Plan Overview

A Data Management Plan created using DMPonline

Title: Mindfulness-based cognitive therapy to improve stress and sleep in patients with inflammatory bowel disease

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Project abstract:

Inflammatory bowel diseases (IBD) mainly consisting of Crohn’s disease (CD) and ulcerative colitis (UC) are chronic inflammatory conditions of the gastrointestinal tract. Many IBD patients suffer from psychological distress, reduced sleep quality and fatigue, for which only limited treatment options are available. The current study aims to investigate the clinical and cost-effectiveness of mindfulness-based cognitive therapy (MBCT) for patients with IBD and elevated levels of psychological distress (N=142). More specifically, we aim to answer the question "can MBCT reduce psychological distress and improve sleep quality and quality of life compared to treatment as usual (TAU)"? The study is a randomized, multicenter, clinical trial with assessments at baseline, post treatment (3 months later) and follow-ups at 6, 9 and 12 months after baseline. Assessments consist of clinical interviews, self-report questionnnaires, sleep EEG measures and wearables.

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Mindfulness-based cognitive therapy to improve stress and sleep in patients with inflammatory bowel disease

1. General features of the project and data collection

1.1 Project leader contact details

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1.2 I have composed my DMP with the assistance of a data stewardship (or management) expert. List his or her name, function, organisation/department, phone number and email address.

- The expert is connected to my department or institution (please explain his/hr expertise related to data stewardship)

Dr. Marten Onnink
Datamanagement consultant
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Radboud universitair medisch centrum
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Philips van Leydenlaan 15 (route 392)
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1.3 In collecting data for my project, I will do the following:

- Use existing data (please specify)
- Generate new data

We will generate new data such as self-assessment questionnaires, sleep EEG, clinical outcomes (calprotectin and c-reactive protein) and clinical interviews.

We will also use some existing data from the IB-Dream database. This is a prospective multi-centre registry in the Netherlands. To compare our study population to a background population and to examine the possibility of a selection bias, we aim to use the IB-Dream registry.

1.4 In my research, I will use:

- A combination of quantitative and qualitative data

Data are mainly quantitative.
A subgroup will be invited for indepth-interviews to investigate the feasibilty of MBCT as an intervention. These data are qualitative.

1.5 I will be reusing or combining existing data, and I have the owner's permission for that.

- Yes, I have permission to use the data

Currently we have permission to use data from IB-Dream.

1.6 In collecting new data, I will be collaborating with other parties.

- Yes, the new data will be (partly) provided by a project partner or supplier
- Yes, I will collect the new data in conjunction with other researchers or research groups
- Yes, we have reached agreements on the user rights of the data used in the project

One academic (Radboudumc) and three non-academic hospitals (Jeroen Bosch Ziekenhuis, CWZ, and Rijnstate) will collaborate. The Radboudumc and Jeroen Bosch Ziekenhuis will jointly coordinate the research project. In addition, the Donders Institute for Brain, Cognition and Behaviour, more specifically the Donders Sleep & Memory Lab, will participate and offer the expertise on the sleep research part.

1.7 I am a member of a consortium of 2 or more partners. Clear arrangements have been made regarding data management and intellectual property. (also consider the possible effect of changes within the consortium on issues of data management and intellectual property)

- Yes, clear arrangements have been made regarding data management and intellectual property through a consortium agreement

1.8 I can give an estimate of the size of the data collection; specifically, the number of participants or subjects (“n=”) in the collection and its size in GB/TB

- Yes (please specify)

Based on 136 participants and 4 measurement moments we anticipate on 3 to 5 GB for self-assessment questionnaires, clinical outcomes and qualitative data and 45 GB for sleep EEG data.
Storage of questionnaires, clinical outcomes and qualitative data has already been arranged. Sleep EEG data are stored on the Radboud DRE.

1.9 The following end products I will make available for further research and verification (please elaborate briefly)

- Data documentation
- (Several versions of) processed data
- Raw data
- Documentation of the research process, including documentation of all participants
- Syntaxes

1.10 During the project, I will have access to sufficient storage capacity and sites, and a backup of my data will be available. (please elaborate briefly)

- Yes, I will make use of my institution's standard facilities for storage and backup of my data

The Radboudumc has good ICT facilities for storage and backup of all data.

2. Legislation (including privacy)

2.1 I will be doing research involving human subjects, and I am aware of and compliant with laws and regulations concerning privacy sensitive data.

- Yes, I will involve human subjects in my research. I will comply with the Algemene Verordening Gegevensbescherming (AVG)
- The Wet Medisch-Wetenschappelijk Onderzoek met Mensen (WMO, or Medical Research (Human Subjects) Act) applies to my project; I will have it reviewed by a Medical Research Ethics Committee. In addition I will comply with the Kwaliteitsborging Mensgebonden Onderzoek (Quality Assurance for Research Involving Human Subjects)

2.2 I will be doing research involving human subjects, and I have (a form of) informed consent from the participants for collecting their data.

- Yes, and this informed consent allows for the reuse of data (note that in the Code of Conduct for Medical Research, ‘reuse’ is also referred to as ‘further use’)
- Yes (please describe the form this consent takes)

Screening and informed consent procedure
If a patient is interested and contacts the research team, the researcher will call the participant and they will first be asked to give verbal consent. Global eligibility will be assessed via telephone screening by a researcher. Remaining questions will be discussed and the researcher will ask if they needs more time to decide whether or not to participate. If they are still interested in participation, they will be asked to sign the informed consent forms in twofold and

send them back in the self-addressed envelope to the researchers. Thereafter, the researcher will also sign both informed consent forms, safely store one informed consent form and send one form back to the subject. After written informed consent, baseline values will be assessed and a face to face meeting/ online meeting (depends on the situation of COVID) will be scheduled.

2.3 I will be doing research involving human subjects, and I will protect my data against misuse.

- Yes, the data will be pseudonymised. (please explain how this will be done, and by which organisation) and

CASTOR edc will generate participant specific codes. This will be initiated by a researcher from the Radboudumc. The data are coded by the following method: Codes that are comprised of consecutive numbers for centre (1-4), followed by a patient number per centre (e.g. 002).

2.4 I will stick to the privacy regulations of my organisation

- Yes

More information on the privacy regulations of Radboudumc:
http://qportaal.umcn.nl/iProva/iDocument/?DocumentID=065a7fb5-c070-4ccc-a193-6991d21f68b0

3. Making data findable

3.1 The data collection of my project will be findable for subsequent research. E.g., on a catalogue, a web portal, or through the search enginge of the repository (note: this is key item 3, which you should report to ZonMw at the end of your project).

- Yes, it can be found through the search engine of the archive or repository in which it is stored (please specify)
- Yes, it can be found through an online (metadata) catalogue or web portal (please specify)

With help from the Library of the Radboud University (https://www.ru.nl/research-information-services/), data will be made findable for subsequent research in the Radboud Data Repository

3.2 I will use a metadata scheme for the description of my data collection (note: this is key item 7, which you should report to ZonMw at the end of your project).

- Yes, I will use a generic metadata scheme (please specify)

We will use the Dublin Core MetaData Element Set (Dublin Core) as a metadata scheme.

3.3 I will be using a persistent identifier as a permanent link to my data collection (note: this is key item 1, which you should report to ZonMw at the end of your project).

- Yes, I will be using the DOI code

4. Making data accessible

4.1 Once the project has ended, my data will be accessible for further research and verification.

- Yes, after an embargo period (please explain)

After publication, we will determine when data will be made accessible for further research and verification.

4.2 Once the project has ended, my data collection will be publicly accessible, without any restrictions (open access).

- No, there will be access restrictions to my data collection (please explain)

Data use will be monitored to ensure that the data is used appropriately and in accordance with the informed consent procedure. The research question will also be discussed by the project team.

4.3 I have a set of terms of use available to me, which I will use to define the requirements of access to my data collection once the project has ended (please provide a link or persistent identifier; also note that this is a key item 4, which you should report to ZonMw at the conclusion of your project).

- Yes, my institution has drafted a set of terms of use with the help of a legal advisor

Terms of use can be find here: https://elsi.health-ri.nl/waar-vind-ik-een-voorbeeld-van-een-material-transfer-agreement-en-data-transfer-agreement

4.4 In the terms of use restricting access to my data, I have included at least the following:

- Conditions related to data security
- Collaboration in using the data set, including agreements on publication and authorship

- The sharing of data for commercial purposes, taking into account the provisions of state aid law
- Whether or not the data set may be linked with another data set (for reasons of privacy)
- The permitted period of use of the data set
- The approval of the participants allows for further research using this data set
- The manner in which the data set can be accessed
- A steering committee, programme committee or project leader will be charged with approving data requests
- Agreements on methodology

5. Making data interoperable

5.1 I will select a data format, which will allow other researchers and their computers (machine actionable) to read my data collection (note: this is key item 5, which you should report to ZonMw at the end of your project).

- Yes (please specify)

We will use CASTOR EDC as data management system.

In line with the preferred formats of the Radboud Data Repository system - Preferred Formats — Radboud Data Repository - we will use the following formats:
-Documents and presentations: PDF/A-1 / PDF/A-2 (.pdf)
-Spreadsheets and datasets: CSV (.csv)
-Images: JPEG (.jpg, .jpeg)
-Code and analysis scripts: SPSS (.dat/.sps)
-Computer Assisted Qualitative Data Analysis: ATLAS.ti

5.2 I will select a terminology for recording my data (e.g., code, classification, ontology) that allows my dataset to be linked or integrated with other datasets (note: this is key item 6, which you should report to ZonMw at the conclusion of your project).

- Yes, metadata standard (please specify)

The following metadata standards will be used:
MedDRA - Medical clinical observations (healthcare) - https://biosharing.org/bsgs002647.
SNOMEDCT - Medical clinical observations (healthcare) - https://biosharing.org/bsgs000098
In Castor EDC metadata standards can be linked to several variables (https://helpdesk.castoredc.com/article/55-metadata-settings).

5.3 I will be doing research involving human subjects, and I have taken into account the reuse of data and the potential combination with other data sets when taking privacy protection measurements.

- Yes, the participants have given their permission for reuse of the data, and the data have been pseudonymised

6. Making data reusable

6.1 I will ensure that the data and their documentation will be of sufficient quality to allow other researchers to interpret and reuse them (in a replication package).

- I will perform quality checks on the data to ensure that they are complete, correct and consistent (please explain)
- I will document the research process (please explain)
- I will document the software used in the course of the project (please specify)
- In addition, I will take further quality assurance measures (please specify)

We will use CASTOR EDC that complies with all laws and regulations: 21 CFR part 11, EU Annex 11, Good Clinical Practice (GCP) and the European Data Protection Directive.
Data monitoring will be performed according the guidelines of the Nederlandse Federatie van Universitaire Medische Centra (NFU). Research assistants were trained in research procedures and guidelines and manuals (standard operating procedures) were made. The protocol of the trial was published and the trial registered at ClinicalTrials.gov.

Further quality assurance measures include the intervention integrity and quality check based on randomly selected videos of the sessions, evaluated by independent mindfulness teachers.

Software used in the course of the project to collect and analyse research data consists of: SPSS version 29; Atlas.ti; CASTOR EDC.

6.2 I have a number of selection criteria, which will allow me to determine which part of the data should be preserved once the project has ended. (see also question 1.9 and 6.1)

- Yes

All data will be securely stored for a period of minimal 15 years.

6.3 Once the project has ended and the data have been selected, I can make an estimate of the size of the data collection (in GB/TB) to be preserved for long-term storage or archival.

- Yes (please specify)

The entire data storage, including the sleep EEG data, used 137 GB in total.

6.4 I will select an archive or repository for (certified) long-term archiving of my data collection once the project has ended. (note: this is a key item, which you should report to ZonMw at the conclusion of your project)

- Yes, and this archive has a data seal of approval (please specify the archive)

Yes, DANS has a data seal of approval (https://dans.knaw.nl/nl).

6.5 Once the project has ended, I will ensure that all data, software codes and research materials, published or unpublished, are managed and securely stored. Please specify the period of storage.

- Yes, in accordance with VNSU guidelines (please specify the number of years)

The VNSU guidelines also apply to all scientific research performed in the Radboudumc. Thus data will be stored for a period of minimal 15 years.

6.6 Data management costs during the project and preparations for archival can be included in the project budget. These costs are:

- Amount ..... (please elaborate)

Costs related to datamanagement (CASTOR edc) are covered by the Radboudumc.
Costs related to the storage of the sleep EEG data are covered by the Radboudumc.

6.7 The costs of archiving the data set once the project has ended are covered.

- Yes (please elaborate)

Archiving via Radboud Data Repository is free of charge for researchers at Radboudumc.