 94000 CRETEIL
Email	marion.leboyer@inserm.fr
Collaborations	
Participation in projects, networks and consortia	Yes
Funding	
Funding status	Public
Details	A contract was established with the "Investissement d'Avenir (Future Investment)" Programme.
Governance of the database	

Sponsor(s) or organisation(s) responsible	Fondation Fondamental
Organisation status	Private
Presence of scientific or steering committees	Yes

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 selection of health institutions and services

Database objective

Main objective	To identify the biomarkers for each stage as defined by the McGorry classification and characterised by clinical, therapeutic, biological, neuropsychological, environmental variables and living conditions.
Inclusion criteria	Subjects must meet the following conditions and characteristics to be included in the study: 1. Men and women meeting the schizophrenia DSM-IV criteria [American Psychiatric Association, 1994] presenting with the first episode of schizophrenia less than 10 years ago (the first episode is defined as the date the first antipsychotic was prescribed for a psychotic disorder by a physician, whether observed or not and, failing this, the date of the first psychotic episode characterised according to the criteria of the Structured Clinical Interview for DSM-IV Disorders Version 1 (SCID-1)); 2. Who have given informed written consent (or given by both parents if the subject is a minor); 3. Patients who understand written and spoken French. .

Population type

Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years)
Population covered	Sick population

Gender	Male Woman
Geography area	National
Detail of the geography area	10 expert centres (Bordeaux; Colombes; Clermont-Ferrand; Créteil; Montpellier; Marseilles; Versailles; Strasbourg; Grenoble; Lyon)

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2015
Date of last collection (YYYY or MM/YYYY)	2019

Size of the database

Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	400

Data

Database activity	Current data collection
Type of data collected	Clinical data Declarative data Biological data
Clinical data (detail)	Direct physical measures Medical registration
Declarative data (detail)	Internet self-questionnaire Face to face interview Phone interview
Details of collected declarative data	Clinical examinations and assessments carried out in the expert centres (regular follow-up as part of management). The patient's personal and family history, as well as essential clinical data will also be gathered at baseline and during each annual visit. The following items will be gathered at these visits (frequency according to § 3.2): I. Assessments carried out at baseline visit: Environmental factors: CTQ (emotional childhood trauma) ? Neuropsychological tests ? Abbreviated WAIS IV ?

	TAP (Test of Attentional Performance) ? Edinburgh Handedness Inventory (Edinburgh) -? CVLT ? CPT-IP ? Six Elements Test ? f-NART ? Doors Test ? TMT A et B ? Verbal fluency II: Assessments carried out at baseline visit and then every year: General clinical examination, including weight, BMI, waist circumference, vital signs (blood pressure lying down, heart rate lying down), ECG. Heteroquestionnaire on mood and suicidal tendencies: ? CDSS (depressive symptoms) ? YMRS (manic symptoms) ? SIS (suicidal thoughts) - Columbia (suicidal intentionality/lethality) ? PANSS (Positive and Negative Syndrome Scale) ? CDSS (Calgary Depression Scale) ? BARS (Brief Adherence Rating Scale) ? SUMD (Scale to Assess Unawareness in Mental Disorder) ? AIMS ? BAS ? Extrapyramidal side effects causing violent behaviour ? SFQ (sexual side effects). Heteroquestionnaires to assess the impact of disorder on functional outcome: ? CGI (Clinical Global Impression) - EGF (Global Assessment of Functioning ? PSP scale). Treatment: ? Somatic and psychiatric treatment undertaken in the last 12 months (or lifetime during baseline visit) ? ongoing treatment. Self-administered questionnaires to assess current symptomatic disease status: ? Fagerström ? Quality of Life ? AQ (Buss-Perry) ? MARS ? Birchwood ? BCIS ? EQ-5D-5L ? STORI ? PSQI (sleep quality) ? SOG (South Oaks Gambling Screen) ? PIUQ-12 III. Assessments carried out at baseline visit and every two years: ? Neuropsychological tests: ? Abbreviated WAIS IV ? TAP (Test of Attentional Performance) ? Edinburgh Handedness Inventory (Edinburgh) -? CVLT ? CPT-IP ? Six Elements Test ? f-NART ? Doors Test ? TMT A et B ? Verbal fluency. Self-administered questionnaires carried out at each visit to the expert centres: ? Physical exercise scale.
Biological data (detail)	Two types of biological data: Data collected systematically by the expert centre as part of routine care and recorded in the case report form; these are managed centrally in the Biological Resource Centres. Biological data not managed centrally (routine monitoring carried out as part of expert centre care). This includes: Biochemical tests (sodium, potassium, chloride, urea, uric acid, creatinine clearance, iron, C-reactive protein, fasting blood sugar); Lipid profile (total cholesterol, HDL, LDL, triglycerides); Liver function tests (alkaline phosphatase, AST/TGO, ALT/TGP, gamma-GT); Thyroid function tests (TSH, ultrasensitive); FBC tests (leukocytes, erythrocytes, haemoglobin,

	haematocrit, neutrophils, MCV, platelets); Plasma hCG (only for women of childbearing age); Prolactin levels; Glycated haemoglobin if blood sugar level is >1.26 g/dL. Results will be recorded in the eBP electronic medical record. Centrally managed biological data (samples taken at the clinical investigation centres (CIC) for biobank creation). The individual tubes allow serum, plasma, peripheral blood mononuclear cells, DNA and RNA to be collected. These tubes will be split into a number of aliquots sufficient for carrying out various analyses to be explored in the near future. Description: Samples for extracting DNA, RNA, serum, plasma, peripheral blood mononuclear cells will be collected by the CIC or, failing this, the expert centres at the baseline visit and then every two years for the duration of the study.
Presence of a biobank	Yes
Contents of biobank	Serum Blood cells isolated Fluids (saliva, urine, amniotic fluid, ?) DNA DNAc/RNAm
Health parameters studied	Health event/morbidity Health care consumption and services Quality of life/health perception Others
Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption
Quality of life/perceived health (detail)	S-QOL self-administered questionnaire, 18 items
Other (detail)	Physical activity; sleep; aggression; childhood trauma; family, personal, psychiatric and somatic history; functioning (EGF [Global Assessment of Functioning] and PSP scale), awareness of disorders, treatment side effects, Niemann-Pick disease type C.
Procedures	
Data collection method	e-schizo(©) electronic database
Quality procedure(s) used	Research will be regulated according to sponsor standard operating procedures. Research conducted at investigation centres and management of subjects will be in accordance with

the Declaration of Helsinki and existing good practices. 9.1 Monitoring procedures. The CRA representing the sponsor shall conduct investigation centre visits scheduled according to the patient follow-up scheme in the protocol, at baseline within the various centres and at the designated research risk level. ? Initiation visit at each centre: before enrolment of patient in study in order to implement the protocol and familiarisation with the various biomedical research stakeholders. ? Case report forms will be reviewed by the CRA as the research advances during subsequent visits. The investigators undertake to receive the CRA at regular intervals. The following items will be reviewed during on-site visits and in accordance with good clinical practice: Adherence to defined research protocol and procedures; verification of patient informed consent; review of source documents and comparison with data recorded in the case report form for accuracy, missing data and data consistency according to the rules set forth by the Fondation FondaMental procedures. The accuracy and consistency of the data exclusively filled out in eCRFs by the expert centres are directly verified on the FACE BD database by a data manager. Checks will be carried out at several levels: Validation of online entry; consistency check of entries followed by a more complex consistency control procedure, generating requests issued by the clinician. Audit trail; back-up and archiving of databases will be automated. ? Final visit: Recovery of clinical report form; verification of research documents; archiving; verification of sample transfer to the centralised laboratory. Data directly entered in the eCRF will be verified on the database and archived on the server in an automated manner. 9.2 Definition of collected clinical data. All data contained in the clinical report form or entered online by the clinician are entered in the database managed by the Fondation FondaMental. 9.3 Description of data circuit before online entry. 9.3.1 Data from the expert centre clinical report form. All phenotypic, clinical, biochemical and neuropsychological data will be collected systematically and either collected in a clinical report form in the subject expert centre and then entered in an online e-CRF (bioinformatics manager from the Fondation FondaMental) or entered directly online by the clinician. 9.3.2 Data from the specific module (§3.3.2.1). All data (environmental factors, health economics and quality of life) collected in the CIC will be reported in a specific form that will be sent to the coordinating expert centre and entered by a

	clinical research associate. 9.4 Electronic data entry. Database management and the generation of data files for conducting analyses will be carried out by the Fondation FondaMental IT team in accordance with the specifications sent by the coordinating centre. Data will either be collected through a web interface or sent directly to the Fondation FondaMental (for large-scale genotype files, for example). Clinical research forms will be completed by the clinician online or on paper, then followed-up and entered. Checks will be carried out at several levels: Validation of online entry; consistency check for entries followed by a more complex consistency control procedure; generating requests issued by the clinician. Audit trail; back-up and archiving of databases will be automated. All CRFs will be returned after being entered in the investigating departments. The generated variables (scale scores; sub-scores; variable combinations) will be dynamically published during analysis file creation. Electronic data on file will be declared to the CNIL. 9.5 Quality control by audit team. Studies may be audited by the sponsor at any time. The investigator and his/her team shall make themselves available during auditor visits, as well as allowing auditors access technical facilities, study material and patient records. Patient anonymity must be respected and information verified during these tests shall remain confidential. 9.6. Quality control by health authorities. The following items may be checked during prospective inspections by the health authorities: ? General organisation of the study ? qualifications of the staff conducting the study ? equipment quality ? informed consent forms ? CPP (Ethics Research Committee) approval ? product delivery and storage methods ? conduct of the study ? archiving documentation related to the study. In the event of inspection by the authorities, the investigator shall notify the sponsor as the soon as the request is made.
Participant monitoring	Yes
Details on monitoring of participants	The duration of patient participation in the cohort may continue for 5 years with clinical and neuropsychological data collected retrospectively for patients already monitored in expert centres. For example, patients monitored in expert centres since 2010 will be monitored for 10 years. The entire cohort will gradually be enrolled over a four-year period. Each enrolment wave will include 100 patients. The cohort will be formed after 4 years and those lost to follow-up will be continuously

	replaced.
Links to administrative sources	Yes
Linked administrative sources (detail)	SNIIRAM

Promotion and access

Promotion

Link to the document	Article CE Sz Eur Psy SCHURHOFF LLORCA.pdf
Link to the document	Godin Girerd Fond FACE SZ MetS.pdf

Access

Presence of document that lists variables and coding procedures	Yes
Terms of data access (charter for data provision, format of data, availability delay)	Validation of cohort access requests 1. General Conditions. Access to clinical, neuropsychological and socioeconomic data, as well as biological samples, shall be possible for both private and public teams that participated in the creation of such collections and teams located in France or abroad. Requests for transferring data (clinical, neuropsychological or socioeconomic) and assigning biological samples will be validated by the scientific committee involved in the study, who will issue its decision based on: ? the scientific relevance of the proposed study; ? non-competition with research already begun by teams participating in creating the collection; ? sample availability. It should be noted in this context that the requirements for obtaining available biological data by type and number shall differ from clinical, neuropsychological or socioeconomic data requirements. The ownership of results and potential terms of transfer (price, publications, etc.) will be drawn up in a contract. 2. Access conditions for clinical data. The availability of clinical, neuropsychological or socioeconomic data will be finalised following approval by the steering committee. The requested items will be sent in the form of a database. 3. Access conditions for biological material. The availability of human biological materials kept at

	the biological resource centre (CRB) as part of the COSED cohort will be finalised according to that set forth in the Research Collaboration Contract previously established between the Fondation FondaMental and heads from various organisations. The contract shall specify the beginning and end of the study; CRB obligations regarding the expected deliverables; guarantees regarding the quality and security of stored samples (preserving anonymity, monitoring temperature, etc.). The financial commitment terms should also be reiterated. Samples will only be available by written request from the initiator throughout the duration of the study (Transfer Agreement). The Transfer Agreement authorises the release of certain samples according to specific conditions (recipient, transport cost, return of unused samples, publication requirements, etc.). All requests are approved in advance by the collection scientific committee, whose members include the head of the CRB in Mondor and the CRB in Pitié-Salpêtrière. Secondary use biological samples for research other than that initially planned is not possible without prior consent and following approval from the cohort scientific committee, as well as the establishment of a Transfer Agreement between the CRB. In the event of biomedical research organised by a public institution or private organisation, the use of human biological samples for research must involve drafting a Material Transfer Agreement (MTA); a contract that ensures the protection of intellectual property belonging to the Fondation FondaMental for research development and patent applications.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only