BRIDGE - Parental and Offspring Brain Imaging in families at risk for severe mental illness

Published: 03-04-2023
Last updated: 03-06-2024

Primary: - Examine longitudinal developmental trajectories of structural and functional brain metrics in relation to genetic, clinical, psychological, environmental, and cognitive information in familial high-risk offspring and control children (...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON53543

Source
ToetsingOnline

Brief title
BRIDGE-Parental and Offspring Brain Imaging (BRIDGE-POBI)

Condition

- Other condition
- Schizophrenia and other psychotic disorders

Synonym
Bipolar disorder, manic-depressive disorder, Schizophrenia, Schizophrenic disorder

Health condition

psychische stoornissen: bipolaire stoornis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Horizon Europe: grant number 101057529

Intervention

Keyword: Bipolar disorder, Familial risk, Offspring, Schizophrenia

Outcome measures

Primary outcome

- Brain volume, cortical thickness, cortical surface, curvature/gyrification

metrics (global measures and local regions) from T1 weighted images.

- Fractional anisotrophy, mean diffusivity, axial diffusivity, radial

diffusivity (per fiber and voxelbased) from DTI images.

- Brain activation during resting state (per region and voxelbased) from rsfMRI

images.

- Graph theory metrics from FA (DTI) and resting state brain activation

(rsfMRI).

Secondary outcome

The following variables are seen as possible confounding or modifying factors:

- sex and age

- age of onset parental and offspring disorder

- marital and/or household status of parents

- income and educational level of parents

- parental psychosis, depression, and/or mania diagnoses and symptoms

- medication use

- handedness

Study description

Background summary

A family history of mental illness is the most important known risk factor for the development of mental health problems. Child, adolescent and young adult offspring of parents with a severe mental illness (i.e. schizophrenia, bipolar disorder, depression) offer a unique opportunity to further the research into intergenerational transmission, as in this group the likelihood of mental health problems is increased.
Brain structural and functional metrics and their developmental trajectories have been hypothesised to underlie the transmission of mental illness. Here we propose to again approach the families from the Dutch Bipolar and Schizophrenia Offspring Study (DBSOS, Dutch name: BRIDGE [BRain Imaging, Development and Genetics]). BRIDGE is an ongoing prospective cohort study, investigating the development of brain, genetics, cognitive functioning, and environment, that contribute to risk and resilience in offspring with at least one parent with schizophrenia (SZo) and offspring with at least one parent with bipolar disorder (BDo).

Study objective

Primary: - Examine longitudinal developmental trajectories of structural and functional brain metrics in relation to genetic, clinical, psychological, environmental, and cognitive information in familial high-risk offspring and control children (BRIDGE cohort only).
- Investigate the relationship between parental and family characteristics and differences (or overlap) in maternal, paternal and child brain metrics and how these differ between at risk families and control families (pooling across European cohorts with the FAMILY consortium: https://family-project.eu/).
Secondary: - assess the role of cognitive, environmental, behavioural, and clinical characteristics on the brain imaging findings.

Study design

Observational study, longitudinal study, family (triad/dyad) study.

Study burden and risks

Study participation involves one visit to the Erasmus MC to undergo an MRI scan of maximally one hour. MRI is a non-invasive technique (i.e., nothing is inserted into the body). However, the CCMO marked MRI as an invasive technique to heighten the safety regulations. There are no known risks associated with MRI acquisition, so there is no need for special preparation for the subject on top of the Erasmus MC standard procedure. The data are primarily used for

research purposes. However, a radiologist will provide a neurodiagnostic evaluation. When the specialist finds that medical treatment is indicated, then the subject will be notified. Subjects may become anxious during the scan. The participant can communicate this by means of a push button, and he/she will be taken out of the scanner.
The risk assessment for participation to this study is minimal. Subjects will experience no direct benefits from our study. In the long run, increased understanding of the aetiology and pathophysiology of schizophrenia and bipolar disorder may contribute to diagnosis, early detection and/or prediction of treatment outcome.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Previously-included offspring: All offspring who participated in the BRIDGE cohort are eligible for inclusion in this MRI study. Offspring will now be 14 years and older. The only other inclusion criterion is ability to provide informed consent.
Parents: All biological parents of offspring who participated in the BRIDGE cohort are eligible for inclusion in this MRI study. The only other inclusion criterion is ability to provide informed consent.
Newly-included offspring: All biological offspring who did not previously participate in the BRIDGE cohort are eligible for inclusion in this MRI study. As this will be their first assessment, subjects will have to satisfy the following criteria in order to participate in the study:

-from 8 years and older
-provide written informed consent (by child and/or parents)
-Dutch speaking
- IQ > 70

Exclusion criteria

Previously-included offspring, newly-included offspring, and parents:
- contraindication for MRI (including claustrophobia, a cardiac implantable electronic device, ferromagnetic metal implants, piercing (in some cases), tattoos (in some cases)) (Ghadimi & Sapra, 2022);
- not having given permission to be approached for further research during an earlier assessment.
- history of closed- or open-head injury
- history of neurological illness
- major medical history
- history of epilepsy

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-07-2023
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	03-04-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-05-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-08-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-05-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL82802.078.22