Original Article

Comprehensive Nursing Program for Children with Epilepsy: A Randomized Controlled Trial

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Abstract

Background: Epilepsy is a relatively common childhood neurological disease. Children with epilepsy need to take precautions to minimize seizure damage in order to adapt to seizures and manage them. **Aim:** The current study aimed to evaluate the feasibility and effects of a comprehensive nursing program for children with epilepsy to reduce children's symptoms of epilepsy. **Subject and Methods:** Participants were children suffering from epilepsy between 2019 and 2021 at Ningbo Women and Children's Hospital. Seventy children were included in a randomized controlled trial with a comprehensive nursing group (CNG) and an active control group (ACG). Measurements were assessed pre- and post-intervention and at a one- and three-month follow-ups. Children in the CNG learned and practiced the strategies related to the comprehensive nursing intervention. The outcomes were anxiety and depression. **Results:** The results showed that anxiety and depression scores were significantly lower in the CNG than the ACG at 1 and 3 months after intervention ($P < 0.05$). According to the feasibility results, whereas most participants believed that the program was informative and meaningful, a minority reported that it was time-consuming. **Conclusion:** The intervention has the potential to support children with epilepsy. The program is easily accessible, cost-effective and could be implemented in epilepsy care rehabilitation.

Keywords: *Children, epilepsy, neurological, nursing interventions, randomized controlled trial*

Introduction

Pediatric epilepsy is one of the most common neurological diseases.[1,2] The existing epidemiological survey data show that the incidence of epilepsy in the world is 0.7%, of which two-thirds of patients are children.[3-5] The incidence of epilepsy in children has declined in recent years but remains high in some countries such as China (151 per 100,000)[6] with highest rate in southwestern China,[7] and Aaberg *et al*.[8] estimated a prevalence ratio of childhood epilepsy in China around 0.5% to 1%.

The pathogenic causes of pediatric epilepsy are significantly different from adults, generally including brain dysplasia or developmental malformation, perinatal asphyxia and hypoxia, and genetic metabolic diseases, and some genetic epilepsy, "benign" epilepsy also mostly appears in childhood.[9-11] In addition, there are also many concurrent diseases at the onset, which cannot be ignored in the process of diagnosis and treatment. Only when the diagnosis determines the cause of epilepsy, can it be treated fundamentally and achieve the best curative effect.[12] The clinical treatment principle of epilepsy is to start early, take drugs regularly, and have a long course of treatment. The drug types, or increasing and reducing of dose should be gradual; otherwise, it may be caused by drug overdose or epilepsy.[13,14] Antiepileptic drugs are usually administered two to four years after

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the last onset, including a gradual tapering process of one to two years.

Children belong to a special age, and children's body and brain are undergoing rapid development stages. Children are different from adults in anatomy, physiology, biochemistry, nutrition, metabolism, immunity, and pathology, as well as in the occurrence, development, symptoms, diagnosis, treatment, prognosis, and prevention of diseases. Children of different ages are also different.[15-17] In addition, epilepsy will also affect the intellectual development of children. Epileptic seizures will cause hypoxia in the brain. At this time, the development of children's nervous system is not well formed. Repeated hypoxia will lead to intellectual decline. If children's epilepsy is not well controlled, the long-term use of antiepileptic drugs will also affect the intellectual development of children.[18,19] Therefore, in the treatment of epilepsy in children, differentiation between individuals should be considered and made different plans according to different situations. If the treatment is improper and repeated, it will affect the development of intelligence and even turn into refractory epilepsy, causing more significant harm.[12] Due to the sensitivity of children's tissues and organs and their dysfunction, the absorption, distribution, metabolism, and excretion of antiepileptic drugs are different from that of adults. Therefore, in the process of medication, it is necessary to analyze the flexible application according to these characteristics, emphasize individualization, control side effects, and adopt comprehensive nursing therapy.[20]

Comprehensive nursing integrates the advantages of group nursing and responsibility nursing. A group of nursing staff (head nurse and nurse) apply the working methods of nursing procedures to complete the nursing work of a group of patients.[21,22] Comprehensive nursing can urge nursing staff to carry out continuous and comprehensive holistic nursing for patients, which has considered broad over wide clinical application value.[23]

Therefore, the purpose of the randomized controlled trial study to evaluate the feasibility and the effects of a comprehensive nursing program with minimal therapist contact for children and adolescents who had been admitted for epilepsy. A hypothesis was that children in the CNG would report decreased levels of anxiety and depression.

Methods

Design

The study used a single-blind, parallel group randomized controlled trial comparing the CNG and the ACG. Participants of the ACG received an alternative program with a different content during the investigation after the first follow-up at three months. The primary objective was to investigate the effects of the comprehensive nursing program on children's symptoms of epilepsy over a 3-month period compared to the alternative program. This controlled trial also tested secondary outcomes relating to the effects on children's quality of life, disease management difficulty, and disease management ability over the 3-month follow-up. Assessment of children's outcomes was performed by a researcher (third author) blind to group allocation. The controlled trial was registered at Ningbo Women and Children's Hospital (ID: NWCH2021).

Participants and procedures

The Ningbo Women and Children's Hospital is a specialized tertiary hospital for women and children, integrating medical treatment, health care, teaching, scientific research, disease prevention, first aid, and rehabilitation. The sample for this cross-sectional study consisted of all consecutively admitted children with epilepsy at the hospital between October 2019 and May 2021. Children in both groups were eligible to join the intervention if they met the following inclusion criteria: (1) children with complete clinical data; (2) children with normal intelligence and communication so that first a picture was shown to the children, part of which was empty, then they had to find a pattern in other pictures so that they could guess the place of the empty picture; (3) parents signed the consent form for the children to participate in the study; (4) children aged 0-9 years old. Children with malignant tumor, children with severe liver and kidney dysfunction, children with incomplete follow-up and lost contact during follow-up, and children with coagulation dysfunction were excluded from both groups. Two hundred and eight children fulfilled the inclusion criteria. Children could withdraw from the study at any point without prejudice to their care.

Figure 1 provides details on the participants' flow. The children were randomly assigned to either the CNG (n = 49) or the ACG (n = 49) by one of the researchers, using a computer-generated list. Of these, 35 (71%) in each group completed the baseline assessment; thus, 98 children participated in the trial.

Children in the ACG should pay attention to maintain the environmental comfort of the child's ward, give real-time care to the child during the onset of the disease, clean up the child's oral foreign body, and provide the child with corresponding antiepileptic drugs on time. Children in the CNG learned and practiced the strategies related to comprehensive nursing intervention.

The program

After the child was admitted to the hospital, a psychiatric advanced practice nurse (APN) gave health education to the child's family members, popularize the relevant knowledge of epilepsy, intervention methods, adverse events, precautions, expected effects, and timely communication with the child's family members to alleviate the psychological burden of the child's family members on epilepsy. In addition, children with epilepsy lack a sense of security due to the affliction of the disease and the strangeness of the hospital environment, and they are prone to negative emotions such as anxiety and depression, so the nursing staff needed to strengthen the daily communication with the children, and can also take the method of diverting the attention of the children, such as watching cartoons and doing games. The APN taught the child's family how to determine the incidence of epilepsy in order to prepare for prevention in advance and reduce the harm to the child during seizures. After the child was discharged from the hospital, the child's family should also be followed up regularly, the nursing plan should be adjusted in real time, the questions of the caregiver should be answered, and the family care should be improved.

Primary outcome measures

The Zung Self-Rating Anxiety Scale (SAS)[23] was used to measure anxiety. It contains 20 items divided into four subscales: cognitive, autonomic, motor, and central nervous system. The scale ranged from 1 (a little of the time), 2 (some of the time), 3 (good part of the time), and 4 (most of the time). The present study obtained an alpha coefficient of 0.81 at time 1, 0.86 at time 2, and 0.82 at time 3.

The Zung Self-Rating Depression Scale (SDS) was used to measure depression. It contains 20 items, with each item rated on a 4-point scale.[24] Empirical evidence supported the reliability and validity of the scale.[25] The scale ranged from 50–59 (mild to moderate depression), 60–69 (moderate to severe depression), and over 70 (severe depression). The present study obtained an alpha coefficient of 0.83 at time 1, 0.79 at time 2, and 0.85 at time 3.

Secondary outcome measures

The basic data (age, gender, height, weight, disease type, attack type, and medication) and the family status (caregiver role, caregiver age, caregiver education, home address, and family income) of the children were obtained from medical records.

The World Health Organization Quality of Life (WHOQL) scale was used to assess the quality of life of children and families.[26] It contains 32 items divided into three subscales: Spirituality, Religiousness, and Personal Beliefs. The present study obtained an alpha coefficient of 0.78 at time 1, 0.84 at time 2, and 0.87 at time 3.

The Family Management Measure (FaMM) scale was used to assess the family management ability (disease management difficulties and disease management ability).[27] The scale is mainly used to evaluate the response and care methods of families with children with chronic diseases and the impact of diseases on daily life. There are 53 items and 6 subscales, including children's recognition (5 items), care (10 items), difficulties (14 items), effort (4 items), management ability (12 items), and family relationship (8 items). The Likert rating method used 1-5 points that are scored from complete disagreement to complete agreement.

Feasibility of the program in the CNG

The study used the participant evaluation scale, which was used in Sveen *et al*.'s study.[28] Participants in the CNG were given evaluation forms after the three and six weeks and at one- and three-month follow-ups. The scale reflected the participant's perception of the modules/program (informative, upsetting, meaningful, neutral, understandable, boring, and supportive) and the situation, better or worse. The scale ranged from 0 (no, not at all) to 4 (yes, to a high degree).

Statistical analysis

Statistical analyses were performed with Statistical Package for Social Sciences version 22 by a researcher who was blind to the program group allocation. The trial was analyzed by the intention-to-treat (ITT) approach that maintained the advantages of random allocation. Chi-square and T-tests were used and a two-tailed significance level of Alpha 0.05 was set. First, a descriptive analysis of demographic and epilepsy-related variables was performed, which showed the values such as frequencies. To investigate the program effects on the primary outcome variables (SAS and SDS) during the four measurements (pre- and post-intervention and follow-ups), a generalized estimating equations (GEE) was performed. T-test with a two-tailed significance level of Alpha 0.05 was used to investigate the program effects on the secondary outcomes (quality of life, disease management difficulty, and disease management ability).

Results

Of the 98 assigned people, 70 children participated in the study. The gender distribution was 29 female and 41 male participants aged between 9 and 14 years, with a M (SD) age of 12.5 (2.74) years [see Table 1]. Table 1 shows the demographic and epilepsy-related variables of

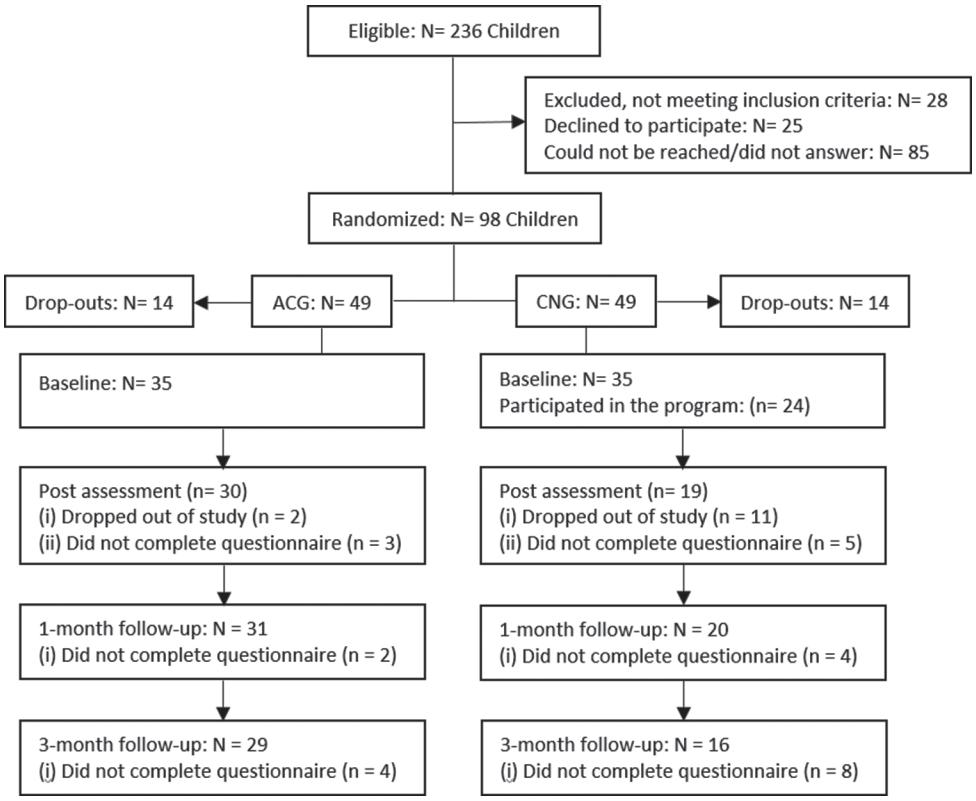

Figure 1: Flow of participants through the study

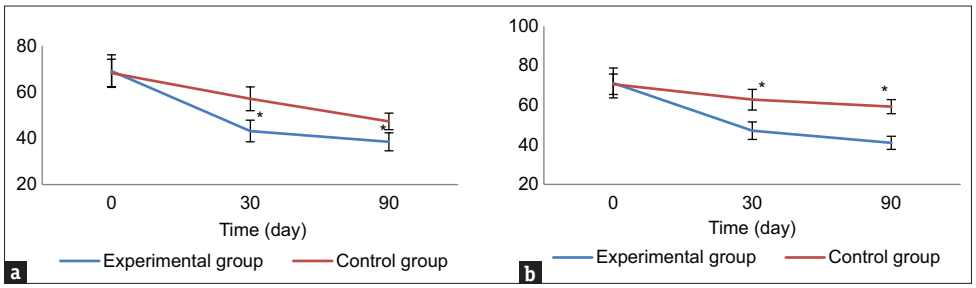

Figure 2: (a) Changes in SAS scores between groups. SAS: Self-Rating Anxiety Scale. (b) Changes in SDS scores between groups. SDS: Self-Rating Depression Scale

Table 1: Characteristics of the children

	CNG (*n*=35)	ACG (*n*=35)
No. of male/female	22/13	19/16
Age in years, mean (SD)	12 (2.5)	13 (2.2)
Birth weight in Kg, mean (SD)	3.02 (502)	3.04 (554)
History of epilepsy, has/has no	15/20	16/19
Parents' family relationship, Yes/No	12/23	10/25
Family history of epilepsy, has/has no	8/27	9/26
Treatment with anticonvulsant drugs, Yes/No	14/21	13/22
Previous history of neurological disease, has/has no	18/17	20/15
Previous history of non-neurological disease, has/has no	11/24	12/23

the children who participated in the study. In general, the majority of children did not have a parents' family relationship and previous history of non-neurological disease. As the table shows, there are no significant differences between the CNG and the ACG, so it can be concluded that they are homogenous groups.

The following tables and figures indicate descriptive data for the primary and secondary outcomes for before and after the intervention. No significant baseline differences were found between the CNG and the ACG. Children reported high symptom levels on quality of life and disease management ability and low symptom levels on disease management difficulty. The percentages of clinical treatment compliance and clinical efficacy as reported by the children were high.

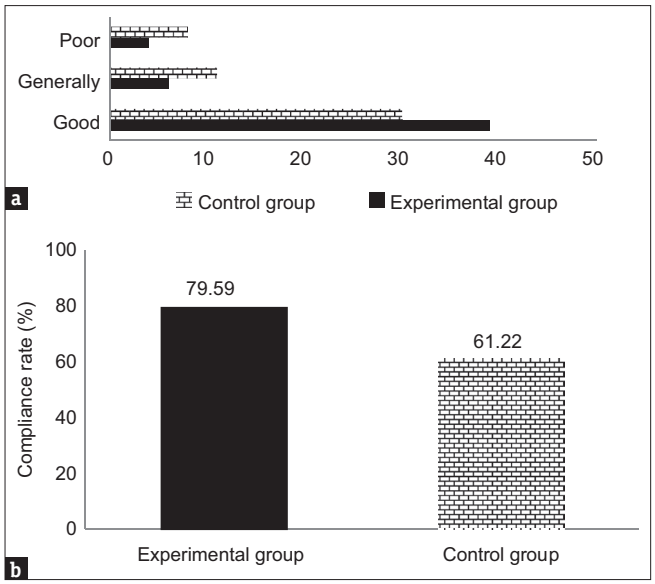

Figure 3: Comparison of clinical treatment compliance after the intervention. (a) the number of cases with good, general, and poor clinical treatment compliance, (b) the clinical treatment compliance rate

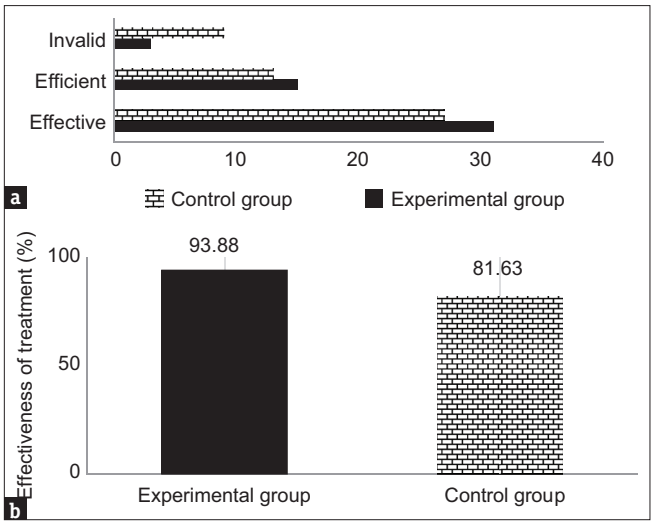

Figure 4: Comparison of clinical efficacy after the intervention. (a) markedly effective, effective, and ineffective cases, and (b) the overall response rate

Table 2: Summary of primary outcomes scores for the children at pre- and post-intervention and follow-ups

	CNG		ACG	
	Mean	SD	Mean	SD
SAS				
Pre-assessment	49.22	33.13	48.97	41.16
Post-assessment	44.16	35.19	48.12	39.72
1-month follow-up	41.55	32.44	49.01	36.18
3-month follow-up	40.49	30.66	50.32	40.58
SDS				
Pre-assessment	68.73	15.46	69.51	16.23
Post-assessment	64.37	12.44	68.19	14.84
1-month follow-up	59.28	13.17	69.03	12.66
3-month follow-up	57.66	14.55	70.11	13.09

Table 3: Summary of quality of life and FaMM scores for the children at pre-intervention and follow-ups

	CNG		ACG	
	Mean	SD	Mean	SD
Quality of life				
Pre-assessment	60.34	5.84	59.28	6.05
1-month follow-up	72.54	4.97	61.77	5.11
3-month follow-up	81.35	6.82	65.83	5.38
Disease management difficulty				
Pre-assessment	51.35	4.91	49.82	5.14
1-month follow-up	44.88	6.03	46.91	4.36
3-month follow-up	33.47	5.1	45.08	4.75
Disease management ability				
Pre-assessment	30.64	3.28	31.84	2.96
1-month follow-up	36.18	3.05	33.95	4.11
3-month follow-up	44.39	3.68	35.06	4.13

The SAS and SDS scores of the CNG at 1- and 3-month follow-ups were significantly lower than those of the ACG [Table 2 and Figure 2]. The CNG had lower scores at post-assessment compared to the ACG (SAS: Mean = 44.16, SD = 35.19 vs Mean = 48.12, SD = 39.72; SDS: Mean = 64.37, SD = 12.44 vs Mean = 68.19, SD = 14.84), at 1-month follow-up (SAS: Mean = 41.55, SD = 32.44 vs Mean = 49.01, SD = 36.18; SDS: Mean = 59.28, SD = 13.17 vs Mean = 69.03, SD = 12.66), and at 3-month follow-up (SAS: Mean = 40.49, SD = 30.66 vs Mean = 50.32, SD = 40.58; SDS: Mean = 57.66, SD = 14.55 vs Mean = 70.11, SD = 13.09).

Although the quality of life and disease management ability scores of the CNG at 1- and 3-month follow-ups were significantly higher than those of the ACG, the disease management difficulty scores were lower [Table 3]. Group comparisons over time regarding clinical treatment compliance and clinical efficacy revealed a significant interaction effect [Figures 3 and 4]. The CNG had higher percentages at after the intervention compared to the ACG.

According to the feasibility results of the program, seventy-nine percent of the CNG (n = 19) completed the scale and reported that the program was informative and comprehensible. Most participants believed that the program was meaningful (89%) and supportive (84%). The minority believed it was upsetting (16%) or boring (5%). Over one quarter of the respondents reported that the situation has improved because of the program. Over half of the respondents reported that the program had a positive impact on solving their problems. Although most of them mentioned the positive aspects of the program such as processing and talking about

epilepsy, some also mentioned its negative aspects such as the program was time-consuming.

Discussion

The present study provided evidence that the comprehensive nursing program has a potential role to reduce symptoms of anxiety and depression in children with epilepsy. Although most of the participants in the CNG reported that the program was informative and meaningful, a minority reported that it was time-consuming. Most of the participants in the CNG and the ACG had a positive opinion on research participation.

In this randomized controlled trial, the SAS and SDS scores of the CNG were significantly lower than those of the ACG at 1- and 3-month follow-ups, which indicated the program could effectively improve the negative emotions of children with epilepsy compared with conventional nursing. In terms of quality of life, it was found that the quality of life scores at 1- and 3-month follow-ups in the CNG were significantly higher than those in the ACG, which was consistent with the study results of Widjaja *et al*.[29] It suggested that the program could develop the corresponding nursing service plan according to the specific circumstances of each family, in order to improve the family function of the children and the family quality of life. Although the disease management difficulty of the children in the CNG at one- and three-month follow-ups was significantly lower than those in the ACG, the disease management ability scores were significantly higher. It revealed that the program increased the attention of the children's families to epilepsy and improved the disease management ability. The compliance rate of clinical treatment after intervention in the CNG (79.59%) was significantly higher than that in the ACG (61.22%), which indicated the program had a better guidance effect for the children and greatly improved the adaptability of the children during the treatment.[30] Finally, the comparison of the children's clinical efficacy indicated that the overall response rate after intervention in the CNG (93.88%) was significantly higher than that in the ACG (81.63%). The program can effectively improve the clinical nursing effectiveness for children with epilepsy, has a high application value, and needs to be given high attention.

As the first study to test the effects of comprehensive nursing on anxiety and depression in children with epilepsy, it was shown that epileptic children benefit from such a program. Therefore, epilepsy in children can be improved with systematic processes, rather than only temporary interventions. Due to the sparse of the psychological determinants of anxiety and depression in the literature, the findings avail as an initial approach for early anxiety and depression prevention in children with epilepsy.

In the evaluation of the effectiveness of a comprehensive nursing program on anxiety and depression, the study made several methodological improvements, including the use of random assignment, an ACG, a three-month follow-up, and forty participants in each group. Nevertheless, the study has some limitations. Although the children were unaware of the purpose of the study, the nurses were aware of the expected positive effects of the comprehensive nursing program on anxiety and depression. It is assumed that the nurses were not able to influence the results. Another limitation of this study was the lack of a double-blind design. A finial limitation may be that most of the participants had minor to moderate epilepsy and temporary hospitalization, which may not be representative of children with epilepsy in general or children with larger epilepsy involving lengthy hospitalization.

Conclusion

In conclusion, the present program had a beneficial effect on parents' posttraumatic stress symptoms; the children confirmed that the study was informative and meaningful. Therefore, the results provide data support for the clinical care treatment of pediatric epilepsy.

Ethical approval

The study was carried out in compliance with guidelines issued by ethical review board committee of Ningbo Women and Children's Hospital, China. The official letter (no. **NWCH2021**) would be available on fair request to corresponding author.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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