Effect of Physical Activity Program on the Quality of Life of Children with Cystic Fibrosis at School Age: A Randomized Clinical Trail

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INTRODUCTION

Cystic fibrosis (CF) is the most common autosomal recessive disorder in childhood and adulthood. The main characteristics of the disease are airway obstruction, recurrent infection, malnutrition, and the related consequent problems (1). In England, CF affects more than 9,000 individuals, of whom 4,000 cases are under 16 years of age. Only about half of the population with CF lives to be over 40 years. Regardless of the geographical location, the overall incidence of the disease is estimated at 1 in 2,500 live births. Unfortunately, there are no exact statistics on the prevalence of CF in Khuzestan province, Iran. The CF is more common due to consanguineous marriage (3, 2).

The most common symptoms of the disease are respiratory tract infections, including cough, sputum, wheezing, and lung infection. In some cases, sinusitis and nasal polyps are also observed. Therefore, maintaining respiratory function helps treat and improve the quality of life of these children. Regular physical activity can improve...
the quality of life of these children, increase life satisfaction, and reduce the rate of hospitalization due to the involvement of the pulmonary system in these children by increasing lung function and reducing respiratory symptoms (4).

Most children with chronic illnesses have low levels of physical activity. Although several studies emphasize the significance of exercise and physical activity in children with CF, children and adolescents with CF usually do not have enough ability to tolerate doing exercise, and this lack of activity has serious effects on well-being and life quality that limit their participation in sports and recreational activities. Physical ability is independent of factors, such as age, gender, lung function, and nutritional status as a major predictor of disease prognosis and mortality in patients with CF (5). However, few studies have been conducted on the effect of physical activity and its effects on the life quality of children with CF.

Most studies in Iran have examined nutritional needs, which are another important factor in the treatment of these patients, and physical activity has received less attention. In addition, more physical activity has been considered at older ages (6). Nevertheless, Moola et al. showed the effect of parental education on increasing the regular physical activity and life quality of children and adolescents with CF (7). Moreover, in a study performed by Hommerding et al., it was shown that physical activity guidelines for aerobic exercise increased such exercises and improved the quality of life of children and adolescents (8).

In another interventional study carried out by Williams et al., despite the improvement in exercise ability and decrease in body mass index (BMI), the results did not show a significant improvement in the life quality of CF children (9). For example, in a study performed by Sullivan and Mascarenhas, the careful monitoring of nutritional status was essential for the overall health of patients with CF and as part of routine care in patients with CF. The CF, weight, and height measurements (and BMI) should be performed (10). In a study conducted by Lusman and Sullivan, it was stated that careful attention to nutrition and growth is essential in caring for children with CF. Growth and nutritional status should be monitored as part of the routine care for CF, and a variety of methods, including dietary supplements, behavioral therapy, medication, and intestinal nutrition, can be used to achieve the optimal nutritional status (11).

Patient education is a dynamic and continuous process that should be implemented to help individuals enhance their life quality, reach maximum physical and psychological growth, and boost their self-esteem. Educating patients on what they will see or hear can help reduce anxiety caused by treatment options (12).

Currently, blended learning as a new mechanism aimed at the right combination for each learning problem stresses the diverse and widespread use of face-to-face learning, group e-learning, and individual learning. A significant issue in blended learning is the right combination of teaching materials and methods and strategies that have the most effect with the least cost (8).

As more than 70% of the health care team is made up of nurses and they have more access to patients and their families, patient education is considered one of the key duties of nurses and their key roles in providing health services (13). Furthermore, legislators and health planners believe that patient education is one of the significant aspects of nursing care that has to be regarded as one of the rights of the patient to reach optimal health behaviors with three main goals of maintaining and promoting health and preventing disease, restoring health, and helping with the adaptation of the individual (14).

Given the low life quality of affected children, it is necessary to develop complementary cost-effective treatment plans for these children. Moreover, limited studies in this regard show contradictory results. There were no domestic studies to examine the effect of exercise on the life quality of these patients. Although the results of studies have shown the effect of physical activity on improving the health status of these children, the method of conducting the aforementioned studies in educational dimension, time, race, age, and climate is very different from the method of the present study. Therefore, the researchers of the present study decided to use group training, telephone follow-up and social networks to raise the level of awareness and function of families with the aim of physical activity’s effect on the quality of life of school-age children.
Therefore, it is necessary for this team to engage these children in “physical activity”. In addition, the adoption of this method, involvement of families in its implementation, and use of their decisions in performing physical activities cause to prevent the recurrence of this disorder. Therefore, the present study aimed to examine the effect of a physical activity program (PAP) using combined education on the life quality of children with CF.

**MATERIALS AND METHODS**

The current investigation was a clinical trial study (IRCT20190407043190N1) with a pretest-posttest design and a control group. The population included all the children aged 8-12 years with CF admitted to educational hospitals of Ahvaz Jundishapur University of Medical Sciences, Khuzestan, Iran. The inclusion criteria were conscious willingness to participate in the study, trainee’s ability to understand Persian language, no acute and chronic mental and physical diseases other than CF, disease severity being moderate as diagnosed by a physician, ability to exercise, and at least 6 months of disease duration. The exclusion criteria were failure to attend at least two intervention sessions and aggravated symptoms of CF.

For conducting this study, after obtaining the necessary authorization (i.e., receiving the ethics code from the Ethics Committee) from the Vice-Chancellor for Research and Technology of University, submitting a written letter to the relevant hospitals, and describing the process and objectives of the research, the researchers succeeded in obtaining authorities’ collaboration. In the first step (i.e., the pre-intervention stage), voluntary and accessible sampling was performed after providing explanations about the study objectives, obtaining written consent from the participants, and assuring the participants of the confidentiality of their information. After their cooperation, a demographic information questionnaire and the Pediatric Quality of Life Inventory (PedsQL) were distributed among the participants. Finally, 70 eligible subjects were included in the present study. The samples were randomly divided into intervention (n=35) and control (n=35) groups. Moreover, the participants in both intervention and control groups underwent anthropometric evaluation. The subjects’ BMI was used to evaluate anthropometric measurements.

In the second stage (i.e., the intervention stage), the subjects of the intervention group were trained in four sessions of physical activity based on interest in aerobic physical exercises, such as cycling, swimming, walking, dancing, playing ball, skipping ropes, jumping, upper extremity stretching, and trunk and lower extremities (gymnastics). However, the control group received no training and was given an instruction manual with a CD containing animation to appreciate them at the end of the intervention.

After coordination with the intervention group, these four sessions were held weekly for 30-45 minutes. The individuals were instructed to repeat the exercise they prefer at home for 20 minutes each day during the week. Additionally, during the intervention period, the researchers contacted the intervention group daily via telephone or social network to do aerobic exercise for the intervention group and answer potential questions about these activities. Furthermore, the researchers received a report of the activities they performed.

All aerobic and anaerobic physical activities were selected and performed in consultation with a physician. In the third stage (i.e., the post-intervention stage), evaluations were carried out for both intervention and control groups. Two months after the last intervention session via telephone and social networks, communication took place with the intervention group and ensuring that they had daily physical activity during this period, both intervention and control groups were evaluated anthropometrically and again completed the PedsQL.

**RESULTS**

According to the results, the mean age values of the patients were 10.11 and 9.77 years (range: 8-12) in the intervention and control groups, respectively. Moreover, 60% and 54.3% of the samples in the intervention and control groups were male, respectively. Additionally, the mean BMI in the two groups was 16.05±2.86 kg/m² (Table 1).
Moreover, according to the results of tables 2 and 3, the mean scores of life quality in the physical, emotional, social, and educational performance of children in both groups before the intervention showed no significant differences (P>0.05). After the intervention in the experimental group, the mean scores of life quality in all aspects significantly increased, compared to those reported for the control group (P<0.001). Additionally, there were no significant differences between the mean scores of life quality in the control group before and after the intervention (P>0.05).

Table 1. Comparison and distribution of relative frequency and percentage of subjects according to demographic characteristics in the intervention and control groups

| Variable     | Intervention group | Control group | P-value |
|--------------|-------------------|---------------|---------|
| N            | 35                | 35            |         |
| Group        | Mean ± SD         | Mean ± SD     |         |
| Age          | 10.11 ± 1.47      | 9.77 ± 1.47   | 0.33    |
| BMI          | 16.56 ± 3.25      | 15.53 ± 3.25  | 0.13    |
| Frequency (%)| Males (60%) 21    | (4.3%) 19     |         |
| Gender       | Females (40%) 14  | (45.7%) 16    | 33%     |

Table 2. Comparison of mean and standard deviation of physical, emotional, social, academic performance and overall life quality of children in the subjects before and after training in control and intervention groups

| Physical performance | Intervention | Control | Independent t-test result |
|----------------------|--------------|---------|--------------------------|
|                      | X ± Sd       | X ± Sd  |                          |
| Before intervention  | 15.54 ± 3.03 | 16.80 ± 2.88 | P = 0.08                |
| After intervention   | 27.11 ± 5.04 | 16.03 ± 2.87 | P < 0.001               |
| Paired t-test result | <0.001       | 0.264   |                          |
| Emotional performance|              |         |                          |
| Before intervention  | 14.71 ± 4.65 | 14.37 ± 3.06 | P = 0.717              |
| After intervention   | 17.23 ± 2.28 | 15.58 ± 3.08 | P = 0.013              |
| Paired t-test result | <0.004       | 0.137   |                          |
| Social performance   |              |         |                          |
| Before intervention  | 10.86 ± 2.83 | 10.54 ± 2.74 | P = 0.639              |
| After intervention   | 17.34 ± 2.27 | 11.46 ± 3.47 | P < 0.001              |
| Paired t-test result | <0.001       | 0.198   |                          |
| Academic performance |              |         |                          |
| Before intervention  | 10.91 ± 3.45 | 11.49 ± 4.28 | P = 0.541              |
| After intervention   | 16.06 ± 3.37 | 11.11 ± 4.48 | P < 0.001              |
| Paired t-test result | <0.001       | 0.701   |                          |
| Overall life quality |              |         |                          |
| Before intervention  | 53.03 ± 7.69 | 53.06 ± 6.59 | P = 0.471              |
| After intervention   | 77.74 ± 6.59 | 54.69 ± 6.60 | P < 0.001              |
| Paired t-test result | <0.001       | 0.531   |                          |

Table 3. Comparison of mean and standard deviation of evaluation of physical, emotional, social, educational performance and overall life quality of the child by parents in the subjects before and after training in control and intervention groups

| Physical performance | Intervention | Control | Independent t-test result |
|----------------------|--------------|---------|--------------------------|
|                      | X ± Sd       | X ± Sd  |                          |
| Before intervention  | 15.77 ± 2.7  | 15.67 ± 2.52 | P = 0.734               |
| After intervention   | 27.26 ± 4.60 | 17.11 ± 2.52 | P < 0.001               |
| Paired t-test result | <0.001       | 0.701   |                          |
| Child emotional performance by parent |            |         |                          |
| Before intervention  | 12.91 ± 2.46 | 13.49 ± 2.53 | P = 0.343               |
| After intervention   | 17.06 ± 1.86 | 12.80 ± 2.68 | P < 0.001               |
| Paired t-test result | <0.001       | 0.266   |                          |
| Child social performance by parent |            |         |                          |
| Before intervention  | 10.86 ± 2.83 | 10.54 ± 2.74 | P = 0.639               |
| After intervention   | 17.34 ± 2.27 | 11.46 ± 3.47 | P < 0.001               |
| Paired t-test result | <0.001       | 0.568   |                          |
| Child academic performance by parent |            |         |                          |
| Before intervention  | 11.51 ± 2.06 | 11.09 ± 2.69 | P = 0.458               |
| After intervention   | 15.91 ± 3.29 | 11.77 ± 2.56 | P < 0.001               |
| Paired t-test result | <0.001       | 0.258   |                          |
| Overall life quality of the child by parent |            |         |                          |
| Before intervention  | 55.11 ± 6.14 | 55.49 ± 6.07 | P = 0.784               |
| After intervention   | 79.09 ± 6.84 | 56.89 ± 6.01 | P < 0.001               |
| Paired t-test result | <0.001       | 0.311   |                          |

DISCUSSION

The progress of lung disease in CF causes abnormal breathing during exercise. These individuals limit doing exercise that affects the health and mental image of the body in turn. Physical training has been intended to enhance physical strength, heart, and muscles through aerobic and anaerobic activities. A lack of regular physical training might lead to severe lung diseases and impaired ability to perform daily tasks (12).

In this study, the effects of PAP on the life quality of children with CF at school age were examined, and the results showed that the mean and standard deviation of physical activity of children before the beginning of PAP increased after the intervention with improvement in physical function in the intervention group and no change in the control group. In this regard, a study performed by Pouyan Majd et al. entitled “Effects of Exercise on Cardiorespiratory Performance of Fat Adolescents with Asthma in Different Humidity Conditions” showed that...
exercise has a positive effect on the physical performance of patients with asthma. Moreover, the physical performance of asthmatic individuals differs in various environments, which is less in wet environments, compared to that reported for the current study (15).

In the present study, the program presented four sessions of training on aerobic physical activities, such as cycling, swimming, walking, dancing, playing ball, skipping ropes, jumping, upper extremity stretching, and trunk and lower extremities (gymnastics), for CF patients in the presence of their companions which had a positive effect on their physical performance in line with the results of the above-mentioned studies (13). Moreover, the results showed that the mean and standard deviation of children’s emotional performance increased before physical activity programs (PAP), compared to that reported after the intervention, where emotional performance improved in the intervention group with no changes in the control group.

In line with the above-mentioned results, a study carried out by Mozaffari et al. showed that life quality in these children was very low, compared to that of healthy children. Furthermore, more attention should be paid to early their diagnosis and treatment and their social and emotional limitations, and further psychological counseling is needed to better deal with the disease, which is in line with the results of the present study (16).

A study conducted by Wilkes et al. showed that in children with CF, exercise programs aiming to improve muscles and aerobic fitness were effective. Exercise training or routine physical activity should be an integral part of the treatment regimen of these patients. Patients and their families should be aware of the positive effects of physical activity (long and short term) and should support the health care team to improve and maintain compliance with physical activity. Moreover, we encourage the child’s emotional performance by encouraging family participation and support, and accompanying those whom the child enjoys being present to improve the patient’s ability to achieve health status (17).

According to the results, the mean and standard deviation of the social performance of the children increased before the start of PAP, compared to that reported after the intervention, which improved in the intervention group and showed no changes in the control group. In line with this finding, a study performed by Britto et al. showed that CF patients had a lower level of general health understanding, compared to healthy individuals. With the increase in pulmonary manifestations, the social and psychological functions of these patients decreased (18), which is consistent with the results of the present study.

On the other hand, the results showed that the mean and standard deviation of children’s academic performance before the beginning of PAP increased, compared to that reported after the intervention, which improved in the intervention group with no changes in the control group. Tremblay et al. argued that regular physical activity enhances adolescents’ self-belief and self-esteem, leading them to perform their daily activities with proper confidence. Additionally, regular physical activity enhances mental processes among adolescents, improves their learning and academic abilities, and helps them achieve successful academic performance that is consistent with the results of the current study (19).

Additionally, the results indicated that the mean and standard deviation of the life quality of the children increased before the start of the PAP, compared to that reported after the intervention, which improved in the intervention group and did not change in the control group. Gaunaurd et al. showed that a three-month rehabilitation program in patients with pulmonary fibrosis significantly improved symptoms and increased physical activity capacity that is consistent with the findings of the present study (20).

Additionally, similar studies conducted by Hebestreit et al. (21) and Nixon et al. (22) showed that high levels of physical activity and good muscle and pulmonary functions are associated with high aerobic capacity in CF that is in line with the results of the present study.
Studies carried out by Staab et al. (23) and de Jong et al. (24) showed that life quality is poor in these patients. Poor life quality in patients with CF is affected by limitations in physical activity. Moreover, in addition to medical care, cognitive and behavioral factors play an important role in understanding mental health and coping with chronic severe illness in patients and their parents that is consistent with the results of the present study.

**CONCLUSION**

Since the implementation of physical activity programs has a tremendous impact on improving the physical, emotional, social and educational performance of children, it is possible to help maintain and improve the quality of life and health of children with cystic fibrosis by implementing strategic educational planning and selecting the most appropriate educational methods in relevant institutions. This is because, with a high level of knowledge and skill in caring for the information transmitted through education, the care team helps patients continue their collaborative learning process that enhances the life quality of these children, reduces the cost of treatment, especially the psychological well-being of their families, and increases the cost-effectiveness of the relevant institutions.

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