The Effects of Parent-Child Activity Program on Physical Activity of Children With Cancer

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1. Summary

Study Population: Children diagnosed with malignant tumors aged 6 to 14 years.

Outcome measures: ① Main outcome measures: physical activity behavior in children with cancer; ② secondary outcome indicators: height, weight, BMI, body fat, muscle, self-efficacy of physical activity, physical activity enjoyment, perceived social support in physical activity, and physical activity of parents.

Study Intervention: ① Control group: the children and their parents receive routine care and health education guidance, receive physical activity guidelines and suggestions for patients with malignant tumors provided by the researchers, and issue health knowledge education manual. In addition, the researchers and other members of the intervention team do not provide information about parent-child activities; ② Experimental group: the experimental group receives online and offline family-based parent-child physical activity intervention. It includes participating in offline group parent-child activities during hospitalization, including family competitive games and knowledge contests, etc., popularizing science of physical activity and parent-child sports activities to children and parents regularly after discharge, and pushing tweets, sports and practice videos related to physical activities and parent-child sports activities. Exercise were followed every 4 weeks and assessed for the previous session. The intervention protocol lasts 12 weeks and is followed up 3 months after the intervention is completed.

Sample size: with physical activity as the outcome indicator, the sample content was used to estimate the sample content calculation method, and the test level α was set to

0.05, and the control degree was 90%. According to the results of the literature review, 20.8621 subjects in the experimental group and the control group, considering 20% lost to follow up, so at least 27 subjects in the experimental group and the control group.

2. Introduction

2.1 Background

According to statistics, there are an estimated 429000 new cases of childhood malignancies each year[1]. In recent years, childhood malignancy has ranked sixth in the total burden of world malignancy and ninth in the burden of childhood disease[2]. At the same time, the incidence of malignant tumors in children and adolescents in China is also increasing, with a significant rate of 2.8% per year, which is the second leading cause of death in children[3]. With the progress of modern medicine, the five-year survival rate of childhood malignancies in developed countries is as high as 80%[1], The five-year survival rate of young children in China has also reached 72%[2]. Therefore, childhood malignancies are a large group, and more professional medical personnel are needed to provide more and better quality treatment and care services. Although the current treatment program has significantly improved the treatment and survival of childhood malignancies in the past few decades, children still face a variety of health problems, especially in economically underdeveloped developing countries[4]These adverse effects may last for months to years, facing not only the physical and psychological effects of malignant tumors, but also various long-term adverse reactions such as growth and development disorders and secondary tumors

caused by treatment[5]. Studies reported that 62.3% of patients with childhood malignancy had at least one chronic disease, such as type 2 diabetes, obesity and cardiovascular disease[4]; 95% of patients with childhood malignancy develop chronic disease before the age of 45, and 80.5% develop disabling or life-threatening complications[5]. Therefore, China launched the National Child Cancer Surveillance Program in 2019[6]To promote the health of patients, prevent and reduce the above health problems.

Physical activity (physical activity, PA) is any body activity caused by the skeletal muscle that leads to energy expenditure[7]. Physical activity has been shown to have many benefits for the physical and mental health of children with malignant ancies and can reduce the occurrence of these health problems. The American Cancer Society (Amarican Cancer Sociation, ACS) states that proper physical activity at all stages of cancer is good for health[8]. However, the status of physical activity in children and patients with malignant tumors is worrying. Data from Western countries show that over 50% of children do not meet the recommended 60 minutes of moderate to high physical intensity per day[9]; About 92.2% in Hong Kong, China did not meet the physical activity level recommended by the guidelines[10]; 88.7% of children in mainland China are far from the daily exercise recommended by WHO[11]. Physical inactivity not only increases the risk of various health problems, but is also an important cause of advanced cardiovascular disease and secondary tumors. Therefore, it is necessary to explore the methods that can effectively improve and maintain the

physical activity of children with cancer and reduce the occurrence of the above adverse reactions.

Scholars have developed various intervention programs for the physical inactivity of patients with childhood malignancy, Showing multiple health benefits, However, the effects of various intervention programs are not the same: the intervention programs supervised by professionals in the hospital has strict requirements on time, site and personnel; Physical activity plans at home due to lack of knowledge, inadequate supervision, Lead to low intervention compliance and no significant effect; With the development of mobile health and electronic health devices in recent years, Such as SMS, apps, real-time video calls, virtual reality technology, It offers broad prospects for remote intervention of physical activity in childhood malignancies[12,13]. But home physical activity programs for children still require parental participation, guidance and supervision. The latest research shows that the parents to participate in the activity plan to improve compliance and intervention effect has positive influence: in professionals (such as medical staff or sports coach), under the guidance of parent-child activity plan participation and completion rate is as high as 90%, after intervention children with physical function, cardiopulmonary function, fatigue, quality of life, etc[14]. However, such studies are still in the exploratory stage, the number of related studies is small, and the long-term health effects of the intervention are unknown, requiring more data to support them.

Cross-sectional studies show that physical activity in children with cancer is associated with multiple factors, including physical and psychological factors, family

support and participation, and peer support, among which children and family-related factors are the most important factors. Welk[15] proposed the Youth Physical Activity Promotion Model which provides researchers with a comprehensive approach to promote adolescent physical activity by systematically understanding and improving the multiple factors that adolescent physical activity behavior. From the perspective of social ecology, the model constructed a framework including propensity factors (psychological attributes), facilitator factors (environment), reinforcing factors (social influence) and demographic variables. Validated by research[16], The three factors covered by the model are able to effectively describe adolescent physical activity behavior, where physical activity self-efficacy and physical activity enjoyment in the tendency factors, and the influence of parents in the reinforcing factors are the most important aspects of the promotion of physical activity in adolescents. The Youth Physical Activity Promotion Model has been widely used in the physical activity research of school-aged children at home and abroad[17], And reported good reliability and effectiveness, but has not been applied to construct physical activity intervention programs in children with tumors.

Therefore, this study is based on the Youth Physical Activity Promotion Model suitable for children child malignant tumor physical activity plan, aims to provide continuity care for children and their parents, by providing parents with physical activity knowledge and skills, increase the participation and interaction, increase social support for children and parents, improve the physical activity efficacy and physical activity enjoyment, so as to improve their physical activity behavior, promote

the life and health of children.

2.2 Risk / benefit evaluation

2.2.1 Potential risks

Due to the particularity of physical activity, children and parents may occur when participating in the activity, or may be due to exercise: ① bleeding; ② serious soft tissue injury; ③ fracture; ④ respiratory tract infection; ⑤ severe pain, intolerable; ⑥ fatigue, physical exhaustion, etc.

Countermeasures: The researchers have been strictly trained to accurately assess the health status of the subjects and timely treatment, and teach the parents common first aid skills, minimize the injury to the children and their parents, and evaluate and report according to the standard of adverse events.

2.2.2 Potential benefits

Studies have shown that effective and moderate physical activity has shown many benefits in both children with acute treatment and children who have finished treatment or are in long-term survival. Appropriate physical activity in children during the treatment of malignant tumors can effectively improve their physical and psychological conditions during the treatment period, such as the recovery of physical activity level[18], And have increased muscle strength[19], To reduce the cardiopulmonary injury caused by the treatment[20], To relieve physical pain and fatigue[19]Other discomfort symptoms and reduce anxiety and depression; proper physical activity can also effectively improve exercise ability and improve negative

mood[21], And enhance the cardiopulmonary function[22], And reduce the all-cause mortality rate[23], enhance the quality of life[21]。

3. Study objectives and outcomes

3.1 Purpose

This study is based on the Youth Physical Activity Promotion Model for children with cancer, aims to provide continuity care for children and their parents, by providing parents with physical activity knowledge and skills, increase the participation and interaction, increase social support for children and parents, improve their physical activity, and promote their life and health.

3.1.1 Main Purpose

Construct a parent-child activity intervention program suitable for children with cancer.

3.1.2 Secondary Purpose

(1) Describe the status quo of the physical activity, physical activity self-efficacy, physical activity enjoyment, family support and the physical activity of the parents of the children with cancer, and analyze the influencing factors of the physical activity of the children with cancer;

(2) To explore the effect of parent-child activity intervention in children with cancer based on Youth Physical Activity Promotion Model on physical activity, physical activity self-efficacy, physical activity enjoyment, family support and parental physical activity of children with cancer.

3.1.3, exploratory purpose

To explore the feasibility of parent-child activity intervention in childhood malignancies based on Youth Physical Activity Promotion Models.

3.2 Study indicators

3.2.1 Main Indicators and Definitions

Physical activity (physical activity, PA): any body activity caused by skeletal muscle contraction higher than the basal metabolism[25], Including occupational work, housework, leisure activities, sports, and physical exercise for fitness and health purposes[26], Is divided into low (1.5~2.9MET), moderate (3.0~5.9MET) and intense (6.0 MET). The physical activity mentioned in this study refers to the regular, planned and organized physical activity to improve or maintain fitness, motor skills or health, the Chinese leisure activity questionnaire (Children's Leisure Activities Study Survey Chinese-version, CLASS-C) to measure the physical activity behavior of children with cancer, and the international physical activity questionnaire measures the physical activity behavior of parents.

3.2.2 Secondary indicators and Definitions

(1) Physiological indicators: height, weight, body mass index (BMI), body fat of children. BMI is a simple index of height and weight, which is defined as the weight by kilogram divided by the square of the height by meter (kg/m^2). Body fat rate refers to the proportion of the fat weight in the human body in the overall body weight, also known as the body fat percentage, which reflects the content of fat in the human body.

(2) Self-efficacy: Self-efficacy is based on Bandura's social cognition theory[27], Refers to the individual's judgment of confidence in his / she performing a specific

behavior, and the individual's judgment of self-efficacy plays an important role in its decision whether to perform the behavior, degree of effort invested, and length of adherence. Physical activity self-efficacy is an individual's confidence in engaging and maintaining physical activity when faced a challenge[28]. In this study, the simplified Chinese version of physical activity self-efficacy scale (shortened Chinese version physical activity self-efficacy scale, S-PASESC) was used to measure physical activity self-efficacy in pediatric patients with cancer.

(3) Enjoyment of physical activity (PA Enjoyment): enjoyment is a process of experiencing feelings such as happiness, interest and happiness, which is a subjective feeling[29]. Physical activity enjoyment is a positive emotion for physical activity and represents a positive attitude towards physical activity, and this psychological experience can be driven by extrinsic support (e. g., social recognition) and internal feeling (e. g., sensory experience)[30]. Enjoying is a key factor in motivating physical activity behavior and sustained participation, especially in the adolescent population[31]; In turn, exercise was able to enhance participants' positive emotions. In this study, the brief physical activity enjoyment scale (short-form Physical Activity Enjoyment Scale, S-PACES) was used to measure the physical activity enjoyment in pediatric patients with cancer.

3.2.3 Safety Indicators

The number of unexpected events during the exercise intervention, including but not limited to fall, sprain, hypoglycemia, and infection during exercise.

4. study population

4.1 Inclusion and exclusion criteria for young children with cancer

4.1.1 Inclusion Criteria

(1) Aged 6~14 years old;

(2) Diagnosed with cancer;

(3) Undergoing cancer treatment;

(4) Able to communicate in Chinese;

4.1.2 Exclusion criteria

Children with physical impairment, cognitive impairment, or impaired mental status are excluded.

4.2 Inclusion and exclusion criteria for parents of children with cancer

4.2.1 Inclusion Criteria

(1) Able to communicate in Chinese and read Chinese;

(2) Able to use smartphone with WeChat;

4.2.2 Exclusion criteria

Parents with emotional or psychiatric disorders and cognitive problems are excluded.

4.3 Removal criteria

(1) Tumor recurrence, bone marrow transplantation, or death during the intervention;

(2) Transfer to a hospital for maintenance treatment;

(3) The child and their families request to withdraw.

Compliance with any of the above conditions can be removed.

4.4 Recruitment and retention strategies

(1) Children were recruited during hospitalization, and children diagnosed with

malignant tumors between 6 to 14 years in pediatric 1 and their parents were selected as the research objects, and baseline data of children and their parents were collected by questionnaire survey;

(2) Ask the children about their subjective feelings, opinions and suggestions on their physical activity intervention, and timely improve the intervention forms, intervention programs and intervention measures to meet the needs of the children and their parents and improve the retention rate and compliance;

(3) In the offline group parent-child activities and knowledge competitions, reward families, children and parents with outstanding performance and obvious progress, including stationery, dolls, toys, candy, etc.

5. Research Design

5.1 Overall design

5.1.1 Study Hypotheses

(1) The physical activity of most children with cancer does not meet the guidelines suggest that their physical activity is positively related to self-efficacy, enjoyment, family support and the physical activity of their parents;

(2) Compared with the control group, parent-child activity intervention can improve the physical activity of children with cancer and their parents, promote the self-efficacy and physical enjoyment of physical activity, and enhance the family support of children.

5.1.2 Study design

This study is a class of experimental study. The pediatric malignant tumor patients and

the parents were selected by convenience sampling.

5.2 Study design process

Establish an intervention team composed of researchers and qualified doctors and nurses, and evaluate the intervention members. Study subjects were recruited according to the exclusion criteria, and after obtaining informed consent and signing the consent form, the study subjects were included in the control group and experimental group. In order to prevent contamination, it was divided into control group and experimental group according to the chronological order, that is, the experimental group was included first, and in the experimental group, the control group was included after the sample size is sufficient. The control and experimental groups received usual care and parent-child activity intervention. Data were collected and analyzed at enrollment (T0), 1 month (T1), 2 months (T2), 3 months (T3), and 3 months (T4) after the intervention.

5.3 Methods to reduce the bias

(1) Adopt the research method of similar experiment, collect all the data of the experimental group, and then recruit the control group to collect the data to avoid the occurrence of contamination;

(2) The intervention team members shall receive unified physical activity training and assessment before the intervention, jointly propose the possible situation during the implementation of the intervention, unify the interpretation method of the questionnaire items, and give unified language answers to the questions about the questionnaire;

(3) In the process of collecting the questionnaire, collect the questionnaire on the spot, evaluate and check the completion of the questionnaire, timely find and correct the missing contents, ensure the integrity and effectiveness of the questionnaire information, and timely input the data after collecting the questionnaire;

(4) When analyzing the data, check the integrity and validity of the data again, and make remedial plan for the incomplete questionnaire; establish a database, and two people jointly input and check the data to ensure the accuracy of data entry.

5.4 Statistical analysis

5.4.1 Sample size

The number of sample cases required for the study was estimated by two sample content calculation using physical activity as the outcome measure. Taking the medium and high intensity physical activity of the study subjects as the observed outcome indicator, according to the results, the mean and standard deviation of physical activity minutes of the control group was 35.88 ± 50,39, the mean and standard deviation of the experimental group was 166.19 ± 116.92, and the test level was set at 0.05 and the control was 90%. Calculate the formula according to the sample size:

$$n = \frac{(Z_\alpha + Z_\beta)^2 * 2\sigma^2}{\delta^2}$$

We calculated 20.8621 subjects in the experimental group and the control group, considering 20% lost to follow-up, so n1=n2=21/0.8=26.2527 cases. At least 27 subjects were needed in the experimental and control groups.

5.4.2 Statistical Analysis

The Epidata3.1 database was established, the data was entered by two people, and the SPSS25.0 statistical software was used for statistical analysis, and the test level was set at α =0.05.

(1) Description statistics: ① Data following normal distribution are described by mean and standard deviation; ② data without normal distribution are described by median and interquartile spacing.

(2) Data analysis: (3) Use Excel to establish the database, double input data, and use SPSS25.0 statistical software for statistical analysis, as follows:

① Using frequency, composition ratio, mean, standard deviation to describe the general data of children with tumors and their parents, the disease data of children and other conditions;

② The t-test, chi-square test or rank sum test were balanced for general data, physical activity, physical activity self-efficacy, physical activity enjoyment, and physical activity social support between the experimental and control groups.

③ One-way repeated measures analysis of variance was used to compare the number of high intensity physical activity minutes between children and parents in the experimental group.

④ If the data of physical activity, physical activity self-efficacy, physical activity enjoyment and physical activity social support meet the normal distribution (Shapiro-Wilk test) and equal variance (scatter plot), the mixed design analysis of variance shall be used to intervene the effects of main effect, time main effect, intervention time effect and confounding factors; if not satisfied, the generalized

estimation equation is used.

6. Research intervention

6.1 Study Intervention

(1) Implement routine care in the control group

Children in the control group and their parents received routine care and health education guidance, as well as guidelines and suggestions on physical activity of patients with malignant tumors provided by the investigator, and issued health knowledge education manuals. In addition, the investigator and other members of the intervention team did not provide information on parent-child activities;

(Ii) The experimental group received the family-based parent-child physical activity intervention combining online and offline, specifically as follows:

(1) Information support:

I . Establish and use wechat groups

After obtaining the informed consent, the children with cancer and their parents were invited to join the wechat group, and the popular science of physical activity related knowledge was regularly pushed to the children and their parents every week. Children and their parents have any questions can be asked to the intervention team members in the group. In addition, every Monday, the researchers sent the physical activity clock in the group, inviting the children and parents to record after completing the physical activity.

II . Create and use a wechat official account

Create a wechat official account, and push tweets and video content related to physical

activity every Thursday, Saturday and Sunday morning.

III . Offline group parent-child activities

Inform the children with cancer and their parents to follow up every 4 weeks, and organize the follow-up children and their parents to participate in offline group parent-child activities.

(2) Personnel support:

I . Promote parental participation

① Improve parents 'physical activity knowledge, belief and ability: through wechat group, wechat public account and other ways, increase parents' understanding of children's physical activity knowledge, improve their belief and ability to supervise and participate in children's physical activity.

② Increase parent-child activities to promote parents' participation: push a variety of parent-child physical activities, such as two-person aerobics, two-person ball sports, and outdoor sports requiring family participation (such as mountain climbing), etc.

③ Organize family competitive games to promote parent-child interest.

④ Enhance parent-child communication, and jointly develop solutions to various problems.

II . Strengthen the role between families —— peer influence

① WeChat group communication, enhance the information interaction and emotional support between peers.

② Family competition, improve the role of role model.

III . Strengthen the role of medical staff —— Medical staff support

① Information and technical support: medical staff shall provide relevant information, venues and goods to the child and their parents.

② Emotional support: When children and parents have problems or emotional needs, intervention team members should provide timely answers and encouragement online; at monthly follow-up, researchers will provide separate face-to-face interviews to help them solve their problems.

③ Other support: In the offline activities, the medical staff also actively participate in the demonstration for the children and their parents.

(3) The intervention program lasts for 12 weeks and is follow-up for 3 months after the completion of the intervention.

6.2 Study Intervention Adherence

Compliance assessment method: Monday morning 08:00 researchers in WeChat group send physical activity clock table, invite children and parents after complete physical activity after the corresponding record, to calculate the amount of exercise per week, if reach 3 times a week, 30 minutes of parent-child activity, is to complete the activity plan this week.

7. Measurements

This study mainly adopts the form of paper questionnaire data collection, the tools to be used including the children's socio-demographic data and disease related data, parents general information, children's leisure activity questionnaire, international

physical activity questionnaire, physical activity self-efficacy scale, physical activity enjoyment scale and physical activity social support scale.

(1) Collect the questionnaire, researchers use unified guidelines and instructions to encourage malignant children and their parents to fill in the questionnaire and scale; For the participants who could not fill in the questionnaire by themselves, the participants will answer the contents of the questionnaire items, and the data collectors will fill in the questionnaire for them;

(2) After recruiting eligible children and their parents according to discharge standards and obtaining informed consent, Collect the baseline (T0) data, Including children's general data, physiopathological indicators, physical activity questionnaire, physical activity self-efficacy scale, physical activity enjoyment scale, family support questionnaire and general data of children's parents, physical activity questionnaire; Physical activity questionnaires, physical activity self-efficacy scale, physical activity enjoyment scale and physical activity questionnaires of parents were collected at the end of intervention week 4 (T1) and week 8 (T2); At the end of the intervention (T3), the physical activity indicators, physical activity questionnaire, physical activity self-efficacy scale, physical activity enjoyment scale, family support questionnaire and physical activity questionnaire of the parents were collected; Three months after the intervention (T4), Phyopathological indicators, physical activity questionnaires, family support questionnaires and physical activity questionnaires of parents were collected.

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