Plan Overview

A Data Management Plan created using DMPonline

Title: Effectiveness of adapted Self-Help Plus (SH+) to reduce psychological distress among university students in Indonesia (APRESIASI)

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Project abstract:

Studies on university students in Indonesia have shown that university students have a high level of psychological distress, anxiety and depression. Therefore, psychological interventions are needed to reduce psychological distress and develop coping strategies in students. Universities have a role to play in providing such psychological interventions. However, there is a gap between the number of mental health professionals within and outside the university and the number of students who need such services. To address the mental health gap, Self-help Plus (SH+), based on Acceptance and Commitment (ACT), has been developed by the World Health Organization (WHO) to reduce psychological distress and increase coping skills. SH+ is a brief, group-based stress management intervention. Based on previous studies in refugee and migrant populations, SH+ has been shown to reduce psychological distress. Therefore, the primary aim of this study is to assess the effectiveness of SH+ in reducing psychological distress among university students in Indonesia at a three-month follow-up. The secondary aims of this study are to assess the improvement in functioning and quality of life, and the prevention of mental health disorders at a six-month follow-up. A qualitative process evaluation will be conducted using individual interviews and focus group discussions with research participants and facilitators delivering the SH+. A two-arm parallel randomised control trial will be conducted at a university in Indonesia. The intervention arm will consist of SH+ plus Enhanced Care as Usual (ECAU) and the control arm will receive Enhanced Care as Usual (ECAU) only.

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Effectiveness of adapted Self-Help Plus (SH+) to reduce psychological distress among university students in Indonesia (APRESIASI)

0. General information

0.1 Document version & date

version 3.0
Date: 23/01/2024

0.2 Project title

Effectiveness of adapted Self-Help Plus (SH+) to reduce psychological distress, improve functioning, and quality of life among university students in Indonesia (APRESIASI)

0.3 Project summary

The primary objective of this study is to assess the effectiveness of SH+ in reducing psychological distress among university students in Indonesia at three months follow-up. The secondary objectives of this study are to assess the improvements in functioning, quality of life, resilience, and prevention indicative of mental health disorders at one week, three months, and six months follow-up. Prior to the efficacy trial, Self-Help Plus (SH+) will be translated and adapted to Bahasa Indonesia and Indonesian culture. After the trial, a qualitative process evaluation will be conducted using individual interviews and focus group discussions with research participants and facilitators to explore the feasibility and acceptability of the SH+ intervention in Indonesia. This study will also evaluate the cost-effectiveness of providing SH+ combined with enhanced care as usual versus enhanced care as usual alone for university students in Indonesia. The hypothesis of this study is that Self-Help Plus (SH+) plus Enhanced Care as Usual (ECAU) will be more effective in reducing psychological distress among Indonesian university students than Enhanced Care as Usual (ECAU) alone at three months follow-up.

0.4 At which VU Faculty is this project situated?

- Faculty of Behavioural and Movement Sciences (FGB)

0.5 Your contact details

Dhini Andriani
Project Manager and Data Manager
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University: Vrije Universiteit Amsterdam
Faculty: Faculty of Behavioural and Movement Sciences
Department: Clinical, Neuro-, and Developmental Psychology

0.6 List other people involved, including those at partner organisations in the project (if applicable)

Prof. Dr. Marit Sijbrandij
Principal Investigator
Telephone Number: 0620386465
ORCID: https://orcid.org/0000-0001-5430-9810
University: Vrije Universiteit Amsterdam
Faculty: Faculty of Behavioural and Movement Sciences
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Department: Psychology

Dr. Anke Witteveen
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Telephone Number:
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University: Vrije Universiteit Amsterdam
Faculty: Faculty of Behavioural and Movement Sciences
Department: Clinical, Neuro-, and Developmental Psychology

0.7 Funding organisation & grant number (if applicable)

Funding organisation: Beasiswa Pendidikan Indonesia
Grant number: B3182022010629185130
URL: https://beasiswa.kemdikbud.go.id/

0.8 Project code (if applicable)

N.A

0.9 Consulted data management expert(s)

Name: Alex van der Jagt
Email: apc.vander.jagt@vu.nl
University: VU Amsterdam

Date of consultation: 23 / 01 /2024

Name: Achraf Taimounti
Email: research.data.fgb@vu.nl
University: FGB VU Amsterdam

Date of consultation: 20 / 07 /2023

1. Data description

1.1 Will you collect and/or process personal data in this project?

- Yes

Demographic data:

- Gender, age, year of study, ethnic group, religion, city of origin, faculty & field of study, GPA, living condition (with whom, what kind of housing), financial support and living allowance.

Mental Health Status

- Psychological distress is measured by the Patient Health Questionnaire Anxiety and Depression Scale (PHQ-ADS).

- Depression symptoms are measured by the Patient Health Questionnaire-9 (PHQ-9)
- Anxiety symptoms are measured by General Anxiety Disorder (GAD-7)
- Perceived stress will be measured by the Perceived Stress Scale (PSS)
- General functioning will be measured by the WHO Disability Assessment 2.0 (WHODAS 2.0)
- Objective microstressors will be measured by the Mainz Inventory of Microstressors (MIMIS)
- Identified problems will use the Psychological Outcome Profiles (PSYCHLOPS)

Quality of life

- Quality of life will be measured by EQ-5D-5L

Cost-effectiveness

- Client Services Receipt Inventory (CSRI)

Interview

Interview conducted during cultural adaptation, after the pilot trial, and after the trial

1. Cultural adaptation: interview consist of free listing interview (30 participants), key informant interview for problems (20 participants), key informant interview on stakeholder (20 participants), focus group discussion (20 participants), cognitive interview (10 participants). Expert review of the material will be used cultural adaptation questionnaire.
2. After the pilot study: the interview will be conducted with participants in both the intervention and control arms and the SH+ facilitators to evaluate the study and the revisions needed to conduct the larger study. It will be conducted after the one-week post-intervention assessment. It is planned to conduct 20 interviews.
3. After the trial: the interview will be conducted with participants in both the intervention and control arms, and the SH+ facilitators to ask about the feasibility and acceptability of SH+ for university students. It will be conducted after three months of follow-up. It is planned to conduct 20 interviews.

1.2 Will you use existing data? If yes, what is their source?

N/A

1.3 Will you collect or produce new data? If yes, please describe how.

Yes.

- A Castor Electronic Data Capture (EDC) will be used to collect data on demographics, mental health status, and quality of life.
- Qualtrics will be used for participant registration, consent forms, mental health questionnaires and intervention monitoring.
- The interviews will be conducted by trained psychology students (ethical and methodological). They will be conducted online using Zoom Meeting, which stores directly on the computer's hard drive. After the interview, the voice recording will be stored in Research Drive and will only be accessible to the research team. After all interviews have been transcribed, the voice recording will be deleted.

1.4 Describe the population/participants/subjects that will be studied

Qualitative study: University students in Indonesia, stakeholders in university, psychologist in university.
Pilot RCT & RCT: University students in Indonesia aged 17-29 years old.

1.5 Do you process any of the following (personal) data?

- Name
- Contact details
- Financial information

Students willing to participate in the study will sign a consent form with their name and date of signature. Contact details such as telephone number and email address will be collected. The telephone number will be used to invite and remind the participant about the intervention session. The email address will be used to send the link to the questionnaire and to send the reminder to complete the questionnaire. At the end of the project, when the last participant completes the questionnaire at the six-month post-

intervention follow-up, all contact details will be deleted.
Financial information: from whom they received financial support (parent, other family member, scholarship, or by themselves). Living allowance they received.

1.6 Do you process the personal data based on informed consent?

- Yes, using digital consent

Informed consent will be obtained prior to data collection and digital consent will be obtained using Qualtrics.

1.7 On what legal ground will the data processing take place if it is not based on informed consent?

- Not applicable, I use informed consent

1.8 Does the data collection include any of the following types of personal data?

- Religious or philosophical beliefs
- Race or ethnic origin

- Race or ethnic origin: The response options will consist of the eight main ethnic groups in Indonesia, plus other: (please fill in) if you do not belong to that ethnic group or if you are mixed between ethnic groups.
- Religion: The response options will consist of the 6 religions in Indonesia, plus the options of not willing to answer and other (please fill in).
- Place of origin: Text Answer Type

1.9 If your research involves special categories of personal data (previous question) and you will not use explicit informed consent, what is the legal ground for the exemption?

N.A

1.10 What kinds of outputs will you produce in this project? Please describe these data assets.

Raw data:
Data asset: Informed consent
Description: signed informed consent
Format: .pdf
Data asset: Interview
Description: Interview will be conducted to facilitator of the intervention and participants of the study.
Format: .mp3
Processed data:
Data asset: Interview transcript
Description: All interview will transcribed and anonymized
Format:.docx and .pdf
Data asset: Data spreadsheet
Description: export data from Castor EDC
Format: .xlsx/.xls and .csv
Analyzed data:
Data asset: Data spreadsheet
Description: cleaned and processed SPSS file
Format: sav
Data asset: Qualitative data
Description: Interview will be analyzed using Thematic analysis using Atlas.ti
Format: .docx
Data asset: R script
Description: R codes for the analysis
Format: R file

Data asset: Descriptive graphic
Description: Graph of score change between pre- and post-intervention
Format: .jpg/ .tif

1.11 How much digital data storage will your project require?

- Other

<= 500 GB

1.12 Will you collect physical data? If yes, please describe these.

No.

1.13 Will you take measures to ensure data quality? Please describe these, if applicable.

Attention check questions will be included in the questionnaire.

2. Legal and ethical requirements, codes of conduct

2.1 What legislation applies to your research project? Please tick the relevant boxes for your project.

- Other, please specify below
- General Data Protection Regulation (GDPR)/ Algemene Verordening Gegevensbescherming (AVG)
- Indonesian Psychology Code of Ethics
- VU and FGB RDM Policies
- Undang-undang Nomor 27 tahun 2022 tentang Perlindungan Data Pribadi (UU PDP) (Law Number 27 Year 2022 on Personal Data Protection (UU PDP)

2.3 Do you require approval of an ethical committee for this project? If yes, please indicate which ethical committee and whether you have obtained approval for this project.

- Yes

Ethics Committee: The Research Ethic Committee Universitas Padjadjaran
Approval status: Approved
Review code: 2210071275
Approval date: 02/12/2022

2.4 Will you work with data for which intellectual property and/ or confidentiality are an issue? If yes, please describe.

- Yes

The data collection is Indonesia, cooperation between VU Amsterdam, Universitas Padjadjaran (UNPAD) and Bandung Institute of Technology (ITB), Indonesia. An agreement on academic and research collaboration, which includes data collection and confidentiality, has been signed by FGB VU, UNPAD and ITB.
For the transcription of the data (interview data): an external transcriber will be hired. Before they start transcribing, the employment agreement will be carried out. The confidentiality of the data will be included in the agreement. Another option is using transcription services provided by the VU Amsterdam and Dhini Andriani will do the reviewed and revised.

2.5 Do you plan on generating a marketable product from your research project? if yes, please describe

- No

3. Storage and back-up during the research process

3.1 What measures will you take to secure and protect data during the research process? Please describe, for each separate data asset you described for question 1.10, how you will ensure data security, where the data assets are stored & backed up, and who has authorization to access the asset.

Raw data:
Data asset: digital informed consent
Storage: SURFdrive
Backup: Research drive
Access: The project manager
Security measures: Folder of the scan informed consent will be password protected

Data asset: Interview
Storage: OneDrive
Backup: Research drive
Access: Marit Sijbrandij, Fredrick D. Purba, Dhini Andriani, and one transcriber to transcript the interview.
Security measures: The audio of interview cannot be download, it only can be play directly in research drive.

Processed data:

Data asset: Interview transcript
Storage: Research drive
Backup: Using encrypted external hardisk
Access: Marit Sijbrandij, Fredrick D. Purba, Dhini Andriani, and qualitative analysis team
Security measures: Pseudonymized and encrypted

Data asset: Data spreadsheet (.xlx and .csv)
Storage: Research drive
Backup: Using encrypted external hardisk
Access: Marit Sijbrandij, Fredrick D. Purba, Dhini Andriani. A special folder for statisticians who will be analysing data
Security measures: Pseudonymized and encrypted.

Analyzed data:

Data asset: Data spreadsheet (cleaned and processed SPPS file, sav)
Storage: Research drive
Backup: Using encrypted external hardisk
Access: Marit Sijbrandij, Fredrick D. Purba, Dhini Andriani.
Security measures: Pseudonymized and encrypted.

Data asset: Qualitative data (result of qualitative analysis, .txt)
Storage: Research drive
Access: Marit Sijbrandij, Fredrick D. Purba, Dhini Andriani
Security measures: no personal data

Data asset: R script
Storage: Research drive
Access: Marit Sijbrandij, Fredrick D. Purba, Dhini Andriani
Security measures: no personal data

Data asset: Descriptive graphic
Storage: Research drive
Access: Marit Sijbrandij, Fredrick D. Purba, Dhini Andriani
Security measures: no personal data

3.3 Which tools are used in the collection, processing or storage of data during research?

- Other (please specify below)
- Research Drive (Surf)
- OneDrive
- Sharepoint

- Castor
- Atlas.Ti *
- SURFDrive
- Zoom
- Qualtrics
- Zivver
- SURFfilesender

SPSS

3.4 What other tools or software do you intend to use during your research?

Name: SPSS
Role: Data processing
Country: United States of America

3.5 Is it necessary to transfer the (physical or digital) data assets to other locations or research partners? If yes, please describe how you secure the file transfer.

- Yes
- Digital data: EQ-5D-5L and cost-utility data will be sent to Indonesia for cost-effectiveness analysis. It will be send using Zivver.

3.7 Do you transfer personal data outside of the European Economic Area (EEA)? If Yes, please provide additional information

- Yes

Country: Indonesia
Reason of transfer: Analysis
Legal Basis: Explicit informed consent
EQ-5D-5L and cost-utility data will be sent to Indonesia for cost-effectiveness analysis. The data have been anonymised prior to transmission.
Country: Indonesia
Reason of transfer: Archiving
Legal Basis: Explicit informed consent
Data collection will be collected in Indonesia using Castor EDC. Therefore, the data will be stored online in Castor EDC server and the data will stay in EEA. After the research project finish and research article has been published, data will be take to Indonesia. Further details will be discussed with the legal of FGB.

4. Data archiving and publishing

4.1 Which data assets will be archived and which will be published?

No personal data will be published, including informed consent, audio file, transcript of audio, and some demographic data (religion, ethnicity, and city of origin). Data from the Mental Health Status Questionnaire will first be anonymised, then archived and published.

4.2 Where will you archive your data assets?

- Yoda
- Open Science Framework (OSF)

4.3 What other archive(s) do you intend to use to archive data assets?

Name:
Role:
Country:

4.4 For how long will the data be available in the archive?

15 years

4.6 Where will you publish your data assets?

Open science network

4.8 How will you ensure your data assets get a persistent identifier (e.g. a DOI-code)?

Publish the data set in open science network

4.9 Will you register your datasets in an online registry other than PURE? If yes, where?

No.

4.10 Are there restrictions to data publishing? If yes, please specify the reasons and list the data assets you do not wish to share publicly.

Informed consent, audio file, audio transcript and some demographic data (religion, ethnicity and place of origin).
All of the above data contains personal and sensitive information. Informed consent, audio file and transcript of audio cannot be fully anonymised.

4.12 When will you share the data? If not immediately after completion of the project, please specify the reasons.

After published four or five scientific article from the data set, the related dataset will be shared on OSF, but only if anonymization is truly possible. Otherwise, only the existence of the dataset will be registered on PURE.

4.13 Please indicate the license and/ or terms of use under which you share your data.

Attribution 4.0 International (CC BY 4.0)

5. Documentation

5.1 What documentation and metadata will accompany the project?

The project has been registry in ISRCTN Trial Registry: ISRCTN15761598 Self-Help Intervention to reduce psychological distress among university students in Indonesia. The statistical analysis plan will added in the trial registry and protocol paper is being written.
Other metadata will accompany the project:

1. Code book of questionnaires
2. Protocol of data collection
3. Log-book of data collection

The team plan to adding metadata in a machine readable format using a common ontology, https://www.dublincore.org/specifications/dublin-core/dcmi-terms/#section-4 using OSF.

5.2 What metadata and documentation will accompany the data assets?

1. Data and variable naming
2. Structure of the data
3. Protocol data collection

5.3 What methods, software or hardware are needed to access and use your data?

Raw data / Processed data:
Data asset: Data spreadsheet (.xlsx)
Sofware: Microsoft Excel
Analyzed data:
Data asset: Data spreadsheet (.csv)
IMB SPSS Statistics 27
Other:
Data asset: Logbooks
Word for Microsoft 365 MSO

6. Data management responsibilities and resources

6.1 Who will be responsible for management of the data assets during the project? Please specify their name, position, role in the project, and faculty/ institution/ group.

Please provide the following details: Dhini Andriani
Your role in the project (please refer to the **CRediT** contributor roles): PA
Telephone number: 0687764395
Email: d.andriani@vu.nl
ORCID (**LibGuide**): https://orcid.org/0000-0002-6718-5789
University: Vrije Universiteit Amsterdam
Faculty/Institute: Faculty of Behavioural and Movement Sciences
Department/Research Group: Clinical, Neuro-,and Developmental Psychology

6.2 Who will be responsible for management of the data assets after completion of the project (e.g. the project lead/ dedicated data manager/ department head)? Please specify their name, position, role in the project, and faculty/ institution/ group.

Full name: Fredrick Dermawan Purba, M.Psi., Ph.D
Your role in the project (please refer to the **CRediT** contributor roles): PA
Telephone number: +628122318534
Email: fredrick.purba@unpad.ac.id
ORCID: https://orcid.org/0000-0002-7336-3043
University: Universitas Padjadjaran
Faculty: Faculty of Psychology
Department: Psychology

6.3 For data that are only available upon request, what methods will be used to handle requests for access and how

will data be made available to those requesting access?

Department head will be responsible for arranging agreements with researchers in their departments regarding the management of research data, particularly when a researcher’s employment is ending.

On the part of UNPAD, the Manager of Research, Cooperation and Innovation of the Faculty of Psychology UNPAD will be responsible for the research data management agreement.

6.4 What resources (for example financial and time) will be dedicated to research data management? Please estimate their cost.

- Project website: Not expect any cost. We will use free social media e.g., Instagram
- Trail registry: € 355 (ISRCTN Trial Registry)
- Storage cost: we do not expect any storage cost
- Protocol: depending on the journal, it may cost up to € 1990 (Trial protocol)
- Open Access publication: depending on the journal, it may cost up to € 2870 (Frontier in Psychology)
- Time invested in RDM: 16 hours writing DMP, 32 hours related to publishing datasets, 32 hours related to archiving, and on average 2 hour/ week (other DMP task)