PROSPECTIVE NON-INTERVENTIONAL STUDY

A Data Management Plan created using DMPonline.be

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Project abstract:
Frontotemporal dementia (FTD) is a group of neurodegenerative brain disorders affecting the frontal and anterior temporal lobes in the brain. The behavioral variant (bvFTD) forms alongside two other language forms the three main clinical syndromes of FTD. In 2011, diagnostic criteria were established for bvFTD. This includes six features, i.e. early behavioral disinhibition, apathy, loss of empathy, compulsive/ritualistic behavior, hyperorality, and deficits in executive neuropsychological tasks. Though three out of six behavioral changes suffice for a clinical diagnosis, the detection of bvFTD remains problematic due to its heterogeneity in symptoms and lack of biomarkers. As a result, patients with bvFTD in its early stages are often misdiagnosed with primary psychiatric disorders or other neurodegenerative cognitive disorders. Having substantial consequences for the quality of life for both the patients and their relatives, early diagnosis is crucial to delay institutionalization, prepare caregivers, and allow future therapies to take maximum effects. The fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-V) has included social cognitive deficits as a functional domain that may be affected in neurocognitive disorders. Social cognition is an umbrella term for a set of mental abilities enabling individuals to process, interpret and utilize information about others in a social environment. In terms of bvFTD, deteriorated social cognition refers to a reduced ability in (i) recognizing facial emotions, (ii) detecting and reasoning violations of social norms, and (iii) inferring mental states of others (mentalizing or theory of mind). Displays of these behavioral impairments such as inappropriate behaviors are often subtle signs of early bvFTD. Despite its diagnostic potential, insufficient study comparability does not allow valid clinical translation, and the assessment of social cognition remains currently underutilized in clinical practice.
Social cognitive skills imply an underlying socio-cultural norm that guides socially appropriate behavior. However, investigations on the relationship between culture and impaired social cognitive skills in neuropsychiatric disorders remain scant. Previous findings showed differences in emotion recognition performance in patients with mental disorders and different cultural backgrounds. One particular study in schizophrenia patients reported that cultural differences in emotion recognition are more extreme in patient groups. They argue that the significantly lower scores of their Indian patients are caused by unfamiliarity with the stimuli using Caucasian faces.
While extensive studies have been conducted to investigate differences in cognition, not much has yet been investigated regarding impaired social cognitive skills of dementia patients with distinct behavioral deficits such as bvFTD. This existing gap in the literature is thus worth further investigation. To fill this gap, we intend to explore the relationship between culture and social cognitive deficits in bvFTD patients by comparing early social cognitive symptoms across two culturally distinct sites (Belgium vs China). We aim to (i) determine different early behavioral symptoms through a semi-structured interview with caregivers of bvFTD patients across two sites in China and Belgium. Through comparison, we want to explore the similarities and differences in symptom types and progress. Based on the retrieved results, we will develop (ii) a questionnaire to measure the symptom impact on early affected life domains. The results will then be validated (iii) through an exploration of its neuroanatomical correlates.

Last modified: 22-05-2023

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RESEARCH DATA SUMMARY

List and describe all datasets or research materials that you plan to generate/collect or reuse during your research project. For each dataset or data type (observational, experimental etc.), provide a short name & description (sufficient for yourself to know what data it is about), indicate whether the data are newly generated/collected or reused, digital or physical, also indicate the type of the data (the kind of content), its technical format (file extension), and an estimate of the upper limit of the volume of the data.

Dataset name / ID	Description	New or reuse	Digital or Physical data	Data Type	File format	Data volume
Oral sources	Transcripts from interviews	***N**(ew data) or*	**D**(igital) and **P**(physical)	**T**extual and **A**udio	.mp3 .docx .txt	>5000 MB
Audiovisual sources	Videos from interviews	***N**(ew data)*	**D**(igital)	**A**udiovisual	.mp4	<60 GB
Personal data	Sociodemographic information	***N**(ew data) or **E**(xisting data)*	**D**(igital)	**S**oftware and	.xlsx .sav .docx	<100MB
Neuropsychological assessments caregiver	Assessment cognitive and psychological well-being caregiver	***N**(ew data)*	**D**(igital)	**SO**ftware	.xlsx .sav	<100 MB
Medical Records	Medical records, diagnostic rapports, neuropsychological assessment results, MRI scans	***E**(xisting data)*	**D**(igital)	**T**extual	.nii.gz .xlsx	>10 GB
NicFTD datasets	Neuropsychological assessment results in the past 10 years from multiple sites	***E**(xisting data)*	**D**(igital)	**N**umerical and **T**extual	.xlsx .sps	<100 MB
Questionnaire	Assessment of domain specific impact of early bvFTD symptoms	***N**(ew data)*	**D**(igital)	**N**umerical and **T**extual	.xlsx .sav	<100 MB
(Social Cognition Screen) SOC-S	Assessment of social cognition	***N**(ew data)*	**D**(igital)	**N**umerical and **T**extual	.sav .sps	<100 MB

If you reuse existing data, please specify the source, preferably by using a persistent identifier (e.g. DOI, Handle, URL etc.) per dataset or data type:

Medical records:

- KWS UZ Leuven (Belgium)

- Online patient registry Peking University (China)

NicFTD neuropsychological test battery results:

- UZ Leuven (Belgium), Peking University Sixth Hospital (China),

Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? If so, refer to specific datasets or data types when appropriate and provide the relevant ethical approval number.

- Yes, human subject data (Provide SMEC or EC approval number below)

For studies concerning informed consent, we are currently working on retrieving ethical approval from EC UZ Leuven. No S-number is currently obtained.
Data concerning human subject data:

- Medical records and MRI data from patients are obtained in agreement with the patient
- Neuropsychological test results from patients and caregivers

Will you process personal data? If so, please refer to specific datasets or data types when appropriate and provide the KU Leuven or UZ Leuven privacy register number (G or S number).

- Yes (Provide PRET G-number or EC S-number below)

The processing and management of data will comply by GDPR and be pseudonymized during analysis. Data are stored in the internal network drive of KU Leuven or protected online data processing platforms (REDCap and Atlas.ti). Data are only shared with researchers during analysis, pseudonymized with an identifier. Only data managers have access to the coding key. We are currently working on retrieving ethical approval from EC UZ Leuven
Data concerning personal data:

- Sociodemographic data from patients and caregivers
- Interview transcripts and recordings

Does your work have potential for commercial valorization (e.g. tech transfer, for example spin-offs, commercial exploitation, …)? If so, please comment per dataset or data type where appropriate.

- No

Do existing 3rd party agreements restrict exploitation or dissemination of the data you (re)use (e.g. Material or Data transfer agreements, Research collaboration agreements)? If so, please explain in the comment section to what data they relate and what restrictions are in place.

- No

Are there any other legal issues, such as intellectual property rights and ownership, to be managed related to the data you (re)use? If so, please explain in the comment section to what data they relate and which restrictions will be asserted.

- No

DOCUMENTATION AND METADATA

Clearly describe what approach will be followed to capture the accompanying information necessary to keep data understandable and usable, for yourself and others, now and in the future (e.g. in terms of documentation levels and types required, procedures used, Electronic Lab Notebooks, README.txt files, codebook.tsv etc. where this information is recorded).

Interviews
Interviews are performed with caregivers of bvFTD patients, producing audio(visual) recordings, transcripts, codebooks, and codes; they contain personal data, neuropsychological assessments, and medical records. Data are stored in the internal network drive of KU Leuven and analyzed using Atlas.ti.

Questionnaire
The questionnaire will assess caregivers of bvFTD, ideally through REDCap. Data are stored in the internal network of KU Leuven

SOC-S
SOC-S is a neuropsychiatric screen and will be used to assess bvFTD patients, using Testable. Data are stored in the internal network of KU Leuven

Documentation and workflow will be collected in an Excel logbook stored in the internal network of KU Leuven.

Will a metadata standard be used to make it easier to find and reuse the data?
If so, please specify which metadata standard will be used.

If not, please specify which metadata will be created to make the data easier to find and reuse.

- Yes

We intend to share our pseudonymized data via KU Leuven Research Data Repository and will follow the standards outlined by DataCite.

DATA STORAGE & BACK-UP DURING THE RESEARCH PROJECT

Where will the data be stored?

- Digital Vault

Our data will be stored on our network drive (L-drive) which is a digital vault from KU Leuven.

How will the data be backed up?

- Standard back-up provided by KU Leuven ICTS for my storage solution

Is there currently sufficient storage & backup capacity during the project?

If no or insufficient storage or backup capacities are available, explain how this will be taken care of.

- Yes

How will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

Most data will be stored in the network L-drive (digital vault) of KU Leuven which is only accessible to researchers of the KU Leuven neuropsychiatry group and managed by the ICTS team of KU Leuven. For collection and analysis, some data will be stored on the secured platforms REDCap and Atlas.ti. Data to be shared with external researchers will be first pseudonymized. All data and communication are conducted using a secured KU Leuven laptop.

What are the expected costs for data storage and backup during the research project? How will these costs be covered?

The costs of storage and backup will be covered by the KU Leuven internal funding.

DATA PRESERVATION AFTER THE END OF THE RESEARCH PROJECT

Which data will be retained for 10 years (or longer, in agreement with other retention policies that are applicable) after the end of the project?

In case some data cannot be preserved, clearly state the reasons for this (e.g. legal or contractual restrictions, storage/budget issues, institutional policies...).

- All data will be preserved for 10 years according to KU Leuven RDM policy

Where will these data be archived (stored and curated for the long-term)?

- Other (specify below)

KU Leuven network drive (K-drive)

What are the expected costs for data preservation during the expected retention period? How will these costs be covered?

The expected cost will be € 100,00 as per lab resources.

DATA SHARING AND REUSE

Will the data (or part of the data) be made available for reuse after/during the project?
Please explain per dataset or data type which data will be made available.

- Yes, as open data

1. Interview audio and transcripts contain personal data that are legally forbidden for distribution (GDPR). However, the codebook retrieved from the raw transcripts will be made available for reuse.

2. Pseudonymized data from the neuropsychological assessments, the questionnaire, and the SOC-S can be made available for further analysis.

If access is restricted, please specify who will be able to access the data and under what conditions.

Are there any factors that restrict or prevent the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions)?

Please explain per dataset or data type where appropriate.

- No

Where will the data be made available?

If already known, please provide a repository per dataset or data type.

- KU Leuven RDR (Research Data Repository)

When will the data be made available?

- Upon publication of research results

Which data usage licenses are you going to provide?

If none, please explain why.

- CC-BY 4.0 (data)

Do you intend to add a persistent identifier (PID) to your dataset(s), e.g. a DOI or accession number? If already available, please provide it here.

- Yes, a PID will be added upon deposit in a data repository

What are the expected costs for data sharing? How will these costs be covered?

None

RESPONSIBILITIES

Who will manage data documentation and metadata during the research project?

Fan Tjang Ji

Who will manage data storage and backup during the research project?

Jan Van den Stock (PI)

Who will manage data preservation and sharing?

Jan Van den Stock (PI)

Who will update and implement this DMP?

Jan Van den Stock (PI)
Fan Tjang Ji