Early View

Invited review

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Please cite this article as: Pimenta S, Hansen H, Demeyer H, *et al*. Role of digital health in pulmonary rehabilitation and beyond – shaping the future. *ERJ Open Res* 2022; in press (https://doi.org/10.1183/23120541.00212-2022).

This manuscript has recently been accepted for publication in the *ERJ Open Research*. It is published here in its accepted form prior to copyediting and typesetting by our production team. After these production processes are complete and the authors have approved the resulting proofs, the article will move to the latest issue of the ERJOR online.

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Role of Digital Health in Pulmonary Rehabilitation and Beyond - Shaping the Future

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Take-home message: Digital health technologies provide opportunities to improve Pulmonary Rehabilitation access and uptake in patients with chronic respiratory diseases and support adherence to more active lifestyles, although there are still several challenges to address.

Abstract

Pulmonary rehabilitation (PR) is a cost-effective intervention with well-known benefits on exercise capacity, symptoms and quality of life in patients with chronic respiratory diseases. Despite the compelling evidence of its benefits, PR implementation is still suboptimal, and maintenance of PR benefits is challenging. To overcome these pitfalls, there has been a growing interest to develop novel models for PR delivery. Digital health is a promising solution, as it has the potential to address some of the most reported barriers to PR uptake and adherence (such as accessibility issues), help maintain the positive results following a PR programme, and/or promote patients' adherence to a more active lifestyle through physical activity (tele-)coaching. Despite the accelerated use of digital health to deliver PR during the COVID-19 pandemic, there are still several factors that contribute to the resistance in the adoption of digital health, such as the lack of evidence on its effectiveness, low acceptability by patients and healthcare professionals, concerns about implementation and maintenance costs, inequalities in access to the internet and technological devices, and data protection issues. Nevertheless, the trend towards reducing technology costs and the higher availability of digital devices, as well as the greater ease and simplicity of use of devices, enhance the opportunities for future development of digitally enabled PR interventions. This narrative review aimed to examine the current evidence on the role of digital health in the context of PR, including strengths and weaknesses, and to determine possible threats and opportunities, as well as areas for future work.

Introduction

Pulmonary rehabilitation (PR) is a cost-effective intervention [1] and a cornerstone of care for individuals with chronic respiratory disease (CRD) [2]. PR is underpinned in a comprehensive model consisting of a thorough patient assessment followed by a multidisciplinary intervention including, but not limited to, exercise training, education, and behaviour change [2]. The main goals of PR are to improve the physical and psychological condition of people with CRD and promote long-term adherence to health-enhancing behaviours [2]. Meeting these goals, PR has shown clinically important benefits in dyspnoea, exercise capacity, and health-related quality of life (HRQoL) [3], as well as reduced healthcare use [1].

Despite the compelling evidence of its benefits, PR is still underutilised in the real-world setting, which clearly shows a gap between the international guidelines and the delivery service [2, 4]. The suboptimal PR implementation arises from low uptake and adherence to 'traditional' centre-based PR programmes, due to problems including transport issues and geographical distance to PR settings [1]. It is estimated that less than 2% of eligible patients have access to PR worldwide [5]. In 2015, the American Thoracic Society (ATS) and the European Respiratory Society (ERS) published a policy statement on "Enhancing Implementation, Use and Delivery of Pulmonary Rehabilitation" [1]. Among the recommendations, the ATS/ERS called for "novel pulmonary rehabilitation programme models that will make evidence based pulmonary rehabilitation more accessible and acceptable to patients and payers". The ATS/ERS statement was supported by a same year final Cochrane review concluding that PR is highly effective, but grossly underutilised, calling for novel models of PR delivery [3]. A second remaining challenge in PR is that, in those patients who complete PR, the benefits appear to gradually fade over 6–12 months in the absence of any maintenance strategy [2], which also emphasises the need for maintenance interventions to preserve PR effects over time.

The use of digital health to improve PR delivery is a promising approach as it can address the challenges of centre-based PR programmes by increasing access to PR and/or helping to sustain positive long-term outcomes. Digital technologies are increasingly used and widely available in patients' day-to-day living and in the healthcare systems [6, 7]. The term 'digital health' is broadly used in various disciplines such as health informatics, but there is no agreed upon definition for this term [6]. In the global strategy on digital health 2020-2025 of the World Health Organization (WHO) [8], digital health was defined as "the field of knowledge and practice associated with the development and use of digital technologies to improve health". Digital health expands the concept of electronic health (eHealth) to include a wider

range of smart and connected devices for digital consumers, and also other uses of digital technologies for health, such as the Internet of things or artificial intelligence [8, 9]. In short, digital health can be defined as the use of digital technologies to improve people's health and provide health services [9], which can be done through audio, text messages or video communication, using technologies such as wireless communication, internet, among others. For the purposes of this review, interventions that consist of telephone calls only are not included in the definition of digital health.

Interest in introducing digital technology into healthcare delivery is not new [1], although the COVID-19 pandemic has spurred strong growth in the use of digital solutions by both patients and healthcare professionals (HCPs) [10]. Specifically in the context of PR, several programmes had to suspend face-to-face activities to limit patient exposure to the virus and reduce the health systems' burden, increasing the adoption of telerehabilitation services [10, 11]. The great potential of digital health in respiratory care was also highlighted in the Presidential Summit of the ERS "Digital respiratory medicine – realism vs futurism", held in 2021 [12]. It was sought to define the innovations that are realistic for digital respiratory medicine in the 'here and now', as well as those that should be considered aspirational and futuristic. Virtual PR was one of the topics for discussion, where the "need to develop engaging digital interventions to support symptom reduction and behaviour change" was emphasised.

Nevertheless, there are still some factors to consider before its widespread dissemination. This narrative review aims to summarise the available evidence on the use of digital health in the context of PR, considering three main goals: as a primary source to deliver PR; as a tool to promote patients' adherence to health-enhancing behaviours, specifically physical activity (PA); and as a maintenance strategy to sustain PR benefits in the long-term. It also examines the micro (individual level) and macro (system level) factors that need to be addressed to ensure that digital technologies are deployed successfully and meaningfully.

1. Use of digital health in pulmonary rehabilitation (PR)

1a. Digital health as a primary source of PR delivery

Digital delivery models of PR have the potential to address many of the patient-related and system-related barriers for PR programmes, including improvements to access (e.g., reducing geographical restrictions using remotely delivered models), uptake (allowing patient preference and reducing barriers related to travel and disability) and completion (decreasing the burden of attendance, enabling continuing participation despite fluctuations in symptoms

and functional status) [13]. In addition to digital delivery of PR, there is now the opportunity to incorporate wearables (e.g., for PA promotion, heart rate monitoring, spirometry measures) for remote monitoring. Digital models also offer the opportunity to embed innovations in education delivery and behavioural change in PR. Lastly, PR is, by definition, a personalised intervention and digital delivery modes can complement this principle, for example by allowing flexibility of the intervention components [14]. Ultimately, the goal must be to provide clinicians and providers with multiple options for effective PR delivery models. This may allow patients to be offered the programme in which they are most likely to succeed, which can vary according to factors such as the disease stage, comorbidities, psychosocial features, digital literacy, previous PR experience and patient preference.

Evidence on the use of digital health as a source of PR delivery is provided in a Cochrane review in 2021 [15]. This review included 15 studies of which six studies were randomised controlled trials (RCTs) delivering four different modes of digital PR requiring internet [16-21]. Findings across the multiple modes of digital delivery suggest that digitally delivered PR and outpatient PR are equally safe and produce similar results on functional capacity, symptoms, HRQoL and hospitalisation rates (p>0.05; Figure 1 and Table S1), whereas completion rates are higher in the digital PR groups compared to participants in out-patient PR settings (93% vs. 70%) [15].

Since the publication of this Cochrane review, three new RCTs delivering digital PR requiring internet access have been published [22-24]: two through mobile/tablet app plus individualised telephone/chat support [22]-[23] and one through in-group supervised videoconference [24]. One of the studies involved participants with Interstitial Lung Disease (ILD) solely [22], another included patients with different CRDs, specifically patients with COPD (69%), ILD (7%), Sarcoidosis (15%) and Asthma (9%) [24], and the last study concerned only participants with COPD [23]. All three RCT studies stated "no adverse event recorded", thus finding safety similar to the results published in the Cochrane review (Table S1)[22-24].

(insert Figure 1 about here)

Besides obvious differences in modes, content and duration, a glance over the presented studies uncover that the level of the participants' technical skills was sparsely defined (Table 1). Consequently, this indicates that the trial participants were selected and likely had a positive attitude towards digitally delivered PR and felt confident in their own technical capabilities beforehand. Knowledge of attitude and capability towards digital delivery of PR within the group of patients to whom these digital solutions are intended for needs to be

uncovered to move forward. This will likely vary within regional, cultural, economic and infrastructural contexts across the world [1, 25].

The description of the digitally delivered PR programmes varied from limited to detailed protocols. Table 1 provides and overview of the digital models requiring internet access. Three studies used a group-based videoconference platform [18, 21, 24], whereas the remaining digital interventions included various technologies delivered to individual patients: website with weekly telephone support [16, 17], website only [20] and a mobile/tablet application with weekly telephone/chat support [19, 22, 23]. The session frequency and duration of the digital PR programme were very heterogeneous, ranging from 2 to 7 sessions/week, and from 6 weeks to 9 months, respectively (Table 1).

A total of seven trials provided exercise equipment including bicycle ergometer [21, 24], free weights [17, 18], step box [18, 22, 23] and pedometer [20]. Six trials also provided mandatory or tailored exercise videos on websites [16, 17, 20] or a tablet [19, 22, 23]. Aerobic exercise included a walking or ergometer cycling programme, step boxes and/or body calisthenics. Resistance training with free weights was used in two trials [17, 18], and another seven used water bottles, TheraBand's or body weight [16, 19-24]. All programmes included an exercise diary.

Provision of formal education was heterogenous and included group-based, structured, live sessions via video or unsupervised web-based modules. Two studies did not provide any formal educative programme or written material [19, 21], which does not fully meet the accepted definition of PR [2].

While existing research provides convincing data that it is possible to deliver remote exercise training, education and self-management, with similar outcomes to traditional centre-based PR, all the existing clinical trials have included an in-clinic assessment module prior to programme commencement and, thus, they do not provide evidence or insight for remote assessments, i.e., which assessment tests are feasible with minimal space requirement with or without remote monitoring [15, 22-24]. Home-based assessment, either supervised or remotely administered and monitored, is potentially relevant for barrier removal in PR uptake and enrolment while maintaining the ability to tailor and evaluate an intervention programme.

More recently, during the COVID-19 pandemic, Holland et al. [26] published a rapid review to uncover potential feasible, reliable, valid, and responsive home-based supervised or remotely administered assessment tests [26]. Home-based assessment tests administered and supervised by an HCP included the 5-times sit-to-stand (STS), 30-sec STS, 1-min STS, Timed Up

and Go (TUG) and five various step tests. From the included studies, only one investigated and compared a remotely administered 3-minute step test (3MST) with an in-person supervised 3MST in adults with Cystic Fibrosis [27]. All included assessment tests presented acceptable clinimetric data, thus indicating they are likely able to measure and detect change over time. However, none of the home-based assessment tests were validated for exercise prescription and safety measures, that are commonly extracted from the 6-minute walk test, the shuttle-walk test and the cardiopulmonary exercise assessment test prior to PR commencement [26]. Summarising the current literature on home-based assessment points out a major need of research, evidence and knowledge for novel remote assessment methods complementary to digital delivery methods. Thus, in-clinic patient assessment seems to be the preferable and safest option whenever possible, yet there must be a delicate balance not to exclude relevant participants who live remotely and/or lack the energy and resources to attend in-clinic assessment before commencing a digitally delivered PR programme. Consequently, home-based assessment tests administered and supervised by an HCP might be considered a second-choice option or performed in combination with in-clinic visits.

The success of all digital delivery models of PR will ultimately be judged on whether the essential PR components are delivered and on whether the expected patient outcomes are achieved, including improved exercise capacity, reduced dyspnoea, enhanced HRQoL and reduced hospital admissions. From current evidence, digital delivery appears to be a safe and a potential alternative to conventional PR [1, 25]. However, the existing heterogeneity in study samples, delivery method, supervision and content published to date makes it difficult to reach a reasonable evidence-based consensus. This calls for consensus around standardised digital models to enable evidence-based implementation. Essentially, future digital PR programme designs must include specific considerations regarding the country-infrastructural condition, delivery form and content and definition of technical skills of the target population, particularly if these programmes are to be offered to people who live remotely and/or lack the energy and resources to attend a conventional PR programme. Doing so will help PR providers get one step closer to sorting out who are best suited to enrol, complete and benefit from a digitally delivered PR programme, and which type of digital delivery mode to use.

Furthermore, quality assurance is important to ensure that any digital delivery model of PR provides optimal outcomes for patients and health services. Lastly, cost-effectiveness studies are missing to evaluate the short- and long-term efficacy and cost-effectiveness of digitally delivered PR programmes.

1b. Digital health used in PA tele-coaching as an add-on to PR

Based on overwhelming evidence, being physically active is known to be important for patients with CRD. A higher physical activity (PA) has been related to important clinical outcomes, such as HRQoL, exacerbation risk and mortality [28, 29]. PA management is therefore a recommended therapy for all patients with COPD [30] and achieving sufficient PA levels should be one of the targets of PR [2].

As a concept, PA is distinct from exercise capacity [28] and it is known that only providing a supervised exercise training programme will not result in an important increase in PA. Based on the definition of PR, which includes exercise training, but also education and behaviour change [2], increasing the patients' PA level is an important target of PR. However, its influence on patients' adoption of active lifestyles is modest if present at all [31]. This effect has been estimated as 350 steps/day based on the available literature [32]. Hence, when aiming to increase PA, additional interventions including behavioural strategies (PA coaching) are the option of choice [33].

These PA coaching interventions specifically aim to increase the amount of PA. Because typically the intensity of PA is not specified and the intervention is provided without direct supervision, the intervention targets PA at the lower intensities. Most coaching programmes are focused on walking behaviour and include the increase of total amount of steps per day as the incentive. Important components in these programmes are **self-monitoring** (e.g., by using a step counter), receiving **feedback** on the behaviour (e.g., during face-to-face contacts with a coach) and the use of **adaptive goal setting** (e.g., discussed during face-to-face contacts and/or written in a diary). When using technology mediated interventions ('tele-coaching'), these components are integrated into a system using communication from a distance (e.g., online platform, smartphone application) [33]. The step counter needs to transfer data to the coach or coaching platform; feedback and goal setting are delivered via the coaching platform. The use of digital health in PA coaching programmes thus allows reaching patients from a distance and interacting regularly with patients without increasing the burden on both the coach and the patient [34].

Most research about the effectiveness of PA coaching interventions is available in patients with COPD, as a standalone intervention outside a PR setting. PA (tele-)coaching interventions have been successful to increase PA in these studies (Figure 2, panel A [35-43]); achieving the

minimal important difference in most studies (600-1100 steps per day) [44]. Both coaching and tele-coaching interventions have been tested with comparable effects. However, it should be noted that the intervention effect was mostly described at the short-term only (3-4 months) and long-term effects are uncertain [35]. In patients experiencing an exacerbation, PA coaching during one month after hospital discharge did not have additional effect on PA on top of usual care (Δ steps/day: Intervention 984 \pm 1208, Control 1013 \pm 1275; interaction effect p>0.05); however, this is only based on one pilot study [45]. It is important to notice that these effective PA coaching interventions did not present clinically relevant exercise capacity improvements, with effects ranging between -4 meters and 19 meters when compared to usual care [35, 36, 38, 41-43].

The question remains whether such PA (tele-)coaching interventions can be effectively combined with a PR programme in order to obtain the desired increase in patients' PA levels [2]. Figure 2 Panel B summarises the effectiveness of (tele-)coaching interventions added to a PR programme compared to a group of patients that only received PR [35, 46-49]. All the included interventions used the above-mentioned behavioural strategies (continuous self-monitoring, receiving feedback and goal setting). Of note, two studies not including self-monitoring feedback (e.g., by a step counter) in the behavioural intervention on top of PR did not show an additional effect of the PA intervention (between group difference 300-500 steps/day at the end of the PR program, p>0.05 in both) [50, 51]. Remarkably, none of the interventions added to PR included tele-communication (Figure 2 panel B). This can potentially be explained by the frequent face-to-face contacts between patient and coaches as part of the supervised exercise training programme, making the use of technology in the communication less needed. However, because more and more PR programmes are provided remotely using tele-rehabilitation, technology will likely be also integrated in add-on interventions focusing on PA in the future.

Future work will also need to identify the best timing to start such PA coaching interventions when added to PR. A higher baseline exercise capacity and lower symptom burden have been associated to a larger increase in PA as result of a smartphone based tele-coaching intervention [36]. Because PR is known to result in an increased exercise capacity and an improved symptom burden [3], it might be more effective to start PA coaching at the final stage of a PR programme. A direct estimate of costs related to adding a PA coaching intervention is needed to test the cost-effectiveness. One study estimated the costs for the equipment of a coaching intervention including an activity monitor (ranging between 35 USD and 200 USD) and access to a website (215 USD for a WiFi-enabled iPod) [52]. Costs for the

HCPs providing the coaching were not included. However, the latter seems reasonable considering the limited contact between patients and HCPs during a 3-month semi-automated coaching intervention [34]. Finally, most literature on PA coaching interventions is solely based on patients with COPD. However, maintaining an active lifestyle has also been shown to be important for other respiratory patient populations such as patients with asthma, interstitial lung disease, lung cancer and patients receiving a lung transplantation. Two studies showed the effectiveness of interventions aiming to increase PA in clinically stable adult patients with asthma [53, 54]. In more detail, both studies investigated a PA coaching intervention including self-monitoring by a step counter and goal setting. In the study of Freitas et al [54], patients received a weekly face-to-face counselling session, compared to a weekly phone call in the study of Coelho et al. [53]. Patients received weekly [54] of biweekly [53] a new target. Both studies showed a significant and large increase in daily step count after 8 weeks (mean between-group difference: 3605 steps/day [54]) or 12 weeks (adjusted mean difference: 2488 steps/day [53]). However, when patients in the latter study were followed up, these differences were not sustained 24-28 weeks after randomisation.

To the best of our knowledge, no studies on PA coaching are available in other patient populations with CRD. Future research will need to investigate whether the results found in COPD could be translated to these other populations.

(insert Figure 2 about here)

1c. Digital health as a post-PR resource: maintenance of the effects

One of the main challenges of PR is the maintenance of its effects. Previous research has shown that the benefits of PR tend to diminish over 6-12 months after rehabilitation, unless patients continue to exercise [2, 55]. One previous study showed that 70% of the patients have difficulty in maintaining endurance activities 3 months after PR, and this difficulty is influenced by disease-related symptoms and functional limitations in some patients, while others report barriers to exercise related to costs, family and exercise facilities [56]. Lack of self-efficacy, motivation and fear of exercise without supervision are other common reasons for patients not to engage in exercise/PA behaviours at home [57, 58]. Repeating PR in regular periods can avoid the deterioration in exercise capacity, dyspnoea, and HRQoL [55]. However, it may not be feasible in the long-term for many reasons, including the limited healthcare resources, the already low accessibility of PR [59], and the rising prevalence of CRDs [60].

This has led to the interest in developing maintenance programmes to sustain the gains achieved with PR [61]. The core component of these programmes is usually exercise training, and they can also include self-management education and support [61, 62]. When supervised, the frequency of supervised sessions is usually inferior to the initial PR programme since it is assumed that patients have already developed skills during the PR programme to self-manage their health independently and, therefore, they need less supervision [61]. Although the optimal means to deliver these maintenance programmes are still unclear [61], digitally delivered home-based maintenance programmes may be a solution, as they can enhance patient engagement in self-management, for example by facilitating long-term integration of exercise routines into daily life, and improve patient-clinician communication [62, 63]. This is an emerging area of research and evidence is still of low-certainty due to the reduced number of studies [15, 61].

To the best of our knowledge, there are only three RCTs implementing digital technology-supported home-based maintenance programmes, two studies from Spain [64, 65] and one from Greece [63], all conducted in COPD. In these studies, maintenance programmes were preceded by an 8-week PR programme including exercise training and education, and were implemented over a period of 10 [65] to 12 [63, 64] months. Studies were focused on different outcomes, although all included at least one outcome measure of exercise capacity and HRQOL. A description of the RCTs is provided in supplementary material (Table S2).

The study from Vasilopoulou and colleagues [63] compared a home-based maintenance tele-rehabilitation programme with a hospital-based programme, both implemented after PR, and with usual care [63]. The authors found that tele-rehabilitation was equally effective as hospital-based rehabilitation in maintaining the improvements achieved with the initial PR programme in exercise capacity, symptoms, PA and HRQoL, and both interventions led to a significantly lower rate of acute exacerbations (home-based tele-PR: incidence rate ratio (IRR)=0.517, 95%CI 0.389–0.687; hospital-based PR: IRR=0.635, 95%CI 0.473–0.853, p<0.05) and hospitalisations for acute exacerbations (home-based tele-PR: IRR=0.189, 95%CI 0.100–0.358; hospital-based PR: 0.375, 95%CI 0.207–0.681, p<0.05). Furthermore, the tele-rehabilitation programme (but not the hospital-based programme) was an independent predictor of emergency department visits (home-based tele-PR: IRR=0.116, 95% CI 0.072–0.185, p<0.001).

Adherence to the tele-rehabilitation programme was 93.5%, showing that this type of intervention is feasible. Both tele-rehabilitation and hospital-based interventions showed better results in exercise capacity, symptoms, physical activity, and HRQoL compared to usual

care (p<0.05), which was already expected as, in this study, the usual care group did not receive initial PR [63]. A previous Cochrane review concluded that additional RCTs comparing (initial) PR to usual care are no longer required in COPD, as the benefits of PR are well-documented and support its implementation as a cornerstone of COPD management [3]. However, PR is not yet a common service provided to suitable patients in many countries [1, 59], including in Greece, where the study was conducted [63].

The other two studies compared a maintenance tele-rehabilitation programme with advice to keep physically active (not supervised) [64, 65]. These studies found that tele-rehabilitation programmes did not significantly or clinically improve patients' exercise capacity and HRQoL, although they were feasible, safe [64] and well accepted by most patients [65].

The small number of studies and the heterogeneity of methodologies hinder conclusions about the role of digital health in maintaining PR effects. Some characteristics were common among studies, such as the inclusion of an individualised exercise training component, a mobile interface for patients to record data and/or receive feedback, pre- and/or post-exercise remote monitoring, and a web-based platform for HCPs to review the data on a regular basis and respond appropriately, if required. Nevertheless, studies diverged in the type of technology employed and its features, components of the maintenance intervention (e.g., exercise training, education, monitoring), equipment required for the exercise training component, type/timing of training provided on how to use the technology, and frequency of contact with HCPs (not reported in two studies [64, 65]). Previous research has shown that professional support after PR is highly valued by patients to enhance their motivation to remain physically active [57, 58]; therefore, it should be a component to consider in future studies. The initial PR programme may also play a role in the success of these interventions, as patients need to achieve sufficient gains during PR to be sustained with the maintenance programme [62]. From the studies presented above, only one clearly showed clinical and/or significant improvements in symptoms, exercise capacity and HRQoL after the initial PR [63].

Findings highlight the need for future research to identify the best mode(s) of implementing digital health in maintenance programmes and to understand its value as a long-term strategy to sustain PR benefits. There are still some questions and areas for future work. First, it would be important to assess the cost-effectiveness of maintenance interventions to justify the resources involved [15]. In their study, Vasilopoulou and colleagues [63] estimated the total cost per patient of the 12-month maintenance tele-rehabilitation programme including the equipment, development of the digital platform, use of 3G network and cost for personnel (1800€). The authors concluded that it was equivalent to approximately 60% of the estimated

total cost saved by reducing the frequency of acute exacerbations and approximately 40% of the estimated cost for 1 year of hospital-based outpatient maintenance rehabilitation sessions [63]. Nevertheless, in this study, no specialised equipment for home-based exercise training was required [63], while in the study of Galdiz et al. [64] an exercise bicycle and dumbbells were provided for patients to continue exercising at the same intensity as in the initial PR. Second, it would be important to determine the 'best candidates' for a home-based telerehabilitation maintenance programme. Although the abovementioned RCTs showed good adherence rates (except for one study [64], 60%), patients often identify barriers and difficulties when using digital technology which should be taken into account when defining the maintenance strategy (this topic will be addressed in the next section). Finally, the ability of these maintenance programmes to promote health-enhancing behaviour changes after their completion, including the adoption of regular exercise training autonomously, is still unknown [66], as none of the studies assessed the short- or long-term effects of the maintenance programme.

2. Patients' and professionals' perspectives of digital health (individual level)

To maximise the potential of digitally enabled PR, achieving successful user-adoption is critical. However, poor retention rates related to user-experience issues are commonly cited as negatively impacting user-adoption for respiratory digital interventions [67-69]. To help address these shortcomings, this section aims to provide HCPs interested or involved in PR digital transformation with a brief overview of user and design considerations to support the development of fit-for-purpose interventions. Firstly, let us consider the salient patient and HCP user-adoption barriers and facilitators facing digital interventions in the respiratory context.

2a. Barriers and facilitators to adoption: Patient Perspective

There are still many challenges and unanswered questions regarding patient and HCP adoption of digitally enabled PR [11, 70]. However, recent work has begun to explore the implementation and adoption needs of patients and HCPs for digital health in the management of COPD, much of which is relevant to the design of digital PR interventions [71]. This research suggests that primary barriers facing respiratory patients are a lack of perceived usefulness, digital literacy, and illness perception [71].

Perceived usefulness refers to the degree to which a person believes the digital health intervention could improve or enhance their ability to manage their condition and is a core determinant of sustained engagement [72]. For example, patients may feel that a digital approach will impinge on the benefits of face-to-face contacts, as they may no longer have physical access to HCPs for support and direction [71, 73]. Interestingly, research has found that patients with COPD perceive several potential benefits arising from digital approaches to support self-management which suggests there are cohorts of patients already primed to adopt them [74].

Digital literacy refers to the person's ability to search, acquire, comprehend, and appraise health information from digital technologies with the goal of improving their quality of life [75]. Research has found that patients feel they would disengage from technology if they were unable to understand its use and content within an intervention [71]. Similarly, research with respiratory HCPs highlighted their concerns regarding low levels of health literacy amongst patients [76]. They felt that the added burden of patients needing to understand a digital intervention on top of their already complex treatment plans could lead to disengagement [76].

A patient's illness perception and social context have also been highlighted as barriers to adopting digital interventions [71]. For example, a patient may feel their symptoms are too severe at present to take on the added workload of a digital component or, if patients live on their own, they may not feel confident to use the technology as they lack support to help them navigate the intervention.

Research has also begun to investigate facilitators to support respiratory patients with the adoption of digital interventions [71, 76]. This work highlighted that both HCPs and patients were eager to avoid the assumption that all patients are suitable for a digitally enabled treatment plan. Instead, a patient-centric approach should be considered to evaluate patient characteristics, such as physical and mental wellbeing, levels of health literacy and self-efficacy, and psychosocial status to determine their readiness to adopt the technology. This research also found that patients with existing digital skills, such as experience using a laptop or smartphone, would find it easier to adopt digital health interventions. Assessing the maturity of the technical infrastructure of the patient's home, such as the presence of a stable internet connection and their access to required technologies, like laptop computers or smartphones, has also been identified as a potential facilitator for patients' adoption of digital interventions [11, 18]. Shared decision-making and concordance approaches were favoured as mechanisms for supporting patients to adopt digital interventions. For instance, when

introducing a patient to a digital intervention for the first time, discussing the intentions, concerns and expectations regarding the intervention was perceived as a valuable approach for determining whether to use the technology [76].

2b. Barriers and facilitators to adoption: the HCP Perspective

Research suggests that HCPs perceive the lack of evidence demonstrating the effectiveness of digital health interventions on patient outcomes as a salient barrier to them adopting this model of care [76]. Although digitally enabled PR has accelerated during the pandemic, there is agreement on the need for large-scale, longitudinal studies to demonstrate the cost and clinical effectiveness of digitally enabled PR [70, 77]. Cardiac tele-rehabilitation, for instance, has developed a strong evidence-base, including a Cochrane review demonstrating that this model reduces re-hospitalisations and is equally cost-effective to standard rehabilitation programmes [78, 79]. As a result, cardiac tele-rehabilitation is considered an important secondary cardiovascular prevention component by the European Association of Preventive Cardiology and European Society of Cardiology [79]. In response, the Netherlands made a recent addendum to the Dutch multidisciplinary cardiac rehabilitation guidelines to incorporate tele-rehabilitation, the first country to do so worldwide [79].

Training and resource barriers are also commonly cited by HCPs [73, 76]. Research evaluating HCP's perspectives regarding a virtual PR programme found that more preparation and training time is needed to empower them to identify and address technical issues when they arise [73]. For example, internet connection issues, such as audio-lag, were common and caused problems for patients receiving information in real-time, but HCPs felt this could have been avoided with training [73]. Added staffing resources during the early stages of the programme were also emphasised as HCPs felt they required an extra person to help with the administration and technical aspects as they increased their competencies in managing a virtual PR session [73].

2c. Design considerations: Aim to understand and involve end-users

Researchers have argued that user-adoption issues may occur from an unwillingness to involve key stakeholders, such as patients and HCPs, in the design process [68, 80]. Without their involvement, solutions are often biased by assumptions of what user needs are. Subsequently, if these assumptions are inaccurate, users are less likely to perceive the intervention as useful and user-adoption issues, such as those outlined above, are probable [81, 82]. To address

these issues, user-centric design methods, such as human-centred design and design thinking, are increasingly being accepted as the gold standard when developing digital health interventions [83-87]. Relevant takeaways from user-centric design methods include:

- Consider user-centred research as the starting point of the design process. User-centred
 research primarily employs qualitative methodologies (e.g., interviewing, observations) to
 garner a deeper understanding of end-user behaviour and needs to inform the
 development of relevant use-cases and user-requirements. It is associated with smoother
 implementation, lower attrition rates, increased user-experience, and sustained
 engagement [88-91].
- Consider an iterative, co-design approach. The aim of this approach is to garner feedback early and often from users so that the design can be iterated to ensure the creation of a solution that makes sense and is perceived as useful and useable to them [92, 93]. For example, include patients and HCPs in brainstorming / ideation sessions the aim is to leverage the knowledge from stakeholders to ideate potential solutions; gain feedback on low-fidelity (i.e., early or initial) concepts from end-users which may be as simple as sharing sketches of potential solutions; and test high-fidelity (i.e., close to final version) prototypes, for instance, testing clickable/functional prototypes for usability.

3. Technical, privacy and regulatory issues in digital health (system level)

In addition to the need for successful user adoption of digital health technologies, there are potential challenges regarding technical, regulatory and privacy issues that need to be considered when developing and implementing digitally enabled PR interventions.

3a. Technology and internet access

Digital technologies offer the potential to overcome barriers to accessing PR services (such as travel, transport and location), by increasing coverage in more isolated areas and enabling closer monitoring of patients [1, 25]. However, they may also aggravate the existing access disparities, due to the need of digital technology and appropriate infrastructures, including internet access [7, 94]. Recent studies have found that, while digital technologies are ubiquitous in daily lives of most patients with CRDs, particularly mobile phones [95-97], only a limited number of patients have access to the internet and/or are confident in using it [95-98], which may create a problem of inequitable access to intervention enrolment. These studies

were conducted in high-income countries, and the scenario may be even worse in low- and middle-income countries (LMICs).

Even though internet acceptance has accelerated worldwide during the COVID-19 pandemic, rising from 54% in 2019 to 63% in 2021, nearly 3 billion people remain offline, 96% of whom living in developing countries [99]. Furthermore, the percentage of Internet users in urban areas is twice higher than in rural areas [99] and, in patients with CRD, lack of internet access was related to an older age [96], lower education [95], lower income and the presence of a mobility-related disease [98]. This raises a potential problem of inclusion, as individuals who could benefit most from digital technologies are the least likely to access them.

The growing availability of the internet and mobile phones and the increasing efforts to improve in digital literacy [8], including in the elderly population [100], may help tackle this issue [7]. However, it is acknowledged that digital interventions are not a "one size fits all" approach [25], and there is a need to better understand the characteristics of patients who can benefit most from digital health. Digital home-based programmes may be more suitable for patients with good connectivity and digital self-efficacy, while centre-based programmes may be a better alternative for those who lack the resources or are uncomfortable using technology [94]. The assessment of patients' suitability for digitally enabled interventions may be facilitated by the use of tools such as the 8-item Dutch Blended Physiotherapy Checklist [101]. This checklist consists of 5 items with prerequisite patient characteristics for being suitable for this model of care, including motivation, safety, equipment, digital skills and health literacy, and 3 items focused on characteristics that can influence the appropriate amount of therapeutic guidance alongside a digital technology, related to self-management, time and financial factors [101].

3b. Data protection and technical issues

Another concern is related to patient privacy and data protection [102]. Expanding the use of digital technologies to deliver PR services and health care has been accompanied by a substantial increase in connectivity and exposure, for example by sharing personal data (i.e., information relating to an identified or identifiable person [103]) and/or sensitive data (e.g., health-related data), which may be variable depending on the technology used (e.g., videoconferencing, websites, mobile apps, connected devices) but is present in all [102, 104]. Health institutions are known to be one of the most vulnerable and targeted systems in terms of cyberattacks [104], even more during the COVID-19 pandemic [102], which can ultimately

lead to suboptimal care or harm to people. Therefore, digital health technologies and software systems, particularly when concerning the use of mobile and web-based tools, must comply with the regulatory and ethical principles to ensure data protection and patient privacy and safety, thus preventing health information security breaches. This should be conducted from the early stages of technology design [102]. There are several national and international privacy protection laws, regulations and best practices that can guide this process – some of these resources are provided in the supplementary material (Table S3).

Other common challenges in the use of digital technologies concern technical issues (e.g., development of the system architecture, redundancy in case of system failure, software and/or hardware updating), clinical validation of the technology employed (e.g., device accuracy and calibration to monitor physiological parameters), usability assessment, patient consent for data collection and transfer, and the anticipated impact of the technological solution on the outcome(s) of interest [7, 105]. These challenges highlight the complexity of designing and implementing interventions with digital technologies and the need for the well-coordinated work of a multidisciplinary team, including professionals from the areas of healthcare, informatics, cybersecurity and design to address clinical and technical issues [106]. Stakeholders and policy makers should also be involved to ensure that the digital solution is meaningful but also ethical, safe, valid, reliable and sustainable [8]. Furthermore, it is important to provide training and raise awareness of all stakeholders about digital literacy and security best practices to facilitate adherence [102, 107].

3c. Reimbursement of digitally enabled PR

The use of digital health as a novel form of PR delivery will need to be endorsed by healthcare payers. Recent ERS/ATS statements highlight that payers can be relatively slow to adopt new concepts, and reimbursement issues are present even in 'traditional' (centre-based) PR [1, 108 101]. This reality was temporarily altered in some countries due to the need for social distancing imposed during the COVID-19 pandemic, through the implementation of reimbursement policies that allowed the spread of remote delivery of PR using technologies instead of face-to-face clinical visits [11]. However, it is still uncertain how this situation will evolve in the long run. Regardless of where PR is delivered (centre-based or digital-based PR), one of the main reasons funding and reimbursement remains a challenge is the inadequate awareness among payers of the clinical effectiveness and cost-effectiveness of PR [1]. Therefore, efforts should be made to improve communication about the benefits, costs and

value of PR to policymakers and payers to support the adoption of PR in healthcare systems as a 'standard of care' component for patients with CRDs [1].

Furthermore, as previously mentioned, the success of any PR should be judged on whether the key components are delivered and whether expected patient outcomes are achieved (i.e., improved exercise capacity, symptoms and HRQOL, reduced hospitalisations) [25]. An official ATS report published in 2021 identified 13 essential components of PR that should be delivered in any PR model, including digitally enabled PR, which comprises aspects related to patient assessment, programme content, delivery method and quality assurance [25]. Still, before digitally enabled PR models can be successfully integrated into the healthcare systems and be widely available, more high-quality evidence is needed on their efficacy and (cost-)effectiveness, as well as on the identification of suitable candidates for this model of PR.

Summary of evidence and future directions

The key points of this narrative review are summarised in the infographic presented in Figure 3. Digital health technologies offer several benefits over 'traditional' models of care and provide opportunities to improve PR access and uptake and promote health-enhancing behaviours in patients with CRDs. Nevertheless, there are still several challenges that need to be considered before its widespread implementation. These include, among others, testing different digital enabled interventions to identify the best modes of implementation considering their purpose (i.e., primary PR, PA coaching, maintenance), identification of patients' characteristics most likely to succeed with this type of PR, patients' and HCPs' acceptance of technologies, paucity of high-quality evidence, and technical and regulatory issues. The present narrative review addressed these topics and highlighted the need to conduct more robust research on the use of digital health in PR, including cost-effectiveness analyses to support its future integration into healthcare settings. Nevertheless, findings should be interpreted with caution as this was a narrative review and, thus, it may be subject to study selection bias.

Most of the existing evidence is focused on patients with COPD, as it is the most prevalent CRD worldwide and one of the top 10 causes of mortality and leading causes of disability [109]. Future studies should also focus on other CRDs. Furthermore, some of the studies included in this review lacked information on patient selection and intervention description, which emphasises the need for future research to follow proper guidelines for reporting studies in digital health (e.g., mERA guidelines if using mobile phones [110]) and/or exercise training [111].

Finally, to summarise the strengths (S) and weaknesses (W), as well as external opportunities (O) and threats (T) of digital health in PR, a SWOT analysis is presented in Figure 4, based on data obtained from studies presented in the different topics of this review. Importantly, it should be noted that not all models of PR are expected to be equally suitable for all patients with CRD [25] and that digital health is not intended to replace the more 'traditional' centre-based PR programmes. Instead, it is aims to extend the known benefits of PR to a greater number of patients who can benefit from it.

Support statement: HD is a postdoctoral fellow of the FWO Flanders, Belgium. SP is a research assistant of a project funded by Portugal 2020 and Lisboa 2020 (ForPharmacy, POCI_POR Lisboa_Projeto_70053), supported by COMPETE-FEDER. JC and SP acknowledge the support of the Center for Innovative Care and Health Technology (ciTechCare), funded by Portuguese national funds provided by Fundação para a Ciência e Tecnologia (FCT) (UIDB/05704/2020).

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Tables

Table 1. Overview of digital delivery modes and content of Pulmonary Rehabilitation.

Mode	Videoconference, supervised, in groups	Mobile/tablet application plus telephone/chat support, Individualised	Website, and possible query via website or Phone/mail support (chat)	Website with no support, Individualised
Studies	Cox et al. 2021 (n= 142) [24] Hansen et al. 2020 (n=134) [18] Tsai et al. 2017 (n=36) [21]	Cerdán-de-las-Heras et al. 2021 (n=29) [22] Cerdán-de-las-Heras et al. 2021 (n=54) [23] Kwon et al. 2018 (n=58) [19]	Bourne et al. 2017 (n=90) [16] Chaplin et al. 2017 (n=103) [17]	Tabak et al. 2014 (n=30) [20]
Programme format	Primary PR 2-3 sessions/wk. 30-60min/session 8-10 weeks Education themes [18, 24]	Primary PR 3-5 sessions/wk. 10-30min/session 7-8 weeks Self-management webmodules [22, 23]	Primary PR 3-7 sessions/wk. Not stated min/session 6-8 weeks Self-management webmodules	Primary PR 7 sessions/wk. Not stated min/session 9-months Self-management web- modules
Technical skills	No technical level required [18] Required technical level [21] Not stated [24]	Knowledge of android OS	Required technical level	Required technical level
Exercise content aerobic training	Stepping Major muscle group exercises Indoor cycling Walking programme	Walking programme Stepping	Calisthenics Walking programme	Calisthenics Pedometer
Exercise content resistance training	Major muscle groups for upper and lower body and limbs	Upper and lower limbs exercises	Upper and lower limbs exercises	Upper and lower limbs exercises
Equipment	Stationary bike	Water bottles	Water bottles	Water bottles

	Body weight	Body Weight	Body weight	Body weight
	Dumbbells	TheraBand	Dumbbells	Pedometer
	Step box	Step box		Video illustrated exercises
Monitoring during programme	Pulse oximeter Exercise diary BORG-CR10 Repetitions	Pulse oximeter	Registry of web-usage Milestone program visualisation Exercise diary Visual analogue scale for intensity/difficulty BORG-CR10	accelerometer-based activity sensor
In-clinic assessments and outcomes	6MWD 30secSTS ISWT ESWT CAT HADS EQ-5D CCQ CRQ PRAISE PA (steps per day) Adverse events Admission Mortality	6MWD CRQ SGRQ GAD-7 PA	6MWD ISWT ESWT CAT HADS SGRQ CRQ PRAISE EQ5D-5L BCKQ mMRC Adverse events	6MWD CCQ MFI-20 EQ-5D MRC PA ED visit LOS

Abbreviations: 6MWD: 6-Minute Walk Distance; 30secSTS: 30-seconds Sit-to-Stand; ISWT: Incremental Shuttle Walk Test; ESWT: Endurance Shuttle Walk Test; CAT: COPD Assessment Test; HADS: Hospital Anxiety and Depression Scale; EQ-5D: EuroQol 5-Dimension; CCQ: Clinical COPD Questionnaire; CRQ: Chronic Respiratory Questionnaire; PRAISE: PR Adapted Index of Self-Efficacy; PA: Physical Activity (steps per day); SGRQ: St George's; GAD-7: General Anxiety Disorder-7; BCKQ: Bristol COPD Knowledge Questionnaire; mMRC: Modified Medical Research Council Dyspnoea Score; MFI-20: Multidimensional Fatigue Inventory; ED: Emergency Department; LOS: Length of Stay.

Figures

Figure 1. Between-group differences in the outcome measures at the end of digital pulmonary rehabilitation, compared to center-based pulmonary rehabilitation or usual care. Figures a-b: differences in exercise tolerance; c-f, differences in symptoms.

Legend: CAT, COPD Assessment Test; CRQ-Dyspnea, Clinical Respiratory Questionnaire - Dyspnea; HADS-A, Hospital Anxiety and Depression Scale - Anxiety; HADS-D, Hospital Anxiety and Depression Scale - Depression; ISWT, incremental shuttle walk test; 6MWT, 6-minute walk test.

Figure 2. The effectiveness of physical activity (tele)coaching.

Open bars present coaching programmes, solid bars present the effect of tele-coaching programmes. * statistically significant between-group difference. The dotted lines present the lower and upper limit of the MID (600-1100 steps per day) [44]. *3-month intervention followed by 9 months of follow up; *9-weeks coaching intervention, of which the first 3 weeks were added to Pulmonary Rehabilitation (PR).

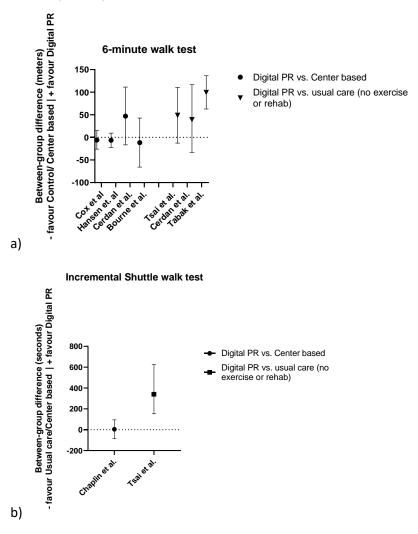
Figure 3. Infographic summarising the key points identified in this review on the role of digital health in Pulmonary Rehabilitation.

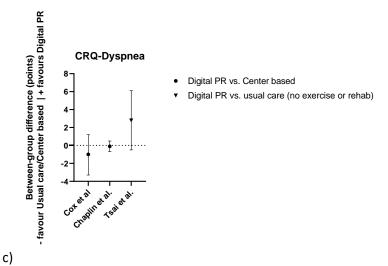
Legend: PA, physical activity; PR, Pulmonary Rehabilitation. Icons were retrieved from the Microsoft® Office Powerpoint® (Microsoft Corporation, United States) and the free icon website The Noun Project (https://thenounproject.com/).

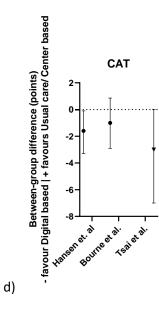
Figure 4. A SWOT (strengths, weaknesses, opportunities and threats) analysis of digital health in the context of Pulmonary Rehabilitation.

Legend: PA, physical activity; PR, Pulmonary Rehabilitation.

Figure 1. Between-group differences in the outcome measures at the end of digital pulmonary rehabilitation, compared to center-based pulmonary rehabilitation or usual care. Figures a-b: differences in exercise tolerance; c-f, differences in symptoms. Legend: CAT, COPD Assessment Test; CRQ-Dyspnea, Clinical Respiratory Questionnaire - Dyspnea; HADS-A, Hospital Anxiety and Depression Scale - Anxiety; HADS-D, Hospital Anxiety and Depression Scale - Depression; ISWT, incremental shuttle walk test; 6MWT, 6-minute walk test.

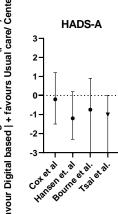






- Digital PR vs. Center based
- ▼ Digital PR vs. usual care (no exercise or rehab)

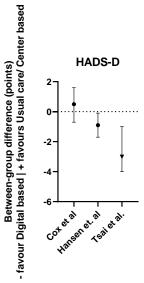
Between-group difference (points) - favour Digital based | + favours Usual care/ Center based



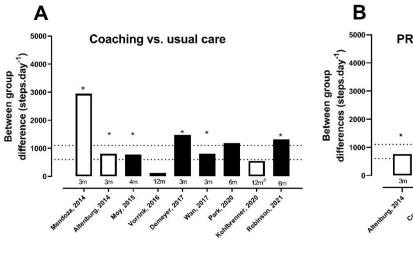
- Digital PR vs. Center based
- ▼ Digital PR vs. usual care (no exercise or rehab)

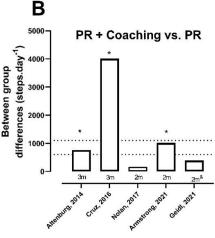
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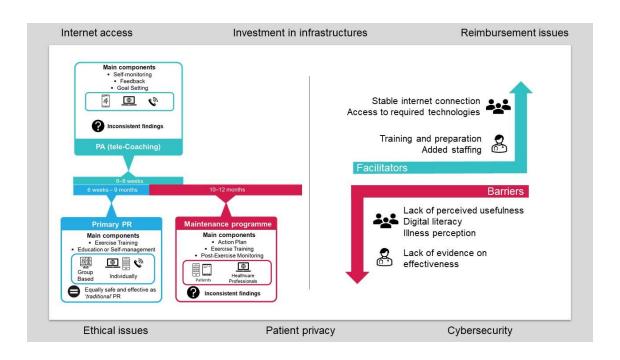
f)



- Digital PR vs. Center based
- ▼ Digital PR vs. usual care (no exercise or rehab)









- · Potential to address barriers found in 'traditional' PR
- · High completion rates and safety
- Enables healthcare professional patient communication
- · Possibility of lifestyle behaviour change strategies (e.g., PA)
- · Consistent with the principle of personalised rehabilitation
- Potential to decrease health-related costs
- · Potential to early detect acute exacerbations

SWOT

Threats

Weaknesses

· Need for users to have technical skills

· Need for in-person assessment

· Lack of evidence on the best models and effectiveness

Need for identification of the 'best candidates'

· Investments in technology and infrastructures

- · Different levels of digital literacy among patients
- Data security and privacy issues
- · Internet access and technological inequities
- · Lack of perceived usefulness and illness perception from patients
- Possible sense of added burden and workload by HCP
- · Limitation of patient autonomy on self-management

Opportunities

- Recognition of digital health as a useful resource by international societies (e.g., ERS, ATS)
- · Decreasing cost of technology
- · Improved ease and simplicity of device use (usability)
- · Ubiquity of digital technology in daily lives
- · Increasing use of co-design approaches

Supplementary material

Table S1. Between-group differences in the outcome measures at the end of the digital rehabilitation, compared to center-based pulmonary rehabilitation or usual care.

Mode	Videoconference, supervised, in groups	Mobile/tablet application plus telephone/chat support, Individualised	Website, and possible query via website or Individualised Phone/mail support (chat) Individualised	ort,
Studies	Cox et al. 2021 (n= 142) [1]	Cerdán-de-las-Heras et al. 2021 (n=29) [4]	Bourne et al. 2017 (n=90) [7] Tabak et al. 2014 (n=30) [9]	
	Hansen et al. 2020 (n=134) [2]	Cerdán-de-las-Heras et al. 2021 (n=54) [5]	Chaplin et al. 2017 (n=103) [8]	
	Tsai et al. 2017 (n=36) [3]	Kwon et al. 2018 (n=58) [6]		
Digital	6MWD	6MWD	6MWD	
rehabilitation	-6.0 meters [-26; 15] [1]	47 meters [-16,5;111.3] [5]	-11.5 meters [-65.7; 42.7] [7]	
vs.	-6.3 meters [-22.1; 9.5] [2]			
center-based		GAD-7	ESWT	
	ESWT	-3.0 [-6.5; 0.5] [5]	4.5 sec [-84; 94] [8]	
	340 sec [153; 620] [3]			
		SGQR total	CRQ-D	
	CRQ-D	-2.13 [-11.84;7.59] [5]	2.8 points [-0.5; 6.1] [8]	
	-1.0 point [-3.3; 1.2] [1]			
		Adverse events	CAT	
	CAT	No adverse events recorded [5]	-1.0 point [-2.9; 0.86] [7]	
	-1.6 point [-3.3; -0.1] [2]			
			HADS-total score	
	HADS-A		-0.74 [-3.5; 0.9] [7]	
	-0.2 [-1.5; 1.2] [1]			
	-1.2 [-2.3; 0.2] [2]		Adverse events	
			Back pain, inguinal pain equally	
	HADS-D		reported (n=3) [7]	
	0.5 [-0.7; 1.6] [1]			
	-0.9 [-1.7; -0.1] [2]		EQ-5D change not reported by	
			Chaplin et al. [8]	
	EQ-5D-VAS			
	0.30 [-5.74; 6.34] [2]		PRAISE change not reported by	
			Chaplin et al. [8]	
	CCQ [2]			
	CCQ function -0.2 [-0.55; 0.15]		SGRQ	
	CCQ mental -0.1 [-0.59; 0.39]		-4.2 [-10.5; 2.5) [7]	
	CCQ symptom -0.1 [-0.45; 0.25]			
	CCQ total -0.2 [-0.42; 0.2]			
	PRAISE cox et al			
	1.0 [-1.1; 3.0]			
	Hospital admission			

	62 vs 50 (p=0.9) [1]		
	21 vs20 (p=0.7) [2]		
	Mortality		
	1 vs 2 (p=1.0) Hansne et al.		
	Adverse events		
	Drop out due to pain (n=2) in the knee and groin, both in the		
	center-based group [2]		
Digital	6MWD	6MWD	6MWD
rehabilitation	49 meters [-12.6; 110.6] [3]	39.5 meters [-33; 116.6] [4]	99.6 meters [62.9; 136.4] [9]
vs.			EQ-5D-VAS (3-month)
usual care	CRQ-D	GAD-7	10.8 [8.00; 13.60] [9]
(no exercise or	-0.1 point [069; 0.49] [3]	Group difference not calculated [4]	, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
rehab)	- Professional Control	, ,	MFI-20 (3-month) Tabak et al
,	CAT	KBILD	Group difference Not
	-3 points [-7; 0] [3]	Group difference not calculated [4]	calculated
	5 points [7, 6] [5]	Group amerence not calculated [1]	carcalatea
	HADS-A	SGQR	CCQ (3-month) tabak et al.
	-1 [-3; 0] [3]	Group difference not calculated [4]	Group difference not
			calculated
	HADS-D	Adverse events	
	-3 [-4; -1] [3]	No adverse events recorded	LOS (3-month)
	- () 1(-1		22days vs. 26 days [9]
	Adverse event		,,. [2]
	No adverse events recorded [3]		ED (3month)
			5 vs. 5 [9]
			[0]
			Adverse events
			No adverse events recorded
			[9]

Abbreviations: 6MWD: 6-Minute Walk Distance; ESWT: Endurance Shuttle Walk Test; CAT: COPD Assessment Test; HADS-A: Hospital Anxiety and Depression Scale – Anxiety; HADS-D: Hospital Anxiety and Depression; EQ-5D: EuroQol 5-Dimension; CCQ: Clinical COPD Questionnaire; CRQ-D: Chronic Respiratory Questionnaire - Dyspnea; SGRQ: St George's; GAD-7: General Anxiety Disorder-7; mMRC: Modified Medical Research Council Dyspnoea Score; MFI-20: Multidimensional Fatigue Inventory; ED: Emergency Department; LOS: Length of Stay.

Note: Positive results favor the digital rehabilitation group, except for the mMRC, CAT and HADS.

Table S2. Summary of the interventions and outcomes of randomised controlled trials implementing technology-supported maintenance programmes after pulmonary rehabilitation (n=3).

First author	Participants	Intervention group (IG)	Comparison group (CG)	Assessment period and outcomes	Main findings
(year)					
Galdiz (2021)	Clinically stable	IG (n=46)	CG (n=48)	Assessment period:	No significant between-group
[10]	patients with	Initial PR: 8-week hospital-based	Initial PR: 8-week hospital-based	0 (baseline, post-PR) and 12	differences or clinically
	moderate to	outpatient PR	outpatient PR	months	meaningful differences were
	severe COPD				found for clinical measures
	according to the	Maintenance:	Maintenance: No	Clinical measures:	(p>0.05)
	BODE index [11]	Duration: 12 months	Duration: 12 months	AECOPD	• 56 AECOPD in IG vs. 47 in CG
	(score 3-7)	Components: home-based maintenance	Components: Advice to walk at least 1	Exercise capacity (6MWT)*	(p>0.05)
		telerehabilitation programme:	hour daily or cycle as in the initial PR;	Health-related quality of life (SF-	Dropouts/excluded from
		1) individual action plan;	general educational material	36, CRQ)	analysis: 5 IG, 8 CG
		2) exercise training as in the initial PR, with		BODE index	Adherence (IG): 60%
		pre-/post-exercise remote monitoring (HR,			No adverse events were
		SpO2, dyspnoea and leg discomfort 0-10		Adherence to the intervention (IG	reported (IG)
		Borg scale);		- non-adherent if no exercise	
		3) access to the call centre (if any technical		performance in ≥8 weeks) ^a	
		issues).			
		Supervision: a physiotherapist periodically			
		monitored the exercises through the web-			
		based platform for feedback (not specified			
		how/when).			
		Technology and equipment:			
		1) Mobile phone with an app (TelePR);			
		2) pulse oximeter;			
		3) dumbbells;			
		4) exercise bicycle;			

		5) web-based platform for healthcare			
		professionals.			
		Training: Instruction guide to use the			
		mobile phone			
Jiménez-Reguera	Clinically stable	IG (n=20)	CG (n=24)	Assessment period:	No between-group differences in
(2020) [12]	patients with	Initial PR: 8-week hospital-based	<u>Initial PR</u> : 8-week hospital-based	0 (baseline, pre-PR), 2 (post-PR), 6	clinical measures at 6 and 12
	COPD GOLD 2-4	outpatient PR	outpatient PR	and 12 months	months (p>0.05)
	[13]				Between-group differences in
		Maintenance:	<u>Maintenance</u> : No	Clinical measures:	treatment adherence and
		Duration: 10 months	Duration: 10 months	Exercise capacity (6MWT)	physical activity adherence at 12
		Components: integrated care plan using a	Components: Advice to perform	Health-related quality of life (CAT,	months (p<0.05) (physical
		web-based app:	physical activity and breathing	SGRQ, EuroQOL-5D)	activity adherence: 25% in IG vs.
		1) daily recording of medication intake,	exercises daily		11% GC)
		exercise time, post-exercise dyspnoea (0-		Adherence*:	Adherence to the app (IG only):
		10 Borg scale), and mood;		Treatment adherence (modified	almost daily recordings (242
		2) weekly and monthly goals (not		CAP FISIO questionnaire)	records/patient in 10 months),
		specified), warning signs, and educational		Adherence to physical activity	~92% patients exercised daily
		content.		(modified Morisky-Green Test)	Dropouts: 8 (various reasons)
		Supervision: healthcare professionals		Adherence to the intervention (IG)	
		accessed data and recorded			
		weekly/monthly goals, with minimal			
		intervention and presence.			
		Technology and equipment:			
		1) Mobile phone with the HappyAir app			
		and Google Fit app (for manual insertion of			
		steps in the HappyAir app);			
		2) Pulse oximeter (manual insertion of			

		SpO2);			
		3) web-based platform for healthcare			
		professionals.			
		Training: one 3-4h educational session on			
		the use of the app, after PR, plus online			
		support aid			
Vasilopoulou	Clinically stable	IG (n=50)	CG1 (n=50)	Assessment period:	Lower rate of AECOPD and
(2017)[14]	patients with	Initial PR: 8-week hospital-based	Initial PR: 8-week hospital-based	0 (baseline, pre-PR), 2 (post-PR)	hospitalisations in the IG and
	COPD GOLD 2-4	outpatient PR	outpatient PR	and 14 months	CG1 vs. CG2 (p<0.001);
	[13]				Lower rate of ED visits in the IG
		Maintenance:	Maintenance:	Clinical measures:	vs. CG1 and CG2 (p<0.001)
		Duration: 12 months (144 sessions)	Duration: 12 months (96 sessions)	AECOPD*	Maintenance of
		Components: home-based maintenance	Components: hospital-based	exercise capacity (CPET, 6MWT)	clinical/statistical improvements
		telerehabilitation programme:	outpatient maintenance	physical activity (Actigraph GT3X)	in exercise capacity (p<0.01),
		1) individual action plan;	rehabilitation:	health-related quality of life and	SGRQ, CAT and mMRC, and
		2) UL/LL exercises with video	1) twice weekly exercise training;	symptoms (SGRQ, CAT, mMRC)	physical activity (p<0.05) in the
		demonstrations and walking drills, and	2) dietary advice;		IG and CG1 vs. CG2;
		remote monitoring post-exercise (HR,	3) instructions on breathing exercises	Healthcare use:	Adherence (IG): 93.5% (all
		SpO2, dyspnoea and leg discomfort 0-10	and self-management (early	hospitalisations*	components >90% except HADS
		Borg Scale);	recognition of an AECOPD).	ED visits*	monitoring)
		3) daily steps, spirometry, oximetry and			Dropouts: 3 in the initial PR (IG)
		questionnaires collected twice weekly	CG2 (n=50)	Adherence rate	
		(SGRQ, CAT, mMRC) or monthly (HADS);	<u>Initial PR</u> : No	(actual number of sessions/total	
		4) access to a call centre 5 days/week;		expected number of sessions*100)	
		5) psychological support;	Maintenance: No		
		6) dietary and self-management support	Duration: 12 months		
		via weekly contacts via telephone or	Components: usual care without		

	1.1	100 / 50) 1	
videoconference with h	ealthcare	initial PR (n=50); optimal	
professionals.		pharmacotherapy and vaccination;	
Supervision: data review	wed by healthcare	regular follow-up by a respiratory	
professionals 3-4 times/	week	physician; training on early recognition	
Technology and equipn	nent:	of an AECOPD	
1) Tablet for manual ins	ertion of steps		
(pedometer), remote m	onitoring and		
responses to questionna	aires;		
2) device to collect vital	signs (HR, SpO2)		
and spirometry, and tra	nsmit data to the		
tablet;			
3) web-based platform t	for healthcare		
professionals.			
Training: patients and the	heir relatives		
trained to use the equip	ment during the		
initial PR			
ata. Driman, and paints of studies are identified with *			

Note: Primary endpoints of studies are identified with *.

Legend: AECOPD, acute exacerbation of COPD; CAT, COPD Assessment Test; CG, Control group; COPD, chronic obstructive pulmonary disease; CPET, cardiopulmonary exercise test; HADS, Hospital Anxiety and Depression Scale; HR, heart rate; IG, Intervention group; mMRC, modified Medical Research Council Dyspnoea Scale; PR, Pulmonary rehabilitation; SGRQ, Saint George Respiratory Questionnaire; SpO2, peripheral oxygen saturation; 6MWT, 6-minute walk test.

Table S3. National and international privacy protection laws, regulations and best practices that should be considered during technology design and implementation.

Name	Description	Source
European Union	European legal framework with the purpose of protecting the collection of personal/confidential	https://eur-lex.europa.eu/eli/reg/2016/679/oj
(EU) General	data. It contains information on the principles relating to processing of personal data and	
Data Protection	individual rights (e.g., individual's consent for data collection/transfer).	
Regulation		
(GDPR)		
2016/679		
European Union	ENISA is a centre of network and information security expertise for the EU, its member states, the	www.enisa.europa.eu
Agency for	private sector and EU citizens, working with these groups to develop advice and	
Network and	recommendations on good practice in information security. network and information security	https://www.enisa.europa.eu/publications/healthcare-
Information	throughout the EU. It has several relevant reports, including one which covers functional	certification
Security (ENISA)	requirements for a potential ICT security certification scheme for a healthcare sector (second	
	link)[15].	
Handbook on	This document provides an overview of the EU and Council of Europe legal frameworks and	https://bit.ly/3Mjt4z2
European data	summarizes major rulings of the EU Court of Justice and the European Court of Human Rights.	
protection law		
(2018)		
Health Insurance	The HIPAA Privacy Rule governs, in general, the use and disclosures of protected health	https://www.hhs.gov/hipaa/for-professionals/index.html
Portability and	information in the United States. The HIPAA Security Rule contains security standards for	
Accountability	protecting electronic protected health information. The healthcare sector has heightened	
Act (HIPAA)	vulnerability to cyber attacks, and these incidents can lead to suboptimal care or harm to people.	
Privacy and		
Security Rules		
(US)		
NIST Health IT	This programme aims to help improve the quality and availability of healthcare and reduce	https://www.nist.gov/healthcare

programme	healthcare costs by enabling the development and harmonization of standards for health IT	
	technologies, creating a health IT technology testing infrastructure, and supporting the usability	https://docs.broadcom.com/doc/adoping-the-nist-cybersecurity-
	of health IT technologies, among others. They have also a White paper on "Adopting the NIST	<u>framework-in-healthcare-en</u>
	Cybersecurity Framework in Healthcare" (second link).	
RECODE Health	Checklist and other resources to support stakeholders involved in digital health research process,	https://recode.health/about/
	aiming to increase awareness of ethical principles and practices from the earliest stages of	
	technology design to the deployment of digital health research. It includes a framework which	
	addresses four intersecting domains including: access and usability, risks and benefits, privacy,	
	and data management.	
SANS Health	This web platform on cybersecurity aims to provide training and education for cybersecurity	https://www.sans.org/blog/sans-healthcare-security-resources/
Care Security	professionals and it has a specific section on cybersecurity in health care, with information	
Resources	provided in different formats including webcasts, whitepapers, and other resources.	
WHO Practical	This document provides guidance to improve the quality and value of monitoring and evaluation	https://apps.who.int/iris/handle/10665/252183
guide for	efforts in the context of digital health interventions, including technical functionality and	
monitoring and	feasibility.	
evaluating digital		
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