Plan Overview

A Data Management Plan created using DMPonline

Title: Health information and education resources for women with epilepsy from preconception to postpartum

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Funder: Health Research Board (HRB) Ireland

Template: Health Research Board DMP Template

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Project abstract:

Epilepsy affects about one in every 100 people. In Ireland, 37,000 people over the age of five live with epilepsy and 25% of these are women of childbearing age. Although most women with epilepsy can expect normal pregnancy outcomes reproductive choices are complex. To date, no study has examined the health information needs of women with epilepsy and their families from preconception through to postpartum in Ireland. This study proposes to identify, with women with epilepsy, their families and healthcare professionals, health information needs along the preconception to postpartum continuum, and to identify and co-develop prioritised evidence-based resources to support women and health professionals during this period.

We will conduct a sequential, mixed methods, participatory study. Firstly, we will identify existing national and international evidence-informed resources to support the health information needs of women with epilepsy from preconception to postpartum. Secondly, we will explore the health information, education and resource needs of women with epilepsy in Ireland, from the perspective of women, families and health professionals, through in-depth interviews. Thirdly, we will undertake a consensus building real-time Delphi study to prioritise and plan health information and education resources. Finally, we will co-design and co-produce health educational resources to support women with epilepsy and health professionals to complement their services during this period.

Throughout the project, women living with epilepsy will be included as experts by experience on their own lives and medical conditions. Through the co-production of resources, women will have better access to evidenced-based health educational resources to improve knowledge from preconception to postpartum. Healthcare professionals can use these resources to complement their services and share with women with epilepsy who use their services, ranging from primary care to specialist epilepsy care, and across maternity settings.

ID: 132548

Start date: 01-08-2023

End date: 31-07-2025

Last modified: 26-09-2023

Grant number / URL: APA-2022-014

Health information and education resources for women with epilepsy from preconception to postpartum

Data description and collection or re-use of existing data

How will new data be collected or produced and/or how will existing data be re-used?

The overall aim of this project is *to work with women with epilepsy, their families and healthcare providers to identify health information needs along the preconception to postpartum continuum, and to identify and co-develop prioritised evidence-based resources to support women and health professionals during this period.* This research aim is organised into four research objectives. Outlined below are the details for new data collection and production, according to each objective.

Objective 1: Review existing online, health information and education resources for women with epilepsy and health professionals from preconception to postpartum.

- Publicly-available online resources for women with epilepsy will be sourced via online searches and consultation with the public and patient involvement (PPI) panel, co-applicants and collaborators.
- Data linage will be documented through search terms and search engines evidenced within a MS Word document. Additionally, any updated sources (e.g., PPI panel provides a new source), will be recorded within the same document following a PRISMA flow chart format.

Objective 2: explore the health information, education and resource needs of women with epilepsy in Ireland, from the perspective of women, families and health professionals from preconception to postpartum.

- Qualitative data will be collected via semi-structured interviews. Interviews will primarily take place remotely via MS Teams. Should a participant request a face-to-face interview, this will be facilitated. Interviews will be will be audio recorded using MS Teams or a portable Dictaphone (for face-to-face interviews).
- Audio files will be stored in an RCSI SharePoint and transcribed by the research team and by an external transcription service, into a written transcript using MS Word. The audio will be transcribed into written data format for the purpose of analysis and destroyed after transcription has been completed.
- Relevant demographic data (including age range, ethnicity, county of residence) will be collected verbally at the end of the interviews.

Objective 3: prioritise and plan health information and education resources to support women with epilepsy, their families, and health professionals to complement their services from preconception to postpartum.

- An online real-time Delphi study will be employed to collect data for this objective. A real-time Delphi study includes participants responding to a single, online questionnaire. Participants will be given a set timeframe (35 days) where they can access the online questionnaire and edit their data, depending on their opinion. This can be done multiple times during this 35-day period. Therefore, new data will be produced during this timeframe and collected by the research team during this time period.
- Real-time Delphi software will be used to construct and operationalise the questionnaire. There are several softeware options including Surveylet, Expert Lens and 4Strat. The Principle Investigator and the Post-doctoral researcher will review these software options to assess their suitability for data collection within the study.

Objective 4: co-design and co-produce the prioritised health information and educational resource(s) to support women with epilepsy, their families, and health professionals to complement their services from preconception to postpartum.

- The resource(s) will be developed from the findings in Objectives 1, 2 and 3, as well as a series of online workshops. These workshops will take place face-to-face and will use breakout rooms and interactive discussion boards. These workshops are likely to collect new data regarding participants input on the development of these resource(s). Data may be collected via the researcher taking notes during the workshops.

All research data will be carefully collected and processed cognisant of (Findable, Accessible, Interoperable and Reusable) FAIR data principles.

What data (for example the kind, formats, and volumes), will be collected or produced?

Objective 1:

- Kind: Health information and education resources for women with epilepsy and/or health professionals will be gathered from online sources including i) national including the national health service websites ii) organisational websites, including regional hospital level, and advocacy resources, iii) resources created by academic institutions, iii) resources created by individuals (video by a woman with epilepsy who is not affiliated with an organisation). This may include online course material and toolkits. E-learning platforms will also be explored, if and where available. These resources will be in the form of texts, audio, video, and apps. The resources will be limited to accessibility in the English language.
- Format: Data produced will mostly include two formats. 1) MS Word (.doc) documents with tables which outlines the resource details (e.g., resource name, aim, who developed them) and the resource link. 2) Text and image resources (such as reports, leaflets, infographics) will be downloaded and stored in the project’s SharePoint folder to ensure they are accessible for the duration of the study. Resources may also be imported into EndNote and exported into either a word (.doc) or text (.txt) format. These will primarily be PDF files, but may also include some image formats such as JPG and PNG. Audiovisual resources will not be downloaded, rather a full citation including hyperlink to these media will be captured and stored in [Word/Endnote]. In the event a resource is no longer available online after data has been collected, the MS Word documents outlining the resource details will be referred to. All data from Objective 1 will be imported into NVivo for narrative analysis and will be stored in an .nvp file format.
- Volume: The volume of storage will depend on the amount of online secondary resources available. The total volume of this phase of the study will not exceed 300GB. 1) The MS Word document will include text and links, so approximately 500KB should be sufficient storage space. 2) The folder including the collection of resources will include .pdf documents so will likely require more space (~20MB). 3) NVivo files can be larger, so depending on number of resources, this may require 80MB.
- Data sharing: Relevant resources and findings from the narrative analysis will be shared within 'Objective 3' of this project. The resources and review findings could have value to wider research users and the research team will aim to share the results as openly as possible.

Objective 2:

- Kind: Qualitative data will be generated from in-depth interviews, which should last around 1 hour. Demographic data will be collected at the end of the online interview. These data will include approximately 30 women with epilepsy and 10 partners/family members, as well as data from 40 healthcare professional from various disciplines.
- Format: Data produced will mostly include three formats 1) audio files (mp3 or wav file), 2) MS Word (.doc) for written transcripts, and 3) a file for the demographic data, which is likely stored in

an Excel (.xls). Data will be imported into NVivo for analysis and therefore data collected will also be stored securely in an NVivo file (.nvp) on a password protected computer that is provided by the RCSI and only accessible to the research team.
- Volume: Provided the participant recruitment numbers are reached, this will include storing 1) 80 audio files (~6GB), 2) 80 written transcripts (~4MB), and 3) a demographic datafile (~1MB). The NVivo file will include the written transcripts and data analysis, so may require ~60MB.
- Data sharing: The research team will consider the potential for sharing the research data as widely as possible on publication of findings. Pseudonymised participant transcripts may be made available under strict access controls (also known as safeguarded data). As previously mentioned, data sharing will only be considered where the participant has consented to having their transcript data shared as safeguarded data. Where a participant does not consent to their data being shared, or where participant confidentiality cannot be assured, then the research team will not share the participant transcript data.

Objective 3:

- Kind: Quantitative data will be collected via online, real-time Delphi software (options include Surveylet, Expert Lens and 4Strat). A mixed expert panel will be recruited for the Delphi study comprising: i) women and their partners and family members (n= 100); ii) health professionals (n = 100). Once participant recruitment goals have been reached, the data analysis will be undertaken in the Delphi online software tool.
- Format: Data will be gathered using the select Delphi software tool, and following data collection will be exported in an accessible format such as .csv or .xls.
- Volume: Data from ~200 participants will be gathered online via the Delphi software and stored/exported to SharePoint following data collection.
- Data sharing: Delphi study data will likely be anonymised at source (personal data not collected). At the end of the project, anonymised files will be deposited in an appropriate, as yet unidentified cost-free data repository, such as Zenodo, under a Creative Commons Licence (CC BY or CC0).

Objective 4:

- Kind: Data will be gathered during online/in person stakeholder workshops with women with epilepsy, and with health professionals.
- Format: It is unclear what data will currently be produced, as this is dependent on the type of resources developed. Researcher notes will be typed into a MS Word (.doc) file and stored online (~2MB).
- Volume: It is anticipated that there will be 2-3 groups of women (with 5 members per group) and 2-3 groups of health professionals (also with 5 members per group).
- Data sharing: The raw data files (images of discussion boards, notes from discussions) from these workshops will be anonymized and where possible, will be shared via a data repository. The resources developed will be disseminated openly to provide a useful source of support for women with epilepsy and their families, knowledge users, and the Irish healthcare services/systems.

Documentation and data quality

What metadata and documentation (for example the methodology of data collection and way of organising data) will accompany data?

A Readme file containing metadata has been completed by the research team and will be included with the research data (.txt format). This template is based on the metadata standard Dublin Core,

which is a flexible standard that most people can understand. This metadata file will continue to be updated by the research team during the course of the project

Data from the project will be organised into RCSI SharePoint folders. File naming and organisation will follow guidance provided by RCSI 'Documentation and Data Quality' within RCSI LibGuides.

Each objective will likely include metadata to provide additional context. These could include (but are not subject to):

Objective 1: A data linage file with search terms and search engines documented.

Objective 2: A spreadsheet including interview transcript pseudonyms and dates/times of interview.

Objective 4: A logbook of workshop materials and information (e.g., time and number of attendees).

What data quality control measures will be used?

The research team will review the data collection quality of each objective during the course of the project, ensuring it is in good shape (e.g., readable).

Objective 1:

- Review criteria will be used to appraise and screen the resources for quality, such as the following: who developed the resources? Are they evidence based and up to date? Are they transferable to the Irish context? This will be captured in the MS Word document outlining the resource details.

Objective 2:

- The project management team and PPI Panel will collaboratively develop and refine the topic guides. Separate topic guides will be developed for women with epilepsy and partners/family members, as well as health professionals. Topic guides will be piloted with one woman with epilepsy, one partner/family member and one health professional prior to use. This pilot feedback will be documented.
- The Postdoctoral researcher will transcribe a sample of 20 interviews to familiarise themselves with the data. The remainder of the transcripts will be transcribed by an external company. A confidentiality contract will be signed between RCSI and the transcription company. The written transcripts will be reviewed by the postdoctoral researcher to ensure they are accurately reflecting the audio interview data.
- Data quality measures for the analysis of qualitative data include, the Postdoctoral researcher and the Principal Investigator aiming to read a sample of 30% of transcripts until familiarity with the data has been established. They will also independently develop provisional codes before agreeing on a final set of codes. The Postdoctoral researcher will apply these codes to all transcripts. An analysis sub-group of the project management team will collaboratively discuss developing themes and also agree any new codes iteratively as analysis continues. Strategies to enhance trustworthiness of the findings, such as negative case analysis, peer-debriefing and reflexivity, will be used. Findings will be presented to the PPI panel who will provide feedback on the findings and assist with interpretation.

Objective 3:

- The real-time Delphi study aims to include 200 panel experts (100 women and their partners and family members, as well as 100 health professionals). Data will be analysed using a recommended and up-to-date statistical software package, where appropriate cleaning and screening of data can be conducted.

Objective 4:

- Once the resource(s) have been developed, the PPI panel will be asked to pilot the resources to

determine the feasibility of using resource(s) and identify further modifications required. The resource(s) will then be amended as necessary and launched at an event.

Storage and backup during the research process

How will data and metadata be stored and backed up during the research process?

- All research data and metadata will be stored in an encrypted and dedicated project folder on MS SharePoint Azure storage, which is provided by the This project has been assigned up to 2TB of cloud-based storage on the Microsoft cloud, with automated back-ups to an alternative location within the EU (GDPR) region. The research team will be supported by RCSI's IT Department should they require assistance with data recovery from SharePoint.
- Following each interview/workshop paper copies of signed consent forms will be scanned electronically into a pdf format, and saved into a password protected folder within the SharePoint project folder. The paper copies will be destroyed once scanned.
- If audio is recorded on a Dictaphone, the audio files will be securely transferred to the SharePoint project folder and deleted from the recorder urgently (within 24 hours). Unless necessary, no audio recording will be taken on personal devices and if this is the case, the same procedures of securely storing and deleting the file(s) will apply.
- Folders containing personal or identifiable participant information will be encrypted and stored separately to the data in a password protected file.

How will data security and protection of sensitive data be taken care of during the research?

- All research data generated by this project will be stored within the dedicated project folder on SharePoint. This folder will only be accessible to members of the research team.
- The project folder on SharePoint will be assessed using laptops/PCs that have been provided by the RCSI and are encrypted in line with RCSI encryption policy, which includes two-factor authentication, to ensure the secure transfer of the data files.

Legal and ethical requirements, codes of conduct

If personal data are processed, how will compliance with legislation on personal data and on security be ensured?

- Personal data will be collected and processed on the basis of informed consent from participants to collect any personal or identifiable information. Only personal/identifiable data that is necessary to achieve the objectives of the study will be collected or stored by the research team. The participant information and consent documentation will include clear details about how data will be shared with third parties (this will vary depending on each objective). This includes data

being included in publications.
- During the consent process, participants will be asked to consent to the sharing of an anonymised/pseudonymised (depending on objective) copy of their data for the purposes of further scientific research. Data will be anonymized by the removal of personal information. Where full anonymization is not achievable, pseudonymous data will be treated in the same fashion as personal data Unlike anonymised data, in the instance of pseudonymisation (e.g., participant interview transcripts), GDPR regulations will still apply. All pseudonymised transcripts will remove direct identifiers such as names or details that could identify the respondent or another living person.
- All data processing will be undertaken in a secured environment on RCSI SharePoint, accessible only to the research team members. Access to the data on this system involves multifactor authentication to access.Where data are processed on local drives (for example Nvivo stored copies of data on the C drive of the user during the analysis) only a computer that has been encrypted by the RCSI IT Department will be used.
- Personal data will not be shared with any third party. If appropriate to share pseudonymised interview data (objective 2) under strict access controls, this will be made clear to participants in the consent process both verbally and in written format. Upon this information, participants will have the right to not share their pseudonymised transcript.

How will other legal issues, such as intellectual property rights and ownership, be managed? What legislation is applicable?

Intellectual property (IP) remains with to RCSI. IP developed at RCSI is managed in line with the National IP Protocol 2019 and the RCSI IP Policy 2019 in conjunction with the Conflict of Interest Policy.

To the researcher's knowledge, there are no limitations on sharing research data as a result of IP.

What ethical issues and codes of conduct are there, and how will they be taken into account?

- Ethical approval will be obtained prior to data collection from participants. For each objective, participants will be made aware of their data storage and sharing during this study. Participants will have the right to participate in the study and their data be included in data analysis and publications. If they do not want to have their data included in analysis and publications, they will be unable to participate. For the qualitative data, participants may also have the option to consent to their data being shared with third parties. Both consent to participate in the research and consent to share data will be requested seperately during the consent process, to allow those who wish to participate to opt out of having their data shared.
- Participants will be told during the information and consent process that they have a period which they can withdraw from the study (e.g., two weeks), after which they will be unable to withdraw their data.

Data sharing and long-term preservation

How and when will data be shared? Are there possible restrictions to data sharing or embargo reasons?

Data will be deposited into a trustworthy and cost-free data repository, such as Zenodo or the Digital Repository of Ireland (DRI) which is suitable for qualitative data, under a Creative Commons Licence (CC BY or CC0). Each objective's data will be reviewed on a case-by-case basis to ensure data is preserved and shared appropriately. Currently it is undecided which repository will be selected. Ongoing advice will be sought from the Research Data Coordinator/Officer (Ruth Geraghty) regarding the most appropriate repository to preserve and archive data long term. In line with RCSI's Research Data Management Guidelines, we will look for a discipline specific and community-recognised repository, and failing this will deposit in a generalist repository such as Zenodo.

A clearer timeline regarding when the data will be made available will be discussed with the Research Data Coordinator/Officer when deciding which repository is most appropriate.

As previously described, anonymised data may be shared openly and pseudonymised data shared securely via the selected repository and possibly the publication journal. Any secure data would be available through request of the PI.

How will data for preservation be selected, and where data will be preserved long-term (for example a data repository or archive)?

In accordance with the RCSI REC, data will also be retained on the RCSI server for ten years following the end of the project after which it will be destroyed.

Data files described in section 1 will be deposited in an appropriate repository (as described above). This will support in the

What methods or software tools are needed to access and use data?

Software needed to access various data will include MS Word, MS Excel, PDF, NVivo (.nvp), Delphi software in .dta of .csv format.

Additionally, a ReadMe metadata file (txt) will include project details to increase sustainability of software and access.

How will the application of a unique and persistent identifier (such as a Digital Object Identifier (DOI)) to each data set be ensured?

During discussions regarding suitable data repositories with the Research Data Coordinator/Officer, it will be important the selected repository has digital identifier DOI for the project data and documentation.

It is possible the project deposits data on Zenodo, as this repository provides a DOI number, and Zenodo has an ORCID integration to identify authors.

Data management responsibilities and resources

Who (for example role, position, and institution) will be responsible for data management (i.e. the data steward)?

Aisling Walsh (project Principal Investigator, Lecturer, RCSI), will be the data controller and have overall responsibility for this study and for the data generated. Aisling's primary responsibilities include data management/stewardship of the project, including ensuring the Data Management Plan (DMP) is complete and updating the DMP as required.

Jade Parnell (project Data Manager, Postdoctoral Researcher, RCSI), will be responsible for the day-to-day running of the project and data management. These tasks include, data collection/capture, metadata production, storage and back up, and data archiving.

Both Aisling and Jade are responsible for the management of sensitive and confidential data, as well as monitoring its implementation throughout the lifecycle of the data.

Throughout the project's data life cycle, the research team will periodically review and update the Data Management Plan.

What resources (for example financial and time) will be dedicated to data management and ensuring that data will be FAIR (Findable, Accessible, Interoperable, Re-usable)?

The project is supported by the RCSI Research Data Coordinator/Officer (Ruth Geraghty), whose time has been allocated for in the project budget. This includes time taken to support in the development of this DMP.

Total storage of 2TB on RCSI SharePoint has been provided, which exceeds the outlined storage needs for this project.

As previously detailed, at the end of the project, anonymised files will be deposited in an appropriate, as yet unidentified cost-free data repository, such as Zenodo or the Digital Repository of Ireland (DRI), under a Creative Commons Licence (CC BY or CC0).