Effects of noise reduction on physical and mental health of postpartum women

Submission date 19/03/2025	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 28/03/2025	Overall study status Completed	 Statistical analysis plan Results
Last Edited 25/03/2025	Condition category Pregnancy and Childbirth	[_] Individual participant data[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Hospital noise is a common environmental stressor that can negatively impact the physical and mental health of postpartum women. This study aims to evaluate whether reducing hospital noise levels can improve mental well-being, sleep quality, and physiological recovery in postpartum women.

Who can participate? Postpartum women aged 22 years or older who have given birth for the first time

What does the study involve?

This study involves assessing the effects of hospital noise reduction on postpartum recovery. Participants are placed in either a noise reduction group, where soundproofing and low-noise medical equipment are used, or a conventional group, where no additional noise reduction measures are implemented. Their anxiety levels, sleep quality, and physiological indicators are monitored during hospitalization to evaluate the impact of noise exposure on maternal health.

What are the possible benefits and risks of participating?

Participants in the noise reduction group may experience improved sleep quality, lower anxiety levels, and better physiological recovery, including reduced inflammation and enhanced hormone balance. There are no known risks associated with noise reduction interventions, as they are non-invasive and designed to create a more comfortable hospital environment.

Where is the study run from? The Second Hospital of Shanxi Medical University (China)

When is the study starting and how long is it expected to run for? March 2024 to September 2024

Who is funding the study? The Second Hospital of Shanxi Medical University (China) Who is the main contact? Huiqiang Liu, sxtycyj@163.com

Contact information

Type(s) Public, Scientific, Principal Investigator

Contact name Mr Huiqiang Liu

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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

A retrospective study on the effects of hospital noise reduction on physical and mental health in postpartum women

Study objectives Hospital noise reduction improves postpartum women's mental health, sleep quality, and physiological recovery

Ethics approval required Ethics approval required

Ethics approval(s)

Approved 20/03/2024, Ethics Committee of the Second Hospital of Shanxi Medical University (Room 1119, 11th Floor, Science and Technology Information Building, Second Hospital of Shanxi Medical University, No.382 Wuyi Road, Xinghualing District, Taiyuan City, Shanxi Province, Shanxi, 030000, China; +86 (0)351-3363698; sydeyztjy@163.com), ref: 2024YX088

Study design

Prospective observational study

Primary study design

Observational

Secondary study design

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

Physical and mental health of postpartum women

Interventions

Based on the noise levels recorded in their respective wards, with a cut-off value of 40 dB, patients were divided into two groups: the conventional group and the noise reduction group (NR group):

 Noise Reduction (NR) Group: Placed in wards with noise reduction measures such as soundproofing, low-noise medical equipment, and environmental modifications.
 Conventional Group: Standard hospital wards without additional noise reduction measures.

The study aimed to assess the impact of hospital noise reduction on postpartum women's mental health, sleep quality, and physiological recovery. A total of 150 participants were enrolled and divided into two groups based on noise exposure levels in their respective wards: the Noise Reduction (NR) Group, which received noise reduction interventions such as soundproofing and low-noise medical equipment, and the Conventional Group, which was exposed to standard hospital noise levels. Data was collected over a 3-month period from June to September 2024. Noise levels were continuously monitored, and key outcome measures - including anxiety levels, sleep quality, and physiological indicators - were assessed at multiple timepoints postpartum.

Intervention Type

Mixed

Primary outcome measure

1. Postpartum anxiety: state and trait anxiety levels assessed using the State-Trait Anxiety Inventory (STAI) at baseline (before treatment), postpartum day 1, day 3, and day 4 (one day before discharge)

2. Sleep quality evaluated using the Pittsburgh Sleep Quality Index (PSQI) at baseline (before treatment) and 4 days postpartum

3. Physiological indicators: CRP levels, prolactin levels, systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), pulse rate, respiratory rate, and body temperature measured using bedside monitors (GE Healthcare, USA) and tympanic thermometers (Exergen, USA) at baseline, postpartum day 1, day 3, and day 4

Secondary outcome measures

1. Socio-demographic data: age, education level, marital status, occupation, medical history, previous intensive care experiences, and reasons for current hospitalization are measured using routine hospital documentation at baseline.

2. Noise levels are measured using a sound-level meter (SLM) (NL-22 Type II, RION, Japan) continuously every second over a 3-month period, with data averaged at four key timepoints per day (8:00, 14:00, 20:00, and 2:00).

Overall study start date

20/03/2024

Completion date

30/09/2024

Eligibility

Key inclusion criteria

- 1. Aged 22 years or older
- 2. Able to hear, speak, and write
- 3. Conscious and cooperative
- 4. Primiparas
- 5. No major comorbidities
- 6. Visual analog scale (VAS) score ≤5, assessed within 24 hours postpartum
- 7. A hospital stay of at least 3 days
- 8. Complete clinical data

Participant type(s) Other

Age group Adult

Lower age limit 22 Years

Sex Female

Target number of participants 150

Total final enrolment

Key exclusion criteria

1. Severe hearing impairment

2. A history of severe psychiatric or neurological disorders

3. Major surgery within the past 6 months

4. Multiple pregnancies or high-risk pregnancies

Date of first enrolment 30/06/2024

Date of final enrolment 01/09/2024

Locations

Countries of recruitment China

Study participating centre The Second Hospital of Shanxi Medical University 382 Wuyi Road Xinghualing District Taiyuan City China 030000

Sponsor information

Organisation Second Hospital of Shanxi Medical University

Sponsor details 382 Wuyi Road Xinghualing District Taiyuan City China 030000 +86 (0)351 3365000 sydeyztjy@163.com

Sponsor type Hospital/treatment centre

Website

150

http://www.sydey.com/

ROR https://ror.org/03tn5kh37

Funder(s)

Funder type Hospital/treatment centre

Funder Name Second Hospital of Shanxi Medical University

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Huiqiang Liu (sxtycyj@163.com). The shared data will include anonymized individual records, and all legal and ethical considerations have been addressed, including consent for data sharing.

IPD sharing plan summary

Available on request