1.1- Study Title:
ASSESSMENT OF QUALITY OF LIFE AND PROBLEMS IN THE PATIENTS WITH IDIOPATHIC PULMONARY FIBROSIS OVER THE PERIOD OF COVID-19 PANDEMIC

1.2- Study Design:
- **Prospective** study performed using materials derived from human (biochemical, microbiological, pathological and radiological collection materials such as blood, urine, tissue and images, genetic materials for identification, or materials obtained during routine examination, assay, analysis and treatment procedures)
- **Retrospective** study performed using archive materials obtained from files, image recordings and/or human

☐ Research that investigates the effects of treatment programs such as physical therapy, exercise and rehabilitation.

☐ Research that is performed using food additives

☐ Research that is performed within the limits of nursing activities

☐ Research that is performed based on anthropometric measurements

☐ Research that evaluates lifestyle habits

☒ Survey study

☐ Other (please specify..................).

1.3- Study Type:
- ☐ Specialty thesis study
- ☐ Postgraduate thesis study
- ☐ Doctorate thesis study
- ☒ Academic study
- ☐ Contracted research
- ☐ Other (please specify)

1.4- Principal Researcher
Assoc. Prof. Dr. Funda Coşkun, Uludag University Faculty of Medicine, Department of Chest Diseases
GSM: 05332500099, e-mail: fundacoskun@gmail.com

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PART 2- STUDY OBJECTIVE, SCIENTIFIC BASIS and VALIDITY

2.1- Study Objective, Scientific Basis and Validity:

Idiopathic pulmonary fibrosis (IPF) is the most common one among interstitial lung diseases (ILD). IPF is a chronic, non-treatable disease with progression that can only be slowed down. There are limited number of studies demonstrating IPF patients' quality of life at diagnosis and the changes in quality of life as the disease progresses (1-3). Today, obtaining real life data are important researches as they potentially make contribution to evaluation of patients and to treatment approach. The aim of the present study is to obtain real-life data about the quality of life during COVID-19 pandemic among patients with confirmed IPF via questionnaires. The validity and reliability analysis of the questionnaire to be used has been done (4).

The family of Coronaviruses (CoV) causes a wide range of clinical diseases from common cold to severe acute respiratory distress syndrome (ARDS). On January 7th, 2020, China reported pneumonia cases caused by a new coronavirus that has not been identified in human previously, and this novel virus was named as 2019-nCoV and the name of the disease was accepted to be COVID-19. The disease may either be asymptomatic or present with a severe picture like ARDS. In Turkey, the first positive case was detected on March 11th, 2020 and then the extensity of disease has reached up to...
pandemic sizes. The tracing and treatment of suspected and confirmed cases are performed in accordance with the COVID-19 guideline of the Ministry of Health (5). Regarding COVID-19 infection, which has influenced the entire world following the initial case reported in December 2019 from China and accepted as pandemic by the WHO, the first case from Turkey was officially reported on March 11th, 2020. Extension of the disease tried to be prevented by the restrictions imposed as of that time in social life and travelling. Nevertheless, requirements of the patients with chronic diseases such as hospital visits for routine controls, reaching to their usual medicines and changing their drugs when necessary can be affected by both the restrictions imposed and the patients’ fear of going out and desire to stay away from healthcare centers. And a question arises; in what way are these situations will influence the course of patients’ underlying diseases? In IPF, which is one of the chronic lung diseases, the patients are usually evaluated every 3 months with respiratory symptoms, respiratory function tests, blood tests and intermittent radiological images. In this case, it is essential to see the patients in the relevant healthcare centers. In general, the guidelines recommend the patients with chronic diseases to postpone their visits to healthcare centers during this period unless there is a significant change in their current disease status and, if possible, to evaluate the progression of their illness with their doctors through communication tools, especially via phone call.

The objective of the present study is to learn about the attitudes and behaviors of IPF patients in relation to the difficulties and problems experienced during COVID-19 pandemic.

2.2-Study Protocol, Methods and Procedures to be performed:
The IPF patients under treatment, who were diagnosed previously by the experts in their fields in 4 different university hospitals (Uludağ, Akdeniz, Dokuz Eylul, Çukurova) in our country, will be enrolled into the study. IPF patients who are under follow-up will be called between May and June 2020 by the researchers and the questions enclosed will be asked to understand what they do for their appointments and current illnesses within this period and their attitudes and behaviors towards these situations, and Hospital Anxiety and Depression scale will also be applied. HAD scale can be used both for ambulatory patients in primary care services and for hospitalized patients. It is a 14-item questionnaire that assesses patient mood. The questionnaire is widely used in our country with available Turkish version and validity in Turkish (4). Questions with odd numbers measure anxiety and the questions with even numbers measure depression. A total anxiety score of > 10 indicates presence of anxiety, whereas a total depression score of > 7 indicates presence of depressive mood. Completion of the whole questionnaire takes 2-3 minutes, and the questionnaire takes 2 minutes. In total, the results will be obtained by 5-minute telephone interview.
U.U. FACULTY OF MEDICINE ETHICS COMMITTEE FOR
CLINICAL RESEARCHES
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RESEARCHES

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PART 3- STARTING DATE AND DURATION OF STUDY *
*Starting date should be later than the date of approval of the Ethics Committee

3.1- Starting date: 15/05/2020
3.2- Duration: Patient enrollment time is 2 months

PART 4 - EXPENSES
4.1- “Research Budget Form” which clearly specifies where and how the research expenses will be covered should be completed and, if available, related documents should be enclosed

No expense will occur because the researches will call the patients using their own telephones for the questionnaires that will be applied via telephone interview.

PART 5 – VOLUNTEER INFORMATION
5.1- Number of volunteers to be enrolled in the study: 100
   5.1.1- Number of healthy volunteers: 0
   5.1.2- Number of ill volunteers: 100

5.2- For retrospective studies
   5.2.1- Number of files to be reviewed:
   5.2.2- The years (months) the study covers:

5.3- Study inclusion criteria for volunteers (should be written in clauses):
1. Idiopathic pulmonary fibrosis patients with confirmed diagnosis (clinical, radiological and pathological diagnosis)
2. Those that can be reached by telephone call
3. Those who are agree to participate in the study

5.4- Study exclusion criteria for volunteers (should be written in clauses):
1. Those who do not want to take part in the interview

References:

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<table>
<thead>
<tr>
<th>PART 6- ENCLOSURES</th>
</tr>
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<tbody>
<tr>
<td>6.1- Application file index page</td>
</tr>
<tr>
<td>6.2- A certified “original” or “as original” copy of the previously rejected approval of the ethics committee, if available</td>
</tr>
<tr>
<td>6.3- Research budget form <em>(it will be completed using the budget form available at the ethics committee website)</em></td>
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<tr>
<td>6.4- Autobiography of the principal researcher <em>(it will be completed using the autobiography form available at the ethics committee website)</em></td>
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<tr>
<td>6.5- At least 3 literatures related to the research subject</td>
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<td>6.6- Questionnaire examples if it is a survey study*</td>
</tr>
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<td>* Regarding the validity/reliability of the questionnaire, the references used in preparing the questionnaire should be specified. In addition, a copy with the principal researcher’s original signature on each page should be enclosed in the application form. Questionnaire forms must be delivered together with the informed voluntary consent forms structured for survey studies. Attention must be paid for the questionnaire to not include questions that may unveil the participants’ identity and that threaten physical and mental health and may cause legal issues.</td>
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<tr>
<td>6.7- “Commitment form” for researchers <em>(signed by each researcher)</em>.</td>
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<td>6.8- “Commitment form” for prospective studies <em>(signed by the principal researcher)</em>.</td>
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<td>6.9- GCP statement signed by the principal and assistant researchers except for survey and retrospective studies.</td>
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<td>6.10- The last version of the Declaration of Helsinki with each page signed by all researchers participated in the study.</td>
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<td>6.11- Document indicating the knowledge and/or approval of the department/science branch or chiefs of institution/unit.</td>
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<tr>
<td>The receipt of the application fee, if available *</td>
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<tr>
<td>* The theses and a copy of the receipt indicating that the application fee, which was determined by the Committee for every clinical research applications except for the situations where the Sponsor is a member of Uludağ University and/or government fund (university research fund, TÜBİTAK, DPT, etc.) and government institutions and organizations, has been paid must be included as well.</td>
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APPLICATION FORM FOR NON-INTERVENTIONAL RESEARCHES

Rev. No: 00  Date of Rev.: 

PART 7- SIGNATURES

Principal Researcher (Full Name/Signature): Assoc. Prof. Dr. Funda Coşkun

Assistant Researchers (Full Name/Signature): Prof. Dr. Ahmet Ursavaş
    Prof. Dr. Aykut Çilli
    Prof. Dr. Can Sevinç
    Prof. Dr. İsmail Hanta

Date: May 5th, 2020

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