

Disease management knowledge is poor in Greek patients with chronic obstructive pulmonary disease before entering pulmonary rehabilitation: A qualitative study

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ABSTRACT

INTRODUCTION Patient knowledge on important self-management topics of COPD is low. Education component of pulmonary rehabilitation may increase knowledge, facilitate health behavior change and improve self-efficacy. The aim of the study was to explore specific to disease knowledge in Greek patients with COPD, before entering in a pulmonary rehabilitation program with education component.

METHODS Twenty-four patients with COPD (15 males), aged 55–75 years (GOLD I–IV) underwent a semi-structured interview that assessed six important self-management topics and completed the Bristol COPD Knowledge Questionnaire (BCKQ). Qualitative data were analyzed with deductive content analysis and methodological triangulation with the quantitative data was incorporated.

RESULTS Qualitative data revealed a low level of knowledge on medication (4–58% of the participants were aware about medication use and any adverse effects), on symptoms and exacerbation management (17% were aware for dyspnea management techniques; 29% used short-acting bronchodilators to manage increased dyspnea). Only 13% of the participants have been informed by their physicians about exacerbation signs. Quantitative data showed total BCKQ score: 45.96% low knowledge shown in medication (inhaled bronchodilators 23.3%, antibiotics 42.5%, oral steroids 29.2%, inhaled steroids 7%), breathlessness 43.4% and infections 36.7%.

CONCLUSIONS The knowledge of Greek patients on topics that are important for the self-management of COPD was low. Qualitative methodology efficiently assisted in pointing out knowledge gaps and misconceptions. These data can contribute to the design of a participant-specific education program for knowledge improvement on these topics, which may increase their self-efficacy in self-management.

INTRODUCTION

COPD patient education on self-management is considered an essential element of pulmonary rehabilitation by internationally validated clinical guidelines^{1,2}. Self-management educational interventions that include action plans and a continuum of communication with a trained health professional might reduce respiratory hospitalization rates in patients with COPD, optimize and preserve physical health, and potentially improve quality of life^{3,4}. Self-management is the day-to-day management of impairments and limitations by the individual, over the span of illness⁵. Successful interventions demand thorough assessment and identification of patients' needs, health beliefs, current knowledge status and coping mechanisms^{4,5}.

Disease-related knowledge can positively influence self-

management behavior, such as adherence to medication, engagement in physical activity and smoking cessation in patients with COPD, and therefore might improve outcomes in COPD⁶. A wide variety of self-management skills could be taught in educational programs⁷. Almost 60–77% of the studied interventions include topics such as medication and oxygen use, early recognition and treatment of exacerbation, action plan for self-management and breathing strategies⁷. The specific and personalized goals of the educational programs can be achieved only after adjusting the content to each individual's needs and her/his potential biases¹.

A number of specific-to-COPD questionnaires have been developed for the assessment either of patients' knowledge or of their disease-related informational needs^{8–11}. These tools are utilized to derive quantitative data from close-

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KEYWORDS

education of patients, health knowledge, qualitative research, interview, chronic obstructive pulmonary disease

Received: 23 October 2021

Revised: 28 December 2021

Accepted: 1 January 2022

ended questions and statements. Despite their tested reliability, such questionnaires might be susceptible to random measurement error and could not depict health beliefs and misconceptions which contribute to low knowledge¹². The latest is a risk factor of anxiety and depression and might lead patients to a sense of losing control over the disease¹³. Qualitative research tools, like semi-structured interviews with open-ended questions, aid in overcoming those limitations and investigate thoroughly these aspects^{12,14}.

Thus, the aim of this qualitative study was to reveal the actual disease-related knowledge level, health-related concepts and ideas and self-management behavior of the participants before their enrollment in a comprehensive pulmonary rehabilitation program. Analysis of these data could guide the development of a COPD-specific educational program, including an action plan for exacerbation management.

METHODS

Study design

This was a cross-sectional qualitative study, incorporating methodological triangulation with quantitative data. It was conducted between September 2019 and March 2020 as a collaboration between the Pulmonary Rehabilitation Unit of the 1st Department of Respiratory Medicine at Sotiria Hospital and the Physiotherapy Department of the University of Thessaly. The study was part of a randomized controlled trial that aimed to determine the effectiveness of an educational and action plan program for patients with COPD on disease self-management and exacerbation control.

Semi-structured, individual interviews were conducted, using a specially designed interview questionnaire, as the main source of data collection. Triangulation (the use of two or more methods for collecting data) was used as the qualitative research strategy to test and enhance validity through the integration of information from different data sources¹⁴. For the method of triangulation, the Bristol COPD Knowledge Questionnaire (BCKQ)¹¹ was used as the second source of data collection. For the investigator triangulation, two physiotherapists participated in all interviews. One physiotherapist was the main interviewer and writer of all patients' responses (MS) and the other (EK), who has extended research and clinical experience, was silently present and participated as a second writer (third source of data). Comparison of the two transcripts was implemented to ensure the validity of the recording. Prior to interview initiation, the participants were given 30 minutes to answer the BCKQ. All interviews incorporated the same open-ended questionnaire of 20 questions. Each interview lasted 60–70 minutes and it was conducted in the Pulmonary Rehabilitation Unit.

Participants

Twenty-four participants (15 males) included in the analysis.

They were all currently non-smokers, with a diagnosis of COPD >5 years, eligible for a 3-month pulmonary rehabilitation program. Inclusion criteria were $FEV_1/FVC < 70\%$, $FEV_1 < 80\%$, and aged 55–75 years². They were all in a stable disease state for at least 6 weeks prior to participating in the study and their clinical status was maintained through optimal medication. Participants were excluded if they had any hearing, speaking or cognitive impairments and/or serious mental illness or could not communicate adequately in Greek. None of them had participated in a pulmonary rehabilitation program before.

All participants were fully informed about the purpose and the importance of the study and they gave written informed consent.

Data collection

Interview questionnaire

The interview questionnaire was designed to investigate thoroughly the knowledge gaps in crucial topics in COPD-management (medication, symptoms, exacerbation signs, exercise and physical activity)¹⁻⁷. Initially, six knowledge topics were identified and forty-eight questions, important for the disease symptoms' management, were generated. Duplicate or unnecessary questions were excluded after discussion between the authors. Finally, 20 standardized open-ended questions designed to examine disease etiology/pathology (1 question), medication (5 questions), oxygen use (2 questions), symptoms and exacerbation signs (7 questions), smoking and vaccination (2 questions) and exercise and physical activity (3 questions), were included in the final version the interview questionnaire and approved by all authors (Table 1). Aiming to avoid any misinterpretation or confusion about the content of these 20 questions, a small independent group of five patients with COPD (3 males), who had already participated in the pulmonary rehabilitation program and had different educational status (1 primary, 2 secondary, and 2 higher education) were asked about questions' clarity. Participants declared that all questions were clear and understandable.

Bristol COPD Knowledge Questionnaire

The BCKQ is a COPD-specific questionnaire evaluating knowledge status on 13 topics: epidemiology, etiology, symptoms, breathlessness, phlegm, infections, exercise, smoking, vaccination, inhaled bronchodilators, antibiotics, oral steroids, and inhaled steroids¹¹. Each topic includes 5 close-ended statements which could be answered by 'True, False, Do not know'. Each correct answer gets 1 point and their sum gives the total result on the questionnaire. The lower the result, the lower the knowledge status. Permission to use the BCKQ was requested from the developer of the questionnaire¹¹. The BCKQ has been translated to Greek following the forward-backward translation method¹⁵. Therefore, the forward translation was done by two independent translators. One of the translators was aware

of the concept the questionnaire intended to measure, to provide a translation that more closely resembled the original questionnaire. Discrepancies between the two translators were discussed and resolved between them. Minor corrections were agreed by the translators and this version was backward translated by a panel of three experts. One of the three experts reviewed the back translation against the original version of the questionnaire. Any discrepancies were identified and discussed between the three experts, leading to the final version of the questionnaire. This was pilot tested on a small group of 5 COPD patients to check clarity and applicability to the Greek culture. Although the adaptation

Table 1. Initial framework of six topics and subcategories distinguished from the interviews, using deductive content analysis approach

A. Etiology and pathology (1 question)
Etiology
Diagnosis
Prognosis
B. Medication (5 questions)
Bronchodilators (and adverse effects)
Inhalation technique
Antibiotics (and adverse effects)
Corticosteroids (precautions)
Adverse effects of steroids (oral/tablets)
C. Oxygen use (2 questions)
Prescription
Adverse Effects
D. Symptoms and exacerbation signs (7 questions)
<i>Common symptoms</i>
Breathlessness (cause, deterioration, management)
Cough (increase, management)
Sputum (increase, management)
Factors of symptom deterioration
<i>Exacerbation signs</i>
Prevention, signs, management
E. Smoking cessation and vaccination (2 questions)
Benefits of smoking cessation
Smoking cessation programs awareness
Benefits of vaccination
Vaccination prescription awareness
F. Exercise and physical activity (3 questions)
Appropriate exercise for COPD
Walking benefits
Activities of daily living (limitations/management strategies)

of the BCKQ to the Greek language has not been published, the questionnaire has been used at the baseline assessment in COPD patients before entering pulmonary rehabilitation¹⁶.

Other measurements

As part of the standard baseline assessment, 2 to 7 days before the interview, all participants underwent measurements for anthropometric indices, pulmonary function parameters, 6-min walking distance (6MWD), COPD-specific health-related quality of life (Saint George Respiratory Questionnaire, SGRQ), anxiety and depression (Hospital Anxiety Depression Scale, HADS), COPD Assessment Test (CAT), and the modified Medical Research Council (mMRC) dyspnea score¹⁷⁻²¹.

Data analysis

Methodological triangulation between the three data sources and deductive content analysis of the qualitative data were performed. Deductive content analysis is an approach of qualitative data analysis with which data can be coded according to a pre-existing structured framework, derived from previous theory or well-established knowledge. Furthermore, deductive content analysis allows the quantification of the qualitative data²². The process flowed as follows: Initially, the two transcripts of each patient's interview were compared by two of the researchers (MS and EK) and combined after discussion. Afterwards, each combined transcript was read several times. Following the initial framework of topics, both researchers separately analyzed all the answers and applied deductive content analysis to encode responses into subtopics. Both processes and list of codes were discussed and one final code list was determined. Lack of knowledge was identified through false answers, misconceptions, rates of correct answers, and declared unawareness. All answers were presented as ratios. All quantitative variables (anthropometric and clinical characteristics) were tested for normality using the Shapiro-Wilk test. Normal distributed variables are presented as mean and standard deviation. This statistical analysis was performed using SPSS for Windows 22.0 (SPSS Inc, Chicago, IL, USA).

RESULTS

Anthropometric and clinical characteristics of all patients are presented in Table 2. Participants were predominantly male with normal BMI (kg/m²) and from the whole spectrum of COPD severity (GOLD Stages I to IV, according to FEV₁ %predicted values measured by spirometry). All had quit smoking since COPD diagnosis, apart from one female who had never smoked. Their educational level ranged from elementary school to higher education (Table 2). Three males in GOLD Stage IV were receiving long-term oxygen therapy for one to two years.

Quantitative data

Percentages of correct answers in each of the 65 items

and the 13 knowledge topics of the BCKQ are presented in Table 3. The mean value of the overall percentage score was 45.96% (mean value of correct answers: 30). The highest percentage of correct responses (100%) was in item 8b ‘Stopping smoking will slow down further lung damage’ whereas the second highest percentage (96%) was in the items 2b ‘COPD can be caused by occupational dust exposure’; 3b ‘The following symptoms are common in COPD: Fatigue (tiredness)’; 7d ‘Exercise helps relieve depression’; 8a ‘Stopping smoking will reduce the risk of heart disease’; and 9a ‘A flu jab is recommended every year’. In contrast, items concerning medication had the lowest rates of correct responses. Only 4% of the participants responded correctly to items 8d ‘Stopping smoking usually results in improved lung function’; 10a ‘All bronchodilators act quickly (within 10 minutes)’; 10c ‘Spacers (e.g. nebulizer) should be dried with a towel after washing’; 11a ‘Antibiotic treatment: To be effective, the course should last at least 10 days’; 13a ‘Inhaled steroids should be stopped if you are given steroid tablets’ and 13d ‘Steroid inhaler should be taken before your bronchodilator’. No correct responses (0%) were given to items 13b ‘Steroid inhalers can be used for rapid relief of breathlessness’ and 13e ‘Inhaled steroids improve lung function in COPD’. Among the 13 topics, the second topic ‘Etiology’ had the most correct answers (75%), while the 13th topic ‘Inhaled steroids’ had the least (7%).

Qualitative data

Knowledge specific to etiology and pathology

Smoking (88%) and occupational pollution (54%) were recognized as the main causative factors of COPD. Although 46% of the participants knew that COPD is not curable, only 4% were informed on the prognosis of the disease by their physician. Although spirometry was stated as essential for diagnosis (96%), none of the participants knew what it is actually measured with it. FEV₁ was recalled as the most important measurement, however only 8% of the participants reported that this index represents lung obstruction.

Knowledge on medication

The majority of the participants (92%) reported that life-long medication is necessary in order to keep the disease status stable. Inhaled medication was stated as the most appropriate, however, only 13% declared that any inhalation technique has been demonstrated by their physician. Almost one-third (33%) knew that there are short and long-acting bronchodilators and some of them can cause tachycardia (13%). It was reported that antibiotic therapy is being prescribed on respiratory infection (88%), green sputum/cough (46%) or fever (42%) and can last 8–10 days (46%). Adverse effects from antibiotic consumption were stated by 29% of the participants. Similarly, they stated that corticosteroids could be administered on infection (58%) acting as anti-inflammatory medication (8%). Osteoporosis (13%), increased blood glucose level

Table 2. Participants’ anthropometric and clinical characteristics (N=24)

Characteristics	Mean ± SD
Age (years)	68.8 ± 6.7
Male/Female, %	62.5/37.5
BMI (kg/m ²)	29.3 ± 5.8
GOLD Stage I/II/III/IV, n	2/14/5/3
COPD Diagnosis (years)	11.3 ± 5.9
Smoking (packs per year)	72.3 ± 29
Education level: ES/HS/HE, n	1/12/11
FEV ₁ predicted, %	60.3 ± 17.5
FEV ₁ /FCV predicted, %	60.1 ± 10.5
LAMA/LABA/ICS, n	24/20/8
SGRQ score (units)	43.01 ± 21.8
HADS anxiety (units)	7.7 ± 6.2
HADS depression (units)	6.9 ± 4.9
CAT (units)	16.4 ± 8.6
6MWD (meters)	423 ± 84.7
mMRC (units)	1.9 ± 1.3

BMI: body mass index; GOLD: global initiative for the lung disease. FEV₁: forced expiratory volume in 1 minute. FVC: functional vital capacity. ES: elementary school. HS: high school. HE: higher education (university, technological education). LAMA: long-acting muscarinic antagonists. LABA: long-acting β₂-antagonists. ICS: inhaled corticosteroids. SGRQ: Saint George Respiratory Questionnaire. HADS: hospital anxiety and depression scale. CAT: clinical assessment test. 6MWD: 6-minute walking distance. mMRC: modified medical research council dyspnea scale.

Table 3. Percentage (%) of participants giving a correct response for all 65 items and 13 topics of Bristol COPD Knowledge Questionnaire (N=24)

Q	Topic	a	b	c	d	e	Total
1	Epidemiology	21	79	79	21	33	46.7
2	Etiology	92	96	46	75	67	75
3	Symptoms	21	96	88	42	58	60.8
4	Breathlessness	21	79	17	46	54	43.3
5	Phlegm	83	71	83	17	79	66.7
6	Infections	25	88	38	25	8	36.7
7	Exercise	63	79	79	96	17	66.7
8	Smoking	96	100	79	4	8	57.5
9	Vaccination	96	8	71	33	17	45
10	Inhaled bronchodilators	4	63	4	21	25	23.3
11	Antibiotics	4	75	33	8	92	42.5
12	Oral steroids	17	29	46	21	33	29.2
13	Inhaled steroids	4	0	25	4	0	7
Overall							45.96

(13%) and edema (13%) were stated as adverse effects of oral steroids. Most of the participants (88%) were aware that not all of the inhalers contain steroids. Oral fungal infection was stated as an adverse effect of inhaled steroids (4%). Abstinence from sugar and salt (54%) and mouth rinsing after administration (21%) was reported as precautions while on oral steroids.

Knowledge regarding oxygen therapy

It was reported that oxygen therapy can be administered on serious dyspnea (63%), hypoxemia (21%) and exacerbation (17%), on severe disease (8%), and during exercise (4%). On the adverse effects, 13% of the participants were informed by their physician that oxygen therapy might cause hypercapnia. A small number (17%) stated that they would withdraw from oxygen therapy volitionally or would receive oxygen therapy without prescription (4%).

Knowledge on the symptoms and exacerbation signs

The most common and well-recognized symptom of COPD was breathlessness followed by cough and phlegm (Table 4). Breathlessness was thought to be related to smoking-induced abnormalities (46%), decreased oxygen level in blood (25%), anxiety (13%), and demanding physical activity (63%). Most of the participants (83%) managed increased dyspnea by pausing their physical activities and by taking short-acting bronchodilators (29%). Knowledge of dyspnea management techniques (pursed-lip breathing, body positioning) was reported only by those (17%) who had received chest physiotherapy previously. Normal phlegm was thought to be transparent or of white color (83%), whilst a change in color

(green sputum) was reported (71%) as a sign of respiratory infection (Table 4). Sputum expectoration could be promoted with sufficient hydration (25%), but only 4% of the participants had been informed on that by their physicians. Interestingly, none of them was referred for tracheobronchial clearance techniques. A small number (13%) expectorates just by coughing while a large percentage (30%) uses mucolytic drugs. A large proportion of the participants (71%) was familiar with the term ‘exacerbations’. Increased breathlessness for longer than a few hours and change in sputum color were considered as the main signs of an exacerbation followed by increased cough (Table 4). However, only three participants (13%) were informed by their physicians about the aforementioned exacerbation signs. Some participants (46%) thought that exacerbation is a period of extremely serious symptom deterioration requiring hospitalization and oxygen support, while others (25%) declared that an exacerbation may vary from mild to severe symptoms deterioration. Serious dyspnea deterioration was considered (67%) as the main reason for communication with the physician. Although, prevention of exacerbations was reported as crucial for the prognosis of the disease (33%); only half of the participants were informed by their physicians on some form of management (communication with doctor, action plan, emergency unit visit, rescue medication). An action plan and stand-by medication had been utilized as an exacerbation management strategy only by one participant. Forty-two percent reported that they knew that they will be given complementary medication and 13% mentioned that they would take volitionally complementary medication, as prescribed in previous likewise exacerbations.

Table 4. Symptoms and exacerbation signs as reported in the interview (N=24)

	%
Common and well-recognized symptoms	
Breathlessness	96
Cough	38
Phlegm	33
Factors of symptoms deterioration	
Respiratory infections	63
Weather (cold, heat, humidity)	25
Air pollution	21
Non-adherence to medication	21
Smoking	13
Poorly ventilated and congested places	8
Exacerbation signs	
Sputum color change	71
Breathlessness	46
Cough	25

Knowledge regarding vaccination and smoking cessation

All participants had been vaccinated and they were aware of suggested vaccination scheme. Half of them stated that vaccination prevents serious illness. Regarding smoking, they stated that cessation might prevent disease progression (54%) and improve fitness and quality of life (33%). Although 63% were aware of smoking cessation programs, only 29% had participated in a program before.

Knowledge on physical activity and exercise

Walking (33%), swimming (13%), respiratory exercises (25%), and cycling (13%) were mentioned as the most appropriate types of exercise for COPD. Most participants reported that walking benefits lung function (71%), blood circulation (17%), musculoskeletal system (25%), and anxiety (96%). However, only 13% of the participants reported engagement in regular exercise and 54% believed that intensive exercise could be harmful. Limitations were reported on several activities of daily living like shopping, bathing, cleaning house, and gardening (83%). Participants managed their ADLs by pausing activity (38%); protracting the activity (33%); using aids or modifying activity (13%), and asking for help (17%).

DISCUSSION

Qualitative assessment of COPD-related knowledge in candidates of a comprehensive pulmonary rehabilitation program (including education) increases our awareness of the patient's needs, knowledge deficiencies, and can guide a well-designed educational program. The results of this study revealed low level of knowledge, especially on COPD medication. Previous studies have shown that the lack of knowledge on medication is a common problem among patients with COPD^{11,13,23,24}; this qualitative study confirmed it is established early in the disease timeline (58% of patients were at GOLD Stage II). More importantly, participants ignore the specific therapeutic effect of each inhaled category (steroids, bronchodilators), any adverse effects, and they seemed confused in regard to the appropriate inhalation technique (Table 3). Patients' concern about medication is a risk factor for poor adherence to medication²⁵.

Additionally, data from this interview revealed that the majority of the participants had low level of awareness on exacerbation symptoms management and they were not aware of any action plan and stand-by medication, although they knew the three main symptoms of an exacerbation (Table 3). Previous research has shown comparable results on BCKQ chest infections topic, whilst patients reported increased information needs about exacerbation self-management with the LINQ questionnaire^{13,26,27}. Improvement in medication knowledge and the rise of awareness on exacerbation management are considered important, as they both decrease emergency department visits and COPD-related hospitalizations^{28,29}.

Physiotherapy techniques, as part of symptoms management, were not known to the majority of the participants in this study. They preferred to use mucolytic medication and cough as the only way to expectorate sputum. Although the low evidence of effectiveness of airways clearance techniques on both acute exacerbations and stable disease, the techniques are considered part of the physiotherapy management and should be part of a personalized self-management educational program^{7,30}.

In contrast, participants were well aware about COPD etiology, pathology, and common symptoms of the disease as well as the benefits of vaccination, smoking cessation, and regular physical activity. Although the beneficial effect of physical activity, daily walking and exercise on respiratory function and mental health is recognized by all the participants of this study (Table 3), some declared that exercise could be harmful as it might cause fatigue or increase breathlessness; only a small number reported engagement in regular walking, and they were mostly those with mild disease severity. The majority declared they faced limitations in activities of daily living and hobbies, and that they managed symptoms by pausing, pacing, modifying or even quitting an activity or using rescue medication and asking for help. No one was aware of breathlessness exertion management techniques during exercise or daily

physical activity. Previous qualitative and quantitative research revealed that people with COPD have not been informed on physical activity and exercise by their physicians, resulting in low knowledge of the effectiveness of exercise on COPD management^{13,26,31,32}. It is not known yet if increased knowledge on exercise and physical activity can enhance engagement in physical activity and exercise, but it might be an enabler³³. Taking into consideration both the above and the benefits of exercise on people with COPD, self-management educational programs must promote an active lifestyle and the attendance in exercise programs¹.

The use of qualitative methods allows the exploration of patients' thoughts, beliefs and experiences and leads to a broader understanding of existing knowledge on various aspects³³. The latest might contribute to the design of more comprehensive COPD self-management interventions, which not only can increase patients' knowledge but also could lead to better adaptation to functional impairments and self-management behavior, decreased risk of stress and depression, and would optimize self-efficacy in exacerbation management^{13,24}. The practical implications of these results are related to the optimization of educational strategies in COPD that aim to strengthen individuals' self-efficacy in exacerbation management and physical activity. Four important implications can be distinguished: 1) recognition of exacerbation signs and medication use, 2) management of adverse effects of medication, 3) symptom management during daily activities and exercise, and 4) engagement in regular physical activity and exercise.

Limitations

This study has some limitations such as the small number of participants and the heterogeneity of the population. Although the population included people with COPD in all stages of the disease severity with a broad spectrum of clinical characteristics, most participants were in moderate disease severity (mainly in GOLD Stage II) and therefore we cannot make any conclusions about the full range of people with COPD. Additionally, the interviews were not audio-taped and transcribed verbatim. However, the combined qualitative and quantitative design of the study allowed us to compare the subjective responses from both data sources and gain more insight into the personal thoughts, ideas, and disease knowledge. Furthermore, the participation of two independent physiotherapists during the interviews, strengthen the validity of the findings.

CONCLUSIONS

This study showed limited knowledge on both fundamental and prominent disease-related topics such as medication, exacerbation signs, symptoms management, and exercise, in Greek patients with COPD of low and mild disease severity. Furthermore, it could be inferred that person-tailored education, must take place during the early stages of the disease, especially on medication and physical activity.

CONFLICTS OF INTEREST

The authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none was reported.

FUNDING

There was no source of funding for this research.

ETHICAL APPROVAL AND INFORMED CONSENT

The study was approved by both the Scientific and Ethics Committee of Sotiria Hospital (Protocol ID-26309/2019) and the Ethics Committee of the Physiotherapy Department (Protocol ID 62/2019-20). All participants provided a written informed consent.

DATA AVAILABILITY

The data supporting this research are available from the authors on reasonable request.

AUTHORS' CONTRIBUTIONS

MS, EK, NR and NK were involved in the concept and the design of the study. MS, EK and AM were involved in the interpretation and the analysis of the data. All authors agree to be accountable for all aspects of the study and they approved the final version of this manuscript.

PROVENANCE AND PEER REVIEW

Not commissioned; externally peer reviewed.

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