DMP title

Project Name Changing Tactics (ChaT) - DMP title

Grant Title TBM project (T003222N)

Principal Investigator / Researcher prof. dr. Pascal Sienaert

Description Electroconvulsive therapy (ECT) is an evidence-based treatment for difficult to treat, severe and sometimes life-threatening depressive episodes. It involves passing an electrical charge through the brain, via electrodes that are placed either on one side of the head (right unilateral RUL) or on both sides (bitemporal, BT), to induce a generalized seizure, under brief anesthesia. Although results are conflicting, RUL ECT has been shown to be less effective than BT ECT, and induces fewer cognitive side-effects, whereas BT ECT is considered to have a faster antidepressant effect, but bears/entails a higher risk of cognitive side-effects. In non-responders, it is common practice to switch from RUL to BT electrode placement. However, no randomized controlled trial (RCT) data are available to support this ubiquitous clinical practice. We designed an RCT to address which treatment strategy (continue RUL ECT of switch to BT) speeds up recovery and has the least impact on memory function. The answerable clinical question can be structured as follows: - Patient: Patients treated with ECT for depression, showing no â€˜responseâ€™ (<50% decrease in depressive symptom severity compared to baseline) after 4 treatment sessions; - Intervention: Switch to BT ECT; - Comparison: Continue with RUL ECT; - Outcome: Depressive symptom severity and autobiographical memory (co-primary outcomes) after 8 treatment sessions. This project addresses the clinical question ECT-practitioners are faced with in daily clinical practice, and for which there is no consistent empirical evidence available. Being the first-ever RCT on the switch from RUL ECT to BT ECT, this project will have an important impact on the clinical practice, guiding clinical decision making.

Institution KU Leuven

1. General Information

Name applicant

prof. dr. Pascal Sienaert

FWO Project Number & Title

Changing Tactics? Optimizing ECT in difficult-to-treat depression (ChaT)

TBM project (T003222N)

Affiliation

- KU Leuven
- Other

Multicenter trial, in collaboration with Universiteit Antwerpen/UPC Duffel, AZ Groeninge Kortrijk and AZ Sint-Jan Brugge.

2. Data description

Will you generate/collect new data and/or make use of existing data?

- Generate new data

Describe in detail the origin, type and format of the data (per dataset) and its (estimated) volume. This may be easiest in a table (see example) or as a data flow and per WP or objective of the project. If you reuse existing data, specify the source of these data. Distinguish data types (the kind of content) from data formats (the technical format).

General patient data and treatment characteristics (ECT and pharmacological) will be collected and stored in the study files in locked closets on the ECT wards.

Data is collected by face to face assessments using validated questionnaires regarding mood and cognition.

This includes:
- Demographics
- Mini International Neuropsychiatric Interview (MINI)
- Maudsley Staging Method (MSM)
- Inventory of Depressive Symptomatology-Clinician Rated (IDS-CR)
- CORE assessment of psychomotor disturbance

- Psychotic Depression Assessment Scale (PDAS)
- Colombia University-Autobiographical Memory Interview Short-Form (CU-AMI-SF)
- Rey Auditory Verbal Learning Test (RAVLT)
- Montreal Cognitive Assessment (MoCA)
- Controlled Oral Word Association Test (COWAT)
- Subjective Assessment of Memory Impairment (SAMI)
- Wechsler Memory Scale - Revised (WMS-R)

Paper questionnaires will be used and stored, afterwards data will be entered into a data platform (Redcap).

Assessments will be performed repeatedly (+- 5 times) for each participant, sample size is estimated at at a total of 196 participants.

3. Legal and ethical issues

Will you use personal data? If so, shortly describe the kind of personal data you will use. Add the reference to your file in KU Leuven's Register of Data Processing for Research and Public Service Purposes (PRET application). Be aware that registering the fact that you process personal data is a legal obligation.

- Yes

Privacy Registry Reference (PRET): G-2022-5776

Short description of the kind of personal data that will be used:

Primary data are collected. Identification data are used to include/exclude participants. If included, participants' data are pseudonymised.
Assessments include:
- Personal characteristics/Health information (medical history, diagnosis,symptoms, medication, treatment characteristics,...)
- Mini-International Neuropsychiatric Interview (M.I.N.I.)
- Informed Consent
- Clinical and cognitive assessment using validated questionnaires regarding mood en cognitive functioning:

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, add the reference to the formal approval by the relevant ethical review committee(s)

- Yes

Privacy Registry Reference (PRET): G-2022-5776

Ethical Committee advice still pending. (CTC S67329)

Research involving human participants (vulnerable patients with depressive disorder) that receive physical interventions (ECT treatment).
Informed consent prior to trial inclusion is signed, which includes consent for study participation, data sharing and preservation.

Identity of participants is protected via the process of pseudonymisation. Data is managed using a protected tool (Redcap), with limited accesibility. Paper questionnaires are stored in a locked closed, only accessible to the research team.

All data collected will be treated in accordance with the "Directive on the protection of individuals concerning the processing of personal data" and national applicable legislation (The European General Data Protection Regulation (General Data Protection Regulation (AVG / GDPR) - EU2016 /697) and the Belgian legislation).

Does your work possibly result in research data with potential for tech transfer and valorisation? Will IP restrictions be claimed for the data you created? If so, for what data and which restrictions will be asserted?

- No

IP restrictions will not be claimed.

Do existing 3rd party agreements restrict dissemination or exploitation of the data you (re)use? If so, to what data do they relate and what restrictions are in place?

- No

4. Documentation and metadata

What documentation will be provided to enable reuse of the data collected/generated in this project?

Details on methodology are noted in the protocol. Questionnaires will be used as stated in their manuals. Data of assessments (informed consent, answers to questionnaires,...) are documented on paper and entered in a data platform (Recap). When access is provided, or data is exported (using a certain standard format such as .xls or .cvs) it can be reused by other researchers. All data is provided with a clear nomenclature, referring to the scores of standardized questionnaires,cognitive assessment tools, ECT parameters,...
Further, published articles by the involved researchers will contain all details necessary to reveal context of data collection, collection methodology, analytical and procedural information, etc.

Will a metadata standard be used? If so, describe in detail which standard will be used. If no, state in detail which metadata will be created to make the data easy/easier to find and reuse.

- No

Metadata can be added in the dataplatform (Redcap), if needed. Collected data will be clearly linked to the scores of questionnaires and cognitive assessment.

5. Data storage and backup during the FWO project

Where will the data be stored?

All acquired patient data will be entered into a data platform (REDcap- a GCP compliant system) that will allow safe data storage and processing from the different study sites. Employees of the project will be granted permission to input data depending on their role in the project.

Paper study records are stored in a locked closet at the ECT units.

At study entry, a study number (patient code) will be assigned and data entered in the data platform will only have this study number.The study files that contain the names and contact details of the patients will be stored in a separate locked closet at the ECT units.

How is backup of the data provided?

The dataplatform REDcap provides automatic data back-up procedures.

Is there currently sufficient storage & backup capacity during the project? If yes, specify concisely. If no or insufficient storage or backup capacities are available then explain how this will be taken care of.

- Yes

The dataplatform REDCAP provides automatic data back-up procedures. There are sufficient storage options (locked closets at each participating center) for paper data at the ECT units.

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

All acquired patient data will be entered into the data platform (REDCap) that will allow safe data storage and processing from the different study sites, with an approximate cost of 80 euros a year. The project allocates sufficient resources in the budget to cover the data storage expenses.

Data security: how will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

All acquired patient data will be entered into a data platform (REDCap) that will allow safe data storage and processing.

To make sure that the privacy of participants of the study is guaranteed, their data will be pseudonymized and processed using a patient code instead of their names. At study entry, a study number (patient code) will be assigned and data entered in the data platform will only have this study number. No other details that could enable identification of the patient will be saved in the data platform. The study files that contain the names and contact details of the patients will be stored in a separate locked closet at the ECT units, which is only accessible to authorized persons (Investigator and his Trial staff). The person responsible for data preservation is the key investigator prof. dr. Pascal Sienaert.

6. Data preservation after the FWO project

Which data will be retained for the expected 5 year period after the end of the project? In case only a selection of the data can/will be preserved, clearly state the reasons for this (legal or contractual restrictions, physical preservation issues, ...).

There is no intention to deviate from the minimum preservation term principle. Data will be stored for 15 years after study completion in the database and in study files. We choose to extend data storage to 15 years to allow secondary analyses on the acquired data after publication of the first results.

Where will the data be archived (= stored for the longer term)?

All acquired patient data will be entered into a data platform (REDCap) that will allow safe data storage and processing from the different study sites.

Paper study records are stored in a locked closet at the ECT units.

What are the expected costs for data preservation during the retention period of 5 years? How will the costs be covered?

There will be no additional costs for data storage after the end of the project.

7. Data sharing and reuse

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

- No

Which data will be made available after the end of the project?

The pseudonymized data can be made available upon request, after permission is granted by the principal investigator and the head researchers.

Where/how will the data be made available for reuse?

- In a restricted access repository

Upon request by mail.

When will the data be made available?

- Upon publication of the research results

Who will be able to access the data and under what conditions?

Researchers from the scientific community that express interest in the data. The principal investigator and head researchers will evaluate each request and provide data when they are convinced that the data will be used according to scientific research standards.

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

No expected costs.

8. Responsibilities

Who will be responsible for data documentation & metadata?

The principal investigator prof. dr. Pascal Sienaert.

Who will be responsible for data storage & back up during the project?

The study coordinator will be responsible for data storage and back up.

Who will be responsible for ensuring data preservation and reuse ?

The principal investigator prof. dr. Pascal Sienaert.

Who bears the end responsibility for updating & implementing this DMP?

The principal investigator prof. dr. Pascal Sienaert.