Plan Overview

A Data Management Plan created using DMPonline

Title: PhD - Nutritional Psychiatry

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Project abstract:

The prevalence of individuals with an Enduring Mental Health Difficulty (EMHD) is a significant concern globally and it is well-recognised that these individuals experience a 20-year mortality gap compared to the general population. Emerging research is showing a strong link between nutrition and EMHD, poor diet quality and negative eating habits contribute towards health disparities, adverse effects on wellbeing and sleep problems. Additionally, technology has shown effectiveness in behaviour change interventions with this population group, however, little is known about how effective these technologies are at improving eating habits or behaviours in EMHD. This research aims to explore the nutrition behaviours of individuals with an EMHD, focusing on developing an effective digital nutrition intervention to promote healthier eating habits and behaviours in this population.

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PhD - Nutritional Psychiatry

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?

New data will be collected by a number of ways:
Study 1: Behaviour Analysis

1. Observations (x4 locations) of service users nutritional behaviours throughout the meal times (breakfast, lunch, dinner).
2. Questionnaire to staff based on COM-B model.

Study 2: Co Design Using BCW and PPI Groups
Data will be collected by PPI Discussions (x3) 45min-1hr long

1. Introductory session

1. Development session

1. Feedback session

Study 3: Intervention (Tbc)

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

Study 1: Observational data
Types: observations of nutritional behaviours in mental health hostels, including kitchen activities (meal practices, menus, food provided), and service users eating behaviours (e.g., slow fast, other food eaten, how much food eaten, drinks consumed).

Format: Recorded notes, photographs of food menus

Volume: 46 residents available for observations depending on number that consent

Questionnaire: Responses from staff on statements based on COM-B model (capability, opportunity, mobility) in relation to their nutrition behaviours and use of technology.

Format: structured questionnaire responses (likert scale from strongly disagree to strongly agree) both electronically and on paper.

Volume: Dependent on number of staff that complete aiming for 30+

Study 2: Co design data
Types: Discussion groups (x3),

1- An introductory session, explaining the specific target behaviour, the purpose of the PPI group, their roles to the research process, and data from the first study.

2- Explanation of the nine types of intervention options, and to identify potential content and implementation options. The data from study 1 will be represented and linked to appropriate

intervention options. Behaviour Change Techniques (BCTs) will also be discussed and the most appropriate BCTs will be shortlisted. Mode of delivery including technology, duration will also be discussed in meeting 2.

3- Thoughts and perceptions of the intervention any other feedback or ideas.

Volume: at least 3 service users and 3 staff members

Study 3: Intervention data

TBC

Documentation and data quality

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

1. **Study Protocols**: description of study protocol, including research objectives, study design, data collection methods, ethical considerations.
2. **Data coding protocols:** for coding of qualitative data (Thematic Analysis - Braun and Clarke) to ensure consistent coding of qualitative data.
3. **Ethical approval** (CREC & MTU) approval from CREC and MTU ethics will be got before study 1 Behaviour analysis (2024) and 2: The intervention.
4. **Information Sheets and Consent Forms:** Information sheets and consent forms will be administered to all eligible individuals at all parts of this PhD project. The consent form must be signed before the participants can partake in any part of the study. Participants will have a chance to answer questions with the researcher before signing the consent form. All service users are assumed to have the capacity to consent but the associated psychiatrist in each residence will also evaluate each participant's capacity to consent. Inclusion criteria for participants include the capacity to understand the research and consent to the research (Assisted Decision-Making (Capacity) Act 2015). Those deemed not to have the capacity will not be invited to participate. Participants can withdraw at any time should they wish to do so, without reason and without any detriment. If they are unwell at the point of study commencement, or at any point during the study, they can withdraw and join again at a later date when they, and their associated clinician, feel they are able to.

What data quality control measures will be used?

Training on behaviour change interventions and how to conduct them based on the COM-B model.

Pilot testing of questionnaire before sending it out to staff.

Regular monitoring of data to check for mistakes, or errors.

Constant review of data collected and analysed by supervisors.

Ethical approval from CREC and MTU ethics

This research is in line with the University's research policy, as well as ADVANCE CRT, Science Foundation Ireland's policies. The research team have all completed Munster Technological University's Academic Research Integrity Certificate (Epigeum).

Storage and backup during the research process

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

Data will be stored securely in password protected, encrypted, files for 2 years after the final data collection date. After this, in order to comply with FAIR research data management protocols, anonymised data will be held in the Zenodo data repository' to the relevant sections of the study protocol document. The hard copy consent forms will be kept in safe storage in double locked cabinets within the head consultant's secured HSE office in Kerry, or a password protected laptop on MTU's encrypted cloud. It will not be shared or supplied to anybody else. This data will be destroyed on study completion (October 2027).

Conduct regular back ups

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

Limited access to data, only main research team will have access to the data

Encryption of sensitive data

Annoymisation and Pseudonymisation of personal data to remove any identifying information

Behaviour Analysis: The data collected from the observations will be pseudo-anonymous. Each participant will receive an identification (ID) number that will be used, instead of their name, in all written/typed/recordings relating to the study. On a separate sheet, the number will be correlated to a description of the service user that only the researcher will have access to. The sole purpose of the descriptions is to help the researcher to re-identify the service user during the repeated observations (breakfast, lunch, dinner). Following the observations, write up of the notes taken will not include any descriptions of participants. The only document where the participants' names are recorded will be on the consent form.

Survey: The survey will be available to the staff in two formats 1. Online and 2. Paper. The online version of the survey will be completed on "Qualtrics" software which used transport layer security (TLS) and encryption for all transmitted data. Anonymise responses is turned on which doesn't record respondents IP address, location data, and contact information

Intervention: Random ID codes

Legal and ethical requirements, codes of conduct

If personal data are processed, how will compliance with legislation on personal data and on data security be ensured?

Data protection: Adhere to relevant data protection regulations (GDPR) and CREC & MTU's Data Protection Policies.

Data will be stored securely in accordance with the MTU's Code of Good Practice in Research
Data minimisation: Minimise amount of personal data collected, only what is necessary.
Consent management: Consent forms must be completed before any data is collected.

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

In the spirit of open-access, we plan to make all data available upon reasonable request to any University or Research Institution that inquires.

How will possible ethical issues be taken into account, and codes of conduct followed?

The studies in this PhD will get ethical approval from both CREC (clinical research ethics committee of the cork teaching hospitals) and Munster Technological University Ethics before starting the research.

A presentation will be given by Ciara O'Sullivan (PhD Student) to service users and staff before the behaviour analysis, so the potential participants are fully informed on the benefits of partaking and what is expected if they decide to take part. The option to withdraw at any point without penalty will also be clearly explained. Anyone eligible that does not wish to participate in the study will continue with their normal daily activities. This includes those who drop out. They will not be penalised for not participating/ dropping out of the study.

Service users and staff will be given the opportunity to ask questions prior to signing the consent form. All participants in the high support hostels are assumed to have capacity to consent but the associated psychiatrist in each residential house will also evaluate each participant's capacity to consent. They will also be provided with the researcher's contact details so that should any problem arise, or if they are unhappy with any aspect of the research, or have any questions, they can discuss this with the researcher and/or principal investigators.

All service users will be supported at all times to make their own decisions. No service user or staff member will be forced to do the survey or take part in the observations if they do not wish to do so. Communication will be encouraged and any questions or worries that may arise will be answered honestly by the researcher/s. Support from the research team and the clinicians within the residential households will be available when required. The service user's and staff member's autonomy and rights will be respected throughout the duration of the research.

This research is in line with the University's research policy, as well as the ADVANCE CRT, (Science Foundation Ireland) policy. The research team have all completed Munster Technological University's Academic Research Integrity Certificate (Epigeum). The research team will also be Garda vetted before commencement of this study.

Data sharing and long-term preservation

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

Following the behaviour analysis study and the co design study the anonymous results will be used to inform the intervention. The anonymous results may also be published and made publicly accessible, so that anyone who is interested can benefit from our study. The findings of the study will be utilised to teach relevant bodies, including the HSE, about the importance of healthy nutritional behaviours for this population, as well as the role that digital technology may play. The findings will also be presented to other researchers and professionals in this field at national and international conferences.

Anonymised data will be archived in an appropriate Research Data Repository service in order for future researchers to be able to avail of it for future comparative research/publication.

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

Anonymised data will be stored securely in password protected, encrypted, files for 2 years after final data collection date. After this, in order to comply with FAIR research data management protocols, anonymised data will be held in the Zenodo data repository.

What methods or software tools will be needed to access and use the data?

Qualitative Data: NVivo

Quantitative Data: SPSS Anonymised data will be stored securely in password protected, encrypted, files for 2 years after final data collection date. After this, in order to comply with FAIR research data management protocols, anonymised data will be held in the Zenodo data repository.

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

DOIs are automatically added to individual project components as part of the service offered by the third-party repositories (Zenodo). Where this is not possible, DOIs will be manually assigned to components as they are made available.

Data management responsibilities and resources

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

The research team will be responsible for data management activities including data quality.

Supervisor MTU & Co-Supervisor MTU will be responsible for data archiving in the repository.

PhD Student MTU: will be responsible for implementing the DMP and for ensuring it is reviewed and if necessary, revised. The PhD student will also regularly update the DMP as the project progresses and to keep the research team up to date. The PhD student will also be in charge of storage and back up.

Head consultant at residences/hostel: will be responsible for managing hard copy consent forms in a double locked cabinet in a HSE office.

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)?

There are no specific financial resources assigned for data management. However, if needed financial resources will be used for storage costs, and repository charges

Specific time will be assigned in the project plans to allow for FAIR curation and appropriate documentation of deposited data and project outputs.