KEMENTERIAN PENDIDIKAN TINGGI, SAINS DAN TEKNOLOGI
UNIVERSITAS ANDALAS
FAKULTAS KEDOKTERAN
KOMISI ETIK PENELITIAN
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KETERANGAN LOLOS KAJI ETIK
DESCRIPTION OF ETHICAL APPROVAL

No : 520 /UN.16.2/KEP-FK/2025

Tim Komisi Etik Penelitian Fakultas Kedokteran Universitas Andalas, dalam upaya melindungi Hak Azazi dan Kesejahteraan Subjek Penelitian kedokteran/kesehatan, telah mengkaji dengan teliti protokol penelitian dengan judul :
(*The Research Ethics Committee Faculty of Medicine Universitas Andalas, in order to protect human rights and welfare of medical/health research subject, has carefully reviewed the research protocol entitled) :*

Pengaruh Psikoedukasi Mitigasi Bencana dan Terapi Dzikir terhadap Depresi Perinatal dan Kortisol Saliva pada Ibu Hamil di Sumatera Barat

Nama Peneliti Utama : Rafika Oktova, SST.,M.Keb
Principal Researcher

Nama Institusi : Departemen Kebidanan Fakultas Kedokteran Universitas Andalas
Institution : *Department of Midwifery Faculty of Medicine Universitas Andalas*

Protokol Penelitian tersebut dapat disetujui pelaksanaannya
and approved the research protocol.

Padang, 13 Agustus 2025

Dekan Fakultas Kedokteran Universitas Andalas
Dean of Faculty of Medicine Universitas Andalas

Dr. dr. Sukri Rahman, Sp.THT-BKL, Subsp.Onk(K), FACS, FFSTEd
NIP 197810072003121001

Ketua
Chairman

Prof. Dr. dr. Yullarni Syafrita, Sp.N (K)
NIP 196407081991032001

Keterangan/*notes:*
Keterangan lolos kaji etik ini berlaku satu tahun dari tanggal persetujuan.
This ethical approval is effective for one year from the due date.
Jika ada kejadian serius yang tidak diinginkan (KTD) harus segera dilaporkan ke Komisi Etik Penelitian.
If there are Serious Adverse Events (SAE) should be immediately reported to the Research Ethics Committee.
re are Serious Adverse Events (SAE) should be immediately reported to the Research Ethics Committee.

TCTR ID : TCTR20260804002

OTHER ID :

Overall Recruitment Status : Completed **(Has Results)**

Retrospective registration
This protocol was registered after enrollment of the first participant.

Tracking Information

First Submitted Date :	03 August 2026
First Posted Date :	04 August 2026
Last Update Posted Date :	05 August 2026

Title

Public Title :	Effects of Disaster Mitigation Psychoeducation and Dhikr Therapy on Perinatal Depression and Salivary Cortisol Levels among Pregnant Women in West Sumatra, Indonesia
Acronym :	No Data
Scientific Title :	Effectiveness of Video-Based Disaster-Mitigation Psychoeducation for Perinatal Depressive Symptoms Among Pregnant Women in Disaster-Affected West Sumatra: A Quasi-Experimental Study
Sponsor ID/ IRB ID/ EC ID :	520/UN.16.2/KEP-FK/2025
Registration Site :	Thai Clinical Trials Registry
URL :	https://www.thaiclinicaltrials.org/show/TCTR20260804002
Secondary ID :	No Secondary ID

Ethics Review

1. Board Approval :	Submitted, approved
Approval Number :	520/UN.16.2/KEP-FK/2025
Date of Approval :	13 August 2025
Board Name :	Research Ethics Committee of the Faculty of Medicine, Universitas Andalas
Board Affiliation :	Faculty of Medicine, Universitas Andalas
Board Contact :	Business Phone : 6275131746 Ext. No Data
	Business Email : dekanat@med.unand.ac.id
	Business Address : Faculty of Medicine, Universitas Andalas, Limau Manis Campus, Pauh, Padang, West Sumatra 25163, Indonesia

Sponsor

Source(s) of Monetary or Material Supports :	Universitas Andalas, Indonesia, through study-assignment financial support (Funding No. 2829/UN16.WR.3/KP/2023)
Study Primary Sponsor :	Universitas Andalas
Responsible Party :	Name/Official Title : Rafika Oktova, Principal Investigator
	Organization : Faculty of Medicine, Universitas Andalas
	Phone : 628117532122 Ext. No Data
	Email : rafikamkeb@gmail.com
Study Secondary Sponsor :	No Study Secondary Sponsor

Protocol Synopsis

Protocol Synopsis :	This multicenter longitudinal nonrandomized quasi experimental study evaluates video based disaster mitigation psychoeducation for pregnant women or MITAMIL, dhikr therapy, and their combination in reducing perinatal depressive symptoms among pregnant women in disaster affected areas of West Sumatra, Indonesia. A total of 240 participants with EPDS scores of 9 or higher were allocated to four groups of 60 participants: MITAMIL, dhikr therapy, combined intervention, and control. Interventions were delivered weekly for 8 weeks. EPDS was measured at baseline and weekly through week 8. The primary outcome was change in total EPDS score from baseline to week 8, while secondary outcomes were longitudinal EPDS changes and group by time interaction. An exploratory substudy assessed salivary cortisol changes in selected MITAMIL and control participants. Study phase was not applicable because all interventions were behavioral and nonpharmacological.
URL (Link to project website / Link to protocol website) :	https://doi.org/10.6084/m9.figshare.33137009
Date :	2025-08-12
Version :	1.0

Health Conditions

Health Condition(s) or Problem(s) Studied : Perinatal depressive symptoms

Keywords : Depression Pregnancy Pregnant People Psychosocial Intervention Disaster Planning Disasters Health Education Maternal Health

Eligibility

Inclusion Criteria :
1. Pregnant at the time of recruitment.
2. Registered for antenatal care at one of the selected community health centers.
3. Residing in a community health center catchment area affected by a natural disaster within the two years before recruitment.
4. Having an Edinburgh Postnatal Depression Scale (EPDS) screening score of 9 or higher.
5. Able to communicate in Indonesian.
6. Able to read and write.
7. Having a smartphone and adequate internet access to use WhatsApp and Zoom.
8. Willing to participate in the study for eight consecutive weeks.
9. Providing written informed consent.

Gender : Female

Age Limit : Minimum : 17 Years Maximum : 45 Years

Exclusion Criteria :
1. History of a severe psychiatric disorder or a psychiatric disorder clinically diagnosed by a healthcare professional.
2. Currently receiving psychiatric treatment.
3. Currently using psychotropic or psychiatric medication at the time of recruitment.
4. History of substance misuse or dependence within the six months before recruitment.
5. Hearing impairment that prevents participation in the video-based intervention or online meetings.
6. An acute mental health condition requiring immediate clinical assessment and treatment.

Accept Healthy Volunteers : No

Status

Overall Recruitment Status : Completed

Key Trial Dates	Study Start Date (First enrollment) : 06 October 2025	Indicate Type : Actual
	Completion Date (Last subject, Last visit) : 15 February 2026	Indicate Type : Actual
	Study Completion Date : 15 February 2026	Indicate Type : Actual

Design

Study Type : Interventional

Primary Purpose : Treatment

Study Phase : Phase 0

Intervention Model : Parallel

Number of Arms : 4

Masking : Open Label

Allocation : Non-randomized

Control : Active

Study Endpoint Classification : Efficacy Study

Sample size

Planned sample size : 240

Actual sample size at study completion : 240

Intervantion Arm 1

Intervention name : Video-Based MITAMIL Psychoeducation

Intervention Type : Experimental

Intervention Classification : Behavioral

Intervention Description : Participants received one standardized video-based disaster-mitigation psychoeducation session through Zoom once weekly for 8 consecutive weeks. Each session lasted approximately 70 minutes, consisting of opening and attendance for 5 minutes, viewing the MITAMIL video for 50 minutes, facilitated discussion and clarification for 10 minutes, and EPDS completion for 5 minutes. Topics included disaster concepts, mitigation during pregnancy, disaster impacts and perinatal

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depression, emergency-bag preparation, psychological resilience, and stress management.

Intervantion Arm 2

Intervention name : Dhikr Therapy

Intervention Type : Experimental

Intervention Classification : Behavioral

Intervention Description : Participants received one structured dhikr therapy session through Zoom once weekly for 8 consecutive weeks. Each session lasted approximately 70 minutes, consisting of opening and attendance for 5 minutes, guided dhikr practice and relaxation for 50 minutes, facilitated discussion and clarification for 10 minutes, and EPDS completion for 5 minutes. The intervention focused on guided dhikr practice, controlled breathing, relaxation, emotional self-regulation, psychological calmness, and strategies for managing stress during pregnancy. Participants received session information and reminders through a separate WhatsApp group, while attendance and participation were monitored during each Zoom session.

Intervantion Arm 3

Intervention name : Combined MITAMIL Psychoeducation and Dhikr Therapy

Intervention Type : Experimental

Intervention Classification : Behavioral

Intervention Description : Participants received one combined video based MITAMIL psychoeducation and structured dhikr therapy session through Zoom once weekly for 8 consecutive weeks. Each session lasted approximately 70 minutes, consisting of opening and attendance for 5 minutes, delivery of MITAMIL psychoeducation and guided dhikr practice for 50 minutes, facilitated discussion and clarification for 10 minutes, and EPDS completion for 5 minutes. The MITAMIL component covered disaster concepts, mitigation during pregnancy, disaster impacts and perinatal depression, emergency bag preparation, psychological resilience, and stress management. The dhikr component included guided dhikr practice, controlled breathing, relaxation, emotional self regulation, psychological calmness, and stress management during pregnancy. Participants received schedules, Zoom links, and reminders through a separate WhatsApp group. Attendance and participation were monitored during each Zoom session.

Intervantion Arm 4

Intervention name : Postpartum Depression Education (Control Group)

Intervention Type : Active Comparator

Intervention Classification : Other

Intervention Description : Participants received a digital pamphlet containing standard information about postpartum depression from the Indonesian Maternal and Child Health Handbook through a separate WhatsApp group once weekly for 8 consecutive weeks. Participants did not receive the MITAMIL video, disaster mitigation content, psychological resilience training, dhikr therapy, or a 70 minute interactive Zoom session. Separate communication channels were used to reduce contamination between groups.

Outcome

Primary Outcome

1. Outcome Name : Change in total EPDS score from baseline to week 8

Metric / Method of measurement : Difference in EPDS total score between baseline and week 8. EPDS has 10 items and a total score from 0 to 30. Higher scores indicate more severe depressive symptoms.

Time point : Baseline T0 and week 8 T8

Secondary Outcome

1. Outcome Name : Longitudinal change in total EPDS score

Metric / Method of measurement : Weekly EPDS total scores from baseline through week 8. EPDS has 10 items and a total score from 0 to 30. Higher scores indicate more severe depressive symptoms.

Time point : Baseline T0 and weekly from week 1 T1 through week 8 T8

Location

Section A : Central Contact

Central Contact	First Name : Rafika	Middle Name :	Last Name : Oktova
	Degree : M.Keb	Phone : 628117532122 Ext. : No Data	Email : rafikamkeb@gmail.com
Central Contact Backup	First Name : Marsi	Middle Name : Sekar	Lastname : Ningrum
	Degree : S.Kep	Phone : 6289527898883 Ext. : No Data	Email : marsisekarningrum@gmail.com

Section B Facility Information and Contact

1. Site Name : Puskesmas Nanggalo

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	City : Padang	State/Province : Sumatera Barat	Postal Code : 25173
	Country : Indonesia	Recruitment Status : Completed	
Facility Contact	First Name : Nanda	Middle Name : Sesmi	Last Name : Oktavia
	Degree :	Phone : 6282268456815 Ext. : No Data	Email : sesminanda@gmail.com
Facility Contact Backup	First Name : Marsi	Middle Name : Sekar	Last Name : Ningrum
	Degree :	Phone : 6289527898883 Ext. : No Data	Email : marsisekarningrum@gmail.com
Investigator Name	First Name : Rafika	Middle Name :	Last Name : Oktova
	Degree :	Role : Principal Investigator	
2.	Site Name : Puskesmas Pauh		
	City : Padang	State/Province : Sumatera Barat	Postal Code : 25176
	Country : Indonesia	Recruitment Status : Completed	
Facility Contact	First Name : Yesi	Middle Name :	Last Name : Maifita
	Degree :	Phone : 6281363078104 Ext. : No Data	Email : 28yesimaifita@gmail.com
Facility Contact Backup	First Name : Marsi	Middle Name : Sekar	Last Name : Ningrum
	Degree :	Phone : 6289527898883 Ext. : No Data	Email : marsisekarningrum@gmail.com
Investigator Name	First Name : Rafika	Middle Name :	Last Name : Oktova
	Degree :	Role : Principal Investigator	
3.	Site Name : Puskesmas Sungai Tarab I		
	City : Tanah Datar	State/Province : Sumatera Barat	Postal Code : 27261
	Country : Indonesia	Recruitment Status : Completed	
Facility Contact	First Name : Rahmiati	Middle Name :	Last Name : Rahmiati
	Degree :	Phone : 6285272286645 Ext. : No Data	Email : rahmiatiofficiall@gmail.com
Facility Contact Backup	First Name : Marsi	Middle Name : Sekar	Last Name : Ningrum
	Degree :	Phone : 6289527898883 Ext. : No Data	Email : marsisekarningrum@gmail.com
Investigator Name	First Name : Rafika	Middle Name :	Last Name : Oktova
	Degree :	Role : Principal Investigator	
4.	Site Name : Puskesmas Sungai Tarab II		
	City : Tanah Datar	State/Province : Sumatera Barat	Postal Code : 27261
	Country : Indonesia	Recruitment Status : Completed	
Facility Contact	First Name : Zelma	Middle Name :	Last Name : Refma
	Degree :	Phone : 6285161719991 Ext. : No Data	Email : zelmarefma101@gmail.com
Facility Contact Backup	First Name : Marsi	Middle Name : Sekar	Last Name : Ningrum
	Degree :	Phone : 6289527898883 Ext. : No Data	Email : marsisekarningrum@gmail.com
Investigator Name	First Name : Rafika	Middle Name :	Last Name : Oktova
	Degree :	Role : Principal Investigator	
5.	Site Name : Puskesmas Lima Kaum I		
	City : Tanah Datar	State/Province : Sumatera Barat	Postal Code : 27215
	Country : Indonesia	Recruitment Status : Completed	
Facility Contact	First Name : Resty	Middle Name : Sri	Last Name : Handayani
	Degree :	Phone : 6282285853606 Ext. : No Data	Email : restysrihandayani@gmail.com
Facility Contact Backup	First Name : Marsi	Middle Name : Sekar	Last Name : Ningrum
	Degree :	Phone : 6289527898883 Ext. : No Data	Email : marsisekarningrum@gmail.com
Investigator Name	First Name : Rafika	Middle Name :	Last Name : Oktova
	Degree :	Role : Principal Investigator	

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6. Site Name : Puskesmas Lima Kaum II

	City : Tanah Datar	State/Province : Sumatera Barat	Postal Code : 27264
	Country : Indonesia	Recruitment Status : Completed	
Facility Contact	First Name : Pratiwi	Middle Name : Rahma	Last Name : Maghfira
	Degree :	Phone : 6282391602480 Ext. : No Data	Email : tiwimaghfira18@gmail.com
Facility Contact Backup	First Name : Marsi	Middle Name : Sekar	Last Name : Ningrum
	Degree :	Phone : 6289527898883 Ext. : No Data	Email : marsisekarningrum@gmail.com
Investigator Name	First Name : Rafika	Middle Name :	Last Name : Oktova
	Degree :	Role : Principal Investigator	

7. Site Name : Puskesmas Rambatan II

	City : Tanah Datar	State/Province : Sumatera Barat	Postal Code : 27271
	Country : Indonesia	Recruitment Status : Completed	
Facility Contact	First Name : Hurriyah	Middle Name :	Last Name : Aufa
	Degree :	Phone : 6285219079116 Ext. : No Data	Email : hurriyahaufa@gmail.com
Facility Contact Backup	First Name : Marsi	Middle Name : Sekar	Last Name : Ningrum
	Degree :	Phone : 6289527898883 Ext. : No Data	Email : marsisekarningrum@gmail.com
Investigator Name	First Name : Rafika	Middle Name :	Last Name : Oktova
	Degree :	Role : Principal Investigator	

8. Site Name : Puskesmas Seberang Padang

	City : Padang	State/Province : Sumatera Barat	Postal Code : 25214
	Country : Indonesia	Recruitment Status : Completed	
Facility Contact	First Name : Laila	Middle Name :	Last Name : Rahmi
	Degree :	Phone : 6285263453245 Ext. : No Data	Email : lailarahmi8708@gmail.com
Facility Contact Backup	First Name : Marsi	Middle Name : Sekar	Last Name : Ningrum
	Degree :	Phone : 6289527898883 Ext. : No Data	Email : marsisekarningrum@gmail.com
Investigator Name	First Name : Rafika	Middle Name :	Last Name : Oktova
	Degree :	Role : Principal Investigator	

Section C : Contact for Public Queries (Responsible Person)

First Name : Marsi	Middle Name : Sekar	Last Name : Ningrum
Degree : No Data	Phone : 6289527898883 Ext. : No Data	Email : marsisekarningrum@gmail.com
Postal Address : Faculty of Medicine, Universitas Andalas, Jl. Perintis Kemerdekaan No. 94, Jati Subdistrict, Padang Timur District, Padang City, West Sumatra 25127, Indonesia		
State/Province : Sumatera Barat	Postal Code : 25163	
Country : Indonesia	Official Role : Study Chair	
Organization Affiliation : Universitas Andalas		

Section D : Contact for Scientific Queries (Responsible Person)

First Name : Rafika	Middle Name :	Last Name : Oktova
Degree : No Data	Phone : 628117532122 Ext. : No Data	Email : rafikamkeb@gmail.com
Postal Address : Faculty of Medicine, Universitas Andalas, Jl. Perintis Kemerdekaan No. 94, Jati Subdistrict, Padang Timur District, Padang City, West Sumatra 25127, Indonesia		
State/Province : Sumatera Barat	Postal Code : 25163	
Country : Indonesia	Official Role : Study Chair	
Organization Affiliation : Universitas Andalas		

Summary Results

Date of posting of results summaries : 01 August 2026

Date of first journal publication of results :	Not yet published
Baseline Characteristics :	The currently available baseline results included 120 participants. There were 60 participants in the MITAMIL group and 60 participants in the information only control group. The mean age was 29.33 years with a standard deviation of 5.03 in the MITAMIL group and 29.13 years with a standard deviation of 5.22 in the control group. The groups were comparable in education occupation monthly family income gestational age parity history of miscarriage and baseline EPDS score. Gravidity differed between the groups. The mean baseline EPDS score was 11.27 with a standard deviation of 1.57 in the MITAMIL group and 11.62 with a standard deviation of 1.63 in the control group.
Participant Flow :	Of 490 pregnant women screened, 235 did not meet the eligibility criteria and 15 declined participation. A total of 240 participants were enrolled in the four-group parent study, with 60 participants in each group: MITAMIL psychoeducation, dhikr therapy, combined MITAMIL-plus-dhikr intervention, and information-only control. The currently available analysis included 120 participants, comprising 60 participants in the MITAMIL group and 60 participants in the information-only control group. All 120 participants included in the currently available analysis completed follow-up through week 8 and were included in the EPDS analysis. Results from the dhikr therapy and combined intervention groups are not included in the current results summary.
Adverse events :	No intervention-related adverse events were reported during the study period
Outcome Measures :	Total EPDS scores were measured using the Indonesian 10 item Edinburgh Postnatal Depression Scale at baseline and weekly through week 8. The available analysis included 60 participants in the MITAMIL group and 60 participants in the information only control group. At week 8 the mean EPDS score was 0.52 with a standard deviation of 0.57 in the MITAMIL group and 5.10 with a standard deviation of 1.81 in the control group.
Brief Summary of Results :	The parent study enrolled 240 participants in four groups with 60 participants per group. The current results included 120 participants from the MITAMIL and information only control groups. Baseline EPDS scores were similar between groups. EPDS scores decreased more in the MITAMIL group. At week 8 the mean EPDS scores were 0.52 in the MITAMIL group and 5.10 in the control group. Results from the dhikr therapy and combined groups are not included.

Deidentified Individual Participant-level Data Sharing

Plan to share IPD :	No
Reason :	Individual participant-level data will not be shared publicly because the dataset contains sensitive maternal mental health information, and the informed consent obtained from participants did not include permission for public sharing of individual-level data. Deidentified aggregate findings will be reported in scientific publications.

Publication from this study

MEDLINE Identifier :	No Data
URL link to full text publication :	No Data

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