FACE-SZ - Cohort Belonging to The National Network of Schizophrenia Expert Centres

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General

Identification

Detailed name	Cohort Belonging to The National Network of Schizophrenia Expert Centres
Sign or acronym	FACE-SZ

General Aspects

Medical area	Psychology and psychiatry
Pathology (details)	Schizophrenia
Health determinants	Addictions Genetic Healthcare system and access to health care services Iatrogenic Lifestyle and behavior Medicine Nutrition Occupation Social and psychosocial factors Others (specify)
Others (details)	insight, adherence, function, physical activity, aggressiveness
Keywords	DNA; RNA; serum; toxoplasmosis; schizophrenia; monitoring; clinical; development; staging; biomarkers; biobank; neuropsychology; biology; vitamin D

Scientific investigator(s) (Contact)

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Collaborations

Participation in projects, networks and consortia	Yes

Funding

Funding status	Mixed
Details	LabEX investment for the future

Governance of the database

Sponsor(s) or organisation(s) responsible	Fondation Fondamental
Organisation status	Public
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 as part of an interventional study	No

Database objective

Main objective	The objective of the National Network of Schizophrenia Expert Centres is to offer diagnostic and therapeutic advice for patients with schizophrenic disorders and then monitor them for a period of three years. These patients will be thoroughly evaluated based on psychiatric (primary and related illnesses); psychological; somatic; cognitive and social assessment (impact of disease on functional outcome).
Inclusion criteria	All patients with schizophrenia and related disorders (schizophreniform or brief psychotic disorder) may participate in cohort monitoring, with no exclusion criteria. These disorders are effectively heterogeneous in nature, from clinical manifestations to illness progression and associated pathologies. The data from this cohort may be the only tool for studying the trajectory of the disease in the long term in accordance with different clinical profiles, differences in treatment and identifying aggravating factors. Due to the clinical heterogeneity of schizophrenia, given the characteristics of the disorder, but also the frequency of related somatic and psychiatric illnesses, it is important to monitor these cohorts in order to identify new treatment strategies and to follow-up specific target subgroups.

Population type

Age	Adolescence (13 to 18 years) Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years)
Population covered	Sick population

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

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2009
Date of last collection (YYYY or MM/YYYY)	No completion date

Size of the database

Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	The network of centres is intended to be a permanent structure where the number of assessed individuals is not restricted.

Data

Database activity	Current data collection
Type of data collected	Clinical data Declarative data Paraclinical data Biological data
Clinical data (detail)	Direct physical measures Medical registration
Details of collected clinical data	General medical examination includes a complete psychiatric and somatic history (weight, BMI, waist circumference, 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. Heteroquestionnaire to assess the impact of the disease on functioning: ? 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 (Medication Adherence Rating Scale) ? Birchwood ? BCIS ? EQ-5D-5L ? STORI ? PSQI (sleep quality) ? SOG (South Oaks Gambling Screen) ? PIUQ-12 ? Physical exercise 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 ? SSTICS ? Self-administered questionnaire: ? Sociodemographic questionnaire parts I and II.
Declarative data (detail)	Internet self-questionnaire Face to face interview
Details of collected declarative data	Self-administered questionnaires to assess current symptomatic disease status: ? Fagerström ? Quality of Life ? AQ (Buss-Perry) ? MARS (Medication Adherence Rating Scale) ? Birchwood ? BCIS ? EQ-5D-5L ? STORI ? PSQI (sleep quality) ? SOG (South Oaks Gambling Screen) ? PIUQ-12 ? Physical exercise
Biological data (detail)	Biochemical tests (sodium, potassium, chloride, urea, uric acid, creatinine clearance, iron, C-reactive protein, bilirubin, albumin, 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; toxoplasma serology; vitamin D dosage.
Presence of a biobank	Yes
Contents of biobank	Whole blood Serum Plasma

	Blood cells isolated Fluids (saliva, urine, amniotic fluid, ?) DNA DNAc/RNAm
Details of biobank content	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.
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services Quality of life/health perception
Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption
Quality of life/perceived health (detail)	Self-administered questionnaire on quality of life; 18 items and EQ-5D.

Procedures

Data collection method	e-schizo(©) software application
Quality procedure(s) used	All studies may be audited by the sponsor at any time. The investigator and his/her team shall make themselves available during the auditor visits, as well as allowing auditors access to technical facilities, study material and patient records. Patient anonymity must be respected and information verified during these tests must 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
Monitoring procedures	Monitoring by contact with the referring doctor Monitoring by crossing with a medical-administrative database

Details on monitoring of participants	Patient follow-up is solely carried out in expert centres (list in Annex 1). All patients enrolled in the study will be monitored up to three years and their medical data shall be recorded in a research database for up to 10 years. Biobank samples will be taken at the clinical investigation centre (CIC) or, failing this, at the expert centre.
Links to administrative sources	Yes
Linked administrative sources (detail)	SNIIRAM

Promotion and access

Promotion

Link to the document	Metabolic syndrome, abdominal obesity and hyperuricemia in schizophrenia: Results from the FACE-SZ cohort. Godin O, Leboyer M, Gaman A, Aouizerate B, Berna F, Brunel L, Capdevielle D, Chereau I, Dorey JM, Dubertret C, Dubreucq J, Faget C, Gabayet F, Le Strat Y, Llorca PM, Misdrahi D, Rey R, Richieri R, Passerieux C, Schandrin A, Schürhoff F, Urbach M, Vidalhet P, Girerd N, Fond G; FACE-SZ group. Schizophr Res. 2015 Oct;168(1-2):388-94. doi: 10.1016/j.schres.2015.07.047.
Link to the document	A National network of schizophrenia expert centres: An innovative tool to bridge the research-practice gap. Schürhoff F, Fond G, Berna F, Bulzacka E, Vilain J, Capdevielle D, Misdrahi D, Leboyer M, Llorca PM; FondaMental Academic Centers of Expertise for Schizophrenia (FACE-SZ) collaborators. Eur Psychiatry. 2015 Sep;30(6):728-35. doi: 10.1016/j.eurpsy.2015.05.004. Epub 2015 Jun 10. PMID: 26072427

Access

Presence of document that lists variables and coding procedures	Yes
Terms of data access (charter for data provision, format of data, availability delay)	Those with direct access in accordance with the laws and regulations in force, particularly Articles L.1121-3 and R.5121-13 of the Public Health Code (e.g. investigators, people in charge of quality control, monitors, clinical research assistants, auditors and all individuals duly authorised by the sponsor), shall take all necessary precautions to ensure the confidentiality of information related to experimental drugs, trials and participating individuals, particularly with regards to their identity

and the results obtained. Data collected by these parties during quality control or auditing procedures shall be made anonymous. All requests from the public or private research body must be approved by the steering committee based on the submission of a project.
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. 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.
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 PSY-COHORTE SZ 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.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only