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Shareable abstract (@ERSpublications)
Online home spirometry can be accurately used to assess lung function trajectories in patients with pulmonary fibrosis in daily practice. Increasing use of home spirometry will hopefully improve access to care and guide personalised management decisions. https://bit.ly/3Qzblaa

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Abstract

Background Monitoring lung function course in patients with pulmonary fibrosis is crucial to guide treatment decisions. Online home spirometry holds great potential for close monitoring and improving care access in times of pressured healthcare systems. However, little data is available on its large-scale use in daily practice. We evaluated the clinical applicability of online home spirometry in pulmonary fibrosis care.

Methods We analysed data of a nationwide Dutch cohort of patients with idiopathic pulmonary fibrosis (IPF) and other forms of pulmonary fibrosis (PF) that used a home monitoring programme with home spirometry (forced vital capacity (FVC)) as part of daily practice. Changes in FVC were evaluated with a joint model. Within-patient variability was measured using coefficient of variation. Home spirometry use over time and patient experiences were assessed.

Results Online home spirometry data of 334 patients (IPF 73.1%) were analysed. Patients with IPF had a mean baseline FVC of 3.02 L (95% CI: 2.27–3.79), with a mean annualised decline of 170 mL (4.0%). Patients with PF had a mean baseline FVC of 2.81 L (95% CI: 2.07–3.55) with a mean annualised decline of 88 mL (1.2%). Mean±SD within-patient variability was 5.6±4.6%. Overall patient satisfaction was high, and after 1 year 63.4% still performed online home spirometry.

Conclusion Online home spirometry is feasible on a large scale in daily clinical practice to monitor disease trajectories in patients with IPF and PF. Online home spirometry could guide management decisions and improve care access for a majority of patients with pulmonary fibrosis.

Introduction

Pulmonary fibrosis comprises a large group of rare diseases, with a heterogeneous disease course, ranging from stable fibrosis, slowly progressive disease to a rapidly progressive disease course [1, 2]. Periodic in-hospital measurement of lung function, specifically forced vital capacity (FVC), is currently the mainstay to monitor disease course in pulmonary fibrosis [3]. However, outpatient clinic visits can be a burden for these patients, who are often elderly, and have complaints of increasing dyspnoea, exercise intolerance and may depend on supplemental oxygen [1, 2]. Furthermore, the typical 3 to 6 monthly clinic

visits may not capture intercurrent problems and disease deterioration in an early stage. Meanwhile, healthcare systems are increasingly strained, with care access being challenged [4].

In the last decade, several studies have explored the use of online home spirometry to remotely monitor disease course in patients with idiopathic pulmonary fibrosis (IPF) and other forms of pulmonary fibrosis (PF) [5–14]. These studies indicated that home spirometry was feasible and reliable in this patient population, but also revealed several practical and analytical hurdles [7, 8, 10, 15]. So far, home spirometry has mainly been studied in the context of clinical trials, but its use in daily clinical practice has increased during the COVID-19 pandemic [8, 15, 16]. Home spirometry enables more frequent lung function measurements compared to in-hospital spirometry, without the burden of additional hospital visits. These more granular data may provide valuable insights into disease trajectory of individual patients, thus enabling early detection of changes in disease course and guiding treatment strategies [3, 15]. However, data on its feasibility and reliability in daily practice are lacking [17–19].

We have previously developed and evaluated an online home monitoring programme for patients with IPF and PF, including home spirometry and patient-reported outcome measures [5, 6]. In line with other studies in the field [5, 7, 8, 11], home spirometry results in our studies correlated well with in-hospital measurements. Moreover, the online programme was highly appreciated by patients [5]. During the COVID-19 pandemic, we have implemented this online home monitoring programme throughout the Netherlands to ensure continuity of care for patients with IPF and PF [20]. This has provided a unique nationwide cohort to evaluate the clinical applicability of online home spirometry in PF care. We evaluated lung function course and patient use, and gathered insights on patients' experiences with the online home monitoring programme.

Materials and methods

Patients and design

In the Netherlands, PF care is organised in a national network. In April 2020, all centres of this network were informed about the availability of an online home monitoring programme. Patients with IPF or PF who had access to internet at home and a compatible smartphone or tablet could use an online home monitoring programme, including home spirometry, as part of their daily care [6, 20]. Besides this patient group, we analysed home spirometry data of patients that had participated in previous home monitoring studies and continued using the programme in daily practice after completion of the study.

To evaluate the clinical applicability to monitor disease course with online home spirometry, we combined lung function data from all patients that used home monitoring in daily clinical care, *i.e.* the former trial participants, and those that started during the COVID-19 pandemic (between 1 April 2020 and 29 December 2021). Patients were followed until death or transplantation. We evaluated the clinical use and patient experiences of online home spirometry in the group of patients that started using the programme during the pandemic. We focused exclusively on patients who started during the COVID-19 pandemic. This approach was chosen to avoid potential bias, as patients who had been using the programme for a longer period were generally positive towards the online home monitoring programme, which could have skewed our results.

All patients gave consent in the online application for the use of their data for research and evaluation purposes. As this was an evaluation of daily clinical practice, this analysis was exempt from ethics (MEC-2021–0394).

Methods

Patients measured their FVC with a Bluetooth enabled spirometer (Spirobank Smart, MIR). Results of these measurements were sent directly to an online CE-certified application (Gezondheidsmeter, Curavista, the Netherlands). Patients received instructions on using the home spirometer and the online application either from their healthcare professional at the outpatient clinic or *via* phone or video. Additionally, all patients were provided with an instruction manual. Patients were instructed to choose their own frequency of home spirometry measurements based on individual preferences and lifestyle, but were advised that performing three consecutive measurements on a single day was preferable. Both patients and healthcare professionals had real-time access to the results *via* the online application. Patients could contact a technical helpdesk for questions relating to the use of the home monitoring programme. Patient experiences were assessed using a cross-sectional 16-item survey (supplementary figure E1) which was sent *via* the online application.

Statistical analysis

Patient characteristics were analysed with descriptive statistics. All patients that had $\geqslant$2 FVC measurements were included in the analyses. The highest FVC value recorded on a single day was used for further

analysis. FVC values that deviated >20% from the previous measurement were defined as outliers and were excluded from analyses.

We analysed 1-year FVC data using all available measurements from the start of the home monitoring programme until 1 year after its initiation to determine the annualised change in FVC. Mean annual change in FVC was estimated using a Joint model. This model included a mixed effect submodel to account for repeated measures, with age, baseline FVC and medication use as covariates, and a survival submodel accounting for the effect of missing data due to death or lung transplantation. Transplantation was considered a competing risk in the survival submodel. The mixed effect submodel accounted for within-patient variability with random intercepts and slopes. The FVC evolution over time was modeled nonlinearly using cubic splines. Based on the fitted joint model, subject-specific trajectories were obtained.

Within-patient variability was assessed by calculating the coefficient of variation (CoV) by using the detrended data points. These were obtained by subtracting the residual of each spirometry measurement from each subject-specific trajectory.

The use of home spirometry per month in each individual patient was assessed by calculating the sum of blows per 28 days, with a maximum of 1 blow per day. We also analysed whether FVC at start of home spirometry influenced its use over time. We grouped the cohort based on their median FVC % predicted in the first month (median FVC: <70%, ⩾70% and <90%, ⩾90%), and compared the use of online home spirometry between these three groups over time. Experiences and satisfaction with the use of the home monitoring programme were analysed with descriptive statistics.

Analyses were performed with R (R version 4.1.0).

Results

Patient characteristics

We analysed home spirometry data from a total of 334 patients, of whom most (n=260, 77.8%) started home monitoring during the COVID-19 pandemic. We had a total of 18 208 readings in the first year with 132 measures defined as outliers (0.72%). In the total cohort, 79.6% were male with a median age of 72 years (IQR 65–76), with IPF as the most frequent diagnosis (73.1%). 81.2% of patients with IPF were treated with antifibrotic medication. In PF, 30.0% were treated with antifibrotic medication and 44.4% with immunosuppressive medication. Patient characteristics are shown in table 1.

TABLE 1 Baseline characteristics of patients with idiopathic pulmonary fibrosis (IPF) and other forms of pulmonary fibrosis (PF)

	IPF	PF
Patients, n (%)	244 (73.1)	90 (26.9)
Age years, median (IQR)	73 (68–76)	66 (59–73)
Male, n (%)	215 (88.1)	50 (55.6)
Baseline medication, n (%)		
Pirfenidone	101 (41.4)	17 (18.9)
Nintedanib	97 (39.8)	10 (11.1)
No medication use	47 (19.2)	40 (44.4)
Other	4 (1.6)	10 (11.1)
Prednisone	2 (0.8)	18 (20.0)
Mycofenolate mofetil	0 (0.0)	12 (13.3)
Diagnosis, n %		
CTD-ILD		23 (25.6)
fHP		17 (18.9)
Unclassifiable-ILD		11 (12.2)
Other		15 (16.6)
Sarcoidosis		9 (10.0)
Asbestosis		8 (8.9)
iNSIP		5 (5.6)
PPFE		2 (2.2)

CTD-ILD: connective tissue disease–interstitial lung disease; fHP: fibrotic hypersensitivity pneumonitis; Unclassifiable-ILD: unclassifiable interstitial lung disease; iNSIP: idiopathic nonspecific interstitial pneumonia; PPFE: pleuroparenchymal fibroelastosis.

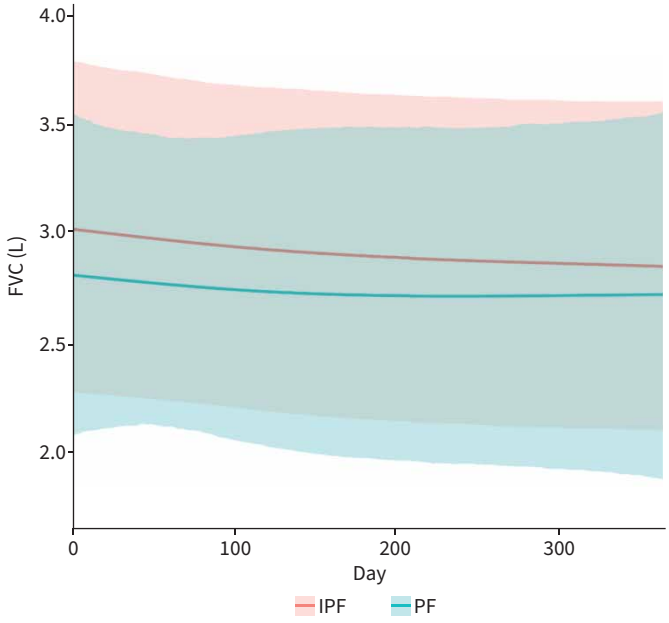

FIGURE 1 The rate of decline in forced vital capacity (FVC) in patients with idiopathic pulmonary fibrosis (IPF) and other forms of pulmonary fibrosis (PF) measured with home spirometry. The lines indicate the modelled trajectories with the 95% CI.

44 patients died, and eight patients had a lung transplantation within 1 year of the start of the home monitoring programme.

Patients with IPF had a mean baseline FVC of 3.02 L (95% CI: 2.27–3.79 L) corresponding with 75.9% predicted (95% CI: 69.9–81.8%). The mean annualised decline in IPF was 170 mL (4.0%). Patients with PF had a mean baseline FVC of 2.81 (95% CI: 2.07–3.55), corresponding with 69.9% predicted (95% CI: 63.1–76.7%). The mean annualised decline was 88 mL (1.2%) (figure 1 and table 2). Figure 2 visualises examples of home spirometry in individual patients during 1 year. The mean±SD CoV of home spirometry measurements was 5.6±4.6%.

We assessed home spirometry use in 260 patients (*i.e.*, the patients that started using it during the COVID-19 pandemic). After 1 year, most (63.4%) patients were still using home spirometry (figure 3). In the first month after the start, patients performed home spirometry with a median of 3 blows (IQR 2–4). After 3 months patients measured their lung function with a median of 3 (IQR 2–4) blows per month, a median of 4 (IQR 2–5) at 6 months, and 3 blows per month (IQR 2–4) at 12 months (figure 4 and supplementary figure E2). The frequency of home spirometry was not dependent on baseline FVC (supplementary figure E3).

The online survey was sent to 257 patients, of whom 116 (45.1%) responded. Responders considered home monitoring to be most useful to get insight into their disease course (89.7%), reduce the rate of

TABLE 2 Mean forced vital capacity (FVC) measurements (95% CI) at time of start of the programme and after 1 year, modelled with joint models

	At start	At 1 year
IPF		
FVC L	3.02 (2.27–3.79)	2.85 (2.10–3.61)
FVC % predicted	75.9 (69.9–81.8)	71.8 (65.8–77.8)
PF		
FVC L	2.81 (2.07–3.55)	2.72 (1.87–3.56)
FVC % predicted	69.9 (63.1–76.7)	68.7 (61.5–76.0)

IPF: idiopathic pulmonary fibrosis; PF: pulmonary fibrosis.

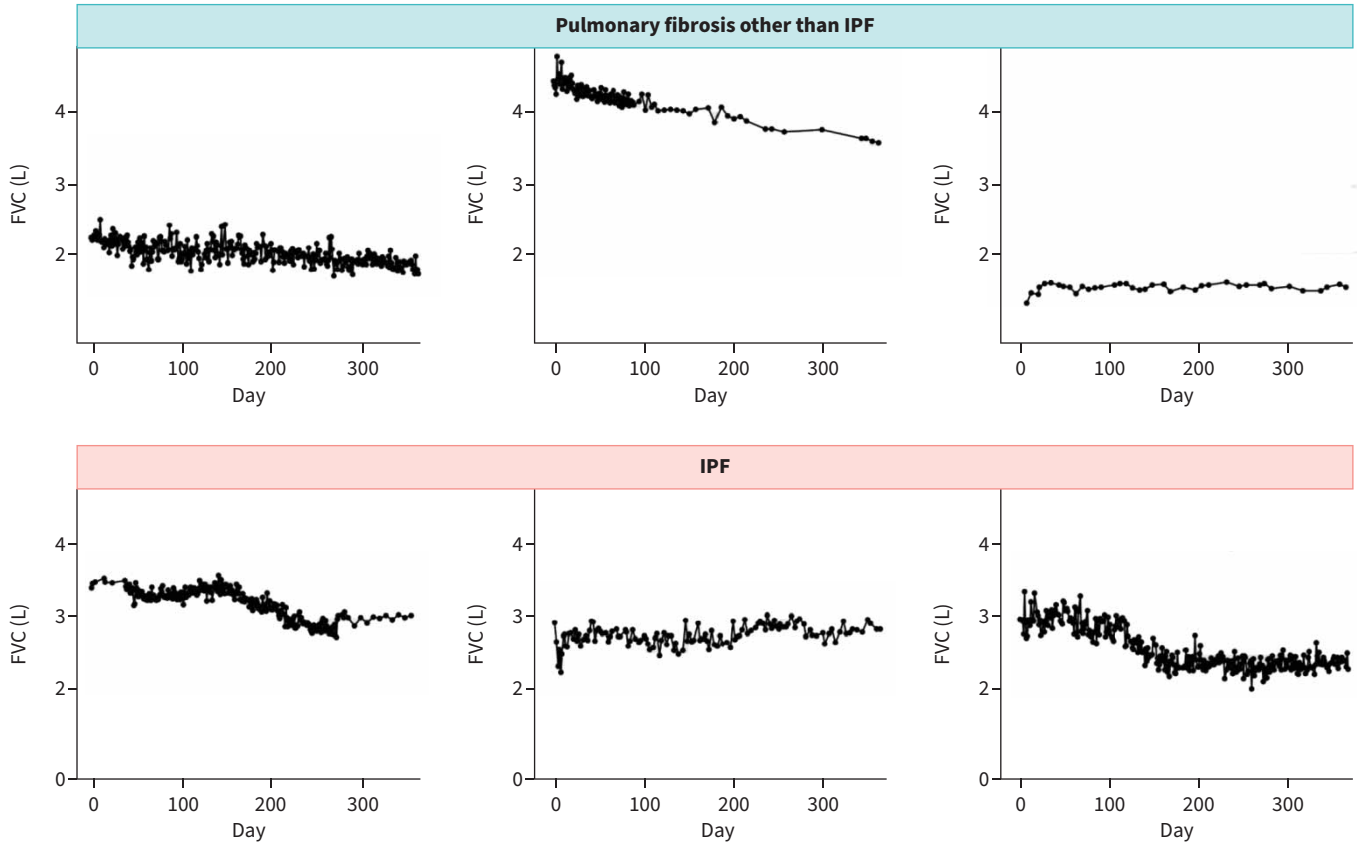

FIGURE 2 Examples of lung function course (forced vital capacity (FVC)) in 1 year in six individual patients with idiopathic pulmonary fibrosis (IPF) and other forms of pulmonary fibrosis measured with online home spirometry.

hospital visits (43.1%) and share their data with others (29.3%). 73.3% of patients stated that home monitoring provided additional insight into their disease course.

45.7% answered that they went less frequently to the hospital during the COVID-19 pandemic because of the home monitoring programme. Patients used phone calls (n=75), eConsultations (n=13), video-consultations (n=12) and e-mail (n=10) to replace outpatient clinic visits. 55.2% of the patients felt safer due to the home monitoring programme. Overall, most patients stated that home spirometry was not burdensome, easy to use and that it was pleasant to see their own spirometry results (figure 5). Almost all patients (98.3%) wanted to continue using the home monitoring app after the pandemic.

Discussion

To our knowledge this is the first evaluation of a real-world nationwide cohort of patients with IPF and PF that used online home spirometry as part of daily clinical care. Our data demonstrate the clinical applicability of home spirometry as a tool for monitoring lung function course in this real-world setting.

The annualised FVC decline in patients with IPF (mean 170 mL) and PF (mean 88 mL) measured with online home spirometry is comparable with previously conducted clinical trials and real-life registries that used in-hospital FVC measurements [21–24]. Our home spirometry data also highlight the heterogeneous disease course in PF; figure 2 visualises examples of home spirometry in individual patients during 1 year. In line with previous studies, some patients with PF had an IPF-like trend in lung function course [21, 25]. Importantly, within-patient variability of home spirometry was low, with a mean CoV of 5.6%. It is encouraging that variability was comparable to in-hospital spirometry and previous clinical trials using home spirometry, even though patients often could not receive in-person instructions before the start of home monitoring during the COVID-19 pandemic [5, 8, 16]. Thus, these results show that home spirometry may be used for early and accurate detection of disease decline in daily clinical practice.

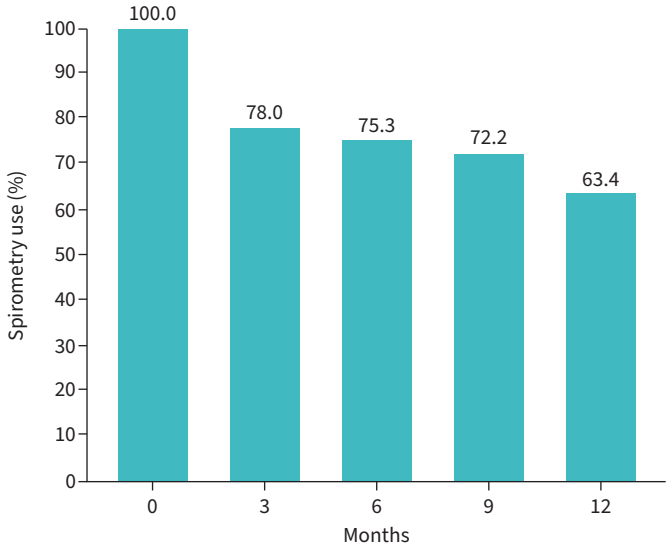

FIGURE 3 Home spirometry use by patients with pulmonary fibrosis in 1 year. The numbers are corrected for mortality and transplantation.

With the establishment of criteria for progressive PF and the therapeutic implications associated with disease progression in patients with other forms of PF, the significance of identifying FVC decline early is undeniable. Nevertheless, in current practice, there is often a gap in the detection of declining lung function, which may delay timely initiation of treatment and conversations about prognosis with patients and families. Online home spirometry offers the opportunity to closely monitor disease course in patients, which could potentially lead to an earlier identification of disease progression, and subsequently optimisation of personalised management strategies. In addition, online home monitoring results can be used to identify patients that are progressive under their current antifibrotic treatment, and facilitate timely enrolment into clinical trials for novel drug compounds.

The adherence rates in our cohort were reassuring, with two-thirds of patients continuing to use online home spirometry after 1 year. These patients had a stable frequency of monitoring over the course of

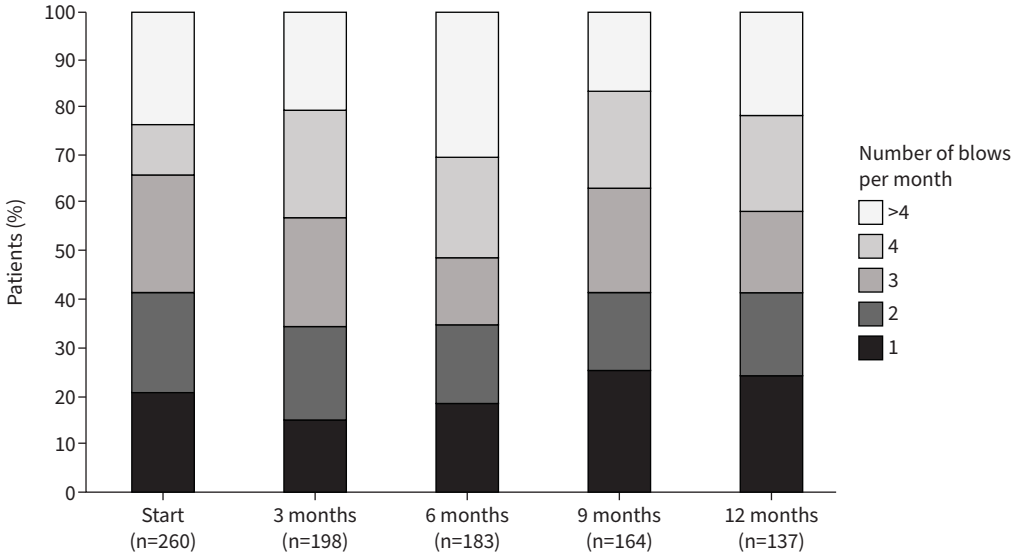

FIGURE 4 The number of home spirometry measurements by patients with pulmonary fibrosis over time. The highest forced vital capacity value recorded on a single day was used for further analysis.

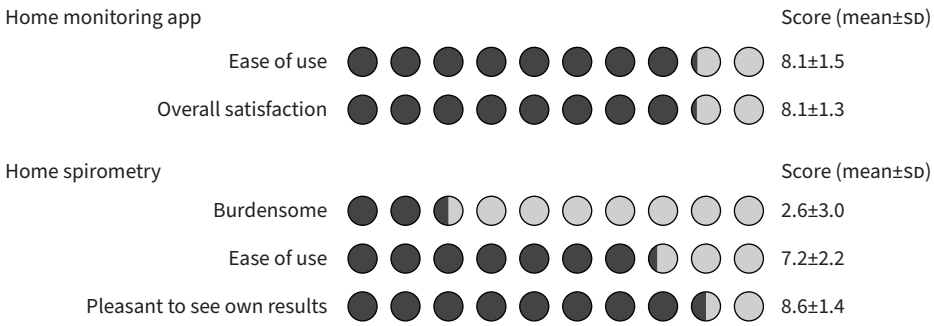

FIGURE 5 Experiences of patients with pulmonary fibrosis using the online home monitoring programme in daily clinical practice. Higher score indicated more positive experience, with the exception of the outcome "burdensome", where a higher score indicated a more negative experience.

1 year. In previously conducted clinical trials, adherence rates to home spirometry were somewhat higher, although most of these studies had a shorter follow-up duration [5, 6, 9, 11, 26]. One clinical study conducted by Noth and colleagues [7] reported an adherence rate of 86% after 1 year. A likely reason for the difference in adherence is that we used this programme as part of daily care, and therefore patients did not receive any reminders for home spirometry measurements. Instead, patients were instructed to determine their own frequency of performing home spirometry measurements, based on their lifestyle and preferences. Our findings suggest that a subgroup of the patients are highly motivated to regularly monitor their lung function as they perceive added value in using online home spirometry. Patient experiences and satisfaction with the home monitoring programme were generally positive, underlining the usability of online home monitoring integrated into daily clinical practice. The fact that the programme had been developed and optimised in several rounds together with patients may have contributed to user satisfaction [5, 6, 27]. Therefore, we frequently update and improve the online home monitoring programme in collaboration with patients to ensure its future usability.

Although our results demonstrate the advantages of monitoring lung function in individual patients with PF using online home monitoring, it might not be fit for all patients.

In this cohort, there could be a potential selection bias in the patients that were offered the online home monitoring programme and those who eventually integrated home monitoring as part of their daily care. During the pandemic, patients with PF were often hesitant to attend in-hospital visits, which may have introduced bias into our results, as home monitoring strategies were likely more favourably received than under normal conditions. However, patient feedback in this cohort aligns closely with previous studies [5, 14], where nearly all participants wanted to continue and recommend the programme to others. We were not able to determine reasons that patients declined to use home monitoring, but it could be hypothesised that not only digital literacy and technical skills play a role, but also patient engagement in their healthcare and capability of self-management. Better insight into the reasons why patients initiate or discontinue using the home monitoring programme may help shape future home monitoring programmes. However, it remains important to ensure that optimal care is accessible and tailored to the needs of all patients, and not completely replace in-hospital care with home monitoring [28].

Another barrier for widespread implementation of home monitoring in daily practice is the lack of reimbursement. During the pandemic, online home monitoring was temporarily reimbursed by insurance companies in the Netherlands, and also in other countries the government temporarily financed home monitoring [29]. However, post-pandemic, securing long-term financial support to structurally implement home monitoring as part of daily clinical practice remains challenging. Nonetheless, reimbursement is essential for providing and sustaining the devices, an online platform and technical helpdesk. It is realistic to assume that these costs would be at least in part counterbalanced by a reduction in hospital visits. Here, we were not able to calculate the effects of using online home monitoring on healthcare costs. A current multicentre Dutch randomised trial will structurally evaluate the impact of partly replacing hospital visits by a home monitoring programme including video consultations.

The current analysis has several limitations, as it was a real-life patient cohort. We cannot compare home with in-hospital spirometry, as hospital measurements were often not possible during the COVID-19

pandemic. However, as described above, reliability and FVC decline are in line with in-hospital data. Although patient experiences were encouraging, it is important to note that the survey response rate was 45%, potentially introducing bias. We conducted a single cross-sectional survey through the online home monitoring application and did not send out reminders. Nevertheless, we know from previous studies that the response rate is on average 44% of online surveys, which is comparable with our response rate [30].

In conclusion, online home spirometry can be of added value in daily clinical practice and can be accurately used to assess lung function trajectories in individual patients with PF. Continuous innovations in eHealth technologies combined with pressure on healthcare systems require us to consider new care processes including collaborating more with patients in self-monitoring and management. We hope that for patients with PF increasing access to home spirometry will improve personalised and timely management decisions and result in better clinical outcomes.

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