ISRCTN58257113 https://doi.org/10.1186/ISRCTN58257113

A mixed-method trial of group-adapted somatic experiencing for Indonesian female survivors of sexual assault to reduce PTSD symptoms and increase resilience and quality of life to waitlist control group

Submission date 24/10/2024	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 29/10/2024	**Overall study status** Ongoing	
Last Edited 06/01/2026	**Condition category** Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims

This study aims to adapt and evaluate a group-based Somatic Experiencing (SE) intervention for Indonesian females who have experienced sexual assault and exhibit symptoms of post-traumatic stress disorder (PTSD). SE, a body-focused therapy, seeks to release trauma-stored energy and restore self-regulation, potentially reducing PTSD symptoms, enhancing resilience, and improving quality of life.

Who can participate?

Females aged 17 years old and above who have experienced sexual assault and exhibit mild to moderately severe PTSD symptoms (PCL-5 score ≥ 31) can participate. Participants should not be currently undergoing PTSD treatment, have no history of substance abuse, and have no diagnosed organic mental health disorder.

What does the study involve?

The study will be conducted in three phases:
1. Development: Tailoring the intervention for cultural relevance.
2. Feasibility: Pilot testing to determine the intervention's acceptability.
3. Effectiveness: Randomized controlled trial to evaluate the impact on PTSD symptoms, resilience, and quality of life.
Participants will attend 10 weekly group sessions, each lasting 60-90 minutes.

What are the possible benefits and risks of participating?

The intervention may reduce PTSD symptoms, increase resilience, and improve quality of life. While some discomfort may occur as participants process trauma, trained facilitators will support participants throughout the sessions to ensure safety and emotional well-being.

Where is the study run from?
Padjadjaran University, Indonesia

When is the study starting and how long is it expected to run for?
September 2023 to November 2026

Who is Funding the Study?
Padjadjaran University, Indonesia

Who is the Main Contact?
Ligina Ayudia, ligina18001@mail.unpad.ac.id

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Effectiveness of group-adapted somatic experiencing on PTSD symptoms, resilience, and quality of life in Indonesian female survivors of sexual assault: A mixed-method trial with waitlist control

Study objectives
The group-adapted somatic experiencing intervention will result in greater reductions in PTSD symptoms, increased resilience, and improved quality of life compared to the waitlist control group.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 16/11/2023, Padjadjaran University Research Ethics Committee (Jl. Prof. Eyckman No. 38, Pasteur, Kec. Sukajadi, Kota Bandung, Jawa Barat, 40161, Indonesia; +62 (0)22-2038697; kep@unpad.ac.id), ref: 1357/UN6.KEP/EC/2023

Study design
Single-centre mixed-methods study comprising a parallel-group randomized controlled trial and qualitative assessments

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Development, feasibility testing, and effectiveness evaluation of a group-adapted somatic experiencing intervention in Indonesian female survivors of sexual assault with PTSD symptoms

Interventions
Current interventions as of 08/11/2024:
The study will utilize a mixed-methods, interventional design with three phases: development, feasibility, and effectiveness. Participants will be female survivors of sexual assault with PTSD symptoms, and the intervention will be a culturally adapted, group-based Somatic Experiencing (SE) program.

Phase 1 (Development): The SE intervention will be developed based on qualitative feedback from experts and survivors, ensuring cultural relevance. This phase will establish the content and structure of each module within the intervention.

Phase 2 (Feasibility): A randomized pilot study will assess the intervention's acceptability and accessibility. Participants will be randomly assigned to either the intervention group or a waitlist control group. The SE intervention will consist of 10 weekly sessions, each lasting 60-90 minutes. Each session will focus on specific aspects of physiological regulation, trauma processing, and resilience-building, as outlined below.

Phase 3 (Effectiveness): The effectiveness phase will use a parallel-group randomized controlled trial (RCT), with participants assigned to either the SE intervention or a control group through block randomization (2:1 ratio). The control group will either receive standard counseling or no treatment, depending on the availability of services. Outcomes, including PTSD symptoms, resilience, and quality of life, will be measured at baseline, post-intervention, and 1- and 3-month follow-ups. Partial blinding will be applied to participants and assessors to minimize bias, with both quantitative and qualitative analyses conducted.

The SE intervention consists of 10 modules, each targeting specific skills and therapeutic goals:
1. Arriving (Welcome): Participants establish group cohesion, set intentions, and practice grounding exercises to foster safety and trust.
2. Physical Engagement and Body Awareness (1): Exercises focus on grounding, centering, and

developing body awareness to build resilience.
3. Physical Engagement and Body Awareness (2): Participants learn to track body sensations, enhancing their ability to connect with and trust their bodies.
4. Psychoeducation on Trauma and Resilience: Participants receive education on the nervous system, trauma responses, and resilience-building techniques.
5. Safety and Boundaries: This module focuses on recognizing and respecting personal boundaries, fostering a sense of embodied safety.
6. Pendulation and Containment: Skills are taught to help participants oscillate between states of stress and relaxation, building resilience and self-regulation.
7. Tracking Bodily Experiences: Participants deepen their understanding of inner bodily experiences, learning to identify and release areas of tension.
8. Discharging Activation (1): Techniques are introduced to process natural aggression and shame, creating healthy channels for emotional energy.
9. Discharging Activation (2): Participants work with basic survival responses, building strength and resilience while managing fear.
10. Returning to Equilibrium and Appreciation: The final session focuses on reflection and consolidation, marking progress over the intervention period.

Previous interventions:
The study will use a mixed-methods, interventional design across three phases: development, feasibility, and effectiveness. In Phase 1 (Development), a culturally adapted group-based Somatic Experiencing (SE) intervention will be created using qualitative insights from experts and survivors of sexual violence. This phase will establish the intervention's cultural relevance and content structure. In Phase 2 (Feasibility), a randomized pilot study will assess the intervention's acceptability and accessibility among women survivors of sexual assault with PTSD symptoms. Participants will be randomly assigned to either the intervention group or a waitlist control group. The SE intervention will consist of 10 weekly sessions, each lasting 60-90 minutes, focusing on physiological regulation and trauma processing. Phase 3 (Effectiveness) will employ a parallel-group randomized controlled trial (RCT) design, with participants assigned to either the SE intervention or the control group using block randomization (2:1 ratio). Outcomes such as PTSD symptoms, resilience, and quality of life will be measured at baseline, post-intervention, and follow-up points (1 month and 3 months). The control group will receive standard counseling or no treatment, depending on the availability of services. Participants and assessors will be partially blinded to minimize bias, and data will be analyzed using both quantitative and qualitative methods.

Intervention Type
Behavioural

Primary outcome(s)
PTSD symptoms measured using the Posttraumatic Stress Disorder Checklist for DSM-5 (PCL-5) at baseline, post-treatment (week 10), and follow-up assessments (at 1 and 3 months)

Key secondary outcome(s))
1. Resilience measured using the Connor-Davidson Resilience Scale (CD-RISC-25) at baseline, post-treatment (week 10), and follow-up assessments (at 1 and 3 months)
2. Quality of Life measured using the World Health Organization Quality of Life (WHOQOL-BREF) at baseline, post-treatment (week 10), and follow-up assessments (at 1 and 3 months)

Completion date
30/11/2026

Eligibility

Key inclusion criteria

Current participant inclusion criteria as of 08/11/2024:
Development Phase:
1. Psychologists:
1.1. Licensed psychologists with authorization to practice
1.2. Experience in providing interventions for females who have survived sexual violence
2. Somatic Experiencing (SE) Practitioners:
2.1. Specialists with expertise in handling cases of sexual violence
2.2. Experience in conducting group interventions
3. Study Experts from SE Institute:
3.1. Experience designing interventions using the SE method for individuals or groups
3.2. Prior experience in researching SE interventions

Feasibility and Effectiveness Phase:
1. Female aged 17 years and above
2. Have experienced sexual assault and exhibit symptoms of Post-Traumatic Stress Disorder (PTSD)
3. Mild to moderately severe PTSD symptoms (PCL-5 score ≥31)
4. PTSD symptoms are not caused by psychotropic substance use or other psychological conditions
5. Not currently undergoing psychological treatment for PTSD or on medication for less than 1 month
6. No history of alcohol or drug misuse
7. No prior diagnosis of an organic mental health disorder
8. PTSD symptoms must not coincide with or precede a diagnosed medical condition

Previous participant inclusion criteria as of 04/11/2024 to 08/11/2024:
Development Phase:
1. Psychologists:
1.1. Licensed psychologists with authorization to practice
1.2. Experience in providing interventions for women who have survived sexual violence
2. Somatic Experiencing (SE) Practitioners:
2.1. Specialists with expertise in handling cases of sexual violence
2.2. Experience in conducting group interventions
3. Study Experts from SE Institute:
3.1. Experience designing interventions using the SE method for individuals or groups
3.2. Prior experience in researching SE interventions

Feasibility and Effectiveness Phase:
1. Women aged 17 years and above
2. Have experienced sexual assault and exhibit symptoms of Post-Traumatic Stress Disorder (PTSD)
3. Mild to moderately severe PTSD symptoms (PCL-5 score >31)
4. PTSD symptoms are not caused by psychotropic substance use or other psychological conditions
5. Not currently undergoing psychological treatment for PTSD or on medication for less than 1 month

6. No history of alcohol or drug misuse
7. No prior diagnosis of an organic mental health disorder
8. PTSD symptoms must not coincide with or precede a diagnosed medical condition

Previous participant inclusion criteria:
1. Women aged 17 years old and above
2. Have experienced sexual assault and show symptoms of Post-Traumatic Stress Disorder (PTSD)
3. Mild to moderately severe PTSD symptoms (PCL-5 score > 31)
4. The PTSD symptoms are not caused by psychotropic substance use or other psychological conditions

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
17 years

Upper age limit
100 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
Current exclusion criteria as of 04/11/2024:
Development Phase:
1. Lack of relevant expertise or experience in treating sexual assault cases
2. Inability to commit to the full duration of the development phase activities

Feasibility and Effectiveness Phases
1. Currently undergoing psychological treatment for PTSD or on medication for less than 1 month
2. Alcohol or drug misuse
3. Previous diagnosis of an organic mental health disorder
4. PTSD symptoms that precede or coincide with a diagnosed medical condition
5. History of psychosis, brain disorders, or suicidal tendencies
6. Comorbid psychiatric conditions or complex trauma situations characterized by prolonged periods of extreme stress

Previous exclusion criteria:
1. Currently in psychological treatment for PTSD on medication for less than 1
2. Alcohol or drug misuse

3. Previous diagnosis of an organic mental health disorder
4. PTSD symptom preceding or coinciding with a diagnosed medical condition

Date of first enrolment
01/11/2024

Date of final enrolment
30/11/2026

Locations

Countries of recruitment
Indonesia

Study participating centre
Padjajaran University
Jl. Raya Bandung Sumedang Km. 21, Hegarmanah, Jatinangor
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Sponsor information

Organisation
Padjadjaran University

ROR
https://ror.org/00xqf8t64

Funder(s)

Funder type
University/education

Funder Name
Padjadjaran University

Alternative Name(s)
Padjadjaran University, UNPAD

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Indonesia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study will be available upon request from the corresponding author:
Name: Ligina Ayudia
Email: ligina18001@mail.unpad.ac.id

Raw participant-level data, anonymized to ensure confidentiality, will be shared. The data includes scores from the PCL-5, CD-RIS-25, WHOQOL-BREF, and demographic variables collected during the intervention sessions.
Data will be available after the completion of the study and publication of the results.
Data will be shared with researchers conducting similar studies, contingent on the provision of a formal data request, a brief study proposal, and a data use agreement that outlines ethical considerations.
Data will be provided in a secure digital format (e.g., encrypted files), accessible via email or a secured link after obtaining appropriate ethical clearance from the researcher's institution.
Consent for data sharing was obtained from all participants, ensuring compliance with ethical and legal requirements.
Data sharing will comply with Indonesian regulations and institutional ethical standards, ensuring participant privacy and confidentiality.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		22/12/2025	06/01/2026	Yes	No
Protocol file			28/10/2024	No	No