Plan Overview

A Data Management Plan created using DMPonline

Title: Project ACCESS - Work Package 2: Development of a Fidelity Measure and Assessing the Implementation Fidelity of Single Session Therapy Delivery in Jigsaw

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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 2: Development of a Fidelity Measure and Assessing the Implementation Fidelity of Single Session Therapy Delivery in Jigsaw

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 will involve both the collection of new primary research data and the re-use of existing routine clinical and documentary data to develop, pilot and evaluate a fidelity measure for Single-Session Therapy (SST) delivery in Jigsaw.

New primary data will be collected through:

- · Consultation meetings with Jigsaw's SST implementation team to refine the fidelity checklist and accompanying coding guidelines.
- · Feedback from clinicians regarding the content, usability and acceptability of the fidelity checklist.
- · Debrief telephone calls with participating clinicians following SST delivery.
- · Anonymous audio recordings of consenting SST sessions to assess fidelity of delivery.
- · Researcher coding and fidelity assessments using the developed checklist.

Existing data will be re-used through:

- · Published fidelity measures identified through a review of the literature.
- · The programme theory developed during WP1.
- · Anonymised clinician case notes from consenting clinicians and young people.
- · Routine pseudonymised data extracted from Jigsaw's Electronic Health Record (EHR) system, including the Youth Service Satisfaction Survey and additional fidelity questions introduced as part of the project.

New data generated during the work package will include:

- · Iterative versions of the fidelity checklist
- · Coding guidelines
- · Consultation notes
- · Anonymised transcripts of clinician debriefs
- · Coded fidelity assessments
- · Derived fidelity scores
- · Quantitative analysis datasets
- · Statistical outputs
- · Qualitative analysis outputs
- · Documentation describing revisions made during checklist development.

These data will support development of a valid and reliable fidelity measure and enable assessment of fidelity of delivery, intervention receipt, intervention enactment and acceptability of SST across Jigsaw services.

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

Kind of data

This work package will generate both qualitative and quantitative research data.
Data will include:

- · Consultation notes
- · Clinician feedback
- · Clinician debrief recordings and transcripts (where applicable)
- · Anonymous audio recordings of SST sessions
- · Anonymised clinician case notes
- · Routine EHR survey responses
- · Fidelity checklist coding forms
- · Coding guidelines
- · Fidelity scores
- · Descriptive statistics
- · Content analysis coding frameworks
- · Statistical analysis datasets
- · Documentation relating to checklist development and validation.

Formats
Data are expected to be stored in commonly used electronic formats including:

- · Word (.docx)
- · Excel (.xlsx)
- · PDF
- · NVivo project files (.nvp)
- · Statistical software files (e.g. SPSS and Stata)
- · Audio files (.mp3)
- · PowerPoint (.pptx).

Volumes
The work package is expected to include:

- · Consultation meetings with the implementation team
- · Clinician consultation feedback
- · Pilot coding of approximately five anonymised case notes
- · Independent coding of a further 10–15 anonymised case notes during checklist refinement
- · Fidelity coding of approximately 60–75 anonymised clinician case notes
- · Anonymous audio recordings of approximately 15–30 SST sessions
- · Clinician debrief calls
- · Routine EHR data from young people attending SST across participating Jigsaw services during the study period.

The work package is expected to generate approximately 5 GB of research data, including audio recordings, transcripts, anonymised case notes, fidelity coding files, statistical datasets 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 data will include:

- · Participant information leaflets and consent forms
- · Fidelity checklist versions
- · Coding manuals and guidance documents
- · Clinician debrief schedules
- · Consultation topic guides
- · Codebooks
- · Statistical syntax files
- · Qualitative coding documentation
- · Data dictionaries for EHR variables
- · README files
- · Version histories documenting revisions to the fidelity checklist and coding guidance.

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

Files will be named using a consistent convention incorporating the date (YYYYMMDD), document/data type, description and version number (e.g., 20261001_FidelityChecklist_V2 or 20261115_EHRDataset_Clean_V1). Data will be organised within a structured folder hierarchy by project stage (e.g., Work Package 2, Checklist Development, Data Collection, Fidelity Coding, Analysis and Outputs), with sequential version control (e.g., V1, V2, Final) applied throughout the project.

What data quality control measures will be used?

Quality assurance procedures will include:

- · Standardised coding guidance for all researchers
- · Pilot testing of the fidelity checklist
- · Independent double-coding of clinical case notes
- · Calculation of Cohen's weighted kappa and percentage agreement
- · Refinement of coding guidance following discrepancies
- · Verification of quantitative datasets prior to analysis
- · Validation of derived fidelity scores
- · Documentation of all coding, cleaning and analytical decisions.

Storage and backup during the research process

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

Research data will be stored within secure, access-controlled University College Dublin (UCD) systems in accordance with UCD Research Data Management policies, GDPR and the approved Data Sharing Agreement with Jigsaw[CF1] . Audio recordings, anonymised case notes, coding files, fidelity datasets, statistical outputs and associated documentation will be stored within structured project folders.

Three copies of research data will be maintained through:

- Secure UCD-managed institutional cloud storage

- Encrypted UCD-managed computers
- Encrypted offline backup stored separately from the primary dataset.

Only approved members of the research team will have access to study files.

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

The work package involves potentially sensitive qualitative and quantitative data relating to youth mental health service delivery.

All processing will comply with GDPR, the Data Protection Acts 1988–2018 and UCD data protection policies. Clinical case notes supplied for fidelity assessment will be anonymised prior to researcher access.

Routine EHR data will be provided as pseudonymised extracts prepared by Jigsaw, who will remain Data Controller for the original records.

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.

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.

Audio recordings will only be collected following informed consent from clinicians and young people (and parents/guardians where required), securely transferred following collection and deleted once transcription, verification and fidelity coding have been completed.

Participant identifiers and consent documentation will be stored separately from research data, with access restricted to authorised researchers.

All members of the research team will install operating system and application updates when they are available, install Sophos endpoint protection software provided by UCD and use a secure network connection when connected to the Internet. While on campus either the cabled network or the Eduroam Wi-Fi network will be used and when off-site the Staff Virtual Private Network (VPN) will be used to secure the network connection.

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 collected for recruitment, informed consent and research participation will be processed in accordance with GDPR, the Data Protection Acts 1988–2018 and UCD data protection policies. Research data will be pseudonymised prior to analysis, with identifiable participant information stored separately and accessible only to authorised members of the research team where required. 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 GDPR and applicable data protection legislation. All processing will comply with the principles of lawfulness, fairness, transparency, purpose limitation, data minimisation, integrity and confidentiality.

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

The study will comply with GDPR, the Irish Data Protection Acts 1988–2018 and UCD research governance policies. Jigsaw will remain the Data Controller for any existing service data used in WP2, while UCD will be responsible for the management and processing of research data generated through the development and validation of the fidelity checklist in accordance with approved governance arrangements.

Intellectual property relating to the fidelity checklist, coding guidance, analytical outputs and associated research materials will be managed in accordance with UCD policies and any collaboration agreements between UCD and Jigsaw. Published fidelity measures reviewed during checklist development will be used in accordance with copyright legislation and appropriate academic citation practices.

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

Ethical approval will be obtained from the appropriate University College Dublin Research Ethics Committee and Jigsaw Research Ethics Committee before commencement.

Key ethical considerations include:

- · Informed consent from clinicians and young people.
- · Parental consent and participant assent where required.
- · Confidentiality of clinical information.
- · Secure handling of audio recordings.
- · Minimising participant burden.
- · Protection of sensitive mental health information.

The informed consent process will provide participants with information on how their data will be processed, including analysis, secure storage and retention. Participants will also be informed about the potential future use of pseudonymised data for approved research purposes.

Only anonymised clinical case notes will be used for fidelity coding.

Participation in audio recording and clinician debrief interviews will be entirely voluntary and will not affect clinical care and this will be made known to participants.

Participants may withdraw from the study at any stage in accordance with ethical approval procedures.

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 inclusion of sensitive qualitative materials, anonymised clinical case notes, audio recordings and pseudonymised routine clinical data, individual-level datasets will not be made publicly available.

Research findings will be disseminated through peer-reviewed publications, conference presentations and reports.

Where appropriate, metadata, methodological documentation and non-identifiable research materials will be shared through the Open Science Framework (OSF).

Any quotations included in publications will be fully anonymised and reviewed to minimise the risk of participant identification

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

Research data will be securely retained within UCD-managed storage systems for a minimum of ten years following study completion in accordance with UCD Research Data Management policies.

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.

Audio recordings will be securely deleted following transcription, transcript checking and pseudonymisation. Consent forms and participant contact information will be retained separately from research data in accordance with ethical and legal requirements.

Due to the potentially identifiable nature of qualitative data, including participant experiences and contextual information, raw transcripts will not be deposited in a public repository. Where appropriate, non-identifiable research outputs, including summarised findings, programme theory documentation, metadata and analytical documentation, may be shared through appropriate platforms to support transparency and future research reuse.

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

Qualitative data will be analysed using NVivo.

Quantitative analyses will be undertaken using appropriate statistical software (e.g. SPSS and Stata).

Documents will be stored using commonly available formats including Word, PDF, Excel, audio formats and image formats.

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

The qualitative dataset will not be assigned a public DOI because it contains sensitive qualitative data that cannot be openly shared.

Where appropriate, metadata and non-identifiable study documentation deposited in repositories such as the Open Science Framework will receive persistent identifiers to support citation, discoverability and long-term access.

Data management responsibilities and resources

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

The Postdoctoral Researcher will have day-to-day responsibility for participant recruitment, data collection, secure storage, organisation, fidelity coding, statistical analysis, qualitative analysis and preparation of research outputs.

The Research Assistant will support data collection, transcription, fidelity coding, quality assurance and data management activities under the supervision of the Postdoctoral Researcher.

Dr Amanda Fitzgerald will oversee implementation of the Data Management Plan and ensure compliance with ethical, legal and governance requirements.

The wider research team will contribute to checklist development, interpretation of findings, quality assurance and dissemination of results.

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 researcher time has been allocated throughout the project for participant recruitment, transcription, fidelity coding, statistical analysis, documentation, secure data management and preparation of research outputs.

UCD-managed secure storage infrastructure will support long-term preservation of research data and documentation.

FAIR principles will be supported through:

- · **Findable:** Metadata describing the study will be made available through OSF where appropriate.
- · **Accessible:** Sensitive qualitative data will not be publicly shared, but non-identifiable documentation and publications will be openly available where possible.
- · **Interoperable:** Data and documentation will be stored using widely used, non-proprietary formats where feasible.
- · **Reusable:** Sufficient methodological documentation will accompany shared outputs to support interpretation and appropriate reuse. Where non-identifiable materials are made publicly available, an appropriate reuse licence (e.g., CC BY 4.0) will be applied to clearly define permitted use and support responsible reuse.