

Effect of mindfulness Kangaroo Care on maternal mental health and preterm infants in Tertiary Care Hospitals in Pakistan

Submission date 27/11/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 09/07/2025	Overall study status Ongoing	<input type="checkbox"/> Protocol
Last Edited 24/06/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Preterm birth, defined as the birth of a neonate before 37 weeks of gestation, is a significant global health concern affecting both infants and the mental health of their parents, particularly mothers. Preterm birth is associated with increased rates of infant mortality and long-term developmental issues, including poor cognitive and mental health outcomes, and reduced quality of life. Beyond these risks to the infant, preterm birth has significant psychological consequences for parents, especially mothers, who experience high levels of stress and emotional strain. Several factors contribute to this parental stress, including the fear of losing their infant, the critical and fragile condition of the newborn, difficulties adjusting to the neonatal intensive care unit (NICU) environment, and the emotional toll of being physically separated from their child immediately after birth. These stressors can lead to the development or exacerbation of mental health issues such as anxiety, depression, and post-traumatic stress disorders in parents, with effects that may persist long after the birth, sometimes for years. For instance, many mothers experience distressing memories of their NICU experience that can last for up to six months postpartum, which can lead to a diagnosis of post-traumatic stress disorder. The current study aimed to integrate mindfulness with kangaroo care to evaluate its effect on maternal mental health and preterm infant outcomes and ensure mental support for maternal mothers for better health outcomes.

Who can participate?

The mothers of preterm infants admitted to the NICU at Ziauddin University Hospital.

What does the study involve?

The study involves a mental health program that will probably improve the psychological and mental well-being of the mothers whose neonates are fighting for their lives in the NICU. Participants will be randomly assigned to either the Mindfulness Kangaroo Care group or the conventional Care group. The intervention will be carried out daily for at least one hour over two weeks. Data will be collected on maternal mental health and infant clinical outcomes.

What are the possible benefits and risks of participating?

The potential benefits include reduced maternal stress and anxiety and improved neonatal health outcomes. The risks are minimal and may include mild discomfort due to prolonged holding during Kangaroo Care.

Where is the study run from?

Ziauddin University, Pakistan

When is the study starting and how long is it expected to run for?

June 2024 to December 2025

Who is funding the study?

Ziauddin University, Pakistan

Who is the main contact?

Shakirullah, Shakirullah.19940@zu.edu.pk, Shakirasf456@gmail.com, shakirlnh456@yahoo.com, a student of PhD at Ziauddin University

Contact information

Type(s)

Public, Scientific, Principal Investigator

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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

Effect of mindfulness Kangaroo Care on maternal mental health and preterm infants in Tertiary Care Hospital, Pakistan

Study objectives

Hypothesis

- Null Hypothesis Ho: There will be no significant effect of mindfulness kangaroo care on maternal mental health and preterm infants as compared to standard care.
- Alternative Hypothesis Ha: There will be a significant effect of mindfulness kangaroo care on maternal mental health and preterm infants as compared to standard care.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 23/05/2025, Faculty of Nursing and Midwifery Departmental Research Committee (Ziauddin University, Karachi, 75950, Pakistan; +92 03484406556; info@zu.edu.pk), ref: 9-15/2022/005

Study design

Embedded mixed-methods research study

Primary study design

Interventional

Secondary study design

Qualitative study

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

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

Health condition(s) or problem(s) studied

Improvement of maternal mental health

Interventions

This study evaluates a Mindfulness Kangaroo Care (MKC) intervention in comparison to standard care, and the outcome will be measured as maternal mental health and its effect on preterm infant outcomes. The intervention consists of traditional Kangaroo Care integrated with mindfulness practices such as guided breathing exercises and present-moment awareness techniques. Further details are available in the study proposal.

Intervention Type

Behavioural

Primary outcome measure

Maternal mental health outcomes: Stress, anxiety, and depression measured using the Parental Stressor Scale (NICU), General Anxiety Disorder (GAD) Scale, and Edinburgh Postnatal Depression Scale (EPDS) at baseline and 4 weeks post-intervention.

Secondary outcome measures

Preterm infant outcomes:

1. Heart rate, respiratory rate and oxygen saturation will be measured from a cardiac monitor and a log sheet that is developed for the study 30 min before, during the intervention and 30 min after the intervention
2. Weight gain recorded in grams using a calibrated digital weighing scale, NICU stay duration from NICU admission to discharge, and incidence of infections, diagnosed based on clinical symptoms and confirmed through diagnostic tests (e.g., blood cultures, CRP levels), are measured using data collected from patient medical records before, at the time of discharge from the hospital, one month after, and then after 2 months

Overall study start date

01/06/2024

Completion date

31/12/2025

Eligibility

Key inclusion criteria

1. Mothers aged 18 years old and above with preterm infants (gestational age less than 37 weeks) admitted to the NICU
2. Mothers willing to participate in the MKC intervention for 05 days
3. Mothers who can understand and communicate in Urdu or English

Participant type(s)

Patient

Age group

Neonate

Lower age limit

25 Days

Upper age limit

45 Weeks

Sex

Both

Target number of participants

Mothers and thier neonates/ Total Participants : 114/57 per group

Key exclusion criteria

1. Mothers with a history of severe mental health disorders that could interfere with the MKC intervention (e.g., psychosis)
2. Mothers whose infants are with severe congenital anomalies or life-limiting conditions that may prevent participation in the study
3. Mothers for whom infant death occurs
4. Neonate with worsening of condition

Date of first enrolment

15/01/2025

Date of final enrolment

01/08/2025

Locations**Countries of recruitment**

Pakistan

Study participating centre

Ziauddin Group of Hospitals

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Karachi
Pakistan
75950

Sponsor information**Organisation**

Ziauddin University

Sponsor details

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Sponsor type

University/education

Website

<https://zu.edu.pk/>

ROR

<https://ror.org/03vz8ns51>

Funder(s)

Funder type

University/education

Funder Name

Ziauddin University

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal.

In planning there are three expected publications:

1. Scoping Review Paper
2. Interventional Study Final Paper
3. Descriptive Paper

Intention to publish date

15/05/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Shakirullah, Shakirullah.19940@zu.edu.pk, shakirasf456@gmail.com.

- Type of data that will be shared: De-identified participant-level data on maternal mental health and infant outcomes.
- Timing for availability: Data will be available upon reasonable request after study completion in December 2025.
- Consent from participants: Informed consent will be obtained from all participants regarding data sharing.
- Data anonymization: All participant data will be anonymized to ensure privacy.
- Ethical or legal restrictions: Data sharing will comply with Ziauddin University's ethical policies and local regulatory requirements.

IPD sharing plan summary

Available on request