

## RESEARCH ARTICLE

# Is tele-rehabilitation superior to home exercise program in COVID-19 survivors following discharge from intensive care unit? - A study protocol of a randomized controlled trial

Zeynep Turan  | Mahir Topaloglu | Ozden Ozyemisci Taskiran

Department of Physical Medicine and Rehabilitation, Koç University School of Medicine, İstanbul, Turkey

**Correspondence**

Zeynep Turan, Department of Physical Medicine and Rehabilitation, Koç University Hospital, Davutpaşa Street No: 4 34010 Topkapı, İstanbul, Turkey.  
Email: [drzynptrn@gmail.com](mailto:drzynptrn@gmail.com)

**Abstract**

**Background and Purpose:** Evaluating the patients with COVID-19 following discharge from intensive care unit for pulmonary rehabilitation is crucial. It could be difficult to participate rehabilitation program due to transportation problems and cautions for contagiousness. Tele-rehabilitation could serve as a favorable alternative. The primary aim of this study is to investigate whether supervised tele-rehabilitation is superior to home exercise program regarding walking distance and secondarily muscle strength, muscle endurance, quality of life, physical activity level and perceived respiratory disability.

**Methods:** This is a randomized assessor blinded control trial with two groups; tele-rehabilitation and home exercise. One hundred twenty-two COVID-19 survivors following discharge from intensive care unit will be allocated into two groups. The tele-rehabilitation group will receive breathing, aerobic, posture, stretching, strengthening exercises at their home under remote supervision via Internet for 3 days/week for 10 weeks. Home exercise group will receive the same program at their home on their own and they will be called weekly. The patients will be evaluated at the beginning, at the end of the program, 6<sup>th</sup> and 12<sup>th</sup> months following the rehabilitation. The primary outcome is the change in 6-minute walking distance; the secondary outcomes are changes in quality of life, physical function, health status, dyspnea and muscle strength.

**Impact Statement:** This detailed description of the rehabilitation protocol will guide to plan the rehabilitation program and help how to design an efficacy study comparing different models of rehabilitation in COVID-19 survivors following discharge from intensive care unit with evidence-based contribution to the literature.

**KEYWORDS**

6-minute walk test, COVID-19, handgrip strength, post-intensive care syndrome, pulmonary rehabilitation, tele-rehabilitation

## 1 | INTRODUCTION

COVID-19 is a contagious infectious disease that mainly affects the respiratory system. The severity ranges from an asymptomatic infection to acute respiratory distress syndrome (ARDS) in a minority (5%) that requires intensive care and invasive mechanical ventilation (Organisation, 2020; 2020a). There is an increased risk for restricted pulmonary function in long term in ARDS survivors.

Following recovery from acute critical illness and discharge from hospital, long-term physical, cognitive and mental complications could be observed, termed as post-intensive care syndrome. Physical dysfunction includes intensive care unit (ICU)-acquired weakness, deconditioning, neuromyopathy and pulmonary dysfunction might lead difficulties in daily living activities, limitation in functional capacity and decreased health-related quality of life (HRQoL) (Held & Moss, 2019).

Pulmonary rehabilitation (PR) is a comprehensive intervention that includes assessment, respiratory and peripheral muscle training, education and support (Kurtaiş Aytür et al., 2020) in order to improve physical and psychological condition of the people with chronic respiratory disease and various other conditions which impair respiration (Spruit et al., 2013). The strategies regarding PR in COVID-19 are developed from the experiences and data from previous similar infections. A six-week PR program including aerobic training, resistance exercises and education in ARDS patients showed significant improvement in the six-minute walk distance (6MWD), maximum oxygen consumption and hand grip strength (Lau et al., 2005). A 6-week exercise in critically ill patients after discharge from hospital, showed improvements in incremental shuttle walk test, functional limitations profile, self-efficacy to exercise and readiness to exercise but these improvements were not sustained at 6 months (McDowell et al., 2017). A randomized controlled clinical trial in elderly patients discharged after COVID-19 infection showed significant improvement in respiratory function, HRQoL and anxiety in 6 weeks hospital PR group than the non-rehabilitation group (Liu et al., 2020). A recent retrospective study demonstrated that inpatient PR including 25–30 sessions of aerobic, strengthening and breathing exercises in COVID-19 patients referred to rehabilitation clinic just after acute care hospital discharge is safe, feasible and effective (Hermann et al., 2020).

The model of rehabilitation is decided depending on the availability and resources of the patient and the rehabilitation center. Tele-, home- or hospital-based rehabilitation are the alternatives (Kurtaiş Aytür et al., 2020). Tele-rehabilitation could improve participation in patients with transportation difficulties or time constraints. During this pandemic, tele-rehabilitation gained further importance. To our knowledge there is not any controlled trial using tele-rehabilitation in COVID-19 during post ICU period. However, tele-rehabilitation was demonstrated as a feasible, effective and safe approach with no major or moderate adverse events in patients with COPD (Chronic Obstructive Pulmonary Disease). Following tele-

rehabilitation, functional capacity, HRQoL, sense of social support improved and severity of dyspnea and utilization of health care systems decreased. It was observed that previous experience of the patients regarding Internet and computer use had no effect on acceptability of the model (Almojaibel, 2016). It was shown that a six-week online PR was not inferior to hospital-based PR applied as group sessions in terms of effectiveness and safety in patients with COPD (Bourne et al., 2017). The clinical efficacy of tele-rehabilitation in COPD is still not clear due to the several limitations such as poor study design, small sample size, lack of control group or recruitment bias (Almojaibel, 2016).

There is an insufficient literature on the implementation of tele-rehabilitation in patients with COVID-19. This paper describes a study protocol for tele-rehabilitation in COVID-19. The primary aim of the present study will be to find out whether supervised tele-rehabilitation is superior to home exercise program regarding functional capacity in COVID-19 survivors following discharge from ICU. Secondary aims will be to compare their effects on handgrip strength, muscle endurance, perceived respiratory disability, and HRQoL.

## 2 | METHODS

The CONSORT (CONsolidated Standards of Reporting Trials) guideline checklist will be followed and flow diagram will be given (Figure 1).

### 2.1 | Study design

This will be an interventional, prospective, parallel group, assessor-blind randomized controlled trial.

### 2.2 | Setting

The study will be performed at the Department of Physical Medicine and Rehabilitation in Koç University School of Medicine in Turkey.

### 2.3 | Study population (participants)

COVID-19 survivors following discharge from ICU will be recruited to this study. The patients are routinely administered to a rehabilitation program during their ICU stay in our hospital. These patients will be invited to the study after 6 weeks following ICU discharge as recommended by European respiratory society and American thoracic society (Spruit et al., 2020). The blind investigator will assess the potential participants for inclusion and exclusion criteria. Inclusion criteria will be as follows; age older than 18 years, being discharged from hospital with a diagnosis of ARDS or severe pneumonia

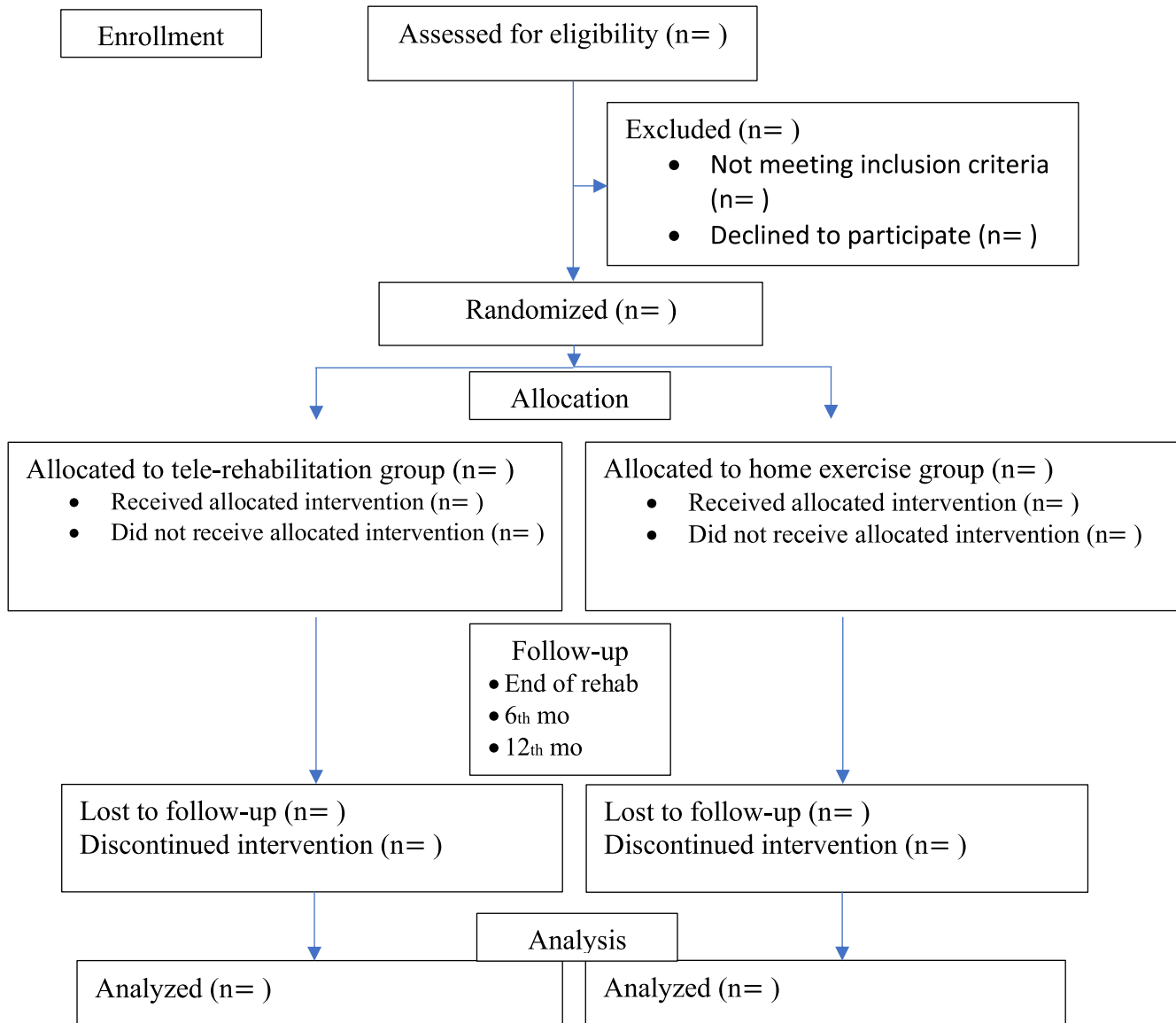


FIGURE 1 CONSORT Flow diagram of the study

related to COVID-19 who stay in ICU, SpO<sub>2</sub> >88, MRC sumscore <48, HGS <11 kg force for males or <7 kg force for females, MRC Dyspnea score 2–3, able to walk independently or have a family member to assist them and able to use a computer, phone or tablet and e-mail. Exclusion criteria will be as follows; dementia, cognitive impairment or symptomatic psychiatric illness which prevents adherence or cooperation to the rehabilitation program, hearing or visual impairment that might interfere to follow the instructions or any severe co-morbidity and other safety contraindications to exercise.

Eligible patients will be informed about the study via verbal and written information by the physician and all participants will be asked to sign informed consent form. Demographic variables, preexisting conditions like heart disease, pulmonary disease, diabetes mellitus, hyperlipidemia, length of hospital stay and length of mechanical ventilation of the patients will be recorded (Table 1).

## 2.4 | Randomization

A concealed allocation will be performed using a computerized program to either the tele-rehabilitation or home exercise group with a 1:1 ratio by an external physician. There will not be a non-exercising control group due to the ethical issues. The randomization will be stratified by the age and gender of the patients to provide equal distribution.

Outcomes will be measured at the beginning, at the end of the program, 6<sup>th</sup> month and 12<sup>th</sup> month following the rehabilitation.

## 2.5 | Blinding

The physician assessing the patient before and after rehabilitation will be blind to the arm of the patient. Patients and physiotherapist will not be blinded due to the nature of the study.

TABLE 1 Demographic variables of the patients

Variable	Tele-rehabilitation group (n = )	Home exercise group (n = )	p value
Gender	x	x	x
Age (years)	x	x	x
Weight (kg)	x	x	x
Height (m)	x	x	x
Body Mass index (kg/m <sup>2</sup> )	x	x	x
Smoking status	x	x	x
Preexisting disease	x	x	x
Length of hospital stay (days)	x	x	x
Length of intensive care unit stay (days)	x	x	x
Length of mechanical ventilation (days)	x	x	x

## 2.6 | Interventions (Rehabilitation program)

These patients received rehabilitation in ICU and quarantine ward. We prescribed an individualized exercise program including passive range motion exercises and neuromuscular electrical stimulation (NMES) to patients while in the ICU; passive, active-assisted and active range of motion exercises, sitting balance training, sit to stand, mobilization exercises and NMES while in the quarantine ward. Exercises performed by physiotherapists for 15 min/day, 6 days/week. NMES applied to quadriceps and tibialis anterior muscles bilaterally for 52 min with symmetrical biphasic square waves with 6 s duration of contraction at a 50 Hz frequency in amplitudes of 20–25 mA (Ozyemisci Taskiran et al., 2021).

The PR program of both groups will be prescribed by a physiatrist based on the physical examination and the functional capacity of the patients. Program will include aerobic, flexibility and strengthening exercises for upper and lower extremity and breathing exercises (Table 2).

The purpose of warm up phase is to prepare the cardiorespiratory and musculoskeletal system to exercise, to reduce dyspnea, to enhance flexibility of the shoulder girdle and chest expansibility. Warm up will include breathing, balance and posture exercises with very light to light intensity for 5–10 min. Conditioning phase includes both endurance and strengthening training. The purpose of endurance training is to increase the aerobic capacity. The intensity of the endurance exercise will be 60%–80% of the average speed achieved on the 6 min walk test and will be adjusted according to patient tolerance with the aim of achieving 12–14 Borg score of perceived exertion (Jenkins et al., 2010).

The exercise intensity will be monitored and tailored by Borg scale of perceived exertion and dyspnea, heart rate and oxygen saturation measured by their individual pulse oximeter during the sessions. The criteria for stopping exercise will be worsening dyspnea (Borg Scale > 15), other symptoms and signs that require stopping exercise such as dizziness, palpitation, pallor or tachypnea, SpO<sub>2</sub> < 88%, decrease in SpO<sub>2</sub> >4%, heart rate <60 or >160 beats per minute.

Interval training will last 10–20 min with a 1:2 ratio (20 s high intensity and 40 s low intensity or rest) for the first 4 weeks, 20–30 min with a 1:1 ratio and for the second 4 weeks and 20–30 min with a 2:1 ratio for the last 2 weeks. The purpose of strengthening training is to improve core stabilization, upper and lower extremity strength and enhance muscle function. The intensity and duration of the exercises are planned according to recommendations of the American Thoracic society/European respiratory Society and American College of Sports Medicine Statement, previous post-intensive care syndrome, COPD and COVID-19 studies (Andrianopoulos et al., 2014; Garvey et al., 2016; Kurtaiş Aytür et al., 2020; Liu et al., 2020; McDowell et al., 2017; Spruit et al., 2013) and tailored to the specific features of the patients. In strengthening exercises, the initial load will be 40%–50% of one repetition maximum and tailored to evoke fatigue after 8 to 12 repetitions in 1 to 3 sets during the sessions. Progression will be done by increasing the repetitions, sets and lastly resistance of the exercise band. In cool-down phase, flexibility exercises for major muscle groups will be performed with very light intensity for 5–10 min. The patients will be evaluated at the beginning, at the end of the program, 6<sup>th</sup> and 12<sup>th</sup> months following the rehabilitation.

## 2.7 | Tele-rehabilitation group

Tele-rehabilitation group will perform the exercise program at their home under remote supervision of a physiotherapist via Internet for 3 days/week during 10 weeks. Each session will last 60 min. Tele-rehabilitation will be performed via Microsoft teams which is the available patient secure telehealth portal used in our hospital that enables both patients and physiotherapists see and speak to each other. The physiotherapist will complete a log for each session that contains number of repetitions and sets, achieved intensity, modifications if required, Borg scale, symptoms, heart rate, oxygen saturation and adverse events if any.

TABLE 2 Exercise program of the patients

Exercise-Type	Exercises	Intensity	Duration (min)	
<b>Warm-up</b>	Breathing	Very light, light; 9–11 (borg)	5–10	
	Breathing			Deep breathing
	Balance			Diaphragmatic breathing
				Pursed lip breathing
				Shoulder circles
				Heel digs
				Side steps
				Heel raises
				Supported standing on one leg
<b>Endurance</b>	Walk on spot	Interval training Heavy; 14–17 (borg)–20 s	10–20	
	March on spot with high knees			
	elbow to opposite knee	Light or rest; 9–11 (borg)–40 s		
	Three steps forward and back			
	Side taps			
<b>Strengthening</b>	Upper extremity	Light; 40%–50% 1 repetition maximum	20–30	
	Lateral arm raise	Moderate; 60%–70% 1 repetition maximum		
	Seated row			
	Biceps curl			
	Lower extremity:			
	Standing hip flexor			
	Standing hip abductor			
	Standing hip extensor			
	Sit-to-stand			
	Mini-squat			
	Lunge			
	Bridge			
	<b>Cool-down</b>	Stretching (e.g. Trapezius, pectoralis)		Very light; 8–9 (borg)
Flexibility				

## 2.8 | Home exercise group

Home exercise group will perform the same exercises at their home on their own for 3 days/week during 10 weeks. The first session will be provided at the hospital to train the patients about their individualized exercise program and self-monitorization of their exercise intensity by Borg scale and pulse oximeter. A document regarding the content of the exercise will be given to the patients. Patients will keep their log for each session that contains number of repetitions and sets, difficulty to perform any specific exercise in the program, Borg scale, symptoms, heart rate, oxygen saturation and adverse events if any.

Patients will receive weekly phone calls from the physiotherapist and modifications will be made according to the patients' reports.

After completion of the 10-week program, both groups will be advised to continue the exercise program on their own.

## 2.9 | Primary and secondary outcomes

The primary outcome measure will be 6MWD. 6-minute walk test is a field test evaluating submaximal aerobic capacity. The technical standards are defined by European Respiratory Society and American Thoracic Society (Laboratories, 2002). The individuals are asked to

walk as far as possible in a 30-m corridor in 6 min and the distance will be recorded. Higher walking distance shows better outcome. It is a valid and responsive measurement of functional capacity and also predicts mortality, hospitalization and HRQoL in ARDS survivors. In these patients, minimal important difference is 20–30 m (Chan et al., 2015).

The secondary measures will be Medical Research Council (MRC) Dyspnea Scale, COPD Assessment Test (CAT), St. George's Respiratory Questionnaire (SGRQ), Short form-36 (SF-36), hand-grip strength, chair-stand test, timed up and go test (TUG) and MRC-sumscore. All these parameters will be evaluated at the beginning, at the end of the program, 6<sup>th</sup> and 12<sup>th</sup> months following the rehabilitation (Table 3). The MRC Dyspnea Scale is a simple method measuring perceived respiratory disability of COPD patients. It consists of 5 items scored from 0 (normal) to 4 (worst) (Bestall et al., 1999). The CAT evaluates the impact of COPD on a patient's life. It includes 8 parameters and provides a scoring range of 0–40, higher score indicates worst health (P. W. Jones, 2013). Turkish validity and reliability of the test exist (Yorgancıoğlu et al., 2012). SGRQ is a 50-item questionnaire with 76 weighted responses that is developed to measure health status/HRQoL in patients with airway diseases. It consists of 3 sections; symptoms (8 items), activity (16 items) and impact of the disease (26 items). Each of the 3 sections is scored separately and a total score is calculated using weights attached to each item in the range 0 (best) to 100 (worst). A minimum change in score of 4 units was established as clinically relevant (Jones et al., 1992). Turkish reliability of the questionnaire exists (Polatlı et al., 2013). SF-36 measures HRQoL. It is a self-reported survey that evaluates individual health status with eight parameters consisting of physical function, pain, role limitations attributed to physical problems, role limitations attributed to emotional problems, mental health, social functioning, energy/vitality, general health perception. There is not a sum score, each section is scored between 0 and 100,

0 indicates the worst condition, 100 indicates the best (Ware, 1993). SF-36 was generally used for defining HRQoL of ARDS survivors, and demonstrated that all domains were reduced in ARDS (Dowdy et al., 2006). Chair stand test will be used to evaluate strength and endurance of lower limbs. Patients will be asked to sit on a chair by crossing their hands over their chest and sit five times consecutively as fast as possible. The test will start in the sitting position and terminate at the last standing position and the time will be recorded. The test will be carried out 2 times and the best performance will be recorded (Beaudart et al., 2016). TUG test will be used to assess physical function/performance. It is an objective, reliable and simple test to evaluate balance and functional movement. The patient will be asked to get up from a chair, walk 3 m, turn around, walk back and sit on the chair again. The time will be recorded in seconds (Podsiadlo & Richardson, 1991). It also predicts mortality (Bergland et al., 2017). MRC-sumscore is a reliable, objective and easy method for evaluating the global muscle strength including post-intensive care syndrome related to COVID-19 (Z. Turan et al., 2020). Manual strengths of shoulder abduction, elbow flexion, wrist extension, hip flexion, knee extension and ankle dorsiflexion will be evaluated on both sides using MRC scale. Summation of scores gives MRC-sumscore that range from 0 to 60 and <48 identifies significant weakness (Hermans et al., 2012). Hand grip strength represents overall muscle strength and predicts mortality in older patients (Rantanen et al., 2003) and correlates with 6 MWD in subjects with COPD exacerbation (Z. Turan et al., 2019). Handgrip strength will be measured using a handheld dynamometer (JAMAR Plus + electronic dynamometer, part number: 563213, serial number: 2019070814, Sutton-in-Ashfield) according to the instructions of the American Society of Hand Therapists (Richards & Palmiter-Thomas, 1996). Patients will be seated placing their arms by their sides with the elbow flexed to 90°, the forearm mid-prone, and the wrist in neutral position. Patients will be asked to grip the dynamometer with maximally to measure

TABLE 3 Study outcomes and measures

	Baseline	At the end of rehabilitation	6 <sup>th</sup> months following the rehabilitation	12 <sup>th</sup> months following the rehabilitation
6-Minute walk distance (m)	x	x	x	x
Short Form-36	x	x	x	x
Chair-stand test (second)	x	x	x	x
Timed up and go test (second)	x	x	x	x
St. George's respiratory questionnaire	x	x	x	x
COPD assessment test	x	x	x	x
MRC dyspnea scale	x	x	x	x
MRC-sumscore	x	x	x	x
Hand grip strength (kg/force)	x	x	x	x
1 repetition maximum	x	x	x	x

Abbreviations: COPD: Chronic Obstructive Pulmonary Disease; MRC: Medical Research Council.

maximal grip strength (in kg) for the dominant hand with standard verbal encouragement. Three trials will be performed with a 30 s rest between trials and the highest value will be recorded. The cut-off values of grip strength are 28.6 kg in men and 16.4 kg in women (Yoo et al., 2017).

## 2.10 | Statistical analysis

### 2.10.1 | Sample size calculation

Sample size is determined using G\* Power 3.1 calculator to detect between group differences in the 6MWD as a primary outcome measure using Lau H. M. et al. study (Lau et al., 2005). One hundred twenty-two patients will be enrolled in the study in order to obtain 95% power with an  $\alpha$  level of 0.05, an effect size of 0.65 and allocation ratio of 1:1 using t tests for two independent means.

### 2.10.2 | Statistical methods (analysis)

Statistical analysis will be performed using SPSS Statistics for Windows, Version 25.0 (IBM Corp. Released 2017). The normality of continuous variables will be investigated using Shapiro-Wilk's test. Descriptive statistics will be presented using mean and standard deviation for normally distributed variables and median (and minimum-maximum) for the non-normally distributed variables. Non-parametric statistical methods will be used for values with skewed distribution. Friedman test will be used for comparison of two dependent non-normally distributed groups for four repeated measurements. Repeated Measures ANOVA will be used for comparison of two dependent non-normally distributed groups. Bonferroni corrected Tukey (for equal variances) and Tamhane (for unequal variances) will be used for Post-Hoc comparisons. Statistical significance was accepted when  $p$  value was lower than 0.05.

## 3 | DISCUSSIONS

To our knowledge, there is no randomized controlled study comparing tele-rehabilitation with home exercise program in patients with COVID-19 with post-intensive care syndrome.

Individualized pulmonary rehabilitation program is recommended in patients with COVID-19 ARDS following discharge (Kurtaiş Aytür et al., 2020). However, the difficulty of transfer to the rehabilitation center and the high infectiousness of the virus, utilization of the hospital-based rehabilitation program is expected to be low. Therefore, tele-rehabilitation or home exercise program might be a better alternative and could increase the attendance to the pulmonary rehabilitation.

The strength of the study is that it will be a randomized controlled study. The intervention will protect safety of the health

professionals and patients by utilization digital health platform. The results will provide information for evidence-based recommendations about effectiveness, usefulness, adherence for recovery in people with limitations from ICU admission due to COVID-19 related ARDS.

The weakness of the study is that patients will not be able to be blinded to their group due to the nature of the intervention. The patient with technological barriers such as absence of Internet access or who need supervision or assistance for walking will not be able to include in the study. This study will not demonstrate the superiority of tele-rehabilitation over hospital-based rehabilitation due to the safety considerations regarding infectious. A hospital-based rehabilitation group will not include in the study due to the safety conditions.

The detailed description of the planned rehabilitation protocol in COVID-19 survivors following discharge from ICU will shed light on both planning the rehabilitation program of these patients and future researches. This study will demonstrate whether tele-rehabilitation is superior, effective and feasible than the home exercise program and provide guidance which rehabilitation approach will be more appropriate for these patients in short and long term.

### CONFLICT OF INTEREST

The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

### ETHICAL STATEMENT

The protocol of study was approved by x University Medical Ethics Committee (2020.219.IRB1.069) and registered in [ClinicalTrials.gov](https://clinicaltrials.gov) (NCT04482634). Written informed consent will be taken from all participants. The data of the participants will be reported without individually identifying information and the study will comply with the Declaration of Helsinki. The funder will play no role in the design, conduct, or reporting of this study.

### AUTHOR CONTRIBUTIONS

Study concept and design: Zeynep Turan, Ozden Ozyemisci Taskiran. Drafting and revising the manuscript for intellectual content: All authors. Final approval of manuscript: All authors.

### DATA AVAILABILITY STATEMENT

Data sharing not applicable to this article as no datasets were generated or analyzed during the current study, this is a study protocol of a randomized controlled trial.

### ORCID

Zeynep Turan  <https://orcid.org/0000-0001-8142-3467>

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