

# Evaluating the Effects of Omega-3 on Quality of Life in Children with Cystic Fibrosis

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## ABSTRACT

**Background:** Cystic fibrosis (CF) is an autosomal recessive disorder chiefly characterized by respiratory and gastrointestinal symptoms. This study investigates whether omega-3 fatty acid affects quality of life in children with CF.

**Materials and Methods:** This was a single-blind, pilot study undertaken at the Cystic Fibrosis Center of Sarvar Children Hospital, Mashhad, Iran from March 2009 until September 2009. In this study, 11 patients aged 2-12 years were assigned to ingest 3 capsules of fish oil daily for 3 months. Each capsule contained fish oil (1 gr), eicosapentaenoic acid (180 mg) and docosahexaenoic acid (120 mg). At the beginning of the study and after the treatment period, questionnaires were used to determine the quality of life of all patients, both totally and separately, in four domains [physical (PH), emotional (EM), social (SOC) and school functioning (SCH)]. Wilcoxon test compared the scores before and after treatment intervention.  $p < 0.05$  was considered significant.

**Results:** The difference in total score of the Pediatric Quality Of Life Inventory TM 4.0 Short Form (Ped-sQLTM 4.0 SF15) before and after intervention showed a significant improvement ( $p = 0.02$ ) in addition to the physical and social domains ( $p = 0.01$  and  $p = 0.04$ , respectively), but was not significant in the other two domains.

**Conclusion:** Fish oil, as a rich source of omega-3 fatty acid could have beneficial effects on improving quality of life in these patients. Other long-term studies including more patients might better clarify omega-3 effects on children with CF.

**Keywords:** Omega-3, Cystic fibrosis, Quality of life

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## INTRODUCTION

Cystic fibrosis (CF) is an inherited multisystem disorder of children and adults, characterized mainly by pulmo-

nary and gastrointestinal symptoms(1).

Quality of life is becoming a very important primary criterion of quality management among patients suffering from chronic progressive diseases such as CF(2-4). Several well-controlled studies have shown that reduced availability of essential fatty acids (EFA) in plasma phospholipids causes plasma lipid deficiencies in CF patients, so that a supplement which could regulate the plasma fatty acids might have useful effects(5, 6).

Although literature concerning the effects of omega-3 on quality of life in CF patients are rather limited, there are some studies which indicate that fish oil as a rich source of omega-3 fatty acid could have beneficial effects on decreasing inflammation as well as improving function and nutritional status (7, 8) Furthermore, it is

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documented that a decrease in respiratory infections and different medications increase the quality of life in these patients(9). According to previous researches, the current study proposes to evaluate whether fish oil as a rich source of omega-3 fatty acid would improve quality of life in children with CF.

## MATERIALS AND METHODS

This single-blind, pilot study included 13 CF patients aged 2-12 years old who referred to the CF Center of Sarvar Children Hospital, Mashhad, Iran. The study took place from March 2009 until September 2009.

Inclusion criteria included the following: CF patients between the ages of 2-12 years with documented disease by sweat test, or current mutations and clinical features. Exclusion criteria were congenital heart disease and CNS abnormalities.

The Ethics Committee of Mashhad University of Medical Sciences approved the study proposal. All parents gave informed consent. At the beginning of the study, quality of life of all patients was determined using questionnaires completed by a nurse blinded to the study. Each patient continued to receive pancreatic enzyme replacement, vitamin supplementation and inhaled bronchodilators. Other therapies including antibiotics were prescribed as clinically indicated.

A total of 13 patients were assigned to ingest 3 capsules of fish oil (NUTRAVITE®, Nutravite Pharmaceutical Inc., Kewlona B.C., Canada) daily for 3 months. Each capsule contained fish oil (1 gr), eicosapentaenoic acid (180 mg) and docosahexaenoic acid (120 mg). Compliance of the patients and regular intake of fish oil were

checked through weekly phone contacts. All patients were visited monthly in order to be observed and receive their fish oil capsules. Symptoms such as severe nausea and vomiting, severe anorexia and intractable diarrhea were considered as intolerance and the patient was excluded. More than 90% compliance was acceptable. Phone contacts and visits were performed by a physician.

Two patients were excluded, one because of the inability to tolerate the treatment despite distributing the intake throughout the day, and the other because noncompliance. Therefore, 11 patients remained on the study.

We used the Pediatric Quality Of Life Inventory TM 4.0 Short Form (PedsQLTM 4.0 SF15) to assess patients' quality of life, which has been validated and tested in several pediatric populations(10-15). This questionnaire has a validity value of more than 0.7 when completed by parents. Validity testing and its repetition show high justifiability in the parents report (0.68-0.79) which was used in this study. The PedsQLTM 4.0 SF15 questionnaire is used for three different age groups: 2-4, 5-7 and 8-12 years of age, and includes four different fields of children's function: physical functioning (PH), emotional functioning (EM), social functioning (SOC) and school functioning (SCH). A five-point scale ranging from 0 (never a problem) to 4 (almost always a problem) is used. After completion of three months treatment period, quality of life was again determined for all patients by the same nurse who used the same questionnaires.

Wilcoxon test compared the difference between the score of quality of life before and after completion of the treatment period.  $p < 0.05$  was considered significant.

**Table 1:** Baseline clinical characteristics of patients.

Pulmonary symptoms	Mild	7 (63.63)*
	Moderate	3 (27.27)
	Severe	1 (9.09)
Gastrointestinal symptoms	Mild	6 (54.54)
	Moderate	4 (36.36)
	Severe	1 (9.09)
Surgery history	-	
Hospitalization history	-	

\* (%)

**Table 2: Pediatric Quality of Life score (parent proxy report) before and after intervention.**

	Pediatric Quality of Life (before treatment)	Pediatric Quality of Life (after treatment)	<i>p</i>
	Mean (SD)*	Mean (SD)	
Physical	8.37 (7.19)	5.36 (3.69)	0.01
Emotional	4.09 (3.70)	3.64 (2.94)	0.67
Social	2.18 (3.15)	1 (1.61)	0.04
School	0	0	1
Total	15 (11.23)	10 (6.08)	0.02

\*Standard deviation

## RESULTS

There were 11 participants in our study, 4 girls and 7 boys. Of these, 8 patients were 2-4 years old, one patient was 5-7 year old and 2 were 8-12 years old. We noted patients' baseline clinical characteristics (Table 1). The score of quality of life was measured totally and separately in four different fields of children's function (Table 2). The difference in total PedsQLTM 4.0 SF15 score showed a significant improvement ( $p = 0.02$ ). There was also a significant improvement in the physical and social domains ( $p = 0.01$  and  $p = 0.04$  respectively), but no significance in the two other domains.

## DISCUSSION

The results in this pilot study document a significant improvement in quality of life in children with CF after 3 months daily treatment with fish oil (omega-3 fatty acid). Patients with chronic illnesses such as CF are at an increased risk for depression, with serious direct and indirect consequences for health outcomes such as lower quality of life scores for emotional functioning and eating disturbances(13,14). With increased lifespan in these patients, improvement in quality of life is becoming more and more important.

Since a correlation exists between polyunsaturated fatty acid plasma levels, decreasing inflammation and increasing quality of life among CF patients; therefore, using anti-inflammatory supplements or treatments might lead to an improvement in quality of life.(5- 8, 13,15,16).

Several studies have evaluated the effect of different

treatments such as growth hormones or other rehabilitation programs on quality of life in CF patients(3,17). This is the first study which evaluates the effects of omega-3 as an anti-inflammatory oral supplement on quality of life in CF children. Despite limited patients, current findings indicate that fish oil as a source of omega-3 fatty acid can be effective on improving quality of life in CF patients, obviously in the field of physical and social functioning.

The authors faced some problems among this research program. There was not a suggestive dose or an adequate treatment period for omega-3 among previous studies and since there were limited patients, it was difficult to assess the role of other intrusive factors. Another limitation refers to an appropriate placebo, which was undetermined in previous similar studies. It is obvious that longer studies following larger groups of case and control patients will be necessary in order to better evaluate the effects of fish oil on quality of life in children with CF.

## CONCLUSIONS

Fish oil as a rich source of omega-3 fatty acid could have beneficial effects on improving quality of life in CF patients. Other long-term studies including more patients might better clarify omega-3 effects on children with CF.

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