Plan Overview

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Title: Project ACCESS - Work Package 1: Co-development of a Programme Theory for Single-Session Therapy Delivery in Jigsaw

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Funder: Health Research Board (HRB) Ireland

Template: Health Research Board DMP Template

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.

ID: 208792

Start date: 01-09-2026

End date: 01-02-2027

Last modified: 06-08-2026

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Project ACCESS - Work Package 1: Co-development of a Programme Theory for 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 qualitative data and the re-use of existing documentary evidence to co-develop a programme theory for Single-Session Therapy (SST) delivery in Jigsaw using the Action Effect Method (AEM).

New qualitative data will be collected through:

· Online pre-workshop meetings with 1). The Project ACCESS Steering Committee (n=7), and 2). with Jigsaw staff (n=5) to clarify the purpose, scope, and objectives of the programme theory.
· A co-production workshop with Jigsaw staff (approximately n=15), including clinicians, service managers and operational leads.

- A co-production workshop with young people (aged 12-18, n=15), and a second workshop with young people (aged 18-25, n=15) with experience of accessing SST in Jigsaw.
- Feedback and sense-checking of the draft Action Effect Diagram by workshop participants.

Existing data will be re-used through:

- A rapid review of the international literature on SST implementation in youth mental health services
- A review of internal Jigsaw documents including service manuals, implementation plans, training materials, programme documentation, evaluation reports, presentations, systems maps, funding proposals and other relevant documentation.

Data collected and generated during the work package will subsequently be analysed to co-develop the Programme Theory and Action Effect Diagram for SST delivery in Jigsaw.

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

Kind of data

This work package will generate predominantly qualitative data together with supporting documentary and analytical materials.

Data collected will include:

- Audio recordings of workshops using Dictaphones and Zoom recording function [CF1] for online

and in-person meetings (where consent is provided)
- Verbatim transcripts
- Facilitator notes
- Field notes
- Participant-generated workshop materials
- Internal organisational documents
- Extracted evidence tables
- Qualitative coding frameworks
- Framework Analysis matrices
- Behaviour Change Technique coding tables
- Action Effect Diagrams
- Programme theory diagrams
- Quality appraisal scoring sheets.

Formats

Data will be stored in commonly used electronic formats, including:

- Word (.docx)
- PDF
- Excel (.xlsx)
- NVivo project files (.nvp)
- Image files (.png/.jpeg) for workshop outputs and Action Effect Diagrams
- PowerPoint (.pptx)
- Audio files (.mp3) where recordings are undertaken.

Volumes

The work package is expected to include:

- One implementation team meeting (n=5).
- One Project ACCESS steering committee meeting (n=7).
- One Jigsaw staff workshop (n=15).
- Two young people's workshop (one aged 12-18 years n=15, one aged 18-25 years n=15).
- One rapid review of published and grey literature and internal service documents[CF2]

The resulting qualitative dataset is expected to comprise several hours of audio recordings (where applicable), verbatim transcripts, field notes, documentary extraction tables, coding frameworks and multiple iterative versions of the programme theory, generating approximately 5 GB of digital research data.

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:

- Workshop topic guides
- Participant information leaflets and consent forms
- Document review extraction forms
- Literature search strategy and screening documentation
- Codebooks
- NVivo project documentation (where applicable)
- Version histories of the Programme Theory and Action Effect Diagram
- Documentation describing coding procedures
- README files describing folder structures and file contents.

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 and codebooks. Where appropriate, metadata will be 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., 20260915_Workshop1_Transcript_V1). Data will be organised within a structured folder hierarchy by project stage (e.g. Work Package 1, Data Collection, Workshops, Document Review, 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 will be maintained through:

- Use of standardised workshop topic guides
- Audio recording and researcher-produced (using Zoom transcription function[CF1]) verbatim transcription (where consented)
- Checking transcripts against recordings for accuracy
- Systematic document extraction using predefined templates
- Framework Analysis using an agreed coding framework
- Independent review of coding and programme theory development by members of the research team
- Documentation of coding decisions and revisions
- Independent scoring of the programme theory using Issen et al.'s appraisal criteria with assessment of inter-rater reliability.

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 and GDPR.

Audio recordings, transcripts, workshop materials, document review data, coding files, Action Effect Diagrams, programme theory diagrams and associated documentation will be stored together within a structured folder hierarchy.

Audio recordings and any files containing directly identifiable information will be securely deleted

following transcription and pseudonymisation. Any documentation relating to pseudonymisation procedures or participant identifiers will be stored separately with restricted access.

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?

Although this work package does not involve routine clinical records, it will involve collection of potentially sensitive qualitative information from staff and young people regarding experiences of service delivery. All data handling will comply with the General Data Protection Regulation (GDPR), the Data Protection Acts 1988–2018 and UCD data protection policies.

Participants will be assigned study identification numbers and transcripts will be pseudonymised before analysis. Direct identifiers will be removed from transcripts wherever possible.

Audio recordings will be securely transferred from recording devices immediately following workshops and deleted once transcription and verification have been completed.

Access to identifiable data (e.g. consent forms and participant contact details) will be restricted to authorised members of the research team and stored separately from research data.

Findings will be reported only in aggregate form and anonymised quotations will be carefully reviewed to minimise the risk of participant identification. 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. 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. 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.

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 participant recruitment and informed consent will be processed in

accordance with GDPR, the Data Protection Acts 1988–2018, UCD policies and the approved Data Sharing Agreement. Research data will be pseudonymised prior to analysis, with access to identifiable information restricted to authorised members of the research team where required for study administration.

The processing of personal data is based on the data subject's 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. All data processing activities will follow 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 be conducted in accordance with GDPR, the Irish Data Protection Acts 1988–2018 and University College Dublin research governance policies.

Intellectual property relating to study outputs, including the Programme Theory, Action Effect Diagram and associated analytical materials, will be managed in accordance with UCD policies and the collaboration agreements established between UCD and Jigsaw.

Published literature reviewed as part of the rapid review will be managed in accordance with copyright legislation and institutional licence agreements.

UCD will act as the Data Controller for the qualitative research data collected and generated, including analysis and dissemination. Jigsaw will remain the Data Controller for any existing service data used to support recruitment. UCD will retain responsibility for the management and retention of WP1 research data following project completion in accordance with UCD policies and data protection requirements.

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 before commencement.

Key ethical considerations include:

- Obtaining informed consent (and parental consent/young person assent where applicable)
- Protecting confidentiality
- Safeguarding young participants
- Ensuring participation is voluntary
- Minimising potential distress during workshops.

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

The workshops are designed to focus on understanding and improving SST delivery rather than discussing participants' personal mental health experiences. A Jigsaw Youth Voice Manager and/or appropriate clinical staff will be present during youth workshops to provide support should any participant become distressed.

Participants may withdraw from the study at any time without consequence.

Data sharing and long-term preservation

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

Because the dataset contains identifiable qualitative data and potentially sensitive discussions regarding mental health services, the full qualitative dataset will not be made publicly available.

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

Where appropriate, metadata, study documentation and methodological materials (excluding identifiable data) will be deposited in 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 and workshop data 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.

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

Action Effect Diagrams and Programme Theory models may be developed using Miro, Microsoft PowerPoint or other diagramming software and exported as PDF and image files.

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 and research team will have day-to-day responsibility for participant data collection, organisation, secure storage, transcription oversight, qualitative analysis and preparation of research outputs.

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

The wider research team [CF1] (Dr Jeff Moore, Dr Sheena McHugh, Dr Jim Lyng, Dr Jason Smith, Dr Conor Boksberger, Dr Rachel Brown and Prof Julie Reed) will contribute to programme theory development, qualitative analysis, interpretation of findings and quality assurance throughout the project.

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 and UCD institutional infrastructure have been allocated to support secure data management, documentation, storage, preservation and sharing throughout the project.

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.