**Version 2.0**

**November 2024**

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

# STATISTICAL ANALYSIS PROTOCOL

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# The effectiveness of adapted Self-Help Plus (SH+) to reduce psychological distress, improve functioning and quality of life among university students in Indonesia (APRESIASI): Randomized Control Trial (RCT)

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**Funded by:**

BEASISWA PENDIDIKAN INDONESIA

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**ABBREVIATIONS**

| Abbreviation | Explanation |
|---|---|
| CSRI | Client Service Receipt Inventory |
| DMW | Doing what matters in time of stress |
| EQ-5D-5L | EuroQol 5-dimensional descriptive system—5-level version |
| ECAU | Enhanced Care as Usual |
| GAD-7 | General Anxiety Disorder |
| ICERs | Incremental cost-effectiveness ratios |
| ITT | Intention-to-treat |
| MIMIS | Mainz Inventory of Micro stressors |
| PHQ-9 | Patient Health Questionnaire |
| PHQ-ADS | Patient Health Questionnaire Anxiety and Depression Scale |
| PP | Per Protocol |
| PSS | Perceived Stress Scale |
| PSYCHLOPS | Psychological Outcomes Profile Instrument |
| QALYs | Quality-adjusted life years |
| SH+ | Self-Help Plus |
| WHODAS 2.0 | WHO Disability Assessment |

# 1. INTRODUCTION

## 1.1 Background and Rationale

The college years are associated with a high prevalence of common mental health disorders such as depression and anxiety (Gustavson et al., 2018; Kessler et al., 2005), including in Indonesia. Studies in Indonesia have indicated that university students have a high prevalence of anxiety, depression, and stress (Astutik et al., 2020; Mardea et al., 2020; Marthoenis et al., 2018). Therefore, there is a need for psychological interventions 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 in need of 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 (World Health Organization (WHO), 2021). SH+ is a brief and group-based stress management intervention. Based on previous studies in refugee and migrant populations, SH+ has been shown to reduce psychological distress (Acarturk et al., 2022; Riello et al., 2021; Tol et al., 2020). In this study, randomized controlled trials (RCTs) will be done to assess the effectiveness of SH+ in university students in Indonesia.

## 1.2 Objectives

### 1.2.1 Primary Objective

The main objective is to evaluate the effectiveness and cost-effectiveness of SH+ combined with enhanced care as usual (ECAU) (SH+/ECAU) in reducing symptoms of psychological distress among university students in Indonesia at three-month follow-up (main time point).

### 1.2.2 Secondary Objective

The secondary objective is to assess depressive and anxiety symptoms, perceived stress, functioning, quality of life, and resilience at 1-week post-intervention, three-month follow-up, and six-month follow-up. A further objective will be the evaluation of the feasibility and acceptability of SH+.

# 2. STUDY DESIGN

## 2.1 Trial Design

This is a pragmatic, superior, single-blind randomised controlled trial with two parallel arms. The final phase of the study will be a qualitative process evaluation using individual interviews and focus group discussions (FGDs). The qualitative phase will include some participants in the RCTs who completed SH+, those who dropped out during SH+, facilitators, supervisors of facilitators and local stakeholders.

## 2.2 Randomization

Eligible participants will be randomly assigned to the intervention or control group in a 1:1 allocation ratio, using randomization with four and six blocks. The allocation sequence will be determined using the Castor electronic data capture (EDC) software (www.castoredc.com), randomised individually and stratified by centre. Neither participants nor facilitators will be blinded to allocation.

## 2.3 Sample Size

Utilizing G*Power (Faul et al., 2007), considering psychological distress as the primary outcome with an effect size of 0.3, a power calculation for a repeated measures design suggests a minimum sample size of N = 148 (power = 0.95, $\alpha = 0.05$, rho= 0.9, two-tailed) to detect an effect size of interest.

Considering 50% of attrition during our pilot, a total of 296 participants will be recruited (148 participants in each arm).

## 2.4 Frame Work

This is a superiority trial: the hypothesis is that SH+/ECAU will be superior to the ECAU only in reducing psychological distress (primary outcome) at the three-month follow-up, as well as the secondary outcomes of depression and anxiety, perceived stress, improved functioning, quality of life, resilience, and identified problems. The SH+/ ECAU will report lower health care costs than ECAU-only.

## 2.5 Statistical Interim Analysis and Stopping Guidance

Data will be analysed once all data have been collected; no interim analyses will be performed.

## 2.6 Timing of Final Analysis

Outcomes will be analysed according to the time when they are measured.

## 2.7 Timing of Outcome Assessment

Outcomes will be collected at $t_2$ (1 week post SH+ intervention), $t_3$ (three-month post SH+ intervention), and $t_4$ (six-month post SH+ intervention).

Table 1. Schedule of enrolment, interventions, and assessment for RCT of SH+

| | **Study Period** | | | | | | |
|---|---|---|---|---|---|---|---|
| | Enrolment | Screening | Baseline | Randomization | Post-Assessment | | |
| Time Point | | $t_0$ | Week 1 $t_1$ | | Week 7 ($t_2$) | 3-month follow-up ($t_3$) | 6-month follow-up ($t_4$) |
| ENROLMENT | | | | | | | |
| Informed consent | X | | | | | | |
| Eligibility screen | | X | | | | | |
| Allocation | | | | X | | | |
| INTERVENTIONS | | | | | | | |
| SH+/ECAU | | | | ← | → | | |
| ECAU | | | | ← | → | | |
| ASSESSMENTS | | | | | | | |
| Sociodemographic | | X | X | | X | X | X |
| PHQ-9 | | | X | | X | X | X |
| GAD-7 | | | X | | X | X | X |
| PSS | | | X | | X | X | X |
| WHODAS 2.0 | | | X | | X | X | X |
| EQ-5D-5L | | | X | | X | X | X |
| MIMIS | | | X | | X | X | X |
| PSYCHLOPS | | | X | | X | X | X |
| CSRI | | | X | | X | X | X |
| Contamination questions | | | | | X | X | |
| Process evaluation | | | | | | X | |

# 3. STATISTICAL PRINCIPLES

## 3.1 Confidence Interval and P-Values

The conventional 0.05 level is used for statistical significance and 95% confidence intervals are reported. To address issues associated with multiple testing, the global statistical significance of the secondary outcomes will be assessed at each time point using the Seemingly Unrelated Regression (SUR) equation model, controlling for baseline values.

## 3.2 Adherence and Protocol Deviations

Adherence will be defined based on attendance at least 3 sessions of SH+ (Purgato et al., 2021). Due to the pragmatic nature of the study, the concept of protocol deviation does not apply.

## 3.3 Analysis Population

All primary and secondary will be analysed using an intention-to-treat (ITT) approach. The ITT population will consist of all participants randomised to the competing intervention strategies who have at least baseline assessment data available. A per protocol (PP) approach will be used to test the robustness of the intervention result in all outcomes, which will only include SH+/ECAU participants who attend at least three sessions of the SH+ intervention (Purgato et al., 2021).

# 4. Trial Population

## 4.1 Screening Data

**Screening (T0)**

Following informed consent, participants will be invited for screening. Screening consists of a self-administered measure to determine whether people meet the inclusion criteria (4.2.1 Inclusion criteria). Furthermore, an interview guide and observation checklist will be used to check whether potential participants meet exclusion criteria.

- **Screening for inclusion criteria**
  To participate in the study, participants must score above 17.9 on the Kessler K10 Psychological Distress Scale (K10) (Duc et al., 2019), a 10-item screening questionnaire for common mental disorders (Kessler et al., 2002). More detailed explanations of all measures are provided in the section *'Measurement Instruments'.*
- **Screening for exclusion criteria**
  If individuals meet the inclusion criteria, they are screened for the exclusion criteria (4.2.2 Exclusion criteria). If they meet one exclusion criteria, they are excluded and referred for appropriate treatment and support. We will assess whether individuals: (a) have an acute medical condition requiring immediate hospitalisation; (b) have plans to end their lives (see measurement tools); (c) have indication of severe cognitive impairment related to a mental, neurological or substance abuse; and (d) are currently taking psychotropic medication with a change in dose in the past 2 months or are currently receiving specialist psychological treatment.

If participants are not selected for the study because they score below the K10 cut-off scores or meet the exclusion criteria described in Exclusion criteria, they will receive immediate feedback, such as the screening results (including the K10 score) and an explanation of why they are not eligible for the study (p. 86 PM+ intervention manual; WHO, 2016). If participants are excluded because to imminent risk of suicide, or because of observed (suspected) severe mental disorders or severe cognitive impairment,

they are referred to appropriate treatment and support, such as to their general practitioner, or specialist mental health care, or to local social services, depending on their clinical characteristics and needs. If patients agree to referral, the results of the assessment will be shared with their general practitioner or treating mental health professional, with the participant's permission.

## 4.2 Eligibility

### 4.2.1 Inclusion Criteria

- University students between the ages 17 and 29 years old
- Increased levels of psychological distress based on the Kessler psychological distress scale-10 items (K10; K10 ≥ 18)
- Willingness to attend five sessions of SH+

### 4.2.2 Exclusion Criteria

- Acute medical conditions requiring immediate hospitalisation.
- Indication of imminent risk of suicide or self-harm or other life-threatening risk based on interview using the imminent risk of suicide question from the Problem Management Plus (PM+) manual
- Evidence of severe cognitive impairment related to mental, neurological or substance abuse based on PM+ observation checklist;
- Started, stopped or significantly changed pharmacotherapy in the previous eight weeks.
- Specialised psychological treatment (e.g., cognitive behavioural therapy, psychoanalysis) initiated or discontinued in the past eight weeks.

## 4.3 Recruitment

The recruitment strategy for the RCT will be pragmatic and will mainly involve the participating universities. Participants will be recruited using social media strategies and snowball sampling. Advertisements for the study will be placed on the web or social media available at the universities.

The qualitative evaluation will include a purposive sampling method called maximum variation sampling. In this sampling method, the sample is selected based on variation in some key characteristics (Suri, 2011). For treatment group participants, relevant variables will include gender, semester, and status of completion of the intervention program (dropout or completion). The selection of variables relevant to SH+ will include gender, age, faculty, and experience in counselling. Mental health professionals/supervisors involved in the study will be contacted directly if they wish to participate in the interviews. Key decision makers or stakeholders will be approached through available professional contacts.

## 4.4 Withdrawal of Individual Subjects

Participants may withdraw from the study at any time, for any reason, if they wish, without any consequences. The investigator may decide to withdraw a participant from the intervention for urgent medical reasons, e.g. imminent risk of suicide. If, during the SH+ session, participants show deterioration with imminent suicidal plans, the facilitator will immediately discuss this with one of the supervising SH+ mental health professionals. Similarly, if there is a clear suspicion of worsening

(severe) mental health problems, participants will be asked to contact the university mental health professional for treatment or for referral to specialist mental health care.

No new participants will be enrolled for each subject withdrawn. The sample size has been calculated with a 50% attrition rate.

If a participant decides to withdraw from the study, the investigator will ask for the reason. The investigator will ask whether the participant wishes to withdraw from the whole study or just a particular session, and whether the subject can be contacted again at a later date.

### 4.5 Baseline Participants Characteristics

Participants proceed to baseline assessment if they meet the eligibility criteria. This step includes the administration of questionnaires on socio-demographic characteristics, the Patient Health Questionnaire Anxiety and Depression Scale (PHQ-ADS), which is a combination of the Patient Health Questionnaire-9 (PHQ-9) and the General Anxiety Disorders-7 (GAD-7), the Perceived Stress Scale (PSS), the WHO Disability Assessment 2.0 (WHODAS 2.0), the Mainz Inventory of Micro-stressors (MIMIS), the Quality of Life Checklist (EQ-5D-5L), the Self-identified Problem (PSYCHLOPS), and Client Service Receipt Inventory (CSRI). Sociodemographic information will be collected with predefined items: age, gender, religion, ethnic group, field of study, GPA, year of study, living condition, financial support, and current general health status.

## 5. EFFECTIVENESS ANALYSIS

### 5.1 General Approach

There will be three endpoints during the trial. The first will be one week after the SH+ intervention assessment, the second three months after the SH+ intervention assessment and the third six months after the SH+ intervention assessment. For the primary endpoint (three months after the SH+ intervention), we are more interested in the medium term than the short-term effects of the SH+ intervention.

### 5.2 Outcomes Definition

#### 5.2.1 Primary Outcome

The primary outcome will be the average PHQ-ADS total score at 3 months follow-up (primary end point) (Kroenke et al., 2016, 2019).

#### 5.2.2 Secondary Outcomes

The secondary outcomes of our study will be:

a. PHQ-ADS score one week at post SH+ intervention assessment and at six months post SH+ intervention assessment;
b. Depression (PHQ-9), anxiety (GAD-7), perceived stress (PSS), general functioning (WHODAS 2.0), quality of life (EQ-5D-5L), resilience, and self-defined psychosocial goals (PSYCHLOPS) at one week, three-and six-month follow-up after SH+ intervention assessment.

**PHQ-9: depression (PHQ-9; subscale of PHQ-ADS)**

Depressive symptoms in the past two weeks are measured using the depressive module of the Patient Health Questionnaire. It asks how often each of the nine DSM-5 criteria bothered a person and scores

responses on a four-point Likert scale ranging from 0 (not at all) to 3 (almost every day) (Kroenke et al., 2001). In addition to the nine items, the PHQ-9 asks: "If you ticked off any problems, how difficult have these problems made it for you to do your job, take care of things at home, or get along with other people?", which is to be answered with "not at all difficult", "somewhat difficult", "very difficult", or "extremely difficult". For the current study, we will examine changes in depression severity. We will use a cut-off score of 10, which has been shown to be a valid cut-off point for diagnosis (Manea et al., 2012). The PHQ-9 has been translated and is available in many languages (see https://www.phqscreeners.com/), including PHQ-9 has been validated to Bahasa Indonesia with Cronbach's alpha 0.885 (Dian et al., 2022). In addition, its brevity makes the PHQ-9 a useful instrument for use in clinical or research settings (Kroenke et al., 2001).

**GAD-7: anxiety symptoms (GAD-7; subscale of PHQ-ADS)**

The Generalized Anxiety Disorder Questionnaire (GAD-7) is a seven-item self-report anxiety questionnaire that assesses the extent to which the patient has been bothered by feeling nervous, worried or on edge in the past two weeks. It has proved valid in the general population (Lowe et al., 2008). Items are scored from 0 to 3 for experiencing symptoms 'never', 'several days', 'more than half the days' and 'almost every day'. The total score ranges from 0 to 21. Cut-off points for mild, moderate and severe anxiety are scores of 5, 10 and 15 respectively (Spitzer et al., 2006a). A score of 10 has been identified as the optimal cut-off to balance specificity and sensitivity (Spitzer et al., 2006b). The GAD-7 has been translated to and is available in many languages (see https://www.phqscreeners.com/), among which is Bahasa Indonesia with Cronbach's alpha 0.867 (Budikayanti et al., 2019).

**PSS: perceived stress scale**

The Perceived Stress Scale (PSS) is a measure of individual perceptions of recent stress (Cohen et al., 1983). The items are designed to measure how unpredictable, uncontrollable and overwhelming respondents feel their lives are. The questions in the PSS ask about feelings and thoughts over the past month. The PSS consists of 10 items that are scored from 0 to 4 with the response options being 'never', 'almost never', 'sometimes', 'fairly often' and 'very often'. The Indonesian PSS has a Cronbach's alpha of 0.79 (Prasetya & Purnama, 2019).

**WHODAS 2.0: general functioning**

The WHODAS 2.0-12 items is a generic assessment instrument that can measure health and disability at the population level or in clinical practice. It consists of 12 items that evaluate six activity domains: understanding and communicating, getting around, self-care, getting along with people, life activities, and participation in society (Federici et al., 2009). In each item, participants will answer the level of difficulty (none, mild, moderate, severe, extreme), WHODAS 2.0 is available in Bahasa Indonesia (Rijanti et al., 2021).

**EQ-5D-5L: quality of life**

The EQ-5D-5L measures quality of life and consists of two parts, the EQ-5D and the EQ-VAS. Part 1, the EQ-5D, assesses the level of impairment in five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems and extreme problems. The EQ-5D-5L has been widely used and is available in over 150 languages, including Bahasa Indonesia (Purba et al., 2017a). Indonesian's utility weights are applied to the EQ-5D-5L data, and changes in participants' quality of life years gained between the intervention and control groups are determined. Part 2, the EQ-VAS, is a visual, vertical, analogue scale. The endpoints of the scale are 'The best health you can imagine' and 'The worst health

you can imagine', and participants are asked to report their current health status for the day, and then to write down the number they have checked on the scale.

**PSYCHLOPS: self-identified problems**

The Psychological Outcomes Profiles (PSYCHLOPS) scale is a patient-generated outcome measure as an indicator of change after treatment (Ashworth et al., 2004). PSYCHLOPS consists of four questions covering three domains: problems (2 questions), functioning (1 question) and well-being (1 question). Participants are asked to provide free-text responses to the problems and functioning domains. Responses are scored on a six-point ordinal scale, with a maximum score of 18 (six points per domain). A formative adaptation of PSYCHLOPS to the Bahasa Indonesian language has been carried out.

**Resilience: Measuring mental health in relation to stressor exposure**

Resilience is defined as an outcome of good mental health in the face of adversity (maintaining or recovering mental health during and after periods of exposure to stressors, including traumatic life events, difficult living conditions, challenging life transitions, or physical illness) (Kalisch et al., 2017). This requires relating changes in mental health to exposure to stressors. The Mainz Inventory of Micro-stressors (MIMIS) has recently been developed to measure objective micro-stressors of modern life in the last 7 days (Chmitorz et al., 2020). Each MIMIS item will has two response scales: a three-point Likert scale indicating the frequency with which a stressor occurred, ranging from 0 (did not happen/ almost never) to 3 (almost every day), and a five-point Likert scale indicating the extent to which the stressor caused mental strain, ranging from 0 (this situation did not happen) to 4 (severe impact).

For the APRESIASI project, the items in the MIMIS generated from the interview result conducted to 30 university students in Indonesia about their problem.

Using these data, outcome-based resilience at each time point T is approximated by relating self-reported psychological distress over the past 2 weeks (assessed with the PHQ-ADS) to the corresponding stressor exposure to this end, a stressor reactivity (SR) score is calculated as an individual score against normal stressor reactivity (Kalisch et al., 2021), where normal stressor reactivity is the regression line of average mental health problems against average stressor exposure across all-time points in the study population, and an individual's SR score at any time point is the distance from the regression line. SR scores are calculated based on the number of stressor exposures that explains the most variance in mental health problems. SR scores are calculated for each time point. The inverse of the SR score is considered an approximate index of outcome-based resilience.

**Client Service Receipt Inventory (CSRI)**

The Client Service Receipt Inventory (CSRI) (Beecham & Knapp, 1992) will be used to examine cost-effectiveness and health service utilization over the past eight months (t1, t2, t3, t4). We adapted the CSRI based on the health system in Indonesia. The questions include type of health services (public, private, university, or others), number of visits, type (in-person/ online), duration of contact, travel and waiting time, and travel costs. Additionally, trial costs will be collected (e.g. training, book printing, supervision, supervision).

## 5.3 Analysis Method

### 5.3.1 Primary Analysis

The primary outcome will be summarised using the number of subjects (n), the minimum and maximum, and the mean, standard deviation (SD) for normally distributed data, or the median and interquartile range for non-normally distributed data. Standardized Mean Difference will be used to compare the two treatment groups as baseline. The primary analysis will simultaneously assess the

treatment effect on the mean PHQ-ADS total score at each time point. We will use an intention-to-treat (ITT) and per-protocol (PP) approach. ITT approach will include all randomised participants (n=194). The PP approach will only include participants in the intervention group who attend at least three sessions of the SH+ intervention. The main conclusion of the trial will be based on the ITT analysis of the primary outcome (i.e. the effect on PHQ-ADS score at the three-month follow-up).

A linear mixed model will be used for the PHQ-ADS analysis to estimate the treatment effect on all endpoints at t2, t3 and t4, with time as a fixed effect, baseline PHQ-ADS as a covariate and participants as random effects. At each time point, the treatment effect will be measured as the interaction between time (as a categorical variable) and treatment, with its value at t3 being our primary endpoint of interest. The mean difference between two treatment arms at each visit/time, together with its 95% confidence interval, will be derived from the mixed model. Robust standard errors are used in all models.

The ITT approach will be used to analyse the secondary outcomes which are the PHQ-9 summary score, the GAD-7 summary score, the WHODAS 2.0 summary score, the EQ-5D-5L summary and domain score, the PSYCHLOPS summary score, and resilience score which will be determined based on the PHQ-ADS total score against the exposure of objective micro stressors.

Health economic analysis will be conducted from a healthcare system and societal perspective using incremental cost per quality-adjusted life year (QALY, based on the EQ-5D-5L) and per change in PHQ-ADS composite score at $t_3$ follow-up assessment point (3 months). To do so, the CSRI will be used to assess the total cost of delivering the intervention and changes in healthcare utilisation. Incremental cost-utility analysis will be conducted from the perspective of the Indonesian health and social care system. The QALYs generates using Indonesia value set (Purba et al., 2017b). Cost difference and QALY difference between two groups estimates using generalized linear regression. The skewed distribution of the cost data was considered by estimating robust standard errors using the Huber-White sandwich estimator.

### 5.3.2 Secondary Analysis of The Primary Outcome Measure

A secondary analysis of the effect of treatment on PHQ-ADS score will be conducted using the per protocol (PP) population, using the same approach as reported above. In addition, a covariate-adjusted mixed model of primary endpoint will be performed by adding pre-specified covariates at baseline (gender, age, year of study, field of study and the stressor list as measured by MIMIS), and those showing imbalance at baseline (as measured by a Standardized Mean Difference above 0.1 in absolute value) into the above model.

A linear mixed model with robust standard errors as mentioned for the primary analysis (PHQ-ADS) will be carried out for analysing each of the following clinical outcomes measured at baseline, at one week, three-and six-months finishing after SH+ depressive symptoms (PHQ-9), generalized anxiety (GAD-7), resilience and quality of life (EQ-5D-5L). The secondary outcomes will be analysed on the ITT population only; no secondary analysis is planned.

*Analysis of other secondary outcomes*

Changes in composite measure anxiety and depression will be calculated for the PP sample using the recommended cut-off of >20 for moderate severity on the PHQ-ADS questionnaire (Kroenke et al., 2016; Kroenke et al., 2019) and will be analysed using a hierarchical logistic model with the same fixed and random effects as the hierarchical linear models above, from which odds ratio of having a depression together with 95% CI at each time point will be derived.

All the analyses on secondary outcomes will be repeated by including variables showing imbalance at baseline and, for the PP population, by adding pre-specified covariates at baseline (gender, age, year of study, field of study, GPA, ethnic group, religion, financial support, living condition, comorbid condition, and the stressor list as measured by MIMIS).

### 5.3.3 Mediation Analysis

Mediation analysis will be done by hypothesis:

- The effect of the treatment on the primary outcome as well as symptoms of depression, anxiety, general functioning, quality of life, and problems will be mediated by its effect on perceived stress.
- The effect of the treatment on the primary outcome as well as symptoms of depression, anxiety, general functioning, quality of life, and problems will be mediated by its effect on resilience (which is determined based on the PHQ-ADS total score against the exposure to objective micro stressors).

### 5.3.4 Additional Exploratory Analysis

Exploratory analyses will be conducted to understand the relationships between perceived stress (as measured by the Perceived Stress Scale) and general stressor exposure (as described in the section 'resilience'). If no relationship between the two is shown, then the two exposures will be treated separately in the computation of resilience

## 5.4 Missing Data

Missing data will be treated as missing at random (MAR). No imputations of missing values will be made, as multilevel models can deal with missing data (Singer & Willett, 2003). In the case only some items are missing for a specific scale, we will perform the Corrected Item mean Substitution method (i.e. the item mean across participants weighted by the subject's mean of completed items; Huisman, 1999), using information from subjects belonging to the same treatment arm for the same follow-up time (estimated values above the maximum or below the minimum admissible value will be set to maximum/minimum).

## 5.5 Harms

Adverse events are defined as any undesirable experience experienced by a subject during the trial, whether considered to be related to the trial procedure or the SH+ intervention. All adverse events reported spontaneously by the subject or observed by the facilitator will be recorded.

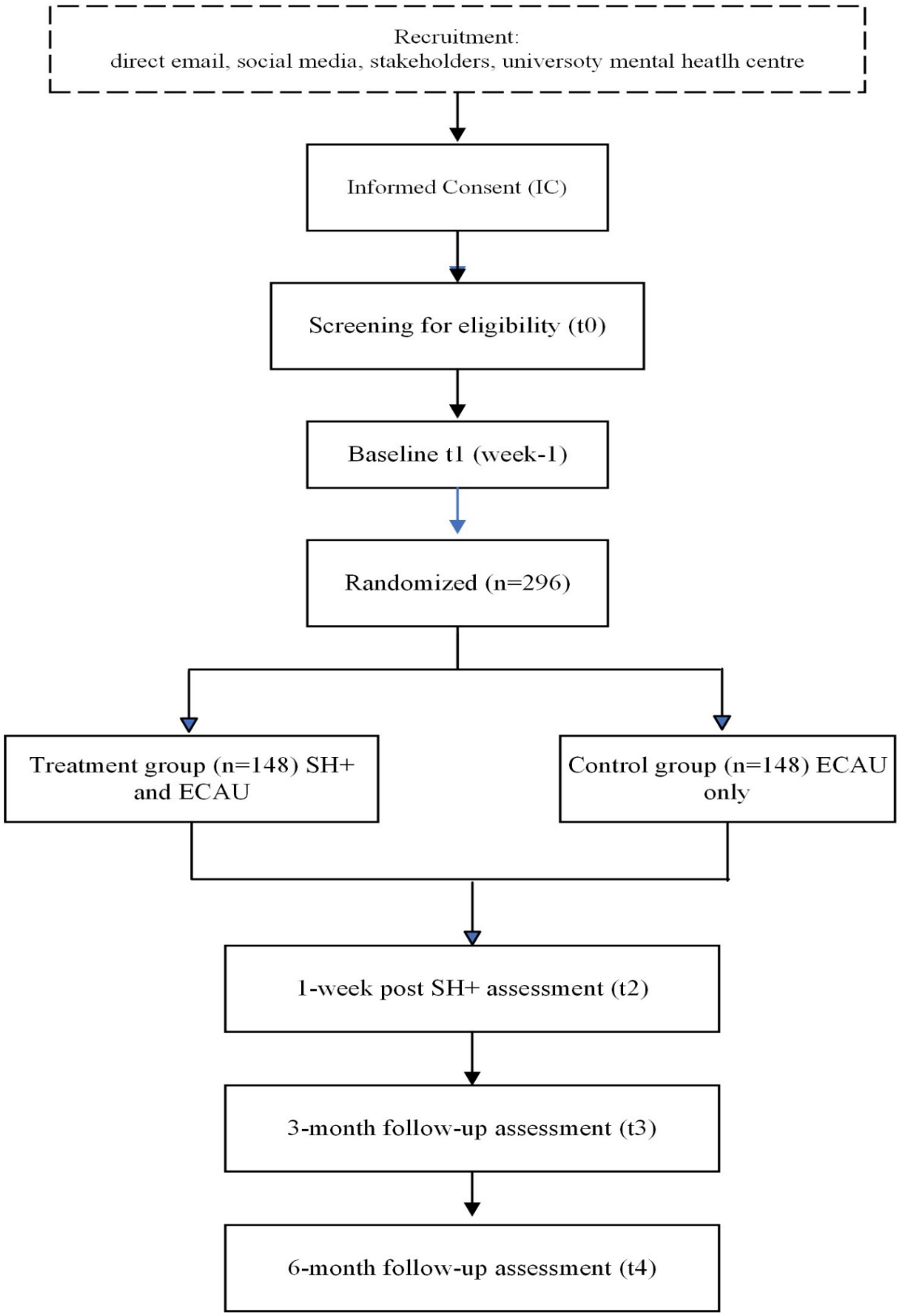
All AEs will be followed until they have resolved or until a stable condition has been achieved, and it will be reported to The Research Ethics Committee Universitas Padjadjaran.

Depending on the event, follow-up may require additional tests or medical procedures as indicated, referral to a general practitioner or specialist. SAEs must be reported until the end of the trial. SH+ facilitators will be supervised by experienced mental health professionals and will receive weekly supervision. If, during the study, participants in the treatment group (SH+ and ECAU) or the comparison group (ECAU only) report severe psychiatric symptoms (e.g. psychosis, imminent suicidal ideation, etc.) or any other symptoms that require immediate specialist treatment and follow-up, they will be referred to specialist staff (e.g. psychiatrists) for immediate follow-up. The Universitas Padjadjaran researcher will be responsible for monitoring this process and ensuring that the appointment has been made.

### 5.6 Statistical Software

All analyses will be performed using Jamovi (The Jamovi Project, 2022), SPSS, and Stata 18.0 (StataCorp, 2023).

## 6. PARTICIPANT FLOW CHART



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