Plan Overview

A Data Management Plan created using DMPonline

Title: METPSY: Metabolic biomarkers of clinical outcomes in severe mental illness

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Funder: Medical Research Council (MRC)

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Project abstract:

This study forms part of the Hub for Metabolic Psychiatry, a multidisciplinary programme of work within the UKRI Mental Health Platform that aims to explore the role of metabolic dysfunction in severe mental illness.

People with severe mental illness have high rates of obesity, type 2 diabetes, and cardiovascular disease. Early evidence thus suggests that metabolic dysfunction may be linked to severe mental illness. However, more research is needed to identify reliable markers of metabolism which may have an impact on mental health outcomes, and to fully understand the mechanisms behind this impact.

In this study, we will investigate the relationship between metabolic markers and clinical outcomes of severe mental illness in young adults. The main purpose of this study is to determine whether changes in metabolic markers are linked to clinical outcomes.

We will recruit 120 young adults aged 16-25 with major depressive disorder, bipolar disorder, schizophrenia, or no severe mental illness for a prospective observational study. During this time, we will assess clinical symptoms using in-person and remote (digital) assessments, measure metabolic biomarkers in blood, and also explore the relationship of these outcomes with sleep and circadian rhythms. Using advanced statistical techniques and machine learning analysis, we will thus seek to better understand the mechanisms linking metabolic health with mental health.

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METPSY: Metabolic biomarkers of clinical outcomes in severe mental illness

0. Proposal name

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METPSY: Metabolic biomarkers of clinical outcomes in severe mental illness

1. Description of the data

1.1 Type of study

This is a prospective, observational study involving the collection of biological and clinical data from participants. Data will be collected from 120 participants total, including 90 participants diagnosed with major depressive disorder, bipolar disorder, or schizophrenia, and 30 participants with no history of these conditions.

1.2 Types of data

This study will primarily collect quantitative data from participants using three in-person visits (baseline, 6 months, and 12 months) and two remote burst assessment period (2 weeks each at 3 and 9 months after baseline). The following data types will be collected:

- Generated from questionnaires
    - Personal data
    - Contact details
    - Demographic data
    - Lifestyle data
    - Psychiatric health data
- Generated from digital data collection tools
    - Sleep data
    - Actigraphy data
    - Continuous glucose monitoring data
    - Ecological momentary assessment data
- Generated from clinical assessments
    - Anthropometry
    - Metabolic and other biomarkers (from blood samples)

Procedure	Baseline Visit	Burst #1	Prospective Visit #1	Burst #2	Prospective Visit #2
Month	**0**	**3**	**6**	**9**	**12**
Assessment of eligibility	X				
Written informed consent	X				
Confirmation of ongoing consent			X		X
Personal data and contact details	X				
Demographic questionnaires	X				
Lifestyle questionnaires	X				
Anthropometry	X				
Psychiatric assessment (SCID-5, current medication use)	X		X		X
Blood sampling	X		X		X
Ecological Momentary Assessment (burst over 2 weeks)		X		X	
Actigraphy (2 weeks)		X		X	
Glucose monitoring (2 weeks)		X		X	
Objective sleep monitoring (radar device)	Continuous and remote				

1.3 Format and scale of the data

Data will be stored in common open-source file formats (such as .CSV) which are easily shareable and widely accessible. The expected data size is 2 TB.

2. Data collection / generation

2.1 Sources of data

Data generated in this study will be new data collected from young adults (aged 16-25) recruited in Scotland.

2.2 Data quality and standards

Consistency and quality of questionnaire data will be ensured using an established quality assurance (QA) programme implemented within the data capture teams at both sites. This programme includes verification of questionnaire completion during digital data capturing into RedCap. Digitally captured data will be periodically reviewed by data managers for accuracy and completeness.
Consistency and quality of blood biomarker data will be ensured using internal standards implemented for the analysis, and by each sample being run in separate replicates.

2.3 Consent for data sharing and re-use

Participants will be explicitly asked to provide informed consent for data collection, sharing, and potential reuse. Consent forms will clearly outline the scope of data sharing and how personal information will be anonymized to protect privacy.
Explicit informed consent will be received from participants through the informed consent form, De-identified data will be shared with the wider UKRI Mental Health Platform collaboration (through the DATAMIND Trusted Research Environment) and the wider research community alongside any publications (through Open Science Framework or Edinburgh DataShare). The final dataset will be stripped of identifiers prior to release for sharing.

3. Data management, documentation and curation

3.1 Managing, storing and curating data

Data will be managed, stored, and curated using Edinburgh DataStore. DataStore provides enterprise-class storage with guaranteed backup and resilience. Data is retained on DataStore until deletion by the data owner. The backups provdie resilience in case of accidental deletion and against incidents affecting the main DataStore storage. The data are automatically replicated to an off-site disaster recovery facility, with 10 days of file history visible online. Off-site tape backups keep 60 days of history of the filesystem. The 60-day rolling snapshots allow important data to be recovered to a prior state, by request if beyond the visible period. Sensitive data stored of DataStore is further protected by the use of 256-bit encryption as required by University of Edinburgh policy.

3.2 Metadata standards and data documentation

Data will be accompanied by a README file with explanations of each included variable, in accordance with FAIR principles, for accessibility and comprehensibility. Metadata will be tagged in XML using the Data Documentation Initiative (DDI) format. The codebook will contain information on study design, sampling methodology, fieldwork, variable-level detail, and all information necessary for a secondary analyst to use the data accurately and effectively.

3.3 Data preservation strategy and standards

For long-term storage and preservation after the end of the study, all study data will be transferred from Edinburgh DataStore to Edinburgh DataVault one year after the end of the study. For one year following preservation in DataVault (i.e. two years after end of the study), data will be held in pseudonymised format. After deletion of identifiable data (two years after study completion), the study dataset will effectively become anonymised. This anonymised digital data will be archived in DataVault for a period of 13 years after the deletion of identifiable data. In total, data will be retained for **15 years** after the end of the study.

4. Data security and confidentiality of potentially disclosive personal information

4.1 Formal information/data security standards

Data security will adhere to institutional policies and the General Data Protection Regulation (GDPR). No formal data security standards apply, however all data will be subject to 256-bit encryption in Edinburgh DataStore. A persistent identifier and suggested citation is provided for any dataset deposited in Datastore.

4.2 Main risks to data security and how they will be managed

Main risks to data security for data collected in this study include:

- Unauthorised access to personally identifiable information or sensitive data
    - Unauthorised access to data will be prevented by storing all data securely in Edinburgh DataStore with access limited by unique login IDs and passwords to members of the research team only
    - Personally identifiable information will also be stored separately from the rest of the data and additionally encrypted within Edinburgh DataStore
- Accidental loss or damage of data
    - Accidental loss or damage of data will be mitigated by automatic backups provided by Edinburgh DataStore, as described in 3.1

5. Data sharing and access

5.1 Suitability for sharing

Data collected in this study is suitable for sharing in de-identified form. Sharing of this data within the research team is necessary to

achieve the research objectives of the study. Sharing of this data with the wider UKRI Mental Health Platform collaboration and with the wider research community alongside any arising publications is necessary to allow further research in the public interest. Risks of re-identification of participants during data sharing will be managed by storing personally identifiable information separately in an encrypted folder within Edinburgh DataStore, and only sharing de-identified data outside the research team.

5.2 Discovery by potential users of the research data

Data will be made discoverable for potential users using data summaries and metadata being published on the study website (www.metabolicpsychiatryhub.com) and through Edinburgh DataShare. This information will thus be publicly available and widely accessible.

5.3 Governance of access

De-identified data will be made publicly available alongside any arising publications and will thus not be subject to access governance.
Access to personally identifiable information may be shared confidentially with other researchers upon request with the approval of the data controller (study CI). Such restricted sharing with other researchers will require that the recipients of the data sign a Data Sharing Agreeement.

5.4 The study team's exclusive use of the data

De-identified data will be made available to the wider research community no later than two years after the end of the study or alongside publication of any arising scientific articles from this study, whichever is earlier.

5.5 Restrictions or delays to sharing, with planned actions to limit such restrictions

Personally identifiable information collected in this study will not be shared with individuals outside the research team, except in cases of an approved research project requiring access to this data, as outlined in 5.3 and 5.6.
No restrictions or delays to sharing will be applicable to the de-identified data.

5.6 Regulation of responsibilities of users

Restricted sharing of personally identifiable information with other researchers will require that the recipients of the data sign a Data Sharing Agreeement before data is shared, and will be subject to standard stipulations including:
- data sharing is for an ethically approved research project;
- recipients will not use the data for any other purpose;
- recipients will not try to reidentify any participants;
- recipients will not share the data with anyone else.

5.7 Working with overseas collaborators or data users

No overseas collaborators or data users are currently involved in this study. We will make de-identified data available publicly through an open access repository (Open Science Framework or Edinburgh DataShare), thus there may be users of this data based outside the UK, but no restrictions will be placed on this data usage as it will be de-identified and openly available at the time of sharing.

6. Responsibilities

6. Responsibilities

Responsibility for data management will be shared by:

- PI: Prof Daniel Smith
- Data Managers: Prof Saturnino Luz and Dr Joanne Kenney

7. Relevant policies

7. Relevant institutional, departmental or study policies on data sharing and data security

Policy	University of Edinburgh Link
Data Management Policy and Procedures	Link
Data Protection Policy	Link
Information Security Policy	Link
Research Ethics Policy	Link

8. Author

8. Author of this Data Management Plan (Name) and, if different to that of the Principal Investigator, their telephone & email contact details

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