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# Feasibility of performing the 3-minute step test with remote supervision in children and adolescents with cystic fibrosis: A comparative study

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## ABSTRACT

**Importance:** The 3-min step test is a simple option to monitor submaximal exercise capacity, although its use via remote video monitoring has not been investigated in children with cystic fibrosis (CF).

**Objective:** This study aimed to assess the feasibility and reproducibility of performing the 3-min step test with remote supervision.

**Methods:** A cross-sectional study including CF patients (6–18 years) from two CF services were performed. Demographic, anthropometric, clinical, and lung function data were collected and two 3-min step tests were performed: (i) in-person supervision, and (ii) remotely supervised by video monitoring. Before and after the tests, heart rate (HR), oxygen saturation ($SpO_2$), and the Borg score for dyspnea and lower limb fatigue were monitored.

**Results:** Twenty-three patients (10.7 ± 3.7 years) with a mean $FEV_1$ of 89.5% ± 23.2% were included. There were no significant differences between tests, with mean differences (95% confidence intervals) in final HR of –3.3 (–8.9, 2.4), change in HR of –1.9 (–6.1, 2.1), final $SpO_2$ of 0.3 (–0.4, 1.0), and final dyspnea of 0.1 (–0.8, 0.9). The intraclass correlation coefficient was 0.852 (final HR), 0.762 (final $SpO_2$), and 0.775 (final lower limb fatigue). Significant and moderate correlations were found between tests for final HR ($r = 0.75$), change in HR ($r = 0.61$), and final $SpO_2$ ($r = 0.61$). The Bland–Altman analysis showed a mean difference in final $SpO_2$ between tests of 0.3% (limit of agreement –3.0%, 3.5%).

**Interpretation:** Physiological responses between tests were similar, indicating it was feasible to perform the 3-min step test with remote supervision in CF children.

## KEYWORDS

Children, Cystic fibrosis, Exercise test, Telehealth

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# INTRODUCTION

Cystic Fibrosis (CF) is a genetic autosomal recessive disease in which there is a modification of ion transport in chloride channels by alterations in the CF transmembrane conductance regulator (CFTR) gene.[1,2] Therefore, different systems are affected, especially the respiratory, gastrointestinal, and reproductive ones.[3] Patients with CF commonly have infectious events that lead to ventilatory obstruction and reduced airway terminal flows, thus leading to damaged lung function, which indicates disease progression.[4,5]

Studies show that around 80 000 individuals are diagnosed with CF in the world.[6,7] The clinical status of the disease is associated with age, type of genetic mutation, nutritional status, pancreatic insufficiency, and adherence to the indicated treatment.[8,9] In addition, aspects such as levels of physical activity, muscle strength, and lung function also influence the evolution of the disease.[10,11]

As CF lung disease progresses, the patient's ability to exercise becomes reduced. Although this reduction is associated with a decline in lung function, it is not always possible to predict functional capacity and exercise tolerance from standard measurements of lung function.[12,13] Therefore, the assessment of functional status and exercise tolerance in CF patients is a useful measure of the impact of the disease, especially when repeated over time.[14]

The 3-min step test is a submaximal, simple, low-cost test that does not require large settings to be performed, it is independent of motivation and verbal encouragement and can be performed in nonlaboratory locations.[15,16] In order to perform the test, the individual has to go up and down, for 3 min, on a 15 cm high step, with a fixed rate of 30 steps/min, wearing an oximeter to measure heart rate (HR) and peripheral oxygen saturation ($SpO_2$), which are usually registered before, during and after the test.[15]

Over the years, advances in healthcare technology have had the potential to provide specialized healthcare services to geographically distant patients. In addition, with the emergence of the coronavirus disease 2019 (COVID-19) pandemic, as well as distancing and isolation measures, the use of technologies has increased globally, enabling classes, meetings, assessments, and consultations through videoconferencing.[17–19] However, to date, no study has evaluated the feasibility of conducting and supervising a 3-min step test via remote monitoring to assess functional capacity in children and adolescents with CF. Thus, the aim of this study was to evaluate the feasibility and reproducibility of the 3-min step test performed in-person or with remote supervision in assessing the functional capacity of children and adolescents with CF. In order to do that, we have evaluated the $SpO_2$ mean difference between both scenarios, the agreement between tests, and the presence of adverse effects.

# METHODS

## Ethical approval

The study was approved by the Research Ethics Committee of both reference centers (reference numbers 32912520.5.0000.5336 and 32912520.5.3001.5119). All legal guardians signed the informed consent form. In addition, children and adolescents up to 18 years of age signed an assent form.

## Study design and sample

A cross-sectional study including patients with a genetic diagnosis of CF, aged 6–18 years, and who underwent regular follow-up at two reference centers for CF treatment was performed. Those patients who had cognitive deficits or any limitation that prevented the performance of the 3-min step test were excluded.

A convenience sample was selected and data were collected from December 2020 to December 2021. The sample size was estimated based on two different calculations. Firstly, we have used a difference between two paired means (8 bpm) for the HR in response to the 3-min step test and a standard deviation of 20.1 bpm,[20] resulting in a sample of 23 participants. Secondly, we performed an estimation based on the intraclass correlation coefficient (ICC), and 21 subjects were estimated as necessary for an ICC of 0.85 between the two tests, considering the ICC for the null hypothesis 0.55. In both cases, an alpha error of 5%, a power of 80%, and the Granmo online calculator were used. Considering that, the more conservative estimation of 23 patients was chosen.

The participants performed two 3-min step tests. The first test was performed with in-person supervision and the second one with remote supervision through a video call. In addition, demographic, anthropometric, presence of pancreatic insufficiency, chronic colonization by *Pseudomonas aeruginosa* (PA), type of genetic mutation, and lung function data were collected. Chronic PA colonization was defined as positive cultures in more than 50% of samples in the 12 months prior to analysis.[21]

## Anthropometrics

Weight was measured in orthostasis using a digital scale (Glass 1 FW; G-Tech) previously calibrated with a precision of 100 grams. Height was obtained using a portable stadiometer (AlturaExata; TBW) with a precision of 1 mm. The body mass index (BMI) in z-score was calculated using the Who Antroplus program.[22]

### Lung function

Spirometry was performed following the recommendations of the American Thoracic Society – European Respiratory Society, with patients in orthostasis.[23] The parameters evaluated included forced vital capacity (FVC), forced expiratory volume in one second ($FEV_1$), $FEV_1$/FVC ratio, and forced expiratory flow between 25% and 75% of vital capacity ($FEF_{25-75}$). Data were expressed as a percentage of predicted and normalized using the Global Lung Function Initiative reference equation.[24]

### Three-minute step test

The 3-min step test was performed according to a standard protocol.[25] The patients were instructed to go up and down a step with a height of 15 cm for 3 min, following an externally paced audio cadence produced by a metronome (30 steps/min).[25] Individuals were allowed to stop if they felt tired or if $SpO_2$ dropped below 75%, interrupting the test and recording the number of steps performed.[26] Before and after the test, HR, $SpO_2$, and the subjective sensation of dyspnea and fatigue in the lower limbs were collected through a modified Borg scale. In addition, the change in HR (final HR − initial HR) was calculated. HR and $SpO_2$ were monitored throughout the test and were also collected at 3 and 5 min of recovery. Patients were encouraged to alternate lower limbs to reduce localized muscle fatigue. We have also monitored for adverse events, including breathlessness, headache, dizziness, and nausea. Feedback on test realization was asked from each patient at the end of the last measure.

### Test supervision

Two 3-min step tests were performed, one with in-person supervision and the other with remote supervision. To avoid a direct learning effect, tests were performed at least 1 week apart. The test with in-person supervision was performed on the day of the routine review appointment. The test with remote supervision was performed with the patients at home, through a video call, in which the participants were instructed to place the oximeter on their index finger and position the cell phone so that the device's display could be seen remotely by the evaluator. The two tests were performed by the same evaluator.

### Data analyses

The distribution of variables was evaluated using the Shapiro–Wilk test. Continuous variables were presented as mean ± standard deviation (SD) or median (interquartile range). Categorical variables were presented in absolute and relative frequencies. The paired *t*-test or the Wilcoxon test was used to compare the physiological variables between the two tests. The Pearson correlation test was used to evaluate correlations. The ICC was used for the reliability analysis. The ICC was interpreted based on the following classification: poor (less than 0.40), fair (between 0.40 and 0.59), good (between 0.60 and 0.74) and excellent (between 0.75 and 1.00).[25] The concordance between $SpO_2$ values in the two tests was graphically demonstrated using the Bland–Altman method. All analyses and data processing were performed using the SPSS version 18.0 program (SPSS Inc.) and the significance level adopted was $P < 0.05$.

**TABLE 1** Characteristics of the patients with cystic fibrosis

| Variables | Patient ($n = 23$) |
|---|---|
| Demographic | |
| Age (years) | 10.7 ± 3.7 |
| Male | 16 (69.6) |
| Anthropometric | |
| Weight (kg) | 38.5 ± 13.7 |
| Height (cm) | 142.6 ± 17.9 |
| BMI (z-score) | 0.05 ± 0.90 |
| Clinical | |
| Pancreatic insufficiency | 20 (87.0) |
| Chronic *Pseudomonas aeruginosa* | 2 (8.7) |
| Genotyping | |
| F508del homozygous | 9 (39.1) |
| F508del heterozygous | 10 (43.5) |
| Other mutations | 4 (17.4) |
| Lung function | |
| $FEV_1$ (% predicted) | 89.5 ± 23.2 |
| FVC (% predicted) | 92.6 ± 20.0 |
| $FEV_1$/FVC (% predicted) | 96.9 ± 12.0 |
| $FEF_{25–75}$ (% predicted) | 89.5 ± 33.1 |

Data were shown as mean ± SD or *n* (%).
Abbreviations: BMI, body mass index; $FEV_1$, forced expiratory volume in 1 second; FVC, forced vital capacity; $FEF_{25–75}$, forced expiratory flow between 25% and 75% of vital capacity.

## RESULTS

A total of 23 patients (16 males and seven females) with a mean age of 10.7 ± 3.7 years were included. The mean BMI (z-score) was 0.05 ± 0.9. Ten patients (43.5%) were heterozygous for the ΔF508 mutation and nine (39.1%) were homozygous. Regarding lung function, the mean (% of predicted) $FEV_1$ was 89.5% ± 23.2% and FVC was 92.6% ± 20.0%. The characteristics of the included sample are shown in Table 1.

Table 2 presents the comparisons of the 3-min step test physiological variables evaluated with both in-person and

**TABLE 2** Physiological responses to the 3-min step test performed with in-person supervision compared to remote supervision

| Variables | In-person supervision | Remote supervision | Mean difference (95% CI) | *P*-value |
|---|---|---|---|---|
| Baseline | | | | |
| HR (bpm) | 98.0 ± 12.7 | 99.4 ± 17.4 | −1.3 (−7.7, 5.1) | 0.68 |
| $SpO_2$ (%) | 97.2 ± 1.5 | 96.7 ± 1.5 | 0.6 (−0.0, 1.2) | 0.06 |
| Borg for dyspnea | 0 (0, 0) | 0 (0, 0) | 0.3 (−0.4, 1.0) | 0.67 |
| Borg for leg fatigue | 0 (0, 1.0) | 0 (0, 1.0) | −2.1 (−2.9, −1.3) | 0.47 |
| Peak | | | | |
| HR (bpm) | 123.5 ± 17.1 | 126.7 ± 19.2 | −3.3 (−8.9, 2.4) | 0.24 |
| Change in HR (bpm)[†] | 25.4 ± 11.3 | 27.4 ± 9.8 | −1.9 (−6.1, 2.1) | 0.33 |
| $SpO_2$ (%) | 96.3 ± 1.8 | 96.0 ± 1.9 | 0.3 (−0.4, 1.0) | 0.45 |
| Borg for dyspnea | 1.0 (0, 4.0) | 2.0 (0, 3.0) | 0.1 (−0.8, 0.9) | 0.84 |
| Borg for leg fatigue | 2.0 (1.0, 4.0) | 2.0 (1.0, 5.0) | −0.4 (−1.3, 0.4) | 0.30 |
| 3-min recovery | | | | |
| HR (bpm) | 101.0 ± 12.2 | 103.5 ± 12.4 | −2.4 (−8.3, 3.5) | 0.40 |
| $SpO_2$ (%) | 96.9 ± 1.3 | 96.5 ± 1.1 | 0.4 (−0.2, 1.0) | 0.20 |
| 5-min recovery | | | | |
| HR (bpm) | 100.1 ± 10.4 | 98.0 ± 13.6 | 2.1 (−3.8, 8.0) | 0.47 |
| $SpO_2$ (%) | 96.8 ± 1.2 | 96.8 ± 1.2 | 0.4 (−0.4, 0.5) | 0.83 |

Data were shown as mean ± SD or median (interquartile range).
[†]Change in HR = final heart rate – initial heart rate.
Abbreviations: CI, confidence interval; HR, heart rate; $SpO_2$, peripheral oxygen saturation.

remote supervision. There were no significant differences between tests, with a mean difference (95% confidence intervals) in final HR of −3.3 (−8.9, 2.4), change in HR of −1.9 (−6.1, 2.1), final $SpO_2$ of 0.3 (−0.4, 1.0), final dyspnea of 0.1 (−0.8, 0.9) and final Borg for lower limbs fatigue of −0.4 (−1.3, 0.4). All participants completed both 3-min step tests and no patient desaturated below 90%. In addition, no adverse events or negative feedback from patients were identified.

Significant and moderate correlations were found between in-person and remotely supervised tests for final HR ($r = 0.75$; $P < 0.001$), change in HR ($r = 0.61$; $P = 0.002$), final $SpO_2$ ($r = 0.61$; $P = 0.002$) (Figure 1).

The ICC for the variables at the end of the 3-min step test between tests performed with in-person or remote supervision was considered excellent for the HR (0.852), the change in HR (0.751), the $SpO_2$ (0.762) and the Borg for lower limbs fatigue (0.775). For the assessment of dyspnea using the Borg scale, reliability was considered good (0.646) (Table 3).

When graphically analyzing the agreement of the tests using the Bland–Altman method, the mean difference in the final $SpO_2$ between the in-person and remote supervision test was 0.3% (agreement limit − 3.0% to 3.5%) (Figure 2).

## DISCUSSION

The results obtained in the present study have shown that it was feasible to use the 3-min step test with remote supervision to evaluate children and adolescents with CF. The mean differences in the main physiological variables measured in response to the test when comparing in-person and remote supervision were small with narrow limits of agreement in $SpO_2$. The possibility of remotely evaluating functional capacity may help healthcare providers to better monitor CF patients.

The 3-min step test is a submaximal, functional capacity test, which is easy to perform and has been proven to be safe and reproducible to evaluate children and adolescents with CF.[26] Desaturation during the 3-min step test is associated with long-term pulmonary deterioration and more hospital days in adults with CF.[27] It has also been demonstrated to be useful in monitoring the effectiveness of inpatient therapy in children.[28] However, in chronic obstructive pulmonary disease patients with mild lung impairment the test duration appeared not to be long enough.[29] Narang et al.[30] showed that in children who have relatively well-preserved lung function, the 3-min step test provided limited information relating to exercise performance. The main outcomes for the test are usually the response of HR, $SpO_2$, and the subjective sensation of dyspnea/fatigue.[30] Our results

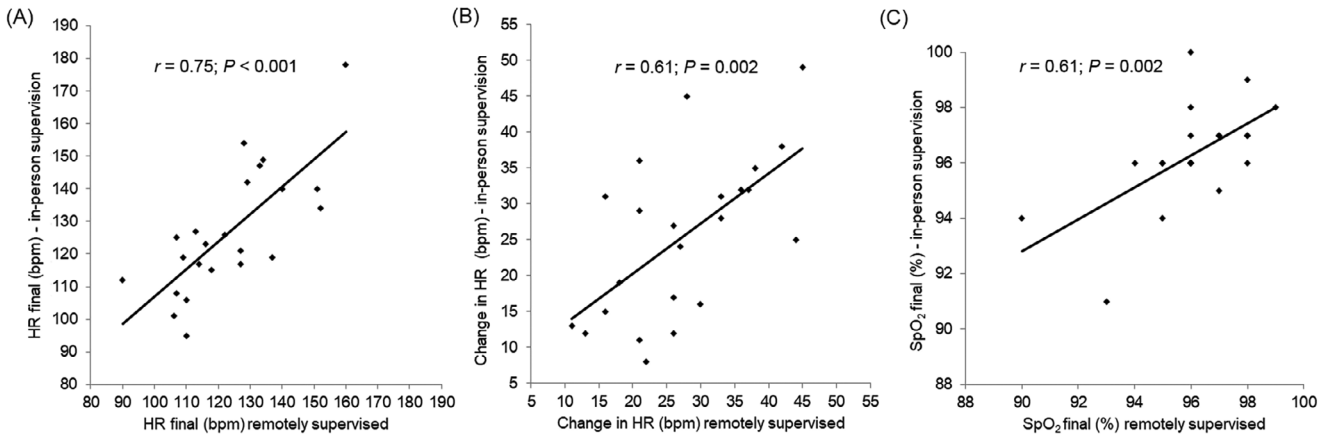


**FIGURE 1** Correlations between the 3-min step tests performed with in-person and remote supervision for 23 patients with cystic fibrosis. (A) Final heart rate (HR). (B) Change in HR (final HR−initial HR). (C) Final peripheral oxygen saturation ($SpO_2$). The Pearson correlation test was used. The significance level was set at 5%. A total of 23 patients were analyzed (in cases where equal values were measured, dots may be superimposed).

**TABLE 3** Reliability analysis of variables at the end of the 3-min step test performed with in-person supervision or remote supervision

| Variables | ICC | 95% CI | *P*-value |
|---|---|---|---|
| HR (bpm) | 0.852 | 0.656, 0.937 | <0.001 |
| Change in HR (bpm)† | 0.751 | 0.419, 0.894 | 0.001 |
| $SpO_2$ (%) | 0.762 | 0.442, 0.899 | 0.001 |
| Borg for dyspnea | 0.646 | 0.148, 0.851 | 0.011 |
| Borg for leg fatigue | 0.775 | 0.477, 0.904 | <0.001 |

†Change in HR = final heart rate – initial heart rate.
Abbreviations: CI, confidence interval; HR, heart rate; ICC, intraclass correlation coefficient; $SpO_2$, peripheral oxygen saturation.

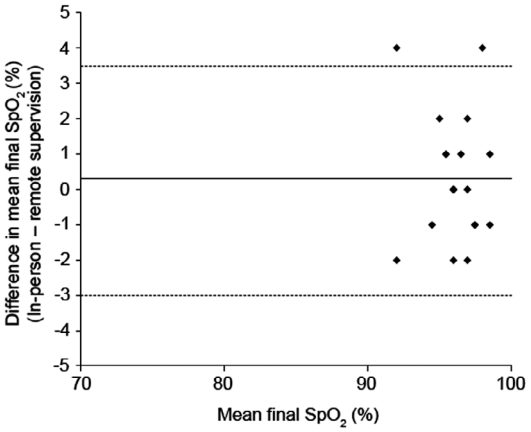


**FIGURE 2** Bland–Altman plot showing the individual differences in final peripheral oxygen saturation ($SpO_2$) between the 3-min step tests performed with in-person and remote supervision for 23 patients with cystic fibrosis. The central line indicates the mean difference between paired measurements and the above/below lines indicate the 95% limit of agreement. A total of 23 patients were analyzed (in cases where equal values were measured, dots may be superimposed).

have shown the expected submaximal responses for the main physiological variables evaluated and no differences between tests on HR and $SpO_2$, both at the end of the test and at recovery times. In addition, when reliability analysis of variables at the end of the test was performed to evaluate both in-person and remote supervision, excellent ICC was found for HR and $SpO_2$ responses. The data obtained confirmed that it is feasible to perform the 3-min step test with remote supervision in children with CF.

The emergence of the COVID-19 pandemic has brought challenges for care providers and patients with CF in order to maintain monitoring and treatment.[31] On the other hand, it has accelerated the development and practical use of telehealth systems and strategies, contributing to major advances in the field. Even after social distancing measures were relieved, regular in-person consultation and monitoring could still represent an important barrier to adherence, considering the high distances for displacement (especially in large countries), costs involved, time spent in public or private transport, and the higher risk for infections.[32] Therefore, remotely supervised tests to allow exercise tolerance and/or functional capacity monitoring may represent an alternative to overcome such barriers. A previous study has shown that the 3-min step test, in adults with CF, was performed and supervised equally as well via remote video-conferencing as it was in-person, as both physiological performance measures and participant comfort were not different.[33] Our results are in accordance with that, as similar responses were identified, including a mean difference in the final $SpO_2$ between the in-person and remote supervision of only 0.3%. However, it is also important to highlight that a variability of around 3% was identified, indicating a less optimal precision. Measurements of $SpO_2$ and HR

during exercise/functional testing are often subject to variations, particularly considering motion artifacts and/or poor capillary perfusion,[34] which indicates that attention must be drawn, especially to patients with borderline low $SpO_2$ values. Despite that, to the best of our knowledge, this is the first study to evaluate the feasibility of performing the 3-min step test with remote supervision in children and adolescents with CF.

With the advent of highly effective CFTR modulator therapies, the CF community enjoys now better health and remarkable improvement in clinical outcomes with increased pulmonary function, reduced numbers of pulmonary exacerbations, and improved nutritional status, among others, have been demonstrated.[35] It is expected that CF patients will live longer and a more diverse range of clinical phenotypes will emerge, leading to the need to rethink and readapt the current model of care, which brings telehealth to the frontline.[34] The present study has shown positive results in performing a functional capacity test through a video call. Telehealth presents several positive aspects, including the ability to reach and connect with patients and families with more flexibility, reducing barriers associated with travel, as well as less time away from work/school. However, it could also present some pitfalls, such as the lack of access to technology and the internet, access to language translation/interpretation, and increased care tasks at home.[36] In the present study, the main logistic barriers found were internet connection problems during the tests, difficulties in visualizing the HR and $SpO_2$ values in the monitor, and the need for patients to have their own home oximeter. Nevertheless, in general, the tests were performed well and patients did not report any negative feedback.

There are also limitations to acknowledge in the study, including (i) the small sample size; (ii) the mild lung function impairment of the cohort, with only a few desaturation episodes in response to the test; (iii) the use of the modified Borg scale to evaluate the perception of dyspnea and leg fatigue in children below 9 years old.[37] Therefore, further studies with a broader spectrum of clinically affected patients are needed to confirm the findings of the present study.

In summary, the results of the present study indicate that performing the 3-min step with remote supervision in children and adolescents with CF seems feasible. Although physiological responses were similar and no negative feedback from patients or adverse events were identified when comparing in-person and remotely supervised tests, attention is required for patients with borderline saturation values during remote testing, considering the variability of measuring HR and $SpO_2$ during exercise. Further studies in patients with more severe clinical impairment may help to confirm the use of the 3-min step test as an alternative to remotely monitor functional capacity whenever in-person visits are not possible or recommended.

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## CONFLICT OF INTEREST

The authors declare no conflict of interest.

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