Plan Overview

A Data Management Plan created using DMPonline

Title: Project ACCESS - Work Package 3: Analysis of Routinely Collected Jigsaw Electronic Health Record Data to Examine Single Session Therapy Delivery and Outcomes

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Project abstract:

Nearly two-thirds of mental disorders emerge before age 25, yet only a minority of young people have access to adequate mental health care. Timely access to mental health care reduces suffering and improves outcomes, yet Jigsaw have struggled with delays in young people accessing their services due to traditional models of talk therapy care requiring screening and assessment followed by a number of therapy sessions over an extended period. To improve accessibility, Jigsaw introduced single-session therapy as a first pathway to care in June 2023.

Single-session therapy (SST) offer a promising path toward improving accessibility, cost-effectiveness and completion rates for youth mental health services. Evidence supports the capacity of SST to reduce youth mental health difficulties. However, less is known about the implementation of SST in primary care services for young people. Documenting the implementation of SST and assessing intervention fidelity across services in Ireland is essential to ensure the delivery of SST is effective, consistent, and aligned with Jigsaw's intended objectives.

This research aims to:

1. Co-develop a programme theory with clinicians (n=15) and young people (n=15), and conduct a rapid evidence review on SST so that a comprehensive understanding of the intervention's core components will be documented.

2. Develop a fidelity checklist to assess whether single-session therapy is delivered as planned.

3. Evaluate intervention fidelity (provider behaviour) and young people's engagement and acceptability (recipient behaviour) of SST. Clinical case notes of sessions (n=75) and audio recordings (n=30) will be reviewed and reliably rated for fidelity against fidelity checklist. Routine feedback captured on Jigsaw's data system will evaluate youth engagement.

4. Analyze Jigsaw's single session's performance by evaluating access to timely care and improvement in therapeutic goals.

The results will help improve the sustainability of SST delivery across services and ensure best practices are followed in SST delivery across sites in Ireland.

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Project ACCESS - Work Package 3: Analysis of Routinely Collected Jigsaw Electronic Health Record Data to Examine Single Session Therapy Delivery and Outcomes

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?

This work package involves the secondary analysis of a pseudonymised extract of routinely collected Electronic Health Record (EHR) data from Jigsaw's clinical information system (Iaptus). Jigsaw: The National Centre for Youth Mental Health will remain the Data Controller for the original clinical records and will prepare the research extract in accordance with the approved Data Sharing Agreement. No new primary data will be collected for this work package.

New data will be generated through processing and analysis of the extracted dataset. These will include:

- Cleaned and analysis-ready datasets.
- Derived variables (e.g. waiting time variables, care pathway indicators, transition to standard care).
- Descriptive statistics and regression model outputs.
- Annotated statistical analysis scripts and supporting documentation.

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

Kind of data

Secondary quantitative data extracted from Jigsaw's Electronic Health Record system.

The dataset will include:

- Demographic characteristics, where available (e.g. age, gender, ethnicity, disability status)
- Referral source
- Stages of the clinical care pathway
- Appointment attendance
- Waiting times and timely care information
- Measures of clinical need (e.g. GAD-7 and PHQ-9)
- Goal-Based Outcome (GBO) scores at baseline and follow-up
- Jigsaw site information
- Clinician/service variables where required (e.g. clinical discipline, time in role and, where available, SST training).
- Follow-up care/onward referral information[CF1]

Formats

Data will be provided in structured electronic formats such as:

- Excel (.xlsx)
- CSV (.csv)

Derived datasets and analysis files may be stored as:

- · Statistical software files (e.g. SPSS (.sav) and Stata (.dta)).

- · Syntax files.
- · Data dictionary.
- · README documentation.

Volumes

The dataset will include routinely collected records for young people who received care through participating Jigsaw services from January 2025 to August 2026.

The research dataset is expected to comprise approximately 11,000 records and require less than 1 GB of secure digital storage, including derived datasets, statistical analysis files and supporting documentation.

Documentation and data quality

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

Documentation accompanying the research dataset will include:

- Data dictionary (codebook) describing variables
- Coding rules and missing value definitions
- Description of the data extraction process
- Documentation of data cleaning, transformation and derived variables
- Version history
- Annotated statistical analysis scripts.

Metadata will include key descriptive information for each dataset and file, including title, creator, date of creation, data type, version, description and access conditions. Metadata will be recorded in README files, data dictionaries and codebooks and, where appropriate, informed by the Data Documentation Initiative (DDI) standard.

Files will be named using a consistent convention incorporating the date (YYYYMMDD), data type, description and version number (e.g., 20260930_EHRDataset_Clean_V1 or 20261015_RegressionSyntax_V2). Data will be organised within a structured folder hierarchy by project stage (e.g., Work Package 3, Data Extraction, Data Cleaning, Analysis and Outputs), with sequential version control (e.g., V1, V2, Final) applied throughout the project.

What data quality control measures will be used?

Data quality procedures will include:

- Assessment of missing data
- Duplicate record checks
- Consistency checks between related variables
- Review of implausible values
- Validation of derived variables
- Documentation of all cleaning and transformation decisions.

Consistent with the grant proposal, data cleaning and analytical outputs will be independently reviewed by a second member of the research team.

Storage and backup during the research process

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

Following secure transfer from Jigsaw using the UCD-approved FileSender system, the pseudonymised research dataset will be stored within secure, access-controlled UCD-managed systems in accordance with UCD research data management policies and the Data Sharing Agreement. Jigsaw will retain responsibility for the storage and management of the original clinical records, while the research team will be responsible for the secure storage and management of the research dataset.

In line with the grant data management plan, three copies of the research data will be maintained: on secure UCD-managed institutional cloud storage, on an encrypted UCD-managed computer, and on an encrypted offline backup device stored separately from the primary dataset. Regular institutional backups will ensure that data can be recovered in the event of accidental loss or system failure.

All research data will be stored exclusively within UCD-approved secure storage systems appropriate for sensitive research data, with access restricted to authorised members of the research team in accordance with UCD's File Storage and Sharing Guidance.

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

All data handling will comply with the General Data Protection Regulation (GDPR), the Data Protection Acts 1988–2018, UCD data protection policies and the approved Data Sharing Agreement.

Direct personal identifiers (e.g. names, addresses, contact details and dates of birth) will not be included in the research dataset.

Access to the research dataset will be restricted to authorised members of the research team named on the study and approved under the Data Sharing Agreement. All individuals granted access, including students and research assistants, must be named, approved, have completed appropriate data protection and information security training, and be covered by the relevant governance arrangements before access is granted. Access will be managed according to the principle of least privilege, with user permissions granted only where necessary for approved research activities. All data will be stored within secure, access-controlled UCD-approved storage environments and accessed only through password-protected, institutionally managed devices. Encryption will be used during data transfer and storage in accordance with UCD security policies.

Research findings will be reported only in aggregate form. All outputs will undergo disclosure risk review prior to dissemination to minimise the risk of participant re-identification, particularly where reporting small cell sizes or site-level results. The research dataset will not be copied to personal devices or shared outside the authorised research team without the appropriate approvals and governance arrangements.

Any actual or suspected personal data breach involving the research dataset will be managed in accordance with UCD's Data Breach Response Procedure and reported through the University's established governance processes. Jigsaw will be notified immediately of any actual or suspected breach involving the research dataset, in accordance with the Data Sharing Agreement and agreed incident management procedures.

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?

Processing of pseudonymised personal data will comply with the General Data Protection Regulation (GDPR), the Data Protection Acts 1988–2018, UCD data protection policies and the approved Data Sharing Agreement. The processing of personal data is based on participants' consent for the use of their data in research. As the dataset contains special category health data, processing will also be undertaken for scientific research purposes in accordance with the GDPR and applicable data protection legislation. In accordance with the principles of lawfulness, fairness, transparency, purpose limitation, data minimisation, integrity and confidentiality, only the variables necessary to address the approved research objectives will be processed.

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

Jigsaw will remain the Data Controller for the original Electronic Health Record (EHR) data. UCD will be responsible for the management and processing of the approved pseudonymised research dataset for the purposes of the approved research, in accordance with the Data Sharing Agreement, UCD policies and the terms of the HRB funding award. Ownership, use and retention of the research dataset and resulting research outputs will be governed by these approved arrangements.

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

The principal ethical considerations relate to protecting the privacy and confidentiality of young people, ensuring the responsible use of sensitive mental health data, and conducting research in accordance with the approvals and conditions governing the original data collection.

Ethical approval will be obtained from the appropriate University College Dublin Research Ethics Committee and Jigsaw's Ethics Committee prior to commencement of the study. The research will be conducted in accordance with the approved research protocol, the Data Sharing Agreement, and all relevant institutional and professional codes of conduct.

The research team will not attempt to identify or re-identify individual participants. Where required for analysis, an internal study identifier will be assigned to records while maintaining the pseudonymisation applied by Jigsaw.

Given the sensitive nature of youth mental health data, findings will be interpreted and reported responsibly to protect participant confidentiality and minimise the risk of inadvertent disclosure, particularly when reporting results for small subgroups or individual Jigsaw sites.

Data sharing and long-term preservation

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

Due to the sensitive nature of the pseudonymised special category health data and the potential risk of participant re-identification, the individual-level research dataset will not be made publicly available or deposited in a public repository.

Metadata and non-identifiable supporting documentation describing the research process will be made available through the Open Science Framework (OSF), where appropriate and following publication of the main study findings. Research findings will also be disseminated through peer-reviewed open-access publications, presentations, and other appropriate research outputs.

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

The original Electronic Health Record data will be retained by Jigsaw in accordance with its data governance and retention policies.

The pseudonymised research dataset generated for WP3 will be securely retained within UCD-managed storage systems for **10 years following study completion,** in accordance with UCD data retention requirements and the approved data governance arrangements.

Following the 10-year retention period, the research dataset will be securely deleted from UCD-managed storage systems in accordance with UCD records management and secure disposal procedures. Dr Amanda Fitzgerald, as Principal Investigator, will be responsible for ensuring that secure destruction is completed and that Jigsaw is notified in accordance with the Data Sharing Agreement and agreed governance arrangements.

To support FAIR data principles, non-identifiable research materials, including metadata, data dictionaries, codebooks and documentation describing data processing and analysis procedures, will be made available through the Open Science Framework (OSF) where appropriate. No shared materials will contain information that could identify individual participants.

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

The dataset will be accessed and analysed using statistical software such as SPSS and Stata for descriptive and regression analyses.

Data and associated documentation will be stored in commonly used, machine-readable formats, including CSV for structured datasets and Excel, PDF and text-based formats for documentation, data dictionaries and supporting materials. Where applicable, analysis-specific formats (e.g., SPSS or Stata files) will be retained alongside relevant documentation to support reproducibility.

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

As the individual-level research dataset will not be publicly deposited, it will not be assigned a public persistent identifier. Instead, non-identifiable research outputs, including metadata and documentation describing the dataset and research processes, will be made available through the Open Science Framework (OSF) where appropriate.

Where supported by the selected repository, persistent identifiers such as Digital Object Identifiers (DOIs) will be assigned to shared research outputs to support discoverability, citation and long-term access. Any shared materials will exclude information that could identify individual participants and will comply with data protection and governance requirements.

Data management responsibilities and resources

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

Overall responsibility for data management will be shared between Jigsaw: The National Centre for Youth Mental Health and the University College Dublin (UCD) research team, in accordance with their respective roles and responsibilities.

Jigsaw will be responsible for the governance and management of the original Electronic Health Record data and for preparing the approved research extract.

Within UCD, the Postdoctoral Researcher will have day-to-day responsibility for implementing the Data Management Plan, including management of the research dataset, documentation, quality assurance and compliance with the approved governance arrangements.

Dr Amanda Fitzgerald, as Principal Investigator, will have overall responsibility for oversight of the Data Management Plan and for ensuring compliance with legal, ethical and governance requirements throughout the project.

Authorised members of the research team will undertake data management activities under the supervision of the Postdoctoral Researcher and Principal Investigator.

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)?

Dedicated staff time and institutional resources have been allocated throughout the project to support data management activities in accordance with HRB requirements and FAIR principles.

UCD-managed secure storage systems will support the protection, organisation and retention of research data throughout the project lifecycle. Resources will also support the creation of supporting documentation, including data dictionaries, codebooks, data processing records and analysis documentation, to enhance transparency and reproducibility.

FAIR principles will be supported through:

- **Findable:** Metadata describing the dataset and associated documentation will be shared where appropriate. [AF1]
- **Accessible:** Individual-level data will not be publicly available due to confidentiality requirements; non-identifiable outputs will be shared where appropriate.
- **Interoperable:** Data and documentation will be stored in widely used, machine-readable formats.
- **Reusable:** Supporting documentation will accompany shared outputs to facilitate appropriate interpretation and reuse.