Plan Overview

A Data Management Plan created using DMPonline

Title: Improving adoption of mental health interventions among low-income university students in Brazil

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Project abstract:

Digital mental health interventions can increase access to care in a scalable and low cost way and reduce burden on health systems; however, a key limitation is their ability to engage users over a sustained period. This project will test two implementation strategies for increasing adoption of an existing evidence-based digital mental health intervention (e-CBT) among low-income university students in Brazil. We hypothesise that combining the digital intervention with: i) a conditional cash transfer (CCT) intervention and (ii) peer support would facilitate implementation outcomes.

Methods

First, we will adapt an existing evidence-based digital group-based CBT intervention and associated implementation strategies (CCT and / or peer support) for use with low-income university students in Brazil. To ensure implementation strategies are maximally congruent to culture and context, we will utilise the "what matters most" approach to optimise these implementation strategies' impacts upon implementation outcomes by focusing adaptation of implementation strategies to what is "most valued" by low-income university students.

Following adaptation, we will undertake a four-arm cluster feasibility study among 32 low-income students from 4 universities (clusters). Participants will be randomised to: 1) digital mental health intervention only, 2) e-CBT+CCT, 3) e-CBT+peer support, or 4) e-CBT+CCT+peer support. After the pilot, we will conduct a four-arm cluster effectiveness implementation hybrid type 3 RCT among 1958 low-income students (4 arms/cluster).

Participants will be randomised to: 1) digital mental health intervention only, 2) e-CBT+CCT, 3) e-CBT+peer support, or 4) e-CBT+CCT+peer support.

We would then model potential mid to longer term mental health and associated social and economic impacts resulting from the different intervention implementation strategies relative to e-CBT only. We would construct decision analytic models to estimate potential economic costs and benefits from increasing adoption/engagement and reducing mental health problems relative to costs of intervention implementation from a societal perspective.

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Improving adoption of mental health interventions among low-income university students in Brazil

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0. Proposal name

0. Enter the proposal name

Improving adoption of mental health interventions among low-income university students in Brazil

1. Description of the data

1.1 Type of study

The study encompasses activities related to the adaptation and pilot evaluation of a digital mental health intervention. It also includes a four-arm cluster effectiveness implementation hybrid type 3 RCT, designed to assess implementation strategies aimed at enhancing adoption of the digital mental health intervention.

1.2 Types of data

The project will generate and collect quantitative (comprising data collected using online surveys) and qualitative data (from interviews and focus groups).

1.3 Format and scale of the data

Data will be stored electronically. Qualitative data will be stored either in NVivo 10.0 or similar programmes that are used locally. Quantitative data will be collected and stored via Redcap and analysed either in Stata or R. All statistical programmes used enable sharing and long-term validity of results.

2. Data collection / generation

2.1 Sources of data

Qualitative data: Qualitative interviews and focus groups will be performed by trained local interviewers in Sao Paulo and qualitative interview data will be collected either in person at the local university or online via Microsoft Teams or Zoom, depending on the participant's preference, as we

have done previously in Brazil. Focus groups will be conducted during a student meeting hosted by UNICEF in a private room. With the permission of participants, qualitative interviews and focus groups will be audio-recorded and transcribed into the local language before being coded for analysis.

Quantitative data: will be collected using Online surveys administered using RedCap. RedCap is a secure web-based application designed for data collection and management in research studies. Electronic surveys will be created employing validated instruments to assess sociodemographic and clinical characteristics of participants. These surveys will be conducted: 1) prior to qualitative interviews and focus groups, and 2) at baseline and follow-up points for the pilot and RCT evaluations. All data will be managed by the Data Manager.

2.2 Data quality and standards

All interviewers will undergo rigorous training in administration of the project questionnaires and procedures, including e.g., confidentiality. Project PI (SEL) and Scientific Coordinator (CZ) will monitor data quality and random quality checks will be performed. Any data collected will be periodically downloaded and saved to a secure server at the local university and all data will be transferred to LSE storage via an encrypted channel. The study PI (SEL) and Scientific Coordinator (CZ) have experience in secure methods of data storage and transfer. We will ensure that any person identifiable data processed complies with the General Data Protection Act (GDPR) UK Data Protection 2018 and Lei Geral de Proteção de Dados (LGPD), 2021. Where MP3 recordings are taken for the qualitative elements of the research, notes will assist transcription of any poor-quality audio. During analysis, transcripts will be analysed by an experienced second coder using a structured codebook to assess inter-coder reliability, and both coders will meet regularly to discuss any disputes in the coding process. The quality of data collection will be supervised by senior researchers in the team, with overall supervision by the PI.

Quantitative data quality will be reviewed every week by the Data Manager. Built-in validation rules and automated data quality checks within RedCap will be used to minimize errors and ensure data accuracy. RedCap forms will include validation checks to ensure data accuracy and completeness. Periodic data audits and reviews will be conducted to identify and rectify inconsistencies. Data cleaning procedures will involve identifying and correcting errors or inconsistencies in the dataset.

2.3 Consent for data sharing and re-use

We will ensure that access to and use of data will be made available in ways that are equitable, ethical and efficient. Data will be shared with collaborators according to predefined access permissions. Data requests will be reviewed and approved by the data management team. Data sharing will follow institutional policies and regulatory requirements.

Participants will be informed about the objectives and procedures of data sharing and will provide consent to participate in the study being aware of the data sharing objectives and procedures. They will be aware that data will be de-identified prior to sharing or publication to prevent re-identification.

3. Data management, documentation and curation

3.1 Managing, storing and curating data

All quantitative data will be stored in RedCap and then exported in text-delimited format, which can be used in all computer platforms or in STATA or R software package file or in any other format needed by the collaborators. Data files will be stored in well-organised folders and file names. Quality checks of the database will take place by double-checking, for example, out-of-range values, double entry of data and performing statistical analyses such as frequencies, means ranges to detect errors and anomalous values. All data will be psudonymised for analysis and will be accessible to the project investigator. Project data will be automatically backed up to local servers. Identifying data will be kept as a separate list with identifying codes which will be used on the research records. The document linking the project identification number with personal data will only be accessible to the study research team. Only anonymised data will be used for analyses. With the permission of participants, qualitative interviews and focus groups will be audio-recorded, will then be transcribed in the local language. Files of anonymised transcripts will be secure.

3.2 Metadata standards and data documentation

Metadata will be structured to international standards of schemes such as Data Documentation Initiative (DDI). The metadata for this study will consist of a detailed data dictionary. We will follow the DDI regulations and provide: names, labels and descriptions of variables; records and their values explanation or definition of codes and classification schemes used; definitions of specialist terminology and acronyms used; and codes of, and reasons for, missing values. A research protocol detailing the methods by which data will be generated and collected will be produced at the beginning of the project. All data will be electronically stored and coded in a way that is understandable to researchers outside of the research team, in case data will be shared at a later time point. Analyses of qualitative data will be undertaken using thematic analysis.

3.3 Data preservation strategy and standards

As described in the UK archive report (https://us.sagepub.com/en-us/nam/managing-and-sharing-research-data/book240297), we will keep a single master file of data; regulate write access to master versions of data files; record all changes to master files; maintain old master files in case later ones contain errors; archive copies of master files at regular intervals; develop a formal procedure for the destruction of master files. All data will be stored electronically in anonymised form for a minimum of seven years, in accordance with LSE requirements, or in accordance with best practice in Brazil and when no longer required the data will be destroyed, both at study sites and at the co-ordinating centre. Audio data recordings will be destroyed after transcription is complete and verified. All data will be password-protected.

4. Data security and confidentiality of potentially disclosive personal information

4.1 Formal information/data security standards

Our data management will be fully aligned with MRC Guidance on Personal Information in Medical Research, and MRC information security policy, and with the requirements of all partner institutions. The formal data security standard adhered to is UK Data Protection Act 2018 and Lei Geral de Proteção de Dados (LGPD), 2021.

4.2 Main risks to data security and how they will be managed

Encrypted data from Brazil will be transferred to LSE using RedCap storage service. All files kept in this manner are managed and backed up by the college's IT department. Study researchers will undergo in-depth training in proper data management, including maintenance of confidentiality and ensuring privacy during data collection. Data will be utilised in conformity with the consent provided by participants. Any data on paper will be kept in a secure cupboard/repository in the project site office. These measures have been used in our previous research projects and have proven feasible and effective. We shall develop and use Standard Operating Procedures in place for all research activities. As part of this protocol, any adverse events that happened within the scope of the project will be systematically documented, reported and reviewed.

5. Data sharing and access

5.1 Suitability for sharing

It is anticipated that the data generated by the formative research, pilot and RCT will be suitable for sharing.

We will align procedures with the Data Sharing Protocol based both upon the data needs of the study researchers, and upon current standards of best practice, and in line with MRC policy. Only anonymised data will be shared within the study team and in accordance with the project data-sharing policy. The study will generate data that may be of interest for other researchers, policymakers or service users within the study and related sites. In principle we shall make data available to others and will create a system to facilitate use of the data. Interested parties will need to complete a proforma that will ask for the specific research question and data needed. The research team will provide an independent view on the scientific merits of the request. We shall ensure that no reasonable request will be refused and there will not be unnecessary delays in providing access. Our data sharing procedure will be guided by: (1) the need to ensure that the datasets are first used to address the primary aims of the project; (2) every effort will be made to offer unrestricted access thereafter, with the only proviso being the continued protection of the anonymity of participants; and (3) due acknowledgement is given by subsequent users to the original source of the data. We will work to ensure that the data, whenever it is to become available to the public, is understandable. Data would be shared only using the anonymous ID number, without any identifying personal information.

5.2 Discovery by potential users of the research data

The data archive will be advertised on the project website, MRC gateway, and LSEs RDM. Metadata, and study questionnaires will be on the project website, as will the data sharing policy.

5.3 Governance of access

Information on data sharing procedures will be made available upon enquiry by a potential

investigator. In principle we shall make data available to others and will create a system to facilitate use of the data. Interested parties will need to complete a proforma that will ask for the specific research question and data needed. Investigators who wish to use the data archive will complete an application form, which will be assessed by the PPIs. Decisions by PI will be guided by the Study team.

5.4 The study team's exclusive use of the data

Data will be made available to others outside of the research team after completion of the project (i.e. after 12 months), though data may be made available earlier than that if the reasons for this are well justified and this does not put the publication of data by the research team at risk

5.5 Restrictions or delays to sharing, with planned actions to limit such restrictions

The consent procedures (participant information sheets and consent forms) will highlight that data may be shared with researchers outside of the research team. Participant information sheets and consent forms will have the procedures for data sharing clearly laid out, and any potential risks will be explained to participants. Shared data will be effectively anonymised.

5.6 Regulation of responsibilities of users

Users will sign a legally binding data use agreement, the main requirements being not to identify participants, to use the data only for the purposes requested, not to share with other users, and to acknowledge the collectors of the data, and the funders. External users of data will be required to complete a proforma that will ask for the specific research question and data needed. On acceptance, external users will be required to complete a Memorandum of Understanding.

5.7 Working with overseas collaborators or data users

Data without personal identification will be shared between partner institutions who will collaborate on data analysis through secure data sharing processes on the REDCap-UNIFESP (Universidade Federal de São Paulo) platform (https://redcap.epm.br/). All data storage and sharing will be maintained in accordance with Brazil's General Data Protection Law and the United Kingdom's Data Protection Law.

To prevent unauthorized access to data saved on the equipment used for data processing, all computerized data will be stored on secure servers of each partner institution.

All researchers with access to the data will receive training on risk management and confidentiality concerning the data and will be required to sign statements agreeing to protect the security, integrity, and confidentiality of the participants.

6. Responsibilities

6. Responsibilities

Dr Evans-Lacko (PI at LSE), Carolina Ziebold (Scientific coordinator at UNIFESP), Ioannis Bakolis (Statistician at KCL) and Data Manager (at UNIFESP) will be responsible for the study data management, including metadata creation, data security and quality assurance of data.

7. Relevant policies

7. Relevant institutional, departmental or study policies on data sharing and data security

Policy	URL or reference
Data Management Policy and Procedures	Project-specific procedures are established using the LSE's frameworks: https://info.lse.ac.uk/staff/divisions/Secretarys-Division/Information-Rights-and-Management/GDPR; https://info.lse.ac.uk/staff/services/Policies-and-procedures/Assets/Documents/resDatManPol.pdf
Data Security Policy	https://info.lse.ac.uk/staff/services/Policies-and-procedures/Assets/Documents/datProPol.pdf
Data Sharing Policy	e.g. a *study policy of sharing research data*
Institutional Information Policy	Information Security Policy: https://info.lse.ac.uk/staff/services/Policies-and-procedures/Assets/Documents/infSecPol.pdf
Other	Data Processing outside EEA by Collaborators – Minimum Standards: https://info.lse.ac.uk/staff/services/Policies-and-procedures/Assets/Documents/internal/staffAndStudents/minStaEEACol.pdf
Other	General Data Protection Law, Brazil: *Lei Geral de Proteção de Dados* https://www.gov.br/esporte/pt-br/acesso-a-informacao/lgpd

8. Author

8. Author of this Data Management Plan (Name) and, if different to that of the Principal Investigator, their telephone & email contact details

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