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Impact of comprehensive nursing based on the "3H" theory on blood gas, recovery speed, and lung function in children with severe pneumonia

Submission date 11/02/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 26/02/2025	**Overall study status** Completed	
Last Edited 25/02/2025	**Condition category** Other	

Plain English summary of protocol

Background and aims
Due to their underdeveloped immune systems and the often atypical early symptoms of pneumonia, the disease can rapidly progress to severe pneumonia, which can then significantly impair their respiratory function, leading to rapid deterioration of blood gas parameters and lung function. This study investigates the effects of comprehensive nursing based on the "3H" theory on blood gas parameters, recovery speed, and lung function in children with severe pneumonia.

Who can participate?
Children diagnosed with severe pneumonia who were treated at our hospital participated in this trial.

What does the study involve?
This study involves the clinical nursing effect of a comprehensive nursing programme on children with severe pneumonia.

What are the possible benefits and risks of participating?
The potential benefit of participating in this experiment is that children with severe pneumonia may recover their physical health faster, the risk is that without long-term follow-up, they may experience recurrence and serious complications.

Where is the study run from?
The Second Affiliated Hospital & Yuying Children’s Hospital of Wenzhou Medical University, China

When is the study starting and how long is it expected to run for?
August 2021 and February 2024

Who is funding the study?
The Second Affiliated Hospital & Yuying Children’s Hospital of Wenzhou Medical University, China

Who is the main contact?
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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
Impact of "3H" theory-based nursing in children with severe pneumonia

Acronym
3H

Study objectives

Comprehensive nursing based on the "3H" hotel-style (Hotel) etiquette services, hospital (Hospital) personalized care services, and home-style (Home) warm services theory can significantly improve the recovery speed of children with severe pneumonia, improve blood gas indicators and lung function, and increase family satisfaction compared to conventional nursing.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/11/2021, Ethics Committee of the Second Affiliated Hospital & Yuying Children's Hospital of Wenzhou Medical University (No. 109 Xueyuan West Road, Lucheng District, Wenzhou City, Zhejiang Province, 325000, China; +86-0577 88832693; feyyb1@163.com), ref: 2021-K-331-03

Study design
Single-center interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, Medical and other records

Study type(s)
Efficacy

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
Comprehensive nursing of children with severe pneumonia

Interventions
Brief methodology: The study group received comprehensive nursing based on the "3H" theory + routine care, the control group received only routine care.

Treatment: After treatment, the study group demonstrated significantly shorter times for cough cessation, fever resolution, improvement in dyspnea, disappearance of pulmonary rales, and overall length of hospital stay compared to the control group. Before treatment, no significant differences were observed in the PaO_2, SaO_2, and $PaCO_2$ levels between the two groups. However, after treatment, the study group exhibited significantly higher PaO_2 and SaO_2 levels and lower $PaCO_2$ levels compared to the control group.

Before treatment, our data showed that there were no significant differences between the two groups in terms of FEV1, FVC, MVV, and PEF. However, after treatment, the study group showed significantly higher levels of FEV1, FVC, MVV, and PEF compared to the control group. Family

satisfaction after treatment was significantly higher in the study group compared to the control group. After the intervention, the study group had higher compliance compared to the control group, and the difference was statistically significant

Total duration of treatment: one month.

Follow-up: All patients in the study group were cured and returned to a healthy state. While two patients in the control group still had some sequelae, such as drowsiness and a small amount of cough. After one week of further recovery, their condition has improved.

Randomisation process: All enrolled children were assigned a number, and a random number generator was used to generate a sequence of random numbers corresponding to the number of children. Odd numbers were assigned to the study group, while even numbers were assigned to the control group.

Intervention Type
Behavioural

Primary outcome measure
1. Observe the clinical indicators of cough cessation time, fever reduction time, shortness of breath improvement time, lung rales disappearance time, and hospitalization time using clinical observation data from patient medical notes two weeks after nursing
2. Compare the changes in blood gas indicators, PaO_2, SaO_2, and $PaCO_2$ using blood gas analyzer before and after intervention
3. Compare the changes in first-second forced expiratory volume (FEV1), forced vital capacity (FVC), maximum ventilation volume (MVV), peak expiratory flow rate (PEF), and FEV1/FVC ratio of lung function parameters by Pulmonary Function Test before and after intervention

Secondary outcome measures
Satisfaction of the child’s family with the nursing care measured using a self-designed anonymous satisfaction questionnaire two weeks after nursing

Overall study start date
01/08/2021

Completion date
01/02/2024

Eligibility

Key inclusion criteria
1. Diagnosed by X-ray, meeting the diagnostic criteria of *Pediatrics (8th edition)*
2. Good compliance
3. No history of drug allergies
4. The child's family members should have at least a primary school education
5. The child's family members agree to participate and sign the informed consent form

Participant type(s)
Patient

Age group

Child

Lower age limit
3 Years

Upper age limit
17 Years

Sex
Both

Target number of participants
90

Total final enrolment
90

Key exclusion criteria
1. Suffering from other severe pulmonary diseases
2. Complicated with liver or kidney dysfunction
3. Suffering from mental disorders
4. Complicated with other malignant tumors
5. Complicated with severe malnutrition
6. Complicated with congenital heart disease

Date of first enrolment
01/11/2022

Date of final enrolment
01/12/2023

Locations

Countries of recruitment
China

Study participating centre
The Second Affiliated Hospital & Yuying Children's Hospital of Wenzhou Medical University
Department of General Pediatrics, No. 109 Xueyuan West Road, Lucheng District
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Sponsor information

Organisation
Second Affiliated Hospital of Fujian Medical University

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Sponsor type
Hospital/treatment centre

Website
https://www.fyey.cn/

ROR
https://ror.org/03wnxd135

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Second Affiliated Hospital and Yuying Children's Hospital of Wenzhou Medical University

Alternative Name(s)
Second Affiliated Hospital of Wenzhou Medical University

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
China

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication