DMP_G0D6322N

Data Management Plan – FWO

ADMIN DETAILS

Project Name: DMP_G0D6322N-red_nose_virtually_better?
Project Identifier: G0D6322N
Principal Investigator / Researcher: Dirk Hermans
Description: In this project a three-arm randomized controlled trial evaluates the efficacy and acceptability of virtual reality (VR) exposure in adolescents with subclinical levels of social anxiety. The three conditions will exist of (1) a VR exposure condition; (2) an in vivo exposure condition; and (3) a waiting list control condition. There are four main objectives. First, we aim to evaluate whether a VR exposure intervention can be effective in reducing symptoms in adolescents at risk for social anxiety and has a positive effect on well-being and resilience. Second, we aim to identify predictors of adolescents' responding to VR exposure. A third objective is to elucidate potential working mechanisms of VR exposure. A fourth objective is to evaluate to what extent adolescents appreciate the VR exposure intervention. The results will contribute to the development of effective early-stage interventions for adolescents to prevent moderate and subclinical social anxiety to further develop into a full-blown anxiety disorder.
Institution: KU Leuven

1. GENERAL INFORMATION

Name applicant
Dirk Hermans

FWO Project Number & Title
G0D6322N Virtually better? Virtual reality exposure for socially anxious adolescents.

This project will run parallel with a Global PhD partnership with the University of Utrecht under supervision of Dirk Hermans, Iris Engelhard and Katharina Meyerbröker.

Affiliation

- KU Leuven

2. DATA DESCRIPTION

Will you generate/collect new data and/or make use of existing data?

- Generate new data

Describe in detail the origin, type and format of the data (per dataset) and its (estimated) volume. This may be easiest in a table (see example) or as a data flow and per WP or objective of the project. If you reuse existing data, specify the source of these data. Distinguish data types (the kind of content) from data formats (the technical format).

(Proposed) overview of the study and objectives:

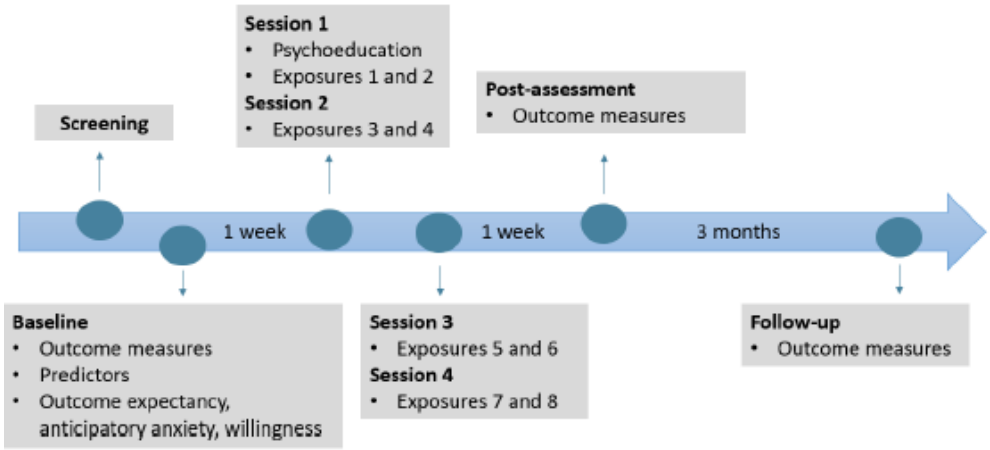

Figure 1. Schematic overview of the design.

Objective 1: To evaluate whether a VR exposure intervention can be effective in reducing symptoms in adolescents at risk for social anxiety and has a positive effect on well-being and resilience
Objective 2: to identify predictors of adolescents' responding to VR exposure.
Objective 3: to examine potential working mechanisms of VR exposure.
Objective 4: to evaluate to what extent adolescents appreciate the VR exposure intervention

Research Phase	Type of data	Format	Estimated Volume	How created?
Screening	Participant information (e.g., demographical and personal data as age, gender, educational level) Questionnaire data (e.g., answers on (social) anxiety questionnaire(s) and clinical interview(s)) Additional data (e.g., youth and parental informed consent forms, payment information forms, inclusion/exclusion criteria forms).	Textual and numerical data stored in .sav, .csv, . docx or .xls files	Less than 20 MB per participant	(online) survey program (e.g., Qualtrics) Paper and pencil questionnaires/formats are transferred to .sav, .csv, or .xlsx Raw and processed data

Baseline	Participant information (e.g., demographical and personal data as age, school, gender, educational level, ethnicity) Self-report data: - questionnaire data (e.g., self-report or parental questionnaires about anxiety, mood, general well-being, resilience, self-esteem, (experiential) avoidance, personality, prior experience with VR, ability to feel a sense of presence, absorption, adherence, treatment expectancy and credibility) - subjective ratings of expectancies, fear, and distress during a behavioral avoidance task (BAT) (e.g., Subjective Units of Distress)	Textual and numerical data stored in .sav, .csv, .docx, or .xls files	Less than 20 MB per participant	Collected before exposure treatment (online) survey program (e.g., Qualtrics) Paper and pencil questionnaires/formats are transferred to .sav, .csv, or .xlsx
	Behavioral data during a behavioral avoidance task (e.g., duration, frequency and latency of avoidance responses)	Multimedia stored in MP3, .wav, .avi, or MP4	Less than 2 GB per participant	Audio/Video recordings during behavioral approach task
	Psychophysiological data during a behavioral avoidance task (BAT) (e.g., skin conductance, startle response, heart rate)	Psycho-physiological data stored in .acq or .mat	Around 250 MB per participant	Psychophysiological data will be Recorded with e.g., Biopac, or Actigraph, … Raw and processed data
Treatment Sessions	Self-report data: Subjective ratings of expectancies, fear (for different situations), distress, arousal, valence, mood, stress	Textual and numerical data stored in .sav, .csv, .docx, or .xls files	Less than 20 MB per participant	Collected during exposure treatment (online) survey program (e.g., Qualtrics)
	Field notes			Notes made by researcher(s) during data collection. Paper and pencil formats are transferred to .sav, .csv, or .xlsx
	Behavioral data during treatment (e.g., proof of doing an exposure)	Multimedia stored in MP3, .wav, .avi, or MP4	Less than 2 GB per participant	Audio/Video recordings during treatment

	Psychophysiological data during treatment (e.g., skin conductance, startle response, heart rate)	Psycho-physiological data stored in .acq or .mat	Around 250 MB per participant	Psychophysiological data will be Recorded with e.g., Biopac, or Actigraph, … Raw and processed data
Post-assessment and follow-up	Same as 'Baseline data' with an addition of: Participant information (e.g., number of drop-outs, refusal to treatment)	Textual and numerical data stored in .sav, .csv, . docx, or .xls files	Less than 20 MB per participant	
	Qualitative data of interviews or focus groups and their transcripts and codings	Multimedia stored in MP3, .wav, .avi, or MP4	Less than 2 GB in total	Audio recordings of focus groups or interviews with participants (who completed the study and dropped out during the study) Transcripts of audio/video recordings and coding done with software (e.g., Nvivo)

3. LEGAL AND ETHICAL ISSUES

Will you use personal data? If so, shortly describe the kind of personal data you will use. Add the reference to your file in KU Leuven's Register of Data Processing for Research and Public Service Purposes (PRET application). Be aware that registering the fact that you process personal data is a legal obligation.

- Yes

We will collect contact information of participants (e-mail address, telephone number), demographic data (gender, age, ethnic origin), name of school, educational level, bank account number, health data (e.g., onset of symptoms, medical and psychiatric history), self-report data about participants' psychological well-being and emotional functioning, and video/audio recordings of the participant in accordance with GDPR and KU Leuven guidelines.

We will submit an ethical application at the Ethics Committee Research UZ/KU Leuven (EC Research) to register our file (a GDPR Questionnaire of the Clinical Trial Centre (CTC)).

Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? If so, add the reference to the formal approval by the relevant ethical review committee(s)

- Yes

The ethical approval will be requested from the Ethics Committee Research UZ / KU Leuven (EC Research). The reference number will be provided when it is available.

Does your work possibly result in research data with potential for tech transfer and valorisation? Will IP restrictions be claimed for the data you created? If so, for what data and which restrictions will be asserted?

- No

The data has no potential for technological transfer and valorization and we will not claim IPR on the data as we use commercial VR software of an external partner.

Do existing 3rd party agreements restrict dissemination or exploitation of the data you (re)use? If so, to what data do they relate and what restrictions are in place?

- Yes

The (minor) participants (and their parents) themselves are the third party. Agreements are thus part of the informed consent, mentioning the use of personal contact information only for a follow-up session, the publication of results in scientific communications and the (re)use of data by other researchers.

As a Global PhD partnership runs parallel we will use a data transfer agreement with Utrecht University. There are no known restrictions at the moment.

4. DOCUMENTATION AND METADATA

What documentation will be provided to enable reuse of the data collected/generated in this project?

Raw data files will be kept in a common structure with individual data files stored within participant sub-folders. Extracted data will be stored within separate participant sub-folders and aggregated data will be stored under the experiment parent-folder. Moreover, metadata files will be created and will be saved in a separate folder (under the experiment parent-folder) that contains the following information:

- Project documentation: This file will be provided in a readme file and will include the project name, keywords, name of researchers who were involved in the collection of the data (e.g., master students, researchers and their ORCID ID), name of funder, funding code, start- and end date of the project, DOIs of shared datasets, creative common license, link to preregistration, approval/registration code of ethical committee, links to publications.
- A general description of the methodology will be provided in the preregistration and ethical application of the planned RCT. The preregistration will be published on a clinical trial register (e.g., OSF, aspredicted.org, clinicaltrials.gov).
    - The link to the preregistration will be provided in the project documentation.

- The ethical application will be saved as a PDF document and the approval/approval code will be added to the project documentation.
- An example of an empty informed consent form will be provided as a word file.
- The data management plan will be provided as a Word file.
- A Word document will be created describing the recruitment strategy, the participant inclusion criteria, instructions and procedure of the study, measurement methods, technical specifications/set up details, references to procedures, software versions, interview protocol, etc. used in the study. In addition, the Word file will contain a specification of the raw data file names (which measures they refer to), transformations of the raw data, and information that describes the variable codes (referring to type and time of specific measurements) in the aggregated data files.
- Information on the variables will also be provided in SPSS or a codebook will be created in R.
- The data preparation and statistical analyses will also be documented in an annotated analysis code file (e.g., SPSS syntax, R code file). The version of the used software will be documented in e.g., used R package or command.
- In a .xlsx document we will provide pseudonymized baseline information about all participants that were enrolled in the study (e.g., age, gender, when they completed a phase of the study, whether they completed the entire study or dropped-out, their compliance, clinical diagnosis, other remarks, etc.). We also provide specific information about the questionnaires we administered (i.e., number of items, reference, their variable labels, ranges and description). Finally, we provide some basic summary statistics (e.g., gender and age distribution, number of participants per condition, overall study compliance, etc.).

For version control the procedures of defining milestones (e.g., draft, final) and subversions (e.g., V1, V2,…) will be implemented.

The separate meta-data folder will never contain sensitive (identifiable) participants information such as names, contact details, audio-files of the clinical interviews, etc.

Will a metadata standard be used? If so, describe in detail which standard will be used. If no, state in detail which metadata will be created to make the data easy/easier to find and reuse.

- No

Project metadata will be stored as Microsoft Word/pdf, .txt or .csv file under the experiment parent-folder (see also documentation above). We will provide the relevant metadata in a structured manner.

Controlled vocabulary (e.g., APA Thesaurus of Psychological Index Terms, MeSH-terms) will be used for the keywords.

5. DATA STORAGE AND BACKUP DURING THE FWO PROJECT

Where will the data be stored?
All digital data will be stored offline on the researcher's personal laptop (which is encrypted and password-protected) and online on KU Leuven central servers such as the researcher's (personal) network drive (Onedrive for Busines and/or Sharepoint, which can only be accessed by the researchers involved with their KU Leuven account and a three factor authenticator). Copies of non-sensitive data can be made and kept on personal devices (e.g., laptops, hard drives which are encrypted and password-protected).

Data in paper format (e.g., informed consents, adverse event forms, questionnaires, personal and field notes) will be stored separately in a key-locked cabinet in a dedicated (archive) room of the research group.

Restricted and sensitive data (e.g. personal information, contact information, audio and video files, etc.) will be stored separately on an encrypted password-protected (personal) drive of the KU Leuven (Onedrive or Sharepoint for our research group) for the duration of this project, and can only be accessed by the main researchers and PhD-students of this project.

As this project runs parallel with a global PhD partnership, the PhD-student from Utrecht University (Elizabeth Uduwa Vidanalage) and her supervisors (Iris Engelhard and Katharina Meyerbröker) will have full access to all the data. Elizabeth Uduwa Vidanalage will be involved in data collection as well.

How is backup of the data provided?
Backups are (manually and daily) made on KU Leuven central servers such as the researcher's (personal) network drive (Onedrive for Busines and Sharepoint) which can only be accessed by the researchers involved with their KU Leuven account and a three factor authenticator. Sharepoint for our research group can only be accessed by the main researchers and PhD-students of this project. All data on KU Leuven drives are backed up automatically on a daily basis. Another back-up will be stored on the Network Attached Storage (NAS) of the research group.

An offline full backup of the data is regularly saved manually on an encrypted archive drive, which is protected by password.

Is there currently sufficient storage & backup capacity during the project? If yes, specify concisely. If no or insufficient storage or backup capacities are available then explain how this will be taken care of.
Probably there is enough storage and back-up capacity as the size of all data files do not exceed the available individual storage space of 3 GB and the available shared storage space of 100 GB.

What are the expected costs for data storage and back up during the project? How will these costs be covered?
No costs are expected. However, if the storage and back-up capacity is exceeded a cost of €160/year per TB is currently is expected (KU Leuven ICTS, Large Volume Storage).
Data security: how will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

All researchers are made aware of a document with general guidelines regarding data security when entering the project. In brief, this document stipulates that all data should be on password-protected and/or encrypted drives, and that all personal laptops should be password-protected and encrypted. Upon request, all PIs can get access to data on network drives.

Personal and anonymized data will be encrypted and password protected. Multi-factor authentication is activated for the KU Leuven login of all researchers having access to the data.

6. DATA PRESERVATION AFTER THE FWO PROJECT

Which data will be retained for the expected 5 year period after the end of the project? In case only a selection of the data can/will be preserved, clearly state the reasons for this (legal or contractual restrictions, physical preservation issues, ...).
The research data and the documentation will be preserved for 10 years in line with the KU Leuven policies. The participants' contact information, payment information, raw (non-anonymized) data files containing highly confidential data, analogue data with a digital equivalent (e.g., paper and pencil questionnaires) will be deleted after the project is finished as they contain personal data.

Where will the data be archived (= stored for the longer term)?
After completion of data collection, and until 10 years after the end of the project, all digital data will be stored on our research unit's central storage facility (a dedicated NAS (network-attached storage), with automatic internal back-up). PIs can request access to this NAS from the group's IT responsibles who manage the NAS.

What are the expected costs for data preservation during the retention period of 5 years? How will the costs be covered?
All datasets will be archived on the servers of KU Leuven. Possible expenses to host these servers are always covered by the research group, but are expected to fall within normal cost ranges (based on the volume of the datafiles). Our current capacity is 8 TB, if additional storage is needed there will be an additional cost of 250 euro per 8 TB.

7. DATA SHARING AND REUSE

Are there any factors restricting or preventing the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions)?

- No

Personal data (strictly confidential) will obviously never be shared beyond the researchers involved in the study.

Which data will be made available after the end of the project?
For reviewers and readers of our published articles a trimmed and pseudonymized dataset (i.e., only containing the variables required to reproduce our results) will be uploaded in a .csv or .xlsx format to the

Open Science Framework under a CC-BY license alongside full dataset documentation. The full pseudonymized dataset will be available for colleague researchers for meta-analytic projects upon request (and signing a data-sharing agreement). Confidential data such as demographic information will be removed if these variables are not part of the research hypotheses. Participants' personal information (e.g., contact information, names, etc.) or audio files will never be shared.

Where/how will the data be made available for reuse?

- In an Open Access repository
- In a restricted access repository
- Other (specify): Upon request by mail

We will use public repositories (e.g., the Open Science Framework (European servers)) for sharing pseudo-anonymized data. Conditions for data usage will be specified in a data sharing agreement.

When will the data be made available?

Data will be made available immediately after publication or else 3 years after completion of the study (in line with international guidelines).

Who will be able to access the data and under what conditions?

Public repositories are open access, searchable through key words, and available to all registered users.

What are the expected costs for data sharing? How will the costs be covered?

No costs are expected. Public repositories are free of charge.

8. RESPONSIBILITIES

Who will be responsible for data documentation & metadata?

The PhD students (Jella De Lee and Elizabeth Uduwa Vidanalage) will be responsible, together with the supervisors (Dirk Hermans, Iris Engelhard, Katharina Meyerbröker and Sara Scheveneels). As a Global PhD partnership runs parallel we will use a data transfer agreement with Utrecht University.

Who will be responsible for data storage & back up during the project?

The PhD students (Jella De Lee and Elizabeth Uduwa Vidanalage) will be responsible, together with the supervisors (Dirk Hermans, Iris Engelhard, Katharina Meyerbröker and Sara Scheveneels).

Who will be responsible for ensuring data preservation and reuse ?

The PhD students (Jella De Lee and Elizabeth Uduwa Vidanalage) and eventual master students will be responsible, together with the supervisors (Dirk Hermans, Iris Engelhard, Katharina Meyerbröker and Sara Scheveneels).

Who bears the end responsibility for updating & implementing this DMP?

The end responsibility for updating and implementing the DMP is with the promotor, Dirk Hermans.