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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

Registration date
09/07/2025

Overall study status
Completed

Last Edited
10/04/2026

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] 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

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

Primary study design
Interventional

Study design
Embedded mixed-methods research study

Study type(s)
Quality of life

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(s)
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.

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
25 Days

Upper age limit
45 Weeks

Sex
Female

Total final enrolment
136

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
1. North Nazimabad Campus
2. Kemari Campus
3. Clifton Campus
Karachi
Pakistan
75950

Sponsor information

Organisation
Ziauddin University

ROR
https://ror.org/03vz8ns51

Funder(s)

Funder type
University/education

Funder Name
Ziauddin University

Results and Publications

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