

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

<b>Submission date</b> 11/02/2025	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/02/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 25/02/2025	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## 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?

Jie Jin, J722\_J@163.com

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Dr Jie Jin

### Contact details

The Second Affiliated Hospital & Yuying Children's Hospital of Wenzhou Medical University, No. 109 Xueyuan West Road, Lucheng District

Wenzhou

China

325000

+86-057785676572

J722\_J@163.com

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

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

## **Study type(s)**

Efficacy

## **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<sub>2</sub>, SaO<sub>2</sub>, and PaCO<sub>2</sub> levels between the two groups. However, after treatment, the study group exhibited significantly higher PaO<sub>2</sub> and SaO<sub>2</sub> levels and lower PaCO<sub>2</sub> levels compared to the control group.

Before treatment, our data showed that there were no significant differences between the two groups in terms of FEV<sub>1</sub>, FVC, MVV, and PEF. However, after treatment, the study group showed significantly higher levels of FEV<sub>1</sub>, 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(s)**

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<sub>2</sub>, SaO<sub>2</sub>, and PaCO<sub>2</sub> 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

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

3 years

**Upper age limit**

17 years

**Sex**

All

**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

Wenzhou City, Zhejiang Province

China

325000

## Sponsor information

**Organisation**

Second Affiliated Hospital of Fujian Medical University

**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**

**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