Plan Overview

A Data Management Plan created using DMPonline

Title: Delineating a full phenotype of health, neurodevelopment and adaptive functioning in children and young adults with Fetal Valproate Spectrum Disorder.

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Template: University of Manchester Generic Template

Project abstract:

Very little is known regarding the impact and phenotype of Fetal Valproate Spectrum Disorder (FVSD) in older children and young adults, particularly from the second decade of life onwards. This project aims to ascertain parent views regarding the health and neurodevelopmental difficulties experienced by young people with FVSD as they get older. This is a preliminary study and utilises both standardised and validated questionnaires, and a set of bespoke questions specific to later outcomes that have been developed through expert collaboration and engagement with key FVSD charities. While the findings will themselves provide key insights into the wider phenotype of FVSD in older children and young adults, the results will also aid the design of a more detailed clinical study regarding the health and neurodevelopment in FVSD, which in turn, will provide the required information to enable optimal diagnosis and intervention through clinical services. A secondary aim of the study is to test the sensitivity of subset of the questionnaires for detecting differences between individuals with FVSD and non-exposed controls. These findings will inform a separate study that is investigating the feasibility of developing a routine surveillance system for assessing the safety or risk of different medications during pregnancy for child health and neurodevelopment. If the subset of questionnaires included in this study are adequately

sensitive, they will be included in the larger feasibility study for the overall surveillance system.

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Copyright information:

Delineating a full phenotype of health, neurodevelopment and adaptive functioning in children and young adults with Fetal Valproate Spectrum Disorder.

Manchester Data Management Outline

1. Will this project be reviewed by any of the following bodies (please select all that apply)?

- Funder
- Ethics

2. Is The University of Manchester collaborating with other institutions on this project?

- Yes - Part of a collaboration and owning or handling data

3. What data will you use in this project (please select all that apply)?

- Acquire new data

4. Where will the data be stored and backed-up during the project lifetime?

- Other storage system (please list below)
- University of Manchester Research Data Storage Service (Isilon)

Participant questionnaire data will be pseudo-anonymised using a unique study ID and stored using the Research Data Storage Service. This data will be stored separately from personal data. Personal data will be stored securely on the Manchester Developmental Neurotoxicology Research Group (DEVTOX) SharePoint that is accessible only to members of the research team. Questionnaire data and personal data can only be linked together by members of the research team using the pseudo-anonymisation key stored on the SharePoint.

5. If you will be using Research Data Storage, how much storage will you require?

- < 1 TB

6. Are you going to be working with a 3rd party data provider?

- No

7. How long do you intend to keep your data for after the end of your project (in years)?

- 11 - 20 years

Questions about personal information

Personal information, also known as personal data, relates to identifiable living individuals. Special category personal data is more sensitive information such as medical records, ethnic background, religious beliefs, political opinions, sexual orientation and criminal convictions or offences information. If you are not using personal data then you can skip the rest of this section.

Please note that in line with data protection law (the General Data Protection Regulation and Data Protection Act 2018), personal information should only be stored in an identifiable form for as long as is necessary for the project; it should be pseudonymised (partially de-identified) and/or anonymised (completely de—identified) as soon as practically possible. You must obtain the appropriate ethical approval in order to use identifiable personal data.

8. What type of personal information will you be processing (please select all that apply)?

- Personal information, including signed consent forms
- Pseudonymised personal data
- Special categories and criminal convictions

Personal Information & Pseudo-anonymised personal data.

All personal data will be held securely by the research team on behalf of the University of Manchester according to the University's data protection and information security policies. Consent forms will hold participant names and email addresses. University approved survey
software (Qualtrics) will be used as a secure paper-free method of obtaining electronic informed consent. Once a participant has submitted the consent form, the form will be downloaded to DEVTOX SharePoint and they will be assigned a unique participant ID. This

ID will be used to generate a unique survey link that will be emailed to each participant. The questionnaire will contain no personal information but will contain special category information regarding individuals' health and well-being. This data will be pseudo-anonymised and will only be able to be linked back to the participant personal information via the embedded participant ID. This linking will only be possible for members of the research team who have access to the anonymisation key stored on the DEVTOX SharePoint. The pseudo-anonymised questionnaire data will be downloaded and stored on the Research Data Storage Service provided by The University. Only members of the research team will have access to the SharePoint and the RDS. Study data will be fully anonymised at the end of the study.

9. How do you plan to store, protect and ensure confidentiality of the participants' information (please select all that apply)?

- Anonymise data
- Pseudonymise data and apply secure key management procedures
- Where needed, follow The University of Manchester guidelines for disposing of personal data
- Encrypt files, folders, computers and devices where personal data is held
- Impose suitable data sharing and collaboration agreements
- Store data on servers or computers that are approved by The University of Manchester and securely backed up

10. If you are storing personal information (including contact details) will you need to keep it beyond the end of the project?

- Yes – Other

Participants will be asked to provide consent for their personal information to be stored so that they can be informed of of future research by the research group.

Participants who do not provide consent for this will have their personal data deleted at the end of the project.

11. Will the participants’ information (personal and/or sensitive) be shared with or accessed by anyone outside of the University of Manchester?

- No

12. If you will be sharing personal information outside of the University of

Manchester will the individual or organisation you are sharing with be outside the EEA?

- Not applicable

13. Are you planning to use the personal information for future purposes such as research?

- Yes

14. Who will act as the data custodian for this study, and so be responsible for the information involved?

Dr Rebecca Bromley

15. Please provide the date on which this plan was last reviewed (dd/mm/yyyy).

2021-06-22

Project details

What is the purpose of your research project?

The study has two aims. The first and primary aim is to ascertain parent views regarding the health and neurodevelopmental difficulties experienced by children and young people with Fetal Valproate Spectrum Disorder (FVSD). This will be done using a parent-report battery comprised of validated questionnaires regarding child health and neurodevelopment, and a set of questions developed in co-operation with leading FVSD charities that pertain to the impact of FVSD on different domains of functioning (e.g. education, social skills, mental health) in older-aged individuals. Currently, very little is known regarding the FVSD neurodevelopmental phenotype from the second decade of life onwards and so the responses to these questions will help to develop the full picture of long-term impact and guide the design of more detailed clinical studies and interventions in the future.

Additionally, while the impact of Valproate on early child development is relatively well known, currently very little is known about the impact of exposure to many other common medications during pregnancy on child health and neurodevelopment. A more efficient and standardised system of reporting development following exposure to medications in the womb is required. Therefore, nested within the questionnaire battery is a set of questionnaires that have been proposed for use as part of a new routine surveillance system (LIFETIME) for assessing the impact of medication exposure during pregnancy on long-term chid health and neurodevelopment. The second aim of the

project, then, is to test the sensitivity of these questionnaires to detect differences in a group of children exposed to a well known teratogen (Valproate) and a group on non-exposed children. If the questionnaires are able to reliably detect the expected differences, they will be approved for use in a wider feasibility study of the overall LIFETIME system.

What policies and guidelines on data management, data sharing, and data security are relevant to your research project?

The University of Manchester research data management policy
https://documents.manchester.ac.uk/display.aspx?DocID=33802
The University of Manchester Records Management Policyhttp://documents.manchester.ac.uk/display.aspx?DocID=14916

The University of Manchester Publications Policy
http://documents.manchester.ac.uk/display.aspx?DocID=28526

The University of Manchester IT policies and guidelines
http://www.itservices.manchester.ac.uk/aboutus/policy/

The University of Manchester Intellectual Property Policy
http://documents.manchester.ac.uk/display.aspx?DocID=24420

The University of Manchester Data Protection Policy
http://documents.manchester.ac.uk/display.aspx?DocID=14914

Responsibilities and Resources

Who will be responsible for data management?

PI - Dr Rebecca Bromley: Overall responsibility for data management and security.
Co-I: Dr Matthew Bluett-Duncan: Responsible for maintaining and updating DMP and for day-to-day data collection and management, including downloading, processing, and pseudo-anonymising consent forms and questionnaire data as needed once they have been submitted to Qualtrics by participants.

What resources will you require to deliver your plan?

Resources required include Research Data Storage (RDS) and use of the Qualtrics survey platform, both provided free of charge by the University of Manchester. Relevant permissions for validated questionnaires used for the study have been secured and do not incur any additional costs.
Data is likely to be small (less than 10 GB) and fit within allocated University of

Manchester data storage, and so no additional costs will be incurred. If both members of staff leave the University before standard retention period has been observed, the data will be archived within a divisional repository.

Data Collection

What data will you collect or create?

This is an observational cross-sectional study that will collect both quantitative and qualitative data via a set of online questionnaires. Data will relate to the health and neurodevelopmental functioning of children and young adults with Fetal Valproate Spectrum Disorder (FVSD).

The questionnaire set consists primarily of validated and standardised questionnaires in order to facilitate comparison with other research and established norms where available. Full permission for using these questionnaires has been acquired as required. However, due to the paucity of existing research in this area, an additional set of questions has been developed in collaboration with leading charities and experts in the area that investigate the impact of FVSD on individuals as they get older. These questions compliment existing questionnaires by extending our understanding of the full FVSD phenotype and represent the first stage in developing a standardised and validated questionnaire to investigate outcomes later in the life-course.

Data collected via the online questionnaires will not exceed 10GB.

How will the data be collected or created?

Data will be collected online using University of Manchester approved survey tools (Qualtrics). The use of Qualtrics allows for standardised data capture from different participants. Standardised questionnaires will be reproduced (with permission) in Qualtrics in a format consistent with the original paper administration and using guidance provided by publishers where provided. In order to reduce missing data, participants will receive an automated prompt drawing attention to items with no response. This will give participants the opportunity to go back and complete items missed accidentally, but will not force participants to answer items they have left purposely unanswered.

Data will be downloaded from Qualtrics into SPSS files and stored securely on University of Manchester approved servers (RDS and Sharepoint).

We will devise naming conventions for all files and data, which will be applied consistently and systematically across all data and study files and documentation. We will ensure accurate version control and clear consistent files structure.

Documentation and Metadata

What documentation and metadata will accompany the data?

Fully, anonymised data from this study will be registered as available to other researchers and can be requested from the PI. Descriptions of data collected and processes of collection, its format, description of analyses completed to date and a data sharing summary will be uploaded to relevant data platforms (Pure, Figshare) and advertised within groups with specific interests in this area (i.e. teratology research networks). Full data sharing agreements will be required to be in place before the information can be accessed.

Ethics and Legal Compliance

How will you manage any ethical issues?

Appropriate ethical approval will be sought from the University of Manchester Research Ethics Committee.

All participants will be provided with participant information sheets and will be required to confirm that they have fully read the document. Participant information sheets will advise participants of what is involved in the research, data storage and confidentiality, outlining how the data will be used, pseudonymised and anonymised, and who will have access. Participants will be asked to provide their consent to take part in the study and for a fully anonymised version of their data to be shared with other researchers on request.

Data collected as part of this study will include information relating to the health and well-being of children and young people with FVSD and so this data will be pseudo-anonymised and stored securely on the RDS. Pseudo-anonymisation keys, to allow for re-identification will be held separately from the questionnaire data on the research group SharePoint and only accessible to members of the research team.

Fully anonymised data from this study will be registered as available to other researchers and can be requested from the PI. Full data sharing agreements will be required to be in place before the information can be accessed.

How will you manage copyright and Intellectual Property Rights (IPR) issues?

The University of Manchester will own the copyright and Intellectual Property Rights (IPR) of the data generated.

Storage and backup

How will the data be stored and backed up?

Data will be stored securely according to GDPR standards and automatically backed up

on University of Manchester approved storage services as detailed below.

Pseudonymised data will be stored separately from personal data as follows@

Consent forms, including participant names and email addresses, will be exported from Qualtrics into an SPSS file and stored on the research group (DEVTOX) Sharepoint. Completed consent forms will be downloaded by a member of the research team on a daily basis and retained on Qualtrics as a back-up until the end of the study.

Questionnaire data will exported from Qualtrics into a separate SPSS file and stored in an encrypted folder on the research group Research Data Storage drive. Completed questionnaires will be downloaded by a member of the research team on a weekly basis and retained on Qualtrics as a back-up until the end of the study. Questionnaire data will be pseudo-anonymised and linked back to participant consent and personal information using a unique study ID. Only members of the research team will have access to the data linkage key.

Once data collection has been completed, the data stored on the Qualtrics servers will be deleted and at the end of the study, the questionnaire data will be fully anonymised.

How will you manage access and security?

All data will be received in an electronic form via the University of Manchester approved online survey platform, Qualtrics. Only Dr Rebecca Bromley and Dr Matthew Bluett-Duncan will have access to the Qualtrics data in its raw form via their secure university accounts.

Data will be exported directly from Qualtrics to the relevant secure data storage service (RDS or Sharepoint) and immediately encrypted. Only members of the research team from the University of Manchester will be given overall access to these storage services and the specific encryption keys for each file.

Selection and Preservation

Which data should be retained, shared, and/or preserved?

Data will anonymised at the end of the study and retained 15 years in line with university's records retention policy for data that relates to public health and due to regulator recommendations. Original source documents will be archived as per the University of Manchester policy and the database stored on the secure internal network (RDS or Sharepoint). Participants will be provided with information about the storage and sharing policy and will be asked to consent to this.

Participants will be asked to provide consent for their personal information (name, email address) to be retained for 5 years and used to contact them regarding future research conducted by the research group. If consent is provided, this data will be stored securely and separately from any questionnaire data on the secure internal network.

What is the long-term preservation plan for the dataset?

Data will be stored on the secure Research Data Storage system at The University of Manchester.

Data Sharing

How will you share the data?

Fully anonymised data from this study will be registered as available to other researchers and can be requested from the PI. Full data sharing agreements will be required to be in place before the information can be accessed. Study metadata that describes the study will be uploaded to the PIs Pure profile and/or Figshare along with instructions regarding how to request access.

Author group, including patient representatives, would meet to review any access requests.

Are any restrictions on data sharing required?

The project will be collecting highly restricted data and so all data will have to be fully anonymised prior to sharing.