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Self-help intervention to reduce psychological distress among university students in Indonesia

Submission date
27/06/2023

Recruitment status
Recruiting

Registration date
14/07/2023

Overall study status
Ongoing

Last Edited
16/07/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Growing up and becoming an adult can be a challenging time for many people, and it's during this period that the risk of developing mental health problems is higher. This includes the college years when common mental disorders like depression and anxiety are quite common, even in Indonesia. Studies have looked at university students in Indonesia and found that many of them experience high levels of anxiety, depression, and stress. To help students deal with these difficulties, it's important to provide psychological support and teach them ways to cope with their problems. Universities have a role to play in offering these interventions, but there is a problem. There aren't enough mental health professionals available to meet the needs of all the students who require help. To bridge this gap, the World Health Organization (WHO) has developed a program called Self-help Plus (SH+), based on Acceptance and Commitment Therapy (ACT). SH+ is a short-term program where students come together in groups to learn how to manage stress. Previous studies involving refugee and migrant populations have shown that SH+ can reduce psychological distress. This study aims to find out if SH+ is effective in reducing psychological distress among university students in Indonesia over a three-month period. Additionally, the study will also look at whether participating in the program improves functioning, quality of life, and resilience, as well as prevents the development of mental health disorders. To understand how well SH+ works and how acceptable it is to the participants, individual interviews and group discussions will be conducted with the students and facilitators involved in the study.

Who can participate?
University students aged 17-24 years; reported psychological distress based on the Kessler Psychological Distress Scale - 10 items (K10; K10 ≥ 18).

What does the study involve?
Following the screening, eligible participants will be assessed at baseline and then randomized to one of the two groups: 1. Self-Help Plus and Enhanced Care as Usual (SH+/ ECAU) or 2. ECAU only. Participants assigned to the SH+/ ECAU group will take part in Self-help Plus (SH+) intervention and ECAU. SH+ consists of five sessions which each last 2 hours each, for a total

duration of 5 weeks. Participants in the control group will receive Enhanced Care as Usual (ECAU), which consists of receiving an e-leaflet with mental health services and activities at the university and how to access them as well as mental health facilities outside university.

Participants in this study will complete several questionnaires to assess symptoms of depression and anxiety, perceived stress, functioning, quality of life, exposure of objective microstressors, self-identified problems, and health service utilization. Assessments will take place at baseline, 1-week post-intervention, 3- and 6-months follow-up.

What are the possible benefits and risks of participating?
The benefit of taking part is that participants will receive a group stress management course and an illustrated self-help book on stress management. The group sessions is expected to help to reduce psychological distress, increase coping skills and improve quality of life.
This study is not expected to have significant risks to participants. SH+ has already been evaluated in other settings (e.g. South Sudanese refugee woman in Uganda, Syrian refugees in Turkey, and refugees and asylum seeker in Western Europe), and has found to be tolerable and safe. Both during the assessments as well as during the SH+ sessions, it is possible that participants may experience discomfort due to talking about stressful experiences. Both the assessors as well as the SH+ facilitators will be trained to observe the participants and if they see participants who are experiencing any discomfort, the facilitator will be responsive during the session, and inform after the session whether the participant may need any additional assistance. If the participant needs help, the facilitator can refer to the services available at the university. Participants can contact the researcher of this study or tell the facilitator directly if they feel uncomfortable.

Where is the study run from?
Faculty of Psychology of Universitas Padjadjaran (UNPAD) (Indonesia) and Faculty of Behavioural and Movement Science Vrije Universiteit Amsterdam (Netherlands)

When is the study starting and how long is it expected to run for?
September 2022 to November 2026

Who is funding the study?
Indonesian Education Scholarship, Program Ministry of Education, Culture, Research, and Technology of Republic Indonesia (BPPT) and Indonesia Endowment Fund for Education (LPDP)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

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

Acronym
APRESIASI

Study objectives
1. Self-help plus (SH+) with enhanced care as usual (ECAU) is more effective in reducing psychological distress among Indonesian university students compared to ECAU only at 3 months follow-up (primary end point).
2. Self-help plus (SH+) with ECAU is more effective in reducing perceived stress, anxiety, depression, and improving quality of life, psychological functioning, and resilience compared to ECAU only at 3 months follow-up.
3. Self-help plus (SH+) with ECAU is more effective in reducing psychological distress, perceived stress, anxiety, depression, and improving quality of life, psychological functioning, and resilience compared to ECAU only at 1 week post-intervention and 6 months follow-up.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 02/12/2022, The Research Ethics Committee Universitas Padjadjaran (Jl. Prof. Eyckman No. 38, Bandung, 40161, Indonesia; +62 222038697; kep@unpad.ac.id), ref: 2210071275

Study design
Pragmatic two-arm randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
University/medical school/dental school

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Psychological distress (symptoms of anxiety and depression)

Interventions
Current interventions as of 06/08/2024:
Self-Help Plus (SH+) and enhanced care as usual
Participants in the experimental arm will receive Self-Help Plus and Enhanced Care as Usual (ECAU). SH+ is a five-session, group-based (20-30 people) stress management intervention for adults. The five sessions last two hours each and take place once a week for a total of five weeks. SH+ consists of a pre-recorded audio course and an illustrated self-help book called Doing What Matters in Times of Stress: An Illustrated Guide. SH+ is delivered by two trained facilitators.

SH+ is based on Acceptance Commitment Therapy (ACT). SH+ and the illustrated book consist of five core skills: (1) grounding (bringing our attention to the present moment); (2) unhooking (letting go of from difficult thoughts and feelings); (3) acting on your values (identifying personal values and acting on the basis the those value); (4) being kind (being kind to oneself and others); and (5) making room (making room for difficult thoughts and feelings, rather than of fighting with them).

The ECAU will consist of an e-leaflet on mental health within and outside universities, which will be sent by a research assistant to participants via email or other media communication.

Enhanced care as usual
Enhanced care as usual (ECAU) consists of an e-leaflet with information of about mental health services and activities provided by the universities, as well as mental health services outside universities, in the form of an e-leaflet. Information about activities includes the schedule of regular mental health seminars or webinars at the university and how to attend it. Other information includes the emergency contact for mental health issues. The ECAU will be sent to participants by email or other media communication of their choice.

Randomisation
The order of allocation will be determined using the electronic data capture (EDC) software Castor (www.castoredc.com) by an independent researcher at the Faculty of Behavioural and Movement Sciences, Vrije Universiteit Amsterdam. Participants will be randomised individually and stratified by the center. Eligible participants will be randomly assigned to the intervention or control group in a 1:1 allocation ratio, with unequal block randomization. The assessor and statistician will be blinded to the block size and randomisation list. Neither participants nor facilitators will be blinded to allocation.

Previous interventions:
Self-Help Plus (SH+) and enhanced care as usual
Participants in the experimental arm will receive Self-Help Plus and Enhanced Care as Usual (ECAU). SH+ is a five-session, group-based (20-30 people) stress management intervention for

adults. The five sessions last two hours each and take place once a week for a total of five weeks. SH+ consists of a pre-recorded audio course and an illustrated self-help book called Doing What Matters in Times of Stress: An Illustrated Guide. SH+ is delivered by two trained facilitators. ECAU is delivered individually to participants by a research assistant.

SH+ is based on Acceptance Commitment Therapy (ACT). SH+ and the illustrated book consist of five core skills: (1) grounding (bringing our attention to the present moment); (2) unhooking (letting go of from difficult thoughts and feelings); (3) acting on your values (identifying personal values and acting on the basis the those value); (4) being kind (being kind to oneself and others); and (5) making room (making room for difficult thoughts and feelings, rather than of fighting with them).

Enhanced care as usual
Enhanced care as usual (ECAU) consists of information about mental health services and activities provided by the university in the form of an e-leaflet, accompanied by an explanation from the research assistant. The e-leaflet provides information about services such as individual and peer counselling and how to make an appointment. Information about activities includes the schedule of regular mental health seminars or webinars at the university and how to attend. Other information includes the emergency contact for mental health issues.

Randomisation
The order of allocation will be determined using the electronic data capture (EDC) software Castor (www.castoredc.com) by an independent researcher at the Faculty of Behavioural and Movement Sciences, Vrije Universiteit Amsterdam. Participants will be randomised individually and stratified by the center. Eligible participants will be randomly assigned to the intervention or control group in a 1:1 allocation ratio, with unequal block randomization. The assessor and statistician will be blinded to the block size and randomisation list. Neither participants nor facilitators will be blinded to allocation.

Intervention Type
Behavioural

Primary outcome measure
Psychological distress as measured by the Patient Health Questionnaire Anxiety and Depression Scale (PHQ-ADS) total score. It will be administered at baseline, 1-week post-intervention, 3- (primary end point) and 6-month follow-up.

Secondary outcome measures
Measured at baseline, 1-week post-intervention, 3- and 6-month follow-up
1. Symptoms of depression will be measured with Patient Health Questionnaire (PHQ-9)
2. Symptoms of anxiety will be measured by General Anxiety Disorder (GAD-7)
3. Perceived stress will be measured by Perceived Stress Scale (PSS)
4. General functioning measured by WHO Disability Assessment 2.0 (WHODAS 2.0)
5. Quality of life will be measured by EQ-5D-5L
6. Exposure to objective microstressors will be measured by the Mainz Inventory of Microstressors (MIMIS), which will be adapted for the current population
7. Self-identified problems measured using the PSYCHLOPS

Added 06/08/2024:
8. Cost-effectiveness from analysis of EQ-5D-5L and Client Service Receipt Inventory (CSRI)

Overall study start date
01/09/2022

Completion date
30/11/2026

Eligibility

Key inclusion criteria
Current inclusion criteria as of 29/05/2025:

1. University students aged between 17-29 years old;
2. score ≥ 5.5 on the Patient Health Questionnaire-9 (PHQ-9);
3. willing to attend five sessions of SH+.

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Previous inclusion criteria :

1. University students
2. Aged between 17-24 years old
3. Increased levels of psychological distress based on the Kessler psychological distress scale-10 items (K10; K10 ≥18)

Participant type(s)
Patient

Age group
Adult

Lower age limit
17 Years

Upper age limit
24 Years

Sex
Both

Target number of participants
190

Total final enrolment
296

Key exclusion criteria
Current exclusion criteria as of 29/05/2025:

1. Acute medical conditions that require immediate hospitalization.
2. Score ≥ 20 (severe depression symptoms) on the PHQ-9

3. Indication of imminent risk of suicide or self-harm or other life-threatening risk based on Suicide Ideation Scale (SIS) with score ≥ 21.89.
4. Indication of severe cognitive impairment related to a mental, neurological or substance abuse based on PM+ observation checklist.
5. Initiated, stopped, or significantly modified pharmacotherapy in the last eight weeks.
6. Initiated or stopped specialized psychological treatment (e.g., Cognitive Behavioural Therapy, psychoanalytic therapy) in the last eight weeks.

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Previous exclusion criteria:

1. Acute medical conditions that require immediate hospitalization.
2. Shows imminent suicide risk or self-harm or other life-threatening risk based on interview based on the question of imminent risk of suicide from Problem Management Plus (PM+) manual
3. Indication of severe cognitive impairment related to a mental, neurological or substance abuse based on PM+ observation checklist; and
4. Initiated, stopped, or significantly modified pharmacotherapy in the last eight weeks.
5. Initiated or stopped specialized psychological treatment (e.g., Cognitive Behavioural Therapy, psychoanalytic therapy) in the last eight weeks.

Date of first enrolment
29/05/2025

Date of final enrolment
30/05/2026

Locations

Countries of recruitment
Indonesia

Study participating centre
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Study participating centre
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Sponsor information

Organisation
Ministry of Research, Technology and Higher Education of Republic Indonesia

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Sponsor type
Government

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Funder(s)

Funder type
Government

Funder Name
Indonesian Education Scholarship from the Center for Financing of Higher Education (BPPT) and Indonesia Endowment Fund for Education (LPDP)

Results and Publications

Publication and dissemination plan
The result of this study will be submitted for publication in high-impact peer-reviewed journals.

Intention to publish date
30/11/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.
e.m.sijbrandij@vu.nl

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan			28/01/2025	No	No
Protocol article		08/07/2025	16/07/2025	Yes	No