ISRCTN13393172 https://doi.org/10.1186/ISRCTN13393172

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

Registration date
26/02/2025

Overall study status
Completed

Last Edited
25/02/2025

Condition category
Other

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

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

Primary study design

Interventional

Study design
Single-center interventional randomized controlled trial

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 PaO2, SaO2, and PaCO2 levels between the two groups. However, after treatment, the study group exhibited significantly higher PaO2 and SaO2 levels and lower PaCO2 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(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_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

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