A database of brain scans and neuropsychological test scores of healthy individuals

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

Summary

ID

NL-OMON56186

Source
ToetsingOnline

Brief title
Database of brain scans and neuropsychological scores

Condition

- Other condition

Synonym
healthy brain, healthy cognition

Health condition

Hersentumoren

Research involving
Human

Sponsors and support

Primary sponsor: Neurochirurgie
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Cognition, Healthy controls, Imaging, Neuropsychological screening

Outcome measures

Primary outcome

The primary study endpoint is a database containing dMRI, rs-fMRI, task fMRI

and data from (repeated) neuropsychological assessment (cognitive testing and

questionnaires) of 100 healthy volunteers across different age rangs, education

levels and sex.

Secondary outcome

n.v.t.

Study description

Background summary

In the last decade, the clinical relevance of advanced neuroimaging has drastically increased, as these techniques can now elucidate the pathological structure and functional alterations in various brain disorders non - invasively. In 2014, we started with funded neuroimaging research (via *Experiment Topzorg*) that resulted in a clinical protocol including noninvasive diffusion MRI (dMRI), resting state MRI (rs-fMRI) and task fMRI. To date, approximately 600 brain tumor patients have been examined with advanced neuroimaging and approximately 1800 patients with neuropsychological screening for clinical and research purposes.

Advanced neuroimaging can provide insights into the underlying mechanisms by elucidating the link between brain structure, brain function, and cognitive functioning. To get a clear understanding of the links between these factors and the way brain lesions affect the interaction between them, a comparison of data from brain tumor patients and healthy individuals is crucial. Although

there are several free-access brain imaging databases available, a direct comparison between our brain tumor patients' data and the available healthy volunteers' data is problematic. Furthermore, for some of the cognitive tests that we use, normative data are lacking, thereby complicating the evaluation of the performances of our patient group in terms of deviation from normal.

By running the identical clinical protocol as in our brain tumor patients, containing an identical neuropsychological assessment and identical neuroimaging sequences on the same MRI scanner with the same imaging hard- and software in 100 healthy volunteers, we will create a database to be used as a reference for our brain tumor patient data. This database can also serve as a baseline for the comparison to other patient groups.

Study objective

The primary objective of this project is to create a database containing diffusion MRI (dMRI), resting state fMRI (rs-fMRI), task fMRI and neuropsychological assessment data of healthy volunteers to be used as a reference for our brain tumor patients data for use in clinical practice and scientific research.

Study design

In this project, healthy volunteers will participate in 2 sessions, in one session (T1) they will go through the clinical imaging protocol, and undergo a neuropsychological assessment (including cognitive testing and filling out questionnaires outside the MRI scanner). The other session (T2) will be planned three months thereafter and will only comprise a neuropsychological assessment.

Study burden and risks

There are no direct benefits expected from participation in this study for the subjects. There are no known risks associated with neuropsychological assessment of MRI acquisition. MRI is painless and does not require the administration of a contrast agent or ionizing radiation. Mild discomfort may occur due to the noise generated by the scanner, or the door lying still with the head and part of the body in a tunnel-like device. For the rest, tingling, muscle twitching and tension can arise. If a subject feels uncomfortable with any aspect of the procedure and wants to stop, the session will be cut short. Incidental findings on the MRI may occur, even though the scans are not actively evaluated for this. Participants are informed prior to participation about the procedure surrounding these incidental findings and need to give consent to this.

In addition, participation in the study takes time and the participant must

adhere to the agreements made.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- between 18 and 80 years of age
- normal or corrected-to-normal vision and hearing

Exclusion criteria

- a history of drug abuse
- a history of head trauma

- a history of significant neurological or psychiatric disorders
- metal objects in or around the body (braces, pacemaker, metal fragments)
- pregnancy
- participation in a concurrent study with neuropsychological testing
- unable to complete test battery and/or study questionnaires due to lack of basic proficiency in
Dutch, or IQ below 85
- claustrophobia

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-10-2023
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	28-08-2023
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL84430.028.23
Other	nummer volgt