Plan Overview

A Data Management Plan created using DMPMaastricht

Title: NWO VICI: Understanding Overweight and Obesity. The End of Average

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Template: UM/MUMC+ Template - Version 1.2

Project abstract:

Overweight is the largest and most prevalent modifiable risk factor for health problems, and significantly contributes to healthcare costs. Researchers generally agree that **overweight is multifactorially determined**, including biomedical, behavioral, environmental, and psychological mechanisms. There is empirical support for each of these mechanisms, but often evidence is not consistent across studies, effect sizes are modest at best, and variability on outcome-measures across participants in a study is often large. This suggests that **contributing factors to overweight likely differ across people**. Similarly, treatments for overweight are, on average, only modestly effective and individual **variability in weight-loss-response to treatment** is large.

This project therefore adopts an urgently needed comprehensive**individualized approach**. We characterize each participant in a large sample of individuals varying in bodyweight by their own baseline comprehensive profile, including person characteristics, biological, psychological, environmental, and behavioral variables. Next, we investigate how baseline **comprehensive individual profiles** cluster in a meaningful way, and relate to bodyweight at baseline, post-treatment, and follow-up. We test if clustering and weight loss are moderated by treatment-condition: **Intensive Lifestyle Intervention** (ILI) versus lifestyle-information control group.

Moreover, we investigate how these individual profiles **translate to behavior in daily life.** We collect time-series data on (un)healthy eating and physical (in)activity, and predictors of these behaviors (e.g., emotions, stress) in daily life during three weeks at baseline and three weeks post-treatment. Based on these time-series data, we estimate daily lifestyle networks per individual (baseline/post-treatment), and relate these to the comprehensive individual profiles. Moreover, we investigate how these daily lifestyle networks relate to bodyweight, and change over time, dependent on treatment condition. We hypothesize that—after ILI and mostly with more weight loss—healthy behaviors increase, and predictors link with healthy behaviors more frequently in these networks. The proposed research puts the individual center stage, paving the way for personalized interventions.

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NWO VICI: Understanding Overweight and Obesity. The End of Average

1. General Information

1.1 Initial title of the project

Understanding Overweight and Obesity. The End of Average

1.2 Project purpose (abstract)

Overweight is the largest and most prevalent modifiable risk factor for health problems, and significantly contributes to healthcare costs. Researchers generally agree that **overweight is multifactorially determined**, including biomedical, behavioral, environmental, and psychological mechanisms. There is empirical support for each of these mechanisms, but often evidence is not consistent across studies, effect sizes are modest at best, and variability on outcome-measures across participants in a study is often large. This suggests that **contributing factors to overweight likely differ across people** Similarly, treatments for overweight are, on average, only modestly effective and individual **variability in weight-loss-response to treatment** is large.
This project therefore adopts an urgently needed comprehensive **individualized approach**. We characterize each participant in a large sample of individuals varying in bodyweight by their own baseline comprehensive profile, including person characteristics, biological, psychological, environmental, and behavioral variables. Next, we investigate how baseline **comprehensive individual profiles** cluster in a meaningful way, and relate to bodyweight at baseline, post-treatment, and follow-up. We test if clustering and weight loss are moderated by treatment-condition: **Intensive Lifestyle Intervention** (ILI) versus lifestyle-information control group.
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1.3 Name and contact details of the (initiating) institution

- Maastricht University, P.O. Box 616, 6200 MD, Maastricht, The Netherlands, +31433882222

1.4 Name and contact details of the department

Clinical Psychological Science - Faculty of Psychology & Neuroscience

1.5 Name and contact details of thelead researcher including their ORCID

Prof. dr. Anne Roefs
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1.6 Name and contact details of theexecutive researcher including ORCID

Prof. dr. Anne Roefs
ORCID: **0000-0002-9935-1075**

A.Roefs@maastrichtuniversity.nl
+31 6 45780733

1.7 I have composed my DMP with the assistance of a research data management expert.
Please note that for ZonMw and NWO it is required to consult a research data management expert! List the name, function, organisation/department, phone number, email address and the date of consultation in the comment area.

Erik Jansen, Faculty of Psychology and Neuroscience, erik.jansen@maastrichtuniversity.nl, 0648338342, consulted on May 4th 2022.

2. Legislation

2.1 I will be doing research involving human subjects.

- Yes

2.1.1 I confirm that I am aware of and compliant with laws and regulations concerning privacy sensitive data.
The following regulations might be relevant:

- **General Data Protection Regulation (Dutch: Algemene Verordening Gegevensbescherming, AVG)**
- **Medical Treatment Contracts Act (Dutch: Wet op de Geneeskundige Behandelingsovereenkomst, WGBO)**
- **Human Tissue and Medical Research: Code of Conduct for responsible use (Dutch: Gedragscode Verantwoord omgaan met lichaamsmateriaal)**

- Yes, I confirm

2.1.2 My research project is registered at my institution by the Local Information and Security Officer (LISO). Please enter the registration number of your project and the name of the LISO.

LISO = Rosanne Janssen of the Faculty of Psychology & Neuroscience (UM).
The project will be submitted to the local METC, and will be registered with that number then.

2.1.3 My study research file (e.g. protocol) has been or will be submitted to the relevant Ethics Committee.

- The Medical Ethics Committee (METC)

2.1.3.1 The 'Act medical scientific research with human beings*(Dutch: 'Wet medisch-wetenschappelijk onderzoek met mensen, WMO)* applies to my project and I will comply with the 'Quality Assurance for Research Involving Human Subjects' *(Dutch: Kwaliteitsborging Mensgebonden Onderzoek).*

- Yes

2.1.4 I will be doing research involving human subjects and I am aware that informed consent is required from the participants for collecting or reusing their data.

- Yes

2.1.4.1 This informed consent also allows for the reuse of data.
Please note that "reuse" can sometimes also be referred to as "further use".

- Yes

2.1.5 I will be doing research involving human subjects and I have taken privacy protection measurements.

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

Data pseudonymisation will be done at Maastricht University, Faculty of Psychology and Neuroscience, making use of the dedicated data management infrastructure, separately storing research data and privacy sensitive information.
Each participant will receive a unique random number as identifier, to connect all data sources.

2.2 In collecting new data, I will be collaborating with other parties.
Multiple answers possible.

- No

All data will be collected by my team of researchers, all employed at the faculty of psychology & neuroscience of Maastricht University.

2.2.1 I am a member of a consortium of 2 or more partners.

- No

3. Data Preparation & Collection

3.1 In collecting data for my project, I will be reusing or combining existing data.

- No

3.2 In collecting data for my project, new (research) data will be generated.

- Yes

3.3 The following type of data will be used/collected:
Multiple answers possible. Please note that standard personal data and special categories of personal data are also considered pseudonymised data.

- Special categories of personal data (sensitive data)
- Standard personal data

3.4 Describe the way you collect the data (e.g. interviews, recordings, literature studies, MRI scans, field notes) mentioned in question 3.3.

*Retrospective questionnaire data
*Ecological Momentary Assessment (smartphone)
*Activity tracker
*Blood samples

*DEXA scan (body composition)
*Body Mass Index

3.5 Describe what tools, instruments, resources or other means you intend to use for collecting your data mentioned in question 3.3.

*Qualtrics
*Ethica Data
*Garmin activity tracker
*commercial radioimmunoassay for ghrelin and leptin
*Dexascan

3.6 I will select a metadata standard/terminology for recording my data (e.g. code, classification, ontology and vocabularies) that allows my dataset to be linked or integrated with other datasets (for describing the variables and values within the dataset).

- No → please explain

Of course the data will be stored in an organized and annotated way, but for my field no appropriate meta data standard exists. We will create a codebook, clearly explaining each variable and possible values.

3.7 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 MB/GB/TB/PB.
Note: This may differ from the size of the dataset for archiving.

600 participants will be recruited, and several measures will be obtained multiple times. A maximum of 500 GB of data will be collected (estimate).

4. Data Processing & Analysis

4.1 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/faculty's standard facilities for storage and backup of my data

The data will be stored according to the code of conduct within the university and the data management protocol within the faculty. Personal identifiable information will be stored separately from the pseudonymized research data. Data storage takes place in the 2 available data centers at the UM. The distance between both data centers is approximately 2 km (in a straight line). In each data center, an identical storage system is located. The total net capacity of each storage system amounts to approximately 1,2 Petabyte. By means of asynchronous replication, data are replicated between both storage systems/locations. This means that, for example, data that are stored in location 1 will also be stored in location 2 within a maximum of 1 hour (and vice versa). The code of conduct, the data management protocol within the faculty, and the storage environment have all been approved by the data protection officer of the university.

4.2 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).
Multiple answers possible.

- In addition, I will take further quality assurance measures → please explain
- I will document the software used during the course of the project → please mention the software used
- Before, during and after the data collection, 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

Research process will be documented and protocol papers will be published. Data will be collected via online platforms to avoid human error with data entry. Software that will be used includes: Qualtrics, Ethica Data, R, Excel, Python.

4.3 All data processing and analysis will be programmed in syntax or script files.

- Yes → please explain which data processing/analysis tools will be used

R, Python, or SPSS script will be used for all data-analyses.

4.4 Descriptive comments will be added to the syntax, script files or documentation.

- Yes

4.5 Syntax or script files will be placed under version control.

- Yes

4.6 Data corrections in this phase are programmed in syntax or script files.

- Yes

4.7 Data will be shared and transferred in a secure way.

- Yes → please explain

Data will be shared using the secure platform SurfDrive and SurfFilesender.

5. Data Archiving and Open Access

5.1 I will select a data format, which will allow other researchers and their computers (machine actionable) to read my data collection.

- Yes → please explain

Data will be stored in CSV format.

5.2 I will use a metadata scheme for the description of my data collection (for describing the dataset as a whole).

- No, I have not yet chosen a metadata scheme

For my field no suitable metadata scheme exists. My datasets will be made available on DataverseNL, along with an appropriate codebook (see my answer to question 3.6.1).

5.3 I will make the following end products available for further research and verification. Consider whether these will make your research verifiable, reproducible and/or viable for further research.
Multiple answers possible.

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

All data will be made available to other researchers upon reasonable request, balancing openness and privacy of participants.

5.4 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 (please elaborate briefly).

- Yes

We will follow published guidelines which stipulate minimal storage periods for research data (15 years) and that personal data be destroyed when no longer necessary.

5.5 The data collection of my project will be findable for subsequent research.
Examples: on a catalogue, a web portal, or through the search engine of the repository.

- Yes, it can be found through the search engine of the archive or repository in which it is stored → please explain

Data will be made available on DataverseNL and we will provide information about the datasets on Open Science Framework (OSF), directing interested researchers to DataverseNL.

5.6 I will be using a persistent identifier as a permanent link to my data collection.

- Yes

DataverseNL assigns a DOI to the dataset.

5.7 Once the associated article is published and/or the project has ended, (part of) my data will be accessible for further research and verification.

- Yes, after an embargo period → please explain

Three PhD students need to write their PhD thesis, and they have first access to the data. After the project has ended, data are made available upon reasonable request.

5.7.1 Once the project has ended, my data collection will be publicly accessible.

- No, there will be access restrictions to the data collection → proceed with question 5.7.2

Data will be made available upon reasonable request.

5.7.2 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 note that even when making your data open access, it is strongly recommended to include terms of use. Provide a link or persistent identifier.

- Not yet, my institution will draft a set of terms of use with the help of a legal advisor

5.7.3 In the terms of use restricting access to my data, I have included at least the following:
Multiple answers possible.

- A steering committee, programme committee or project leader will be charged with approving data requests
- Person(s) who is/are authorised to give access to the data collection
- Conditions related to data security
- The approval of the participants allows for further research using this data set
- The permitted period of use of the data set
- The manner in which the data set can be accessed
- 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)
- Agreements on methodology
- Collaboration in using the data set, including agreements on publication and authorship

I have not set this up yet, but the checked answers would be topics I wish to include.

5.8 I will select an archive or repository for (certified) long-term archiving of my data collection once the project has ended.

- The archive is provided by my institution → Please provide the name of the archive

DataverseNL

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

- Yes, in accordance with UM Code of Conduct or the MUMC+ Research Code → please specify the number of years

We will follow published guidelines on the minimal storage duration of research data, which stipulate a minimal duration of 15 years.

5.10 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 storage or archival.

- Not yet → please explain

Rough estimate would be a maximum of 100 GB, but it is hard to tell.

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

- Unknown → please explain

These are covered by FPN (UM).

5.12 Once the project has ended and the data have been selected, I can make an estimation of the costs involved for storage.

- Not yet → please explain

Probably free, as I don't think there will be more than 100 GB of data to be stored.