Plan Overview

A Data Management Plan created using DMPonline

Title: Improving shared-decision making and psychotropic medication: A qualitative study and co-designing a shared-decision making tool to explore and improve experiences of young adults with first episode psychosis and the role of pharmacist-led consultations

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Project abstract:

Psychosis is a serious mental health condition that frequently affects young adults between the ages of 18 and 25, often treated with antipsychotic medications. While these medications can be beneficial, they also pose risks of side effects that may impact wellbeing, confidence, and adherence to treatment. Young people and their families often report a lack of involvement and understanding in medication decisions.

This research aims to explore how young adults experiencing a first episode of psychosis, their family members or carers, and mental health professionals experience conversations about antipsychotic medication. Specifically, it will examine what facilitates or hinders these discussions and how healthcare teams, particularly pharmacists, can enhance shared decision making. Shared decision making involves clinicians and patients collaborating to make treatment choices that reflect professional advice and personal preferences.

The study will adopt a three-stage approach:

- Stage 1: A systematic review will be completed to research shared decision-making and pharmacological management of young adults with first-episode psychosis.
- Stage 2: Interviews will be conducted with young adults (18–25) with recent psychosis, their families/carers, and mental health professionals (psychiatrists, nurses, pharmacists) to capture their experiences and perspectives. Discussions will cover experiences with medication conversations, barriers, facilitators, and involvement in treatment decisions.
- Stage 3: A subset of participants from all groups will be invited to co-design workshops to collaboratively develop a practical tool (e.g., conversation guide or checklist) to support clear and collaborative medication discussions in clinical appointments.

The overall goal is to improve how NHS mental health services involve young people and their families in treatment decision-making, clarify the role of pharmacists in medication-related discussions, and ultimately improve patient experience, safety, and long-term outcomes. Participation in the study is voluntary, with ethical considerations to minimize distress and ensure informed consent.

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Copyright information:

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proposal

Improving shared-decision making and psychotropic medication: A qualitative study and co-designing a shared-decision making tool to explore and improve experiences of young adults with first episode psychosis and the role of pharmacist-led consultations

Data Collection

What data will you collect or create?

Data will be generated for stages 2 and 3 of the proposed project.

For stage 2 (interviews), qualitative data will be collected via

1. Interview transcripts

1. *Volume:* Aiming for ~40-55 one-to-one interviews with the participants (20-25 for patients, 10-15 for family/carers, and mental health professionals respectively). This is of negligible storage space, and data will be stored on a cloud drive linked to the University Microsoft (MS) account or the Filestore Service.
2. *Format:* The transcripts will be either handwritten, in paper or typed in a computer, or documented via a dictating software. All data will be ultimately digitised using the online Microsoft Word software, and all documents will be saved in the University account MS Cloud drive or the Filestores Service.
3. *Description:* Semi-structured interviews to explore participants' views on certain processes around shared decision-making and pharmacological management. Current data are not group-specific, which is addressed with this research

2. Digital audio data

1. *Volume:* Is expected to be within the range of gigabytes. The University's MS cloud drive and the Filestore Service will have adequate space to host these. Processing of this data form will be disseminated to participants in a jargon-free fashion prior to them consenting to the collection of such data.
2. *Format:* mp3 or wav depending on the device used to collect these data. This will be recorded directly using the University account's OneDrive platform. Any audio data shall ultimately be converted to a MS Word transcript of the recording. The word document will occupy negligible space as per data 1. The audio data will be deleted post their transcription.
3. *Description:* Audio content from one-to-one interviews with participants, after consent has been obtained. All audio recordings will be deleted after transcripts for these have been completed.

3. Demographic data

1. *Volume:* Negligible volume and storage space required. All digital documents will be saved on the University MS cloud drive or the Filestore Services
2. *Format:* MS Word and/or MS Excel
3. *Description:* Demographic data from participants (age, professional role, relationship to patient, sex, ethnicity)

4. Field notes/reflective memos

1. *Volume:* Negligible volume and storage space required. Any handwritten documentation will be digitised and subsequently destroyed using a shredding machine. All digital documents will be saved on the cloud drive linked to the University MS cloud drive or the Filestore Services
2. *Format:* Handwritten scripts, Microsoft Word, PDF
3. *Description:* Documenting observations, context, or researcher reflections during/after interviews

5. Shared decision-making (SDM) consultation tool draft

1. *Volume:* Single document and therefore negligible volume and storage space required. The document will be saved on the university account MS cloud drive or the Filestore Services
2. *Format:* Microsoft Word
3. *Description:* The consultation model tool draft will be created after analysing all data of stage 2 described above. This will be completed by the lead researches after discussions with their supervisory team and will be the foundation for further development via co-production methods at stage 3 of the research project.

For stage 3 (co-designing workshops), qualitative data will be collected via

1. Workshop discussion transcripts

1. *Volume:* Aiming for a single focus groups including all groups of participants. Each participant group will contribute with ~5 participants. Multiple sessions for the focus group may be required. This is of negligible storage space, and data will be stored on a cloud drive linked to the University Microsoft (MS) account or the Filestore Service.
2. *Format:* The transcripts will be either handwritten or documented via a dictating software. All data will be ultimately digitised using the online Microsoft Word software, and all documents will be saved in the University account MS Cloud drive or the Filestores Service.
3. *Description:* Focus groups to discuss the interviews' outcomes and explore improvement of shared decision-making and

pharmacological management. A selected number of participants from stage 2 will be asked to participate in stage 3 of the study.

2. Digital audio data

1. *Volume:* Is expected to be within the range of gigabytes. The University's MS cloud drive and the Filestore Service will have adequate space to host these. Processing of this data form will be disseminated to participants in a jargon-free fashion prior to them consenting to the collection of such data.
2. *Format:* mp3 or wav depending on the device used to collect these data. This will be recorded directly using the University account's OneDrive platform. Any audio data shall ultimately be converted to a MS Word transcript of the recording. The word document will occupy negligible space as per data 1. The audio data will be deleted post their transcription.
3. *Description:* Audio content from the co-designing workshops with the participants, after verbal consent has been obtained. All audio recordings will be deleted after transcripts for these have been completed.

3. Field notes/reflective memos

1. *Volume:* Negligible volume and storage space required. Any handwritten documentation will be digitised and subsequently destroyed using a shredding machine. All digital documents will be saved on the cloud drive linked to the University MS cloud drive or the Filestore Services
2. *Format:* Handwritten scripts, Microsoft Word, PDF
3. *Description:* Documenting observations, context, or researcher reflections during/after workshops

4. Online surveys for co-production

1. *Volume:* One survey per participant, ~15 surveys overall. Data will be stored on a cloud drive linked to the University Microsoft (MS) account or the Filestore Service.
2. *Format:* Microsoft Forms due to easy access digitally, a user-friendly interface, and automated link with other helpful applications, namely MS Excel, MS Power Automate, MS Power BI. The later will facilitate data analysis and report generation.
3. *Description:* Survey data to explore participants' views on the initial 'SDM consultation tool draft'.

5. Online surveys for participant feedback (optional)

1. *Volume:* One survey per participant, ~15 surveys overall. Data will be stored on a cloud drive linked to the University Microsoft (MS) account or the Filestore Service.
2. *Format:* Microsoft Forms due to easy access digitally, a user-friendly interface, and automated link with other helpful applications, namely MS Excel, MS Power Automate, MS Power BI. The later will facilitate data analysis and report generation.
3. *Description:* Survey data to explore participants' experience of the research project and their ideas of what future research should focus on.

6. Co-designed shared decision-making tool

1. *Volume:* Numerous versions of a single document. Data will be stored on a cloud drive linked to the University Microsoft (MS) account or the Filestore Service.
2. *Format:* Two copies of the final document will be stored, a Microsoft Word and a PDF version.
3. *Description:* This tool will be the final output of the research and its aim is to provide with evidence-based guidance on conducting efficient shared decision-making consultations for young adults prescribed psychotropic medications. The initial document will be n. 5. from stage 2 of the research, 'SDM consultation tool draft', and the final document will be refined after analysis of data 1., 2., and 3., from stage 3 of the research and discussions with the supervisory team.

How will the data be collected or created?

Data will be collected using qualitative methods aligned with the aims of the study: exploring experiences of shared decision making (SDM) around psychotropic medication (stage 2) and co-designing a practical tool to support medication conversations for young adults with first episode psychosis (stage 3).

Stage 2

Individual interviews and will be conducted in this stage using semi-structured interview guides. These guides will be developed in collaboration with clinical supervisors and PPI advisors, reflecting recognised qualitative interviewing standards. Participants' written consent will be required prior to conducting and documenting the interviews, and after the research is explained to the participants both in writing, via a participant information sheet, and verbally in a jargon-free fashion. The participants will be allowed questions regarding the research. The consent process will include requesting whether audio recording of the interview is accepted by the participant.

Consent may be completed and documented directly via Microsoft Forms, whereby the participant will be able to 'tick' a box indicating consent is given. The form will prompt the participants to enter certain personal details, namely name, surname, date of birth, and contact details. Such details will be required in order to link the consent form with the relevant participant. The MS Form will be generated by the lead researcher's university MS account.

Moreover, personal data will be collected which will include name, surname, date of birth, NHS number, and contact details for patients and name, surname, profession/relationship to patient, and contact details for family/carers and mental health professionals. Identifiable data will be pseudonymised at this stage using a participant numbered system, e.g P01, F01, C01, MHP01.

All consent and personal data will be saved in the lead researcher's university account MS cloud drive in a Word/Excel formats. The relevant documents will be locked and require another password in order to access them, which will maximise security.

Demographic data will be document and will vary depending on the group of the participants. For patients, demographics will include age, mental health diagnosis, ethnic background, and gender in view of maximising equity, diversity, and inclusion. For family/carers, demographics will include age, gender, and relationship to the patient. For mental health professionals, demographics will include, age, gender, profession and level of practice (e.g. banding), years of experience with the NHS. All demographic data will be documented in an excel spreadsheet and will be used to draft the demographical identity of the research.

Interview transcripts will be completed using directly the pseudonymised system. The transcripts will be handwritten on paper, or typed directly to an online MS Word document either by the interviewer or via using a dictating software. The transcripts will be titled accordingly to indicate which participant do they refer to, e.g. INT_P01, INT_F01, INT_C01, INT_MHP01.

If the participant consents, audio will be recorded using encrypted digital devices or Microsoft Teams through the university account. Files will be saved in MP3 or WAV format, using the pseudonymised system, and immediately transferred to secure University OneDrive/SharePoint storage when an independent device is used. Each recording will be checked immediately post-interview for sound quality and completeness as part of the quality assurance process. All audio recordings will be transcribed as soon as possible and will be deleted right after their full transcription is completed and saved. Titling of the transcribed document will indicate the document derives from an audio file, e.g. INTa_P01.

Field notes and reflective memos, will use the pseudonymised system and be either handwritten or typed directly to an online MS word document. Where the interview transcripts are documented manually, field notes and reflective memos will be part of the interview transcript. However, they will be annotated in order to be later extracted and saved to an independent document. Where the interview transcripts are documented using a dictating software, field notes and reflective memos will be documented separately in a manual fashion.

Because some participants will be NHS service users, clear information will be provided in plain language about how their data will be recorded, stored, preserved, and anonymised. If required, the project will complete a Data Protection Impact Assessment (DPIA). The project was run through the relevant flowcharts of the NHS Data Security and Protection Toolkit (DSPT) framework and it was identified that no DSPT completion is required as no NHS Digital or Public Health England data will be used.

After analysis of all data obtained during stage 2, the research team will draft a provisional 'SDM consultation tool draft'. This will be the foundation of the workshops and discussions in stage 3 of the research project.

Storage and organising of the above data will follow a folder system as explained below:

/SDM_Psychosis_Research_Project

1. /01_Personal_Data
2. /02_Consent_Material
3. /03_Demographics
4. /04_Stage_2_Data
5. /01_Interview_Transcripts
6. /02_Interview_Audio
7. /03_ Field_Notes_And_Reflection_Memos
8. /05_SDM_Tool

Stage 3

Participants of stage 2, will be contacted to participate in stage 3 if they have consented to it. Three different focus groups/workshops will be conducted, one workshop for each group of participants (patient, family/carer, mental health professional).

Workshops' content will be transcribed on paper, or typed directly to an online MS Word document either by the interviewer or via using a dictating software. Participants will be directly anonymised during the workshop process and no personal data will be kept. The transcripts will be titled accordingly to indicate which group do they refer to, e.g. FG_P01, FG_FC01, FG_MHP01.

If all participants, of a certain workshop, consent verbally, audio will be recorded using encrypted digital devices or Microsoft Teams through the university account. Files will be saved in MP3 or WAV format, and immediately transferred to secure University OneDrive/SharePoint storage when an independent device is used. Each recording will be checked immediately post-interview for sound quality and completeness as part of the quality assurance process. All audio recordings will be transcribed as soon as possible and will be deleted right after their full transcription is completed and saved. Titling of the transcribed document will indicate the document derives from an audio file, e.g. FGa_P01.

Field notes and reflective memos, will be either handwritten or typed directly to an online MS word document. Where the workshop transcripts are documented manually, field notes and reflective memos will be part of the workshop transcript. However, they will be annotated in order to be later extracted and saved to an independent document. Where the workshop transcripts are documented using a dictating software, field notes and reflective memos will be documented separately in a manual fashion.

Participants of stage 3 of the research project will be asked to complete two online surveys. The first one will be completed during the workshops and its aim will be to research the participants' view on the provisional SDM consultation tool draft. The second survey will constitute a feedback form and may be completed at any time after stage 3 of the research project is completed. The feedback survey will be optional for the participants and will aim to explore the participants' experience of the research project and their ideas of what future research should focus on. Both surveys will be completely anonymous. The surveys will be completed via Microsoft Forms, using the lead researchers university account. A copy of the outcomes will automatically be saved on the account's MS cloud drive and automatic export to Excel, and compatibility with Power BI and Power Automate workflows will be pre-set. The documents will be renamed accordingly to ensure easy identification, e.g. SUR_CP_FGP, SUR_CP_FGFC, SUR_CP_FGMHP, SUR_FB_FGP, SUR_FB_FGFC, SUR_FB_FGMHP.

After analysis of all data obtained during stage 3, the research team will finalise the SDM consultation tool. This will be saved as both a MS Word and a PDF copy.

Storage and organising of the above data will follow a folder system as explained below:

/SDM_Psychosis_Research_Project

1. /05_SDM_Tool
2. /06_Stage_3_Data
3. /01_Workshop_Transcripts
4. /02_Workshop_Audio
5. /03_ Field_Notes_And_Reflection_Memos
6. /04_Workshop_Surveys
7. /07_Feedback_Surveys

Standards and Methodological Framework

Data collection will follow standards from:

- Qualitative research methodology (semi-structured interviews, thematic exploration, participatory co-design),
- Co-production frameworks (e.g., NIHR principles of co-production),
- NICE SDM guidance,
- Mental health research ethics (e.g., sensitive interviewing practices, minimising distress).

All instruments, including interview schedules, workshop plans and survey questions, will be piloted. The same core guide, prompts and sequence will be used across all interviews to ensure consistency.

Quality Assurance

To ensure consistency and high-quality data:

- Interviews: Microphone checks and environment checks will be conducted before every session. All interviews will be conducted by the researcher to maintain consistency.
- Transcripts: Where applicable, transcriptions (manual or software-assisted) will be checked against original audio for accuracy.
- Co-design sessions: Activities will be predefined, structured and time-bound, ensuring consistent data generation across groups.
- Survey: Required fields, controlled vocabularies, branching logic and pilot testing will support data reliability.
- Documentation: Notes will be typed up promptly and stored in standardised templates.

Version Control

- Versioning will be maintained manually using suffixes (v01, v02, FINAL).
- Microsoft 365’s automatic version history will provide an audit trail.
- A “Changes Log” document will record modifications to instruments, coding schemes, and workshop materials.

Documentation and Metadata

What documentation and metadata will accompany the data?

Although the project will not deposit data in an external repository for future reuse, comprehensive documentation and internal metadata will be maintained to ensure the data is well organised, interpretable, auditable, and compliant with University and NHS governance requirements throughout the research lifecycle.

File Naming and Metadata Conventions

A standardised pseudonymised naming system will be applied across all data types. Each participant group will receive a prefix (e.g., P01 = patient, F01 = family, C01 = carer, MHP01 = professional), applied consistently to transcripts, audio files, field notes, and workshop materials. Filenames will follow the conventions described in the Data Collection section (e.g., INT_P01, INTa_P01, FG_P01, FGa_P01, SUR_CP_FGP). These filenames constitute core internal metadata, ensuring files can be traced to the correct data source without revealing personal identities.

All stored documents will contain embedded metadata where applicable (author, date, version), automatically generated by Microsoft 365 and retained in OneDrive/SharePoint’s version history. Additional contextual metadata will be recorded in a separate Changes Log, which documents alterations to interview guides, coding frameworks, workshop procedures, and survey instruments.

Documentation During Data Collection

Each dataset will be accompanied by a structured README file that describes:

- data type (interview transcript, survey output, workshop file, memo)
- method of data collection

- pseudonymisation status
- date created and by whom
- file format
- relationship to other files (e.g., link to related audio file or field notes)
- any transformations applied during processing

For survey datasets downloaded from Microsoft Forms, a data dictionary will be created describing variable names, response options, scoring, controlled vocabularies, and any branching logic used.

Interview transcripts, workshop transcripts and audio-derived documents will include metadata within the document header: participant pseudonym, date, setting, interviewer, and anonymisation status. This supports auditability and ensures that transcripts can be interpreted independently of the original data collection context.

Documentation of Field Notes, Reflective Memos and Co-design Activities

Field notes and reflective memos will be kept alongside transcripts using the pseudonymised system. Where notes are embedded in manually produced transcripts, annotations will flag them clearly for later extraction. Where dictation software is used, field notes will be documented in separate linked files.

Documentation of Stage 3 co-design workshops will include structured templates describing the activity sequence, materials used, and decisions made during each session, maintaining consistency across patient, family/carer, and professional groups.

Version Control

Microsoft 365’s automatic versioning and audit trail will be used for all documents. Important files (e.g., interview guides, coding frameworks, SDM tool drafts) will additionally be manually versioned using suffixes (e.g., v01, v02, FINAL). The Changes Log will provide high-level metadata describing:

- rationale for changes
- date implemented
- person responsible
- effects on data collection or analysis

This approach ensures transparency and reproducibility.

Standards and Methodological Metadata

Documentation will be aligned with recognised standards relevant to the project, including:

- principles of semi-structured qualitative interviewing
- NIHR co-production guidance
- NICE shared decision making standards
- ethical guidelines for mental health research and sensitive interviewing

All instruments (interview guides, workshop plans, survey questions) will be piloted, and pilot changes will be documented in the Changes Log.

No Repository Deposit

Although no external data repository will be used, all documentation and metadata will be retained securely within the University’s Microsoft 365 environment until the end of the retention period. Metadata will therefore support internal understanding, auditability, and compliance but will not be prepared for external indexing or reuse.

Ethics and Legal Compliance

How will you manage any ethical issues?

This research will be ethically reviewed using the Integrated Research Application System (IRAS). "IRAS is a single system for applying for the permissions and approvals for health, social and community care research in the UK" (NHS Health Research Authority, 2021). During the process, the project's ethics application will be reviewed by a Research Ethics Committee who will ensure that the dignity, rights, safety and well-being of research participants are preserved.

Consent will be completed and documented directly via Microsoft Forms, whereby the participant will be able to first read the participant information sheet and subsequently to 'tick' a box indicating consent is given. The form will prompt the participants to enter certain personal details, namely name, surname, date of birth, and contact details. Such details will be required in order to link the consent form with the relevant participant. The MS Form will be generated by the lead researcher's university MS account.

Personal data will also be collected and will include name, surname, date of birth, NHS number, and contact details for patients and name, surname, profession/relationship to patient, and contact details for family/carers and mental health professionals. For stage 2, identifiable data will be pseudonymised at this stage using a participant numbered system, e.g P01, F01, C01, MHP01.

All consent and personal data will be saved in the lead researcher's university account MS cloud drive in a Word/Excel formats. The relevant documents will be locked and require another password in order to access them, which will maximise security.

After the workshops for stage 3 of the research process are set, all data of stage 2 and the subsequent data generated during stage 3 will be completely anonymised and the document entailing the participants' identifiable/personal information will be permanently deleted. This will be explained to participants prior to seeking for their consent.

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

This project does not involve the creation of commercially sensitive materials, inventions, or datasets with potential for commercialisation. The research will generate qualitative data in the form of interview transcripts, workshop outputs, memos, and survey responses. These materials will not be shared publicly or deposited in a repository, and therefore no licensing for reuse is required.

In line with Newcastle University policy, the University will retain ownership of the intellectual property rights and copyright for any data created during the project. As the sole researcher generating and analysing the data, I will be responsible for ensuring compliance with institutional policies and any obligations set out by the funder or the University's Research Data Management Policy.

No third-party copyrighted materials will be incorporated into the dataset, and no copyrighted tools, proprietary measures, or external datasets will be reused. Workshop materials and co-design outputs will be generated by participants as part of the research process; these will be treated as research data and will therefore fall under standard University IPR ownership. Participants will be made aware of this in the Participant Information Sheet.

The study does not aim to develop commercial products, and no delays to dissemination or publication are anticipated on the basis of IPR. If any unexpected issues relating to intellectual property arise during the project, advice will be sought from the University's Business Development and Enterprise team.

Storage and Backup

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

All data management procedures will comply with the GDPR, the Data Protection Act (2018), the University's Information Security and Data Protection Policies, and NHS Information Governance requirements where applicable.

Primary storage and backup (University systems)

All research data, including consent forms, participant information, personal identifiers, and pseudonymised datasets, will be stored within the University's secure Microsoft 365 environment using the lead researcher's University MS account. Data will be held within:

- University OneDrive (for identifiable/personal data)
- A dedicated, access-restricted University SharePoint folder (for pseudonymised and working datasets)

These platforms offer secure storage, encryption in transit and at rest, full audit logging, and recovery options in the event of accidental deletion. Access will be restricted solely to the lead researcher.

Should the volume of data exceed standard allocations, or if required following advice from Research IT, the data will be transferred to the University Filestore Service (Research Data Warehouse). This provides:

- Secure project-specific storage
- Access only for authorised project staff
- Hourly backups
- A high-availability mirrored off-site copy

This ensures robust disaster recovery and long-term storage resilience.

Consent data

Consent will be collected through Microsoft Forms, created using the researcher's University MS account. The Form will be configured so that:

- Responses are stored directly in University OneDrive,
- Personal identifiers (name, DOB, contact details) are securely captured, and
- The file containing consent information is password-protected (in addition to standard MS security) to provide an extra layer of protection for identifiable data.
- Pseudonymisation and later full anonymisation

For Stage 2, identifiable data will be pseudonymised immediately upon transcription using a standardised participant coding system (e.g., P01, F01, C01, MHP01).

Right after commencing Stage 3 workshops:

- All datasets (Stage 2 and 3) will be fully anonymised
- The document linking identifiers to pseudonymised codes will be permanently deleted from the University system
- Participants will be informed of this timeline during the consent process

Restrictions on tools for NHS data

Because the study involves NHS service users and staff:

- MS Teams will not be used to store or share any research data, in line with Newcastle guidance for studies involving NHS data.
- Any NHS-derived personal information will only be stored and processed on University MS systems.

Portable devices

Portable devices (laptop/tablet used for note-taking during visits or fieldwork) will:

- Have full-disk encryption enabled
- Never store master copies of research data
- Only contain temporary working files, which will be transferred to University storage immediately upon return
- Be wiped of any local copies after synchronisation

The University Filestore or OneDrive will hold the master version of all data.

How will you manage access and security?

All data access and security procedures will comply with the GDPR, the Data Protection Act (2018), the University's Information Security and Data Protection Policies, and NHS Information Governance requirements.

Access controls

Access to research data will be strictly limited to the lead researcher, who will be responsible for managing, handling, and analysing the data throughout the project. No other individuals, including supervisors, will have access to identifiable data.
Pseudonymised and anonymised materials may be shared with supervisors only when all identifiers have been removed.

All files stored in the University Microsoft 365 environment (OneDrive and SharePoint) will be protected by:

- Role-based access control, limiting access solely to the lead researcher
- Multi-factor authentication (MFA)
- University-managed device security policies, including automatic updates, antivirus protection, and encryption

Security of identifiable and sensitive data

Identifiable data (e.g., name, DOB, NHS number, contact details) and consent forms will:

- be stored exclusively within the lead researcher's University OneDrive,
- be held in password-protected Word/Excel files,
- be encrypted at rest and in transit through Microsoft 365 security, and
- never be stored, transmitted, or discussed via personal devices, personal email accounts, or non-secure applications.

The dataset linking participant IDs to personal identifiers will be held separately from any transcripts or research materials and will be permanently deleted prior to Stage 3.

Handling NHS data

Because the project involves NHS service users and staff, the following additional protections apply:

- Research data will not be stored or shared in Microsoft Teams, in line with Newcastle University guidance for NHS-linked research.
- NHS-derived data will only be stored within the University MS systems.

Data transfer and portable devices

If temporary portable storage or devices (e.g., encrypted laptop/tablet) are needed during fieldwork or interviews:

- Devices will have full-disk encryption enabled.
- Only temporary working copies will be stored locally.
- Data will be transferred to University storage as soon as possible.
- Local files will be deleted immediately after transfer.
- No identifiable data will be stored on USB sticks or unencrypted devices.

Pseudonymisation and secure workflow

At Stage 2, all identifiable data will be pseudonymised using a unique participant code (e.g., P01, F01, C01, MHP01).
At Stage 3, datasets will be fully anonymised, and the linkage file will be destroyed.

Once anonymised, data will no longer be considered personal data and may be shared with supervisors for analysis and discussion.

Monitoring and audit

All access events, modifications, and file movements within Microsoft 365 are logged through the University's audit systems.
The lead researcher will review data handling periodically to ensure ongoing compliance with University, GDPR, and NHS policies.

Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

Given the nature of this project, which involves small-scale qualitative interviews and co-design workshops with NHS service users, carers, and clinicians, the data generated will not hold long-term value for reuse or wider dissemination, and therefore will not be deposited in a public data repository.

Data to be retained

In line with Newcastle University's Research Data Management Policy, any anonymised data that directly supports research findings (e.g., anonymised thematic frameworks or summary analytic documents) will be:

- retained securely within the University's research storage systems,
- preserved for 10 years following any publication, after which retention will be reviewed.

These materials will be retained exclusively for:

- audit purposes,
- verification of the research findings,
- compliance with University (and potentially funder) expectations.

No personal data will be included in these retained files.

Data to be destroyed

The following materials must be destroyed due to their identifiability and their lack of long-term research value:

- Consent forms (after statutory retention requirements have been met)
- The participant identification/metadata file
- Any audio recordings, raw transcripts, workshop notes, or working documents containing identifiable or potentially identifiable content
- Any unredacted field notes

Identifiable data will be destroyed according to the timeline already defined in the data management plan (e.g., the linkage file will be deleted prior to Stage 3; identifiable source data will be deleted after analysis is complete).

Data sharing

The project does not produce datasets suitable for external reuse due to:

- the inclusion of highly sensitive mental health information,
- small sample sizes,
- contextual specificity (local service issues, individual experiences),
- risk of deductive disclosure even after anonymisation.

Therefore, no research data will be shared publicly beyond what is included in academic publications (e.g., fully anonymised quotes that cannot be linked to individuals).

Preservation format

Any retained materials will be stored in standard, non-proprietary or widely supported formats (e.g., .docx, .pdf, .xlsx), ensuring long-term accessibility.

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

Given the nature of this project, the dataset does not have long-term value for external reuse, and therefore no data will be archived in a public repository. The project will generate small-scale qualitative data relating to sensitive mental health experiences, which cannot be sufficiently anonymised for wider sharing without significant loss of meaning and with ongoing risk of deductive disclosure.

Retention of essential anonymised materials

In accordance with Newcastle University's Research Data Management Policy, only the minimal anonymised materials necessary to verify research findings (e.g., anonymised analytic summaries or thematic frameworks) will be retained. These will be preserved within the University's secure research storage systems for 10 years following any publication, after which retention will be reviewed.

No personal data will be retained, and the linkage file will have been deleted before Stage 3 of the project.

Deletion of identifiable and source data

All identifiable data, including consent forms, raw transcripts, audio files, workshop outputs containing personal details, and the participant identification file, will be securely destroyed once analysis is complete and in line with the schedule defined in the data management plan.

Repository decision

Because the dataset does not meet criteria for long-term sharing (sensitivity, limited reuse potential, contextual specificity), it is not appropriate for deposit in data.ncl or any external repository. Therefore, long-term preservation will be restricted to internal retention of anonymised summary documents only.

Data Sharing

How will you share the data?

Given the qualitative and highly contextual nature of this study, along with the sensitivity of the clinical population involved, the dataset will not be shared publicly. The research will generate anonymised interview transcripts, demographic summaries, and thematic analysis outputs. While transcripts will be fully anonymised (all direct and indirect identifiers removed), the depth of personal experiences described by participants means that full de-identification cannot be guaranteed without materially compromising the integrity or interpretability of the data. For this reason, the dataset is not suitable for deposit in an open repository and will not be made available for reuse.

During the active research period, data will only be accessed by the researcher and supervisory team and will be stored on secure, access-controlled University (OneDrive for Business, M365) system, as previously outlined. No external sharing, cross-organisational transfer, or data sharing agreements are anticipated.

A metadata record will be created and retained internally as part of the project documentation, in line with Newcastle University's Research Data Management Policy, but no discoverable public metadata record (e.g., via data.ncl) will be generated because the dataset will not be deposited.

If there is any future interest in secondary use, requests will not be accommodated, as consent for data sharing will not be sought from participants and the dataset will not be archived for reuse.

Are any restrictions on data sharing required?

Yes. Restrictions on data sharing are required due to the sensitive nature of the qualitative interviews and the clinical population involved. Although transcripts will be fully anonymised, the depth and context of participants' experiences mean that complete de-identification cannot be guaranteed without significantly compromising the integrity of the data. As consent for data sharing will not be sought, and because the dataset is not suitable for meaningful reuse, the data will not be shared outside the immediate research team.

As a result, the dataset will not be deposited in a public repository, and no external access requests will be permitted. Access will be restricted to the researcher and supervisory team, in accordance with GDPR, the UK Data Protection Act 2018, NHS information governance requirements, and Newcastle University Research Data Management Policy.

These restrictions ensure participant confidentiality, uphold ethical approvals, and reflect the purpose and design of the project.

Responsibilities and Resources

Who will be responsible for data management?

Overall responsibility for implementing and maintaining the Data Management Plan lies with Vasileios Voulgaropoulos, the lead researcher and PhD student. You will oversee all data-related activities, ensuring compliance with Newcastle University's Research Data Management Policy, NHS information governance requirements, GDPR, and the UK Data Protection Act 2018.

Specific responsibilities are as follows:

- Data collection:
  The lead researcher will be solely responsible for conducting and recording all qualitative interviews.
- Data transfer:
  The lead researcher will securely transfer any data using encrypted institutional systems.
- Data checking and quality assurance:
  The lead researcher will check audio files, transcripts, and metadata for accuracy and completeness before analysis.
- Data storage and backup:
  The lead researcher will maintain files within the approved university secure cloud environment, ensuring appropriate folder structures, naming conventions, and version control. The system provides automatic backup in line with institutional policies.
- Data analysis:
  The lead researcher will conduct the qualitative analysis on encrypted, institutional devices. Supervisors will have access only to anonymised transcripts stored within the Newcastle University OneDrive environment.
- Preparation of data for archiving and destruction:
  At project completion, the lead researcher will ensure personal data are securely destroyed in line with the retention periods agreed in your ethics approval, and that any required documentation (e.g., metadata summaries) is retained by the University.

There are no external collaborators and therefore no data-sharing agreements or split responsibilities across institutions. All data ownership remains with Newcastle University as the sponsoring institution. Supervisors will provide oversight but will not handle

raw identifiable data.

What resources will you require to deliver your plan?

The data management activities for this project will be supported primarily by existing institutional infrastructure and will not require significant additional financial resources.

Technical infrastructure:

- Secure storage and backup will be provided through Newcastle University's institutional OneDrive Microsoft 365 environment. This system offers encrypted cloud storage, version control, and automated backup, meaning no additional storage costs are anticipated.
- Approved NHS and University devices will be used for data collection, transcription checking, and analysis. No additional hardware is required.

Software:

- Qualitative data will be handled using software already available through institutional licences (e.g., Microsoft Office 365).
- Transcription will be completed via the University's approved transcription service or manually, depending on ethics approval; associated costs are not expected to exceed the standard budget covered by the research programme.

Staff time:

- The lead researcher will carry out all data-related tasks, including collection, organisation, analysis, documentation, and preparation for archiving or deletion.
- Supervisor input will be limited to reviewing anonymised materials and ensuring compliance. No additional staffing is required.

Training and expertise:

- The lead researcher has already completed basic training in research methods, GDPR, and information governance as part of their PhD preparation and NHS employment.
- Further specialist training is not anticipated, though optional support from Newcastle University's Research Data Service will be accessed if needed.
- Relevant training opportunities via Newcastle University, the NHS, or any third party providers will be sought on a continuous basis.

Data archiving:

- As datasets will not be deposited in an external repository, no repository fees will be incurred.
- Long-term preservation needs are minimal given that identifiable data will be destroyed at the end of the project, and only minimal documentation (e.g., metadata records) will be retained by Newcastle University without additional cost.

Overall, the project's data management needs will be adequately supported by existing University systems, with no exceptional resource requirements.

Planned Research Outputs

Instrument - "Consultation tool"

A co-designed consultation tool to support mental health professionals to conduct improved shared-decision consultations, particularly around the use of psychotropic medications.

Planned research output details

Title	DOI	Type	Release date	Access level	Repository(ies)	File size	License	Metadata standard(s)	May contain sensitive data?	May contain PII?
Consultation tool		Instrument	Unspecified	Open	None specified		None specified	None specified	No	No