

User-centred design of ChestCare: mHealth app for pulmonary rehabilitation for patients with COPD; a mixed-methods sequential approach

Suad J. Ghaben^{1,2} , Arimi Fitri Mat Ludin³ , Nazlena Mohamad Ali⁴
and Devinder Kaur Ajit Singh¹ 

Abstract

Background: The increasing prevalence and burden of chronic obstructive pulmonary disorder (COPD), the challenges in implementing pulmonary rehabilitation (PR) programs and the limited availability of alternatives and supportive programs to serve patients with COPD necessitate the development of pulmonary telerehabilitation (PTR) systems to provide patients with COPD with PR programs.

Objective: This study aimed to design and develop the ChestCare mobile Health app using user-centred design (UCD) approach. Thus, it provided PTR for patients with COPD, enhancing their self-management of symptoms and improving their compliance with PR programs.

Methods: In this mixed-methods sequential research, we deployed the UCD iterative design through the prototype app design and development sequence. The first phase was built based on the results of a previous needs assessment study and an analysis of related apps. This produced the initial mock-up, the foundation for the focus group discussions with physiotherapists and patients. Six physiotherapists with cardiorespiratory specialisation evaluated each app module and item of the latest mock-up using the content validity index (CVI) document. The I-CVI (S-CVI/Ave) and (S-CVI/UA) were computed. Qualitative and quantitative data were integrated, and decisions were made by comparing their results.

Results: The UCD iterative design through sequential MMR has generated four mock-up app versions. The latest version identified 13 modules through 150 items validated by six experts using a CVI document. The I-CVI calculation of 145 items was 1, while 0.83 for the remaining items, was within accepted values. The S-CVI scored 99.4, indicating an overall validity of the ChestCare app as a PTR system for patients with COPD.

Conclusions: The development and validation of the ChestCare app resulted from conducting UCD iterative design and sequential MMR, which identified 13 functionalities, including symptom assessment, tracking lung volume, functional capacity test, action plan, intervention program, COPD education, COPD community, monitoring and reminders.

Keywords

UCD, COPD, mHealth, telerehabilitation

Submission date: 22 May 2024; Acceptance date: 7 November 2024

¹Physiotherapy Programme & Center for Healthy Ageing & Wellness, Faculty of Health Sciences (H-CARE), Universiti Kebangsaan Malaysia, Kuala Lumpur, Malaysia

²Department of Physiotherapy, Faculty of Applied Medical Science, Al Azhar University, Gaza, Palestine

³Biomedical Science Programme & Center for Healthy Ageing and Wellness (H-CARE), Faculty of Health Sciences, Universiti Kebangsaan Malaysia, Kuala Lumpur, Malaysia

⁴Institute of Visual Informatics (IVI), Universiti Kebangsaan Malaysia, Bangi, Malaysia

Corresponding authors:

Suad J. Ghaben, Physiotherapy Programme & Center for Healthy Ageing & Wellness, Faculty of Health Sciences (H-CARE), Faculty of Health Sciences, Universiti Kebangsaan Malaysia, Jalan Raja Muda Abdul Aziz, Kuala Lumpur 50300, Malaysia; Department of Physiotherapy, Faculty of Applied Medical Science, Al Azhar University, Gaza 00970, Palestine.
Email: s.ghaben@alazhar.edu.ps

Arimi Fitri Mat Ludin, Biomedical Science Programme & Center for Healthy Ageing and Wellness (H-CARE), Faculty of Health Sciences, Universiti Kebangsaan Malaysia, Jalan Raja Muda Abdul Aziz Kuala Lumpur 50300, Malaysia.
Email: arimifitri@ukm.edu.my



Introduction

Background

Chronic obstructive pulmonary disorder (COPD) is ‘a heterogeneous lung condition characterised by chronic respiratory symptoms (dyspnea, cough, expectoration, exacerbations) due to abnormalities of the airways (bronchitis, bronchiolitis) and/or alveoli (emphysema) that cause persistent, often progressive, airflow obstruction’.¹ It is the third most common cause of death,² and the sixth most common cause of disability globally.³ It affects 4% of the global population, with higher prevalence and premature mortality in the lower- and middle-income countries (LMICs).³ Pulmonary rehabilitation (PR) COPD is effective in enhancing physical endurance, managing breathlessness, improving patients’ quality of life (QoL) reducing hospital admission and likely enhancing survival.^{4–6} However, environmental, personal, professional and institutional factors limit referral, uptake, compliance and completion of PR programs.^{7–10} Despite its growing economic and societal burden,² COPD remains a low-priority issue in healthcare policy worldwide,¹¹ especially in LMICs.^{12,13} This identifies the necessity of developing user-centred PR programs, such as pulmonary telerehabilitation (PTR) programs to overcome this issue. Pulmonary telerehabilitation is also recommended by the American Thoracic Society and the European Respiratory Society.⁴

Self-management is the most appropriate and successful approach for managing chronic health conditions’ recurrent, long-lasting and slowly progressive nature and their progressively increasing burden. Self-management (SM) offers continuous management, motivation and monitoring, along with the utilisation of self-regulation skills.^{14–18} Self-management has been the common feature of most mobile health (mHealth) apps designed for COPD over the last five years.^{19–23} Other objectives were to monitor symptoms and medicine adherence,^{19,22,23} and to enhance exercise capacity.²⁰ These objectives were achieved by developing certain features and modules, including the diagnosis, supervised intervention, behavioural change and self-management exemplified in monitoring and education.^{19–23} In some cases, the apps were backed with hardware to track symptoms.^{19,22,23} Self-management involves the transfer of information to the patients along with fostering their ability to utilise their self-regulation skills to manipulate risk factors, engage in healthy behaviours, and therefore, control chronic disease.^{18,24} This requires encouraging specific skills such as reflective thinking, setting goals, self-evaluating and monitoring, decision-making, undertaking specific behaviours, implementing coping mechanisms and managing physical, emotional and mental reactions to changes in health conditions.^{14,18,25} The prevalence of COPD increases significantly with age,

particularly above 60,²⁶ and the ‘grey digital divide’ challenges the integration and benefits of the digital revolution for the elderly, especially in healthcare.^{27,28} The elderly-associated frailty and comorbidities that would impede their ability to use the mHealth technology should be considered.

Mobile Health is defined by the World Health Organization (WHO) as the mobile-supported medicine and public health practice.²⁹ Mobile Health is a form of telerehabilitation (TR) system that is generally employed to deliver basic rehabilitation functionalities: evaluation including diagnosis, supervised intervention, self-management, behavioural change, psychosocial support, monitoring and follow-up.^{30,31} While mHealth apps have the potential to enhance patients’ health and improve QoL, there is a lack of robust evidence, as well as a lack of guidelines for the development and evaluation of the mHealth apps by the regulatory bodies worldwide.^{30,32} Another aspect of mHealth is the schism, which identifies the distinction between market-driven mHealth and science-driven mHealth, and highlights the necessity for developing standardised and sustainable mHealth systems, interventions and ecosystems to support science-driven mHealth.³³

The mHealth provides advantages over the conventional healthcare delivery system, including promoting and enhancing patient-centred care, patient-therapist engagement, resource-limited service delivery and patient empowerment exemplified in behavioural changes and self-management.³⁴ In addition to its extensive accessibility, portability, cost-effectiveness and data resourcefulness.³⁴ The development, evaluation and deployment of mHealth apps face challenges due to the complexity of generating evidence, interaction difficulties and a rigid ecosystem that restricts the transferability of app-related evidence. Additional challenges include the limited generalisation as different apps may yield different outcomes; the diagnostic potential associated with clinical outcomes; and the unavailability of consolidated purchasing mechanisms.^{32,34} Institutional challenges of mHealth deployment comprise the lack of funding, issues integrating health solutions with electronic health records and organisational, technical and human resources to support project implementation.³⁵ World Health Organization has provided the SMART guidelines to facilitate the localisation and deployment of digital systems, including mHealth. Developers, technologists and even countries were instructed to localise, institutionalise, integrate and upgrade digital systems in compliance with the scientific evidence.³⁶ The WHO has also prioritised developing and implementing the mHealth program, notably for NCDs, to foster universal health coverage.³⁷

The COPD burden and the challenges of managing COPD in Malaysia are aligned with those related to the worldwide situation, including underdiagnosis,³⁸ under-

recognition^{11,13} and underdevelopment of PR programs.³⁹ There is a high prevalence of COPD in the Malay Archipelago, which equals 16–20%,⁴⁰ with moderate to severe prevalence in Malaysia, where about 448,000 cases (4.7%) were reported two decades ago and are likely to increase.⁴¹ In 2019, Malaysia's annual management cost per patient was calculated at US \$2206.68, with workplace productivity losses of 31.87% and activity limits of 17.42%.⁴² The social burden was high, compromising QoL and workplace productivity, and the caregiver's social life was also limited by 21.63%.⁴³ Additionally, the limited accessibility to PR programs in Malaysia, the limited availability of alternatives, such as home-based PR,⁴⁴ the low referral rate to PR – in some cases, 16% – and the limited implementation of PR⁴⁵ are aligned with the worldwide challenges.⁷ Limitations to PR implementations in Malaysia encompass the HCPs' lack of knowledge and awareness; lack of structured PR programs; limited resources, including trained personnel and logistics; limited accessibility and high patients' barriers to participation, such as severe illness and comorbidities to attend program requirements; and lack of awareness about PR's effects on health and activity.⁴⁵ Home-based PR programs, as a potential alternative to limited accessible PR, have demonstrated their feasibility, particularly on family roles, and promised to be upgraded to maximise patient benefits.⁴⁴ Telerehabilitation might be a practical alternative to PR. However, Malaysia's lack of urgency to change, lack of awareness and lack of participation in planning and decision-making are limiting factors in establishing PTR programs. Other limiting factors of PTR include inadequate exposure to e-health knowledge, resistance to change, lack of internet connectivity and limited experience with hardware and software use.⁴⁶ Engaging stakeholders and communities in managing respiratory disease and supporting health is promising in providing solutions; however, it is challenging, necessitating effective collaborative work, which is undervalued, underfunded and under-resourced.⁴⁷

The rationale beyond the development of the ChestCare mHealth app was the progressively increasing prevalence and burden of COPD, the challenges in implementing PR programs, and the limited availability of alternatives and supportive programs, such as PTR and mHealth apps to serve the patients with COPD despite their needs to such intervention. 'The ChestCare mHealth app was developed to fulfil the patient's needs and bridge the current gap. This app provides unique functions through its comprehensive examinations and interventions for patients with COPD. It provides education, an interaction platform, reminders and risk factor monitoring. Other apps allow limited examination and interventions; such as daily records of symptoms and weather to plan activities,¹⁹

exacerbation tracking,^{20,21} physical activity^{20,22} and medication tracking.^{19,20} Self-management is the key to ChestCare and other apps.^{21,23} The ChestCare also allows for tracking the lung volume changes throughout treatment, either via the desk spirometer or the forthcoming Smart OPEP.⁴⁸ Finally, the app allows passive patient engagement through examinations and monitoring functions and active engagement through the intervention and COPD community functions'.

This study aimed to design the ChestCare mHealth app using the user-centred iterative design approach. Thus, it provides holistic PTR for patients with COPD, enhances their self-management of symptoms and improves their compliance with PR programs.

Methodology

In this mixed-methods sequential research (MMR),⁴⁹ we followed the proposed Input–Process–Output (IPO) framework³¹ to develop the ChestCare app. We created the initial mock-up based on the results of a study of user requirements (unpublished research), and an analysis of related apps (Figure 1). Then, we conducted qualitative research, including focus group discussions (FGD) with users to build up the complete app prototype, which was subsequently validated in quantitative research via an expert panel. The matured app should be tested in usability, feasibility and efficacy studies.

Phase 1: User-centred design approach

The user-centred design (UCD) highlights the end users' needs through iterative rounds of design, development and adaptations to best respond to users' demands.^{50,51} We implemented the UCD by conducting a needs assessment study and a series of FGDs with physiotherapists and patients, along with content validation by experts.⁵² Each sequence resulted in the development of a version of the ChestCare prototype. Four prototype versions were developed until the actual app was developed, as shown in Figure 1. Users of the ChestCare app were patients with COPD who received physiotherapy interventions or PR, and respiratory physiotherapists providing PR. We explained all study information to the participants before data collection, and the signed informed consent was obtained from individual participants: patients signed the paper consent, while participants of the online FGDs filled in the online demographic form which included the sentence, 'Please be informed that by filling out this form, you provide your consent to participate in this discussion. Your response will be confidential'.

Step 1: Needs assessment. In the mentioned needs assessment study (unpublished research), we asked potential users about their requirements related to the mHealth app,

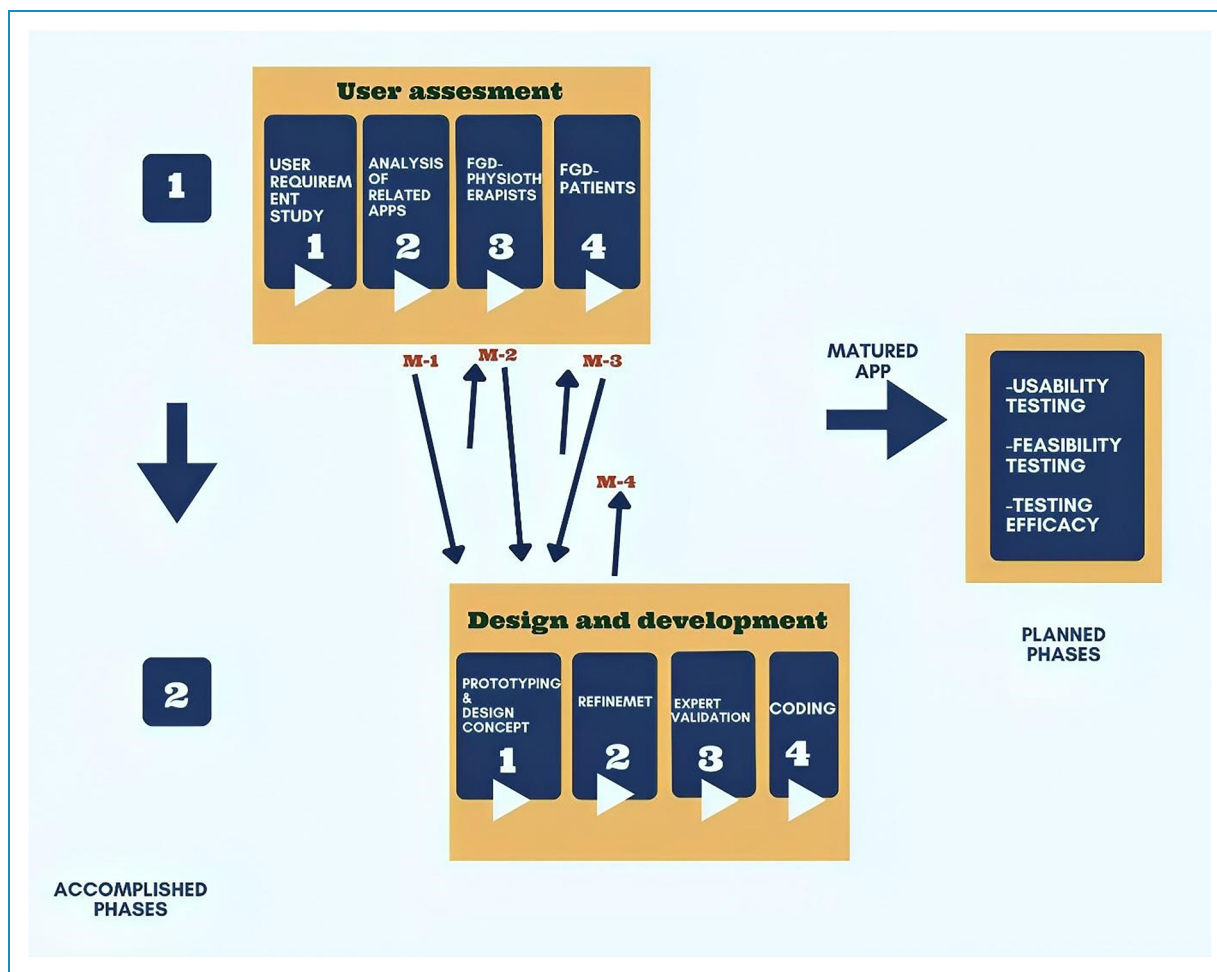


Figure 1. The UCD and the sequence of ChestCare prototyping; (1) the user assessment focuses on the user requirement study, which was augmented by related app analysis to produce the first mock-up (M-1). FGD with physiotherapists and patients has resulted in developing (M-2) and (M-3), respectively. Discussions among the MDT have resulted in refinement and to produce (M-4). (2) The design and development of the app prototype have continued including the validation of the latest version by an expert panel, and finally, coding has been performed.^{31,49–51} The resulting matured app should be tested in usability, feasibility and efficacy studies.

their willingness to collaborate through the app, and the possibility of learning therapeutic exercises and other topics related to their condition through the mHealth app. The participants were physiotherapists and patients with COPD who received in-hospital physiotherapy. All participants were recruited purposely according to the predetermined inclusion criteria, and no incentives were given at this phase.

Step2: Analysis of related apps. The IPO framework highlighted ‘analysis of related apps’ as a possible method to inform the TR system design.³¹ Analysis of related apps would guide the design and development more effectively than copying the app’s functions. Over the last five years, five TR systems were developed to serve patients with COPD.³¹ We analysed these apps based on pre-set criteria, including the app components, objectives, theory-informed

development, main menu and developed modules and functionalities. Integration of the user needs from the needs assessment study and related app analysis has informed the development of the first version of the ChestCare app prototype using mockitt.wondershare website, which encompassed 11 displays.

Sequential FGD

Step 3: FGDs with physiotherapists. We conducted three sequential FGDs with potential users of ChestCare. The participants were recruited purposely according to predetermined inclusion criteria, and incentives were not provided at this step. The first FGD was conducted with respiratory physiotherapists who provided respiratory physiotherapy or PR for patients with COPD, with a minimum experience of three years. The FGD was conducted according to the pre-tested moderator guide, as shown in Supplemental 1. The

framework method of analysing qualitative data,^{53,54} along with deductive coding was adopted; the coding framework was captured from the literature.⁵⁵ The content and layout were reported as essential topics of discussion,⁵⁶ and visuals were also reported as essential.³¹ The visuals were interpreted by the research team as colours and icons. The first FGD was held in March 2023 online via Google Meet, and the meeting was recorded. The discussion was held in English, lasted for 107 min, moderated by SG, a female physiotherapy consultant experienced in qualitative research, and facilitated by a research assistant in physiotherapy. The information sheet was sent to the participants prior to the meeting by email, entailing the objectives of the app and the discussion, as well as the FGD timeline and ground rules. We started the session by asking the participants about their experiences with mHealth apps, followed by a discussion about their perspectives on the app prototype. Supplemental 1 identifies specific questions and the discussion's flow.

The second FGD was held with respiratory physiotherapists in July 2023, adopting the same inclusion criteria. Five therapists participated in an online discussion that lasted for 45 min. SG presented the second version of the app prototype to the participants and enquired about their perspectives regarding the app layout, content, colours and icons.

Step 4: FGD with patients. Participants of the third FGD were patients with COPD who received physiotherapy intervention or PR using the OPEP devices. The participants were recruited purposefully by calling the eligible patients from the list of appointments to the outpatient respiratory clinic. Incentives were not provided at this step. The discussion was held onsite at a hospital with three patients on 6 September 2023. SG initiated the discussion by enquiring about their experience with OPEP devices and mHealth apps; then, SG presented the second version of the app prototype. The patients were asked to provide their perspectives on the proposed app layout, content, colours and icons. The discussion was held in English, video recorded and lasted for 104 min; translation to and from Malay was done by a physiotherapy expert as required due to the participation of a monolingual patient. The analysis of this discussion has resulted in upgrading to the third version of the app prototype, with the addition of two features.

Phase 2: Design and development

Step 1: Prototyping and design concept. The mock-up app was an essential milestone of mHealth design and development.³¹ SG has utilised the mockitt.wondershare website to develop the four versions of the mock-up app. At each milestone, the developed mock-up was discussed with and verified by the research team; the second version of the app

mock-up is shown in Supplemental 2. Then, SG developed the storyboard, which provided a visual guide for the developer and identified the app modules, the steps in using the app and the relationship between displays along with the user journey.^{57,58} The storyboard also identified each step in using the app linked with the input, output and the specified role of each user.⁵⁸

Step 2: Refinement. The multidisciplinary team thoroughly discussed the third version of the app prototype in several rounds of online meetings using Google Meet in November and December, which resulted in the enhancement of the prototype and several technical criteria and features.

Step 3: Expert panel validation. Expert panel validation of the app content is an essential procedure for app development, as proposed by the IPO framework.³¹ Therefore, the research team conducted the content validity evaluation according to the proposed steps.^{59–61} The content validity document aimed to provide the expert panel with a clear understanding of content validation and the app objectives, modules and content. SG prepared the content validity document (form) to encompass clear instructions on the rating scale and a detailed description of the app modules. Hereafter, each module's contents were transferred into items to judge its degree of relevance on a 4-level rating scale: (1) the item is not relevant to the measured domain, (2) the item is somewhat relevant to the measured domain, (3) the item is quite relevant to the measured domain and (4) the item is highly relevant to the measured domain. The research team SG, AFML, NMA and DKAS discussed and agreed on the content validity document (form). Although validating and piloting the content validity document were not essential steps,^{59,60} SG piloted it with one expert and discussed the proposed amendments with the team before the validation.

The selection of the experts was decided based on preset criteria, including respiratory physiotherapists who provided management for patients with COPD, and had a minimum of a bachelor's degree and five years of experience, either from academic or clinical fields. Invitations were sent to potential participants by email. Upon acceptance, the content validity document was sent to each participant by email for review. Then, an online meeting was held to clearly describe the app objectives, modules and contents and present the app prototype.

The evaluation processes encompassed reviewing modules and their items. The ChestCare app included 13 modules with a total of 155 items that covered the user profile, browse contents, assessment and evaluation, supervised intervention, education, COPD community, monitoring and reminder module. The definition and objective of the module, as well as its items, were provided to the experts and supplemented with a 4-level rating scale for

each item. The experts were requested to critique each module and its items and to provide verbal comments to enhance the content validity. Then, the experts were asked to judge the degree of relevance of each item and to complete and send the content validation document within 48 h of the meeting to avoid bias. SG followed up with experts to ensure their response clarity and consistency. Finally, SG computed the I-CVI, the (S-CVI/Ave) and the (S-CVI/UA), and reviewed the results with the research team.

Step 4: Development. The ChestCare mHealth app was developed based on the findings from previous phases. The development of the ChestCare mHealth app used the programming language Typescript or Angular, and the backend used PHP and WordPress CMS.

Data analysis

User requirements and analysis of related apps. Results of the needs assessment study and related app analysis were integrated and merged to identify the content of the intended app, which informed the development of the first version of the app prototype.

Qualitative analysis. The discussions were moderated by SG and facilitated by the moderator assistant, following the pre-tested moderator guide. The discussions were conducted in English and recorded via video. The framework method was applied to analyse the qualitative data^{53,54}; the recorded videos were transcribed verbatim using the Happy Scribe website, and the discussion scripts were revised, verified and reviewed line by line by SG. Deductive coding was applied,⁵⁵ initial codes were generated and grouped into codes that reflected the adopted coding frame (layout, content, colours, icons, suggestions and wish list)^{31,56} by using Microsoft Word. The codes were phrases that enclosed the extracts, and the codes were then discussed with DKAS, AFML and NMA until a mutual agreement was reached. The working analytic framework was developed and applied based on the adopted codes, and finally, data was charted into the framework (Table 2). The required refinements and improvements of the app prototype were identified and applied through three iterations of discussions.

Quantitative analysis. The content validation documents were transferred to Excel format, and the item content validity index (I-CVI) was computed for each item. Results of I-CVI were discussed among the research team to decide on item validation. Afterwards, the (S-CVI/Ave) and the (S-CVI/UA) were computed.

Triangulation. Credible and consistent results required a well-justified MMR design and triangulation methods.^{62,63}

In this study, the qualitative and quantitative data were arranged and integrated by applying recommendations for triangulation and reporting of MMR,^{62,64} which enhanced data and validated results.

Results

The results of this study were obtained from the UCD approach, which included the needs assessment, the related app analysis and the FGDs with therapists and patients. Results were also obtained from the MDT discussions, resulting in refinements and content validation by the expert panel.

Need assessment

Based on the previous needs assessment results, we presented the users' requirements for the TR system. Users were willing to adopt TR and collaborate through the mHealth app, which, in particular, combined diagnostic and therapeutic devices, including the OPEP and spirometer. Users preferred the visual and audio contents of the mHealth app along with the hybrid rehabilitation regime. They were willing to learn therapeutic exercises and related topics through videos, SMS and the mHealth app.

Analysis of related apps

Analysis of five TR systems entailed mHealth apps that were developed for patients with COPD.^{19–23} Adjoined with the identified users' requirements has resulted in identifying the functionalities of the ChestCare app. The results of this analysis are presented in Table 1 and show the ChestCare components, objective, theory-informed development, main menu and modules. Accordingly, SG identified the app displays and discussed the content with AFML, NMA and DKAS until reaching an agreement; initial app sketches were designed, encompassing 11 displays, as shown in Figure 2.

Focus group discussions

Six respiratory physiotherapists with an average duration of experience of 12.4 ± 202 years participated in the first FGD; one held a PhD, three held a bachelor's degree, and two held a diploma in Physiotherapy. Their experience in mHealth apps was limited to the personal use of obesity management apps and the COVID-19 tracking app MySejahtera. Discussions with physiotherapists focused on the app prototype's layout, content, colours and icons, as shown in Figure 3. The wish list and refinements were also included, as described in Table 2. Generally, they described the app layout as simple and easy to understand, with recommendations to add more descriptive icons to the symptoms assessment module and replace words with

Table 1. Applying related apps analysis to inform the design of the ChestCare app.

App name	User requirements previous publication	CityVerve (Davies et al. 2020)	WeChat (Deng et al. 2021)	None (Korpershoek et al. 2020)	(efil breath) (Kwon et al. 2018)	The EDGE digital health system (Velardo et al. 2017)	ChestCare
Components	mHealth app + therapeutic devices (OPEP) + spirometer + hybrid regime	mobile App connected with the smart inhaler	mobile health + cloud server + doctor workstation	Mobile app	2 Mobile Apps + One mentoring website + wearable device	Mobile app + oximetry + cloud \server	Mobile app + cloud \server + lung measure tracker
Objective	To provide PR from remote as a replacement for conventional PR.	<ul style="list-style-type: none"> - To enable daily symptom recording (experience sampling), medication recording and weather updates to help plan activities. 	<ul style="list-style-type: none"> - To provide optimal medical & pharmacological treatment + O2 therapy - To provide a personalised exercise program - To track acute exacerbations 	<ul style="list-style-type: none"> - To enhance exacerbation-related self-management of patients with COPD 	<ul style="list-style-type: none"> - To improve Physical Activity and Quality of life in Patients with COPD. 	<ul style="list-style-type: none"> - To support patients suffering from COPD disease in self-managing their condition 	<ul style="list-style-type: none"> - To enable patients with COPD to receive PR from remote, self-manage their symptoms and enhance their adherence to the PR program.
Theory-informed development	-	Self-management	Behaviour change wheel (BCW)	Behaviour change wheel (BCW)	Self-management	Self-management	Self-management
Main menu	<ul style="list-style-type: none"> - Willing to adopt PTR - Prefer therapeutic devices such as OPEP. - Prefer the mHealth app. - Prefer visual and audio contents of the app - Prefer videos to learn 	<ul style="list-style-type: none"> - My symptoms - View my symptoms (stats) - What is COPD? - About - Setting - Weather 	NA	<ul style="list-style-type: none"> - The main Logo - My complaints today icon - My action plan icon - My calendar icon - My profile icon - Symptom monitoring Question 	<p>Ap:</p> <ul style="list-style-type: none"> - Exercise time, distance & frequency. <p>Tracker:</p> <ul style="list-style-type: none"> - SPO2, HR, Step walked - Patient feedback Exercise difficulty (Borg scale) 	<ul style="list-style-type: none"> - Complete my symptom diary - Look after myself - Review my data and self-management - Read my messages 	<ul style="list-style-type: none"> - Login page: authentication - Symptom assessment - Lung measure tracker - Breathing exercise - Chest clearance - Aerobic exercise - Talk to physio (Clinical OMs) - What is COPD? (education) - Auto reminder

(continued)

Table 1. Continued.

App name	User requirements previous publication	CityVerve (Davies et al. 2020)	WeChat (Deng et al. 2021)	None (Korpershoek et al. 2020)	(efil breath) (Kwon et al. 2018)	The EDGE digital health system (Velardo et al. 2017)	ChestCare
	therapeutic exercises.						
	- Prefer a hybrid regime.						
	- The need to use a spirometer for diagnosis.						
Modules	--	-	-	-	-	- Data collection (SP02) - Communication - Self-management	- Communication - Data collection - Exercise supervision - Education module - Self-management

Table 2. Analysis of the FGDs with users by framework matrix.

Participants	Layout	Content	Colours	Icons	Suggestions & wish list	Developments & refinements as a result of feedback
P1 -(Female, 52 years old, physiotherapist)	<ul style="list-style-type: none"> - 'I think it's a bit wordy, you may use some infographic, it is more reflection of breathlessness and cough.. and you may add picture'. 	<ul style="list-style-type: none"> - 'probably you can incorporate the BODE index inside the App. As predictors for mortality. It predicts how are they progressing well or are they declining'. - 'we'd like to know what's happened to the patient, whether they use the inhale at the time of physiotherapy'. - 'you may add risk factors assessment'. 	<p>The right out the question, how is your symptom today? Maybe you can use the blue colour</p> <p>-But I guess the colour, you try to avoid green colour because I think it's for blind people. I'm blind, isn't it? Green, red.</p> <p>They're not supposed to use it.</p>	<p>'I think for patient to determine good, bad, maybe a small icon to actually just write in. What does it mean by good? What does it mean by bad? Just an icon there.</p> <ul style="list-style-type: none"> - Quantify the scaling system'. - D4 (connect to Smart OPEP) .. add Some screening questions that actually they don't skip this test. 	<ul style="list-style-type: none"> - 'You can always do the validation study with the patient, better they understand it or not. Instead of we actually hypothesis that the patient will not understand'. 	<ul style="list-style-type: none"> - the BODE index was added. - The symptom assessment was replaced with the CAT test
P2-r1 (Female, 35 years old, physiotherapist)	<p>for how is your symptom today? you may change the caption, the question and the colour'.</p> <ul style="list-style-type: none"> - 'for sign up ask patient when the onset of the diagnosis and medical history related to COPD. - 'for sputum production, is that good, mild or bad or is it like large, moderate or small? I thought sputum production is how much the sputum produced a day'. 	<ul style="list-style-type: none"> - The physio can monitor at home or by their own phone?-' 		<p>'Maybe you can put breathlessness. Besides it, you can put the icon. Put pictures instead of words; its eye capture</p>	<ul style="list-style-type: none"> - who will monitor the patient? - How long it takes to finish the whole programme? - Examinations and interventions - this is important for us because we need to approximate how long would it take for one patient ... me: this is a home care intervention - How about the cost of the app? Is it free at the moment? Does the patient need to pay to use the app? 	<ul style="list-style-type: none"> - these questions were included in the sign-up module\risk factor monitoring - the chest clearance module was updated to inquire about sputum quantity, viscosity and colour
P2-r2 (Female, 35 years old, physiotherapist)	None	'I think including smoking tracking is good, because COPD are normally smokers'	<ul style="list-style-type: none"> - 'the colour and the font are suitable for patient'. - 'as for now, we all 	None	None	<ul style="list-style-type: none"> - Tracking of risk factor module was added

(continued)

Table 2. Continued.

Participants	Layout	Content	Colours	Icons	Suggestions & wish list	Developments & refinements as a result of feedback
			agree with the colours, the font and all the information that really being there'.			
P3-r1 (Female, 35 years old, physiotherapist)	'I think the display screen is simple and easy to understand'.	'You can put it on for CAT COPD assessment test together with the mMRC and CRQ. That's very easy and simple questionnaire'.	None	None	'Maybe You can put any picture which can be more attractive to the patient'.	None
P3-r2 (Female, 35 years old, physiotherapist)	None	None	None	None	None	None
P4-r1 (Female, 33 years old, physiotherapist)			'my opinion about your symptom today, maybe you can put some green colour, mild, maybe yellow, bad, red. So, the patient will be more alert about their current health status, something like that'. 'can use the colour to motivate the patient to do the exercise'.			
P4-r2 (Female, 33 years old, physiotherapist)	None	None	None	None	None	None
P5-r1 (Female, 39 years old, physiotherapist)	None	None	- 'the white colour at the background is okay because for the older patient, we don't have to mix a lot of colours'. - 'for the grading of	None	None	None

(continued)

Table 2. Continued.

Participants	Layout	Content	Colours	Icons	Suggestions & wish list	Developments & refinements as a result of feedback
P6r1 (Female, 30 years old, physiotherapist)	<ul style="list-style-type: none"> - 'maybe for breathlessness. Usually, we use a box scale. We count 0 to 10 instead of description'. - I would like to suggest for you to add on audio instruction for the 'let's do the lung test' section or else patient will easily lost with the wording instruction without description - you can also add on more infographic and animation picture on this section 	<ul style="list-style-type: none"> - 'So maybe would be a good point to replace the symptom screen with the CAT test'. - 'Maybe you need to add more exercise, so the guidelines for them to do the exercise, maybe increase the intensity, increase the frequency'. - 'The sputum, what do you mean by its good. That's mean good for sputum production. Usually we use small amount, moderate amount and then you can add no secretion'. 	None	None	None	scale, maybe we can put the different colours so that they can see, okay, today is a good one because it's green. So today is not very good because it's either yellow or red'.

(continued)

Table 2. Continued.

Participants	Layout	Content	Colours	Icons	Suggestions & wish list	Developments & refinements as a result of feedback
P7-r2 (Female, 37 years old, physiotherapist)	<ul style="list-style-type: none"> - 'what would happen if the patient did not fully fill the assessment?' - Will you remind the patient to complete the assessment? 	<ul style="list-style-type: none"> - 'How about the medication?' - 'I think it's good to add tracking for smoking because it's related to the condition. How many cigarettes per day' - I think 2-way communication is good for patient. - I think the idea of coordinated care is good. patient can get information from people other than physio-doctors also. its good may be for physio we stick about COPD exercise, but for doctors about COPD itself as a medical problem, so the patient understands the 2 way. 	None	None	None	<ul style="list-style-type: none"> - A module to Track risk factor including smoking was added. - the two-way communication module was upgraded
P8-r2 (Male, 30 years old, physiotherapist)	None	'I think the content is already enough for the patient. It's well prepared already'.	None	None	None	None

(continued)

Table 2. Continued.

Participants	Layout	Content	Colours	Icons	Suggestions & wish list	Developments & refinements as a result of feedback
Pt1 (Male, 69 years old, Hindu patient)	<ul style="list-style-type: none"> - 'clean, clear and nete screens'. 	<ul style="list-style-type: none"> - 'These questions (CAT) are very good .. not too much, very comfortable for us. '.. - 'Probably better to answer once a week'. - Breathlessness, cough, energy. - 'the information about breathlessness by the mMRC more than enough'. - 'enough information about breathing exercise'. - Home activities is the only exercise we do at home, we don't go for walking or to the gym .. - Walking is also good; I can't do juggling'. - its not necessary to pause in the middle, I can do the functions. 	None	None	<p>'earlier when I was --, I was not told much, but this time when I was there, they gave me the idea how to sleep what you should do what you shouldn't do, don't take food before 2 h to sleeping .. I follow these up. I am feeling very strong .. very active .. only suddenly the attack happens, I got cough first, breathlessness, then bedrest ... all is suddenly.</p>	None

(continued)

Table 2. Continued.

Participants	Layout	Content	Colours	Icons	Suggestions & wish list	Developments & refinements as a result of feedback
Pt2 (Male, 69 years old, Chinese patient)	<ul style="list-style-type: none"> - 'Very clean and clear screens, no distractions as some apps do'. 	<ul style="list-style-type: none"> - 'About CAT I think the interval for the weekly basis will be fine'. - Breathlessness, phlegm, cough. - 'enough information about breathing exercise and Aerobika'. - clear information about chest clearance. - does it measure the SPO2? - the best exercise is walking, we don't prefer juggling .. also we do all exercise at home using dumbbells and other things .. maybe you can add open space so we can add our preferred convenient activity - I think the most important is to understand the patient. what is the basic cause of the disease... I am sure different patients are triggered by different things,, so it's important to understand what is the main thing that trigger the disease and how to overcome this problem .. and understand the place he lives in, the lifestyle, - I think its ok to perform all the functions for once .. no need to pause in the middle 	None	None	<ul style="list-style-type: none"> - 'for breathlessness, if they ask us about the environment, the intake of food, it all affect breathlessness'. - 'add information about what you think trigger breathlessness, may be smoking, dust, food, certain smell triggers breathlessness'. - 	<ul style="list-style-type: none"> - 'new displays to ask the patients about what trigger his symptoms, what are the living and working environment were added - he two-way communication module was upgraded to the COPD community to provide more interactions between patients and therapists, transfer if knowledge

(continued)

Table 2. Continued.

Participants	Layout	Content	Colours	Icons	Suggestions & wish list	Developments & refinements as a result of feedback
Pt3 (Male, 63 years old, Malay patient)	<ul style="list-style-type: none"> - 'it is clean and clear'. 	<ul style="list-style-type: none"> - 'about CAT, its possible to answer the test every day, but may be better to have 0-4 questions'. - Breathlessness, cough, sleep. - 'sufficient information to guide us to do breathing exercise with Aerobika'. - 'I need to know more about the effectiveness of sleep in the education. - I like the idea of reminders ... it helps to keep using the app . - I think I need to pause in the middle. I can't perform the functions. 	None	None	<p>'I want to see summary of the tests I've done in one place, so I understand my case and therapist guide me how to deal with my case'.</p>	Development of the action plan,

*Representative quotes and iterative changes made throughout the three rounds of FGDs with potential users.

*Participants participating in round 1, 2 or 3 of FGDs.

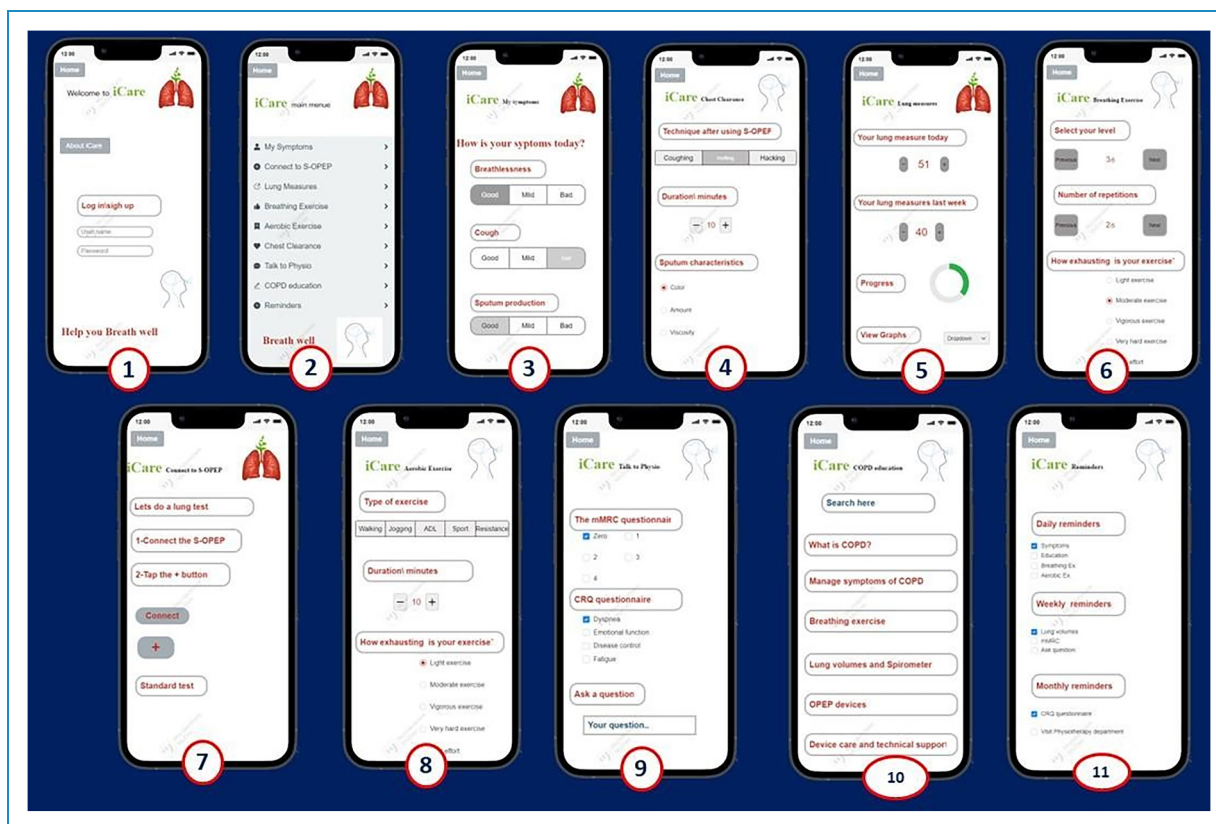


Figure 2. Initial sketches of the app prototype.

pictures. Additionally, physiotherapists described the app content as good, with recommendations to replace the symptom screen with a more descriptive and reliable COPD Assessment Test (CAT). They also recommended adding tracking for risk factors, including smoking, and enhancing two-way communication through the app. Participants described colours as good and not distracting, and they recommended implementing colours to distinguish patients' symptoms and motivate patients to exercise. They recommended adding descriptions to the icons and quantifying the scaling systems. The second version of the app prototype was prepared according to this discussion, formulating the basis for the second FGD.

The second FGD was conducted with five respiratory physiotherapists, with an average duration of work experience of 10.4 ± 3 years, holding a bachelor's degree in physiotherapy. Their experience with the mHealth app was limited to the personal use of obesity management and fitness apps, and a single experience in stroke rehabilitation app. The physiotherapists' perspectives regarding the app prototype's layout, content, colours and icons were identified, and the related subthemes are presented in Multimedia Appendix 2. Generally, the participants have confirmed the upgraded version of the app prototype, emphasising risk factor monitoring, smoking and two-way communication.

Three patients with COPD participated in the third FGD; their mean age was 67 years, and the mean year since they were diagnosed with COPD was 3.7 years. All patients liked the app layout and described it as clear, clean and neat. They also liked the colours, icons and amount of information provided by the app, with an option to pause throughout the provided PR program. The participants suggested individualising the app by including questions about factors that trigger symptoms, living and working situations, eating and surrounding environments. The research team considered these suggestions and upgraded the app prototype to its third version.

Ultimately, the three rounds of FGDs have generated participants' perspectives on the literature-derived themes: content, layout, colours, icons and suggestions as shown in Figure 3 and Table 2. The discussion about participants' perspectives on the layout revealed its simplicity and clarity. Discussions about the prototype content created several additions related to assessment and education topics modules. Discussions about the colours and icons demonstrated their suitability and acceptability by the participants. Finally, the inquiries about their wish list and suggestions include monitoring of risk factors and a summary of their tests' results.

Development of mock-ups and storyboard

Through four phases of UCD iterative designs, SG developed four versions of the mock-up app or prototype. At each phase, the developed mock-up was presented to the research team AFML, NMA and DKAS before discussing with the potential users via FGDs and inquiring about their feedback and wish list. Accordingly, the mock-up version was upgraded and refined, as shown in Multimedia Appendix 3. The app storyboard was prepared after reaching a satisfactory version, providing a visual guide to the app modules. The steps in using the app related to users' inputs, outputs and roles, as well as the relationship between displays along the user flow.

Refinement

The multidisciplinary team discussed the app's functionalities, objectives, modules, contents and intended users through several online discussions. The discussions have resulted in the refinement of app functions and the addition of several technical features as shown in Table 2. The text of reminders, risk factors notifications and refinements of the monitoring risk factors, and COPD community modules have been considered, resulting in the development of the fourth version of the app prototype.

Expert panel validation

Six experts in respiratory physiotherapy were asked to complete the CVI document, with a mean year of experience of 20.3 ± 12 years, two from the clinical field and four having mixed academic and clinical experience. Results of CVI calculations showed that 145 items scored 1, and only five items scored 0.83. These items were the employee number, the phone number of the therapist sign-up module, the instructions about the BODE index and the daily reminders to perform the CAT and the Modified Medical Research Council (mMRC) tests. However, these results suggested an agreement on the inquired 150 items, and therefore, all items have remained within the app prototype. The S-CVI scored 99.4, indicating an overall validity of the ChestCare app as a PTR system for patients with COPD. See Appendix 2: Content validity of the symptom monitoring module.

Triangulation

In this sequential MMR, we integrated the results of the qualitative FGDs, exemplified in the latest version of the app prototype, with the quantitative results derived from the expert panel validation using the CVI document. Based on this integration, decisions were made to maintain the evaluated items within the

app. The outputs of each mentioned phase, along with the administration of the IPO framework, are illustrated in Table 3.

The ChestCare app

To achieve the main goal of developing the ChestCare app, it was essential to develop basic functionalities that serve PR, including assessment and interventions as shown in Figures 4 and 5. The assessment included symptom assessment, lung volume tracking and functional capacity testing. Intervention encompassed breathing exercises, chest clearance, staying active (physical activity) and education. These functionalities have evolved from the previous needs assessment study along with an analysis of related apps. The latter has highlighted the reminder module as well. It's worth noting that All app's figures were created by the developer unless otherwise, they were from open source and properly cited. Since the development of ChestCare was for academic and research purposes, approval is not required, and where applicable, we adhered to the required licensing conditions. We understand that obtaining approval is necessary for commercialising the app. If we proceed with this project toward commercialisation, we will do so.

Symptom assessment module. The CAT is a patient-reported outcome measure (PROM) deployed to quantify the COPD symptom burden along with its risk exacerbation.⁶⁵ The CAT scores have been shown to correlate with mortality^{66,67} and risk of exacerbations.^{67–69} Moreover, the CAT shows high responsiveness to PR with the ability to distinguish categories of responses⁷⁰ and identify AECOPD patients who are responsive or not responsive to medical intervention.⁷¹ The CAT has been deployed for online use by creating a digital calculator, which facilitates the assessment of COPD severity and functional capacity deterioration along with the efficiency of PR.⁷²

The mMRC module. Evaluation of dyspnoea is crucial to categorise functional disability and response to treatment. The mMRC is a PROM and has been deployed for decades to assess and grade dyspnoea severity and establish effective interventions.⁷³ It is correlated moderately with lung volume tests,⁷³ moderately to strongly with the cardiopulmonary fitness of patients⁷⁴ and highly correlated with the disease-specific QoL.⁷⁵ The mMRC has also been deployed for online use, which facilitates patients' assessment and counselling.⁷⁶

6-min walk test module. The module is deployed to evaluate the effectiveness of treatments for patients with cardiopulmonary disorders, and the functional capacities for patients with frailty who cannot tolerate treadmill activities such as elderly, COPD, heart failure, arthritis and neuromuscular disorders.⁷⁷ The 6-min walk test computes reference

Table 3. Applying mixed-methods sequential research, UCD and the IPO framework in developing the ChestCare mHealth app (the added features throughout the sequences of the app design).

Phase	Methods same as process	Inputs	Process	Outputs	Added features	Timeline
Prototype development	Need assessment	<ul style="list-style-type: none"> Results of need assessment study 	Identification of users' need	The first version of the app prototype (11 displays)	<ul style="list-style-type: none"> Assessment, Supervised intervention Education 	March, 2023
	Analysis of related apps	<ul style="list-style-type: none"> Analysis of related apps 	Identification of pillars of mHealth apps for COPD		symptom assessment lung volume tracker breathing exercise chest clearance aerobic exercise education module reminder	
	Qualitative research	Two FGDs with physiotherapists	Content refinement: Inclusion of	The second version of the app prototype	+ CAT, mMRC & 6-min walk test	April-July, 2023
Refinement	Qualitative research	FGD with patients	Patients requested to consider their daily lives and living situations and know more about them	The third version of the app prototype	+ Risk factors monitoring + COPD community module	September, 2023
	Discussion with developer	Discussion with developer	Inclusion of technical features	The fourth version of the app prototype	<ul style="list-style-type: none"> Refine monitoring risk factors module add text notifications to the monitoring module add text of reminder add therapist sign-up display add therapist & other users display for the COPD community 	October, 2023
	Quantitative research	<ul style="list-style-type: none"> Validation tool Panel of experts 	<ul style="list-style-type: none"> Online presentation and discussion about the mHealth app prototype. Completion of the Content validity document \form. 	Validated app Ready for programming	<ul style="list-style-type: none"> Validate 13 modules contain 150 items I-CVI (145 items) = 1 I-CVI (5 items) = 0.83 S-CVI = 99.4 Refine several technical features. 	November & December 2023
Final programming	Several iterative refinements of features					December 2023 - March 2024

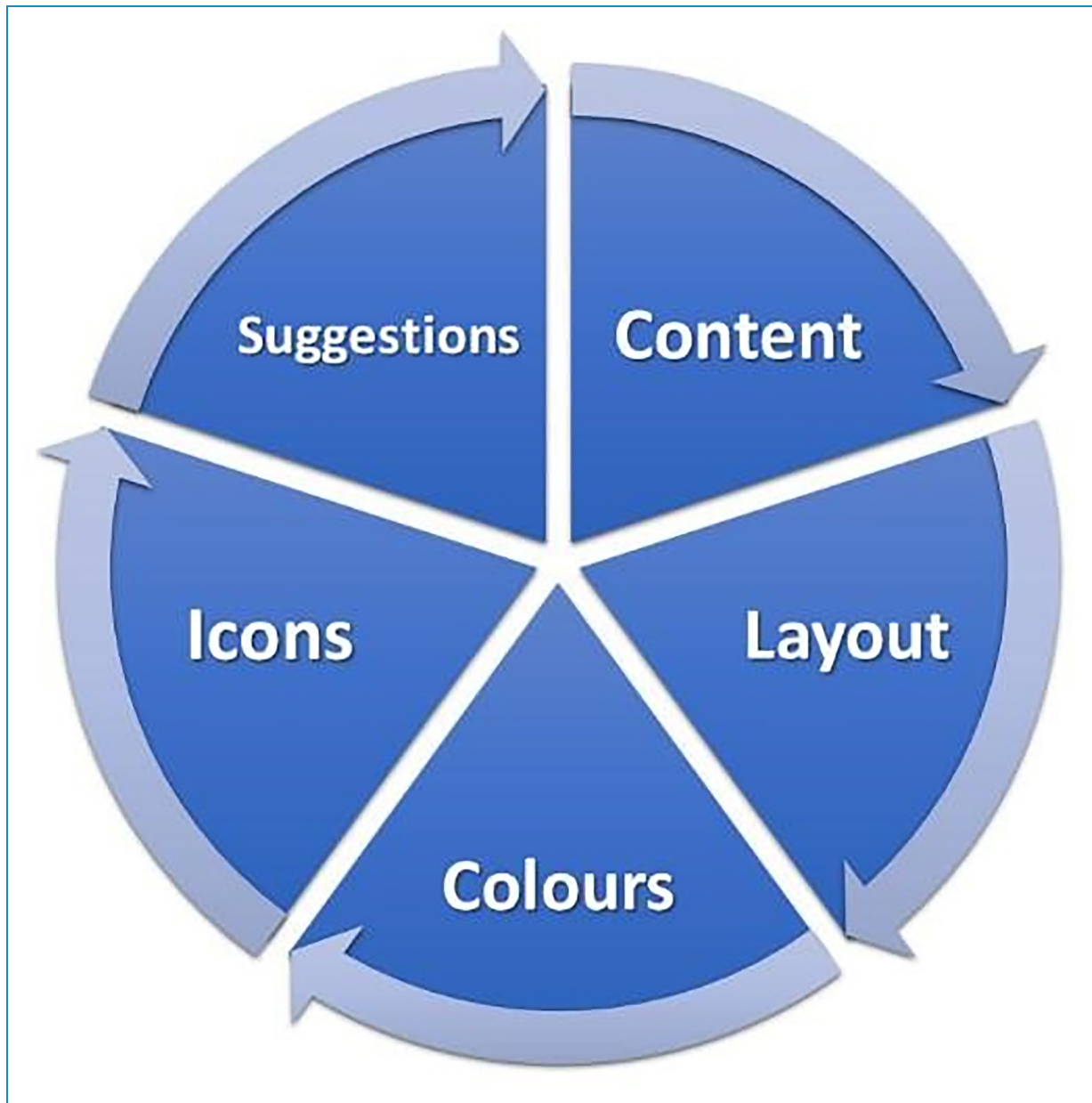


Figure 3. Pillars of FGDs 1, 2 and 3, adopted from literature.^{31,56}

values for a walking distance as a measure of functional status.⁷⁸ It is safer, easier to administer, more tolerated and more reflective of activity daily living than other tests.⁷⁹ Therefore, it has been deployed for online use, facilitating patients' assessment and simplifying calculations.⁸⁰

Lung volume tracker module. Spirometer testing is crucial to confirm the COPD diagnosis.² However, it is underutilised in diagnosing and managing COPD.⁸¹ Efforts to enhance its utilisation^{81–84} and facilitate access to it have been encouraged to provide solutions for the underutilisation and under-diagnosis of COPD in both HICs and LMICs.^{3,85,86}

Utilisation of a spirometer can help direct the patient's admission to the emergency department,⁸⁷ guide the one-month post-discharge⁸⁸ and predict the post-discharge relapse,⁸⁹ mortality and readmissions.⁹⁰ This was the first stage of developing the Smart OPEP device,⁴⁸ which aimed at enhancing the utilisation of spirometry functionalities along with providing effective physiotherapy intervention. Thus, we started developing and validating the mHealth app and tracking lung volume using desk spirometry. Therefore, we hypothesised that tracking the lung volume, FEV1/FVC² during PR would guide the decisions related to patient management for better effectiveness.

The BODE index module. Survival prediction for patients with COPD, however, should not be deployed for patients with acute exacerbations or to guide therapeutic interventions.⁹¹ It uses the body mass index, lung volume measures, dyspnoea and exercise capacity indexes to evaluate the COPD systemic symptoms.⁹¹ The BODE index is more reliable in predicting hospitalisation⁹² and acute exacerbation⁹³ than the FEV1. It has been deployed for online use, and it helps therapists educate their patients about prognosis and adjust the goals of the interventions.⁹⁴

In summary, the GOLD guidelines² have recommended the CAT and mMRC for evaluating all COPD patients. The mMRC is a component of the BODE index which predicts mortalities and risk of hospitalisation.^{76,91} The online experience of the CAT, mMRC, 6-min walk test and patient counselling inspired our endeavours to facilitate COPD management. Thus, we included the mentioned tests in the ChestCare app and embedded algorithms for results calculation. A patient can carry out the CAT, mMRC and 6-min walk test individually, and the app automatically shows results, with guidance and support from physiotherapists through the COPD community, and instructions provided through the education module. The BODE index will be computed automatically and shown only to physiotherapists, which will help predict exacerbations and hospitalisation, thus helping to avoid flare-ups.^{92,93}

Breathing exercises, chest clearance and stay active module.

A basic PR program for patients with COPD encompasses breathing exercises, chest clearance techniques, physical activity program and education.^{95,96} Additionally, OPEP devices such as Aerobika are increasingly deployed for their effectiveness, ease of use and possibility for deployment in tele-context.⁴⁸ Evaluation of the post-intervention exertion was induced by utilising the Borg CR scale (CR10).⁹⁷ We considered the recommendations for setting up a virtual PTR⁹⁸ and recommendations for HCPs for setting up PR programs.⁹⁹ The patient will independently use the intervention module and will be supplied with the necessary education through an icon embedded in each content of the intervention to direct the patient to the respective part of the education. Additionally, physiotherapists will supervise the patients' performance and guide the COPD community.

Other related modules

The action plan. Setting up a treatment plan or 'action plan' is a core constituent of the PR program. It summarises the results of tests and examinations, identifies the intervention goals and strategies, and therefore helps in the early detection of flare-ups of COPD. The treatment plan identifies the actions to be carried out to manage the disease symptoms along with early detection and avoidance of flare-ups.^{98,99}

It was reported that SM interventions that included an agreed-on action plan for exacerbating symptoms decreased the likelihood of hospitalisation for respiratory and non-respiratory related reasons. It also helps to manage improvements and monitor patients' progress.⁹⁵ Development of the action plan within the ChestCare app has evolved from the participants' wishes to visualise the results of their tests and examinations summarised in one display, with clear guidance on what to do in each case. Development of the treatment plan in PR aligned with the physiotherapists' qualifications and responsibilities.¹⁰⁰ The plan was designed and programmed to summarise the patient's tests and examination results automatically. It was claimed that attracting patients' visual attention would facilitate compliance with performing the tests, examinations and intervention strategies. Considering the individual nature of the treatment program and the patient's needs, physiotherapists will manually assign the treatment plan rather than making automated decisions.

The education module. Education is an essential component of PR programs,¹⁰¹ and it has been recommended by the IPO framework to build a TR system to include five main functionalities; one of them is self-management support, which necessitates patient education.³¹ Education was also one of the identified modules to be developed according to the analysis of related apps. It was emphasised by the UCD approach through discussion with physiotherapists and patients with clear identification of its topics.

Education, as part of self-management programs, has contributed to enhance its efficiency and effectiveness along with improving the therapeutic outcome measures.^{102,103} The content of the education module of the ChestCare system was developed based on the Lung Foundation Australia (LFA) guidelines,¹⁰¹ its PR toolkit¹⁰⁴ and the patient guide.¹⁰⁵ Additionally, we considered the Health Service Executive of Ireland provided through the national management guidelines,⁹⁵ the HCPs' guidelines for developing PR,⁹⁹ and the guidelines for setting up PTR.⁹⁸ The education module aims to enhance self-management of the disease symptoms by providing knowledge, teaching patients how to perform treatments and helping teach coping strategies. To achieve this goal, the education module was established to include 12 topics: (1) knowledge about the disease, (2) risk factors of COPD, (3) the importance of PR of COPD, (4) breathing exercise, (5) sputum expectoration, (6) staying active, (7) spirometry testing and lung volumes, (8) managing flare-ups, (9) psychological support, (10) medications, (11) healthy eating and (12) living well with COPD. According to the LFA recommendations, the education module was developed to provide patients with variable modes of presentation and allow for patient interaction.¹⁰¹

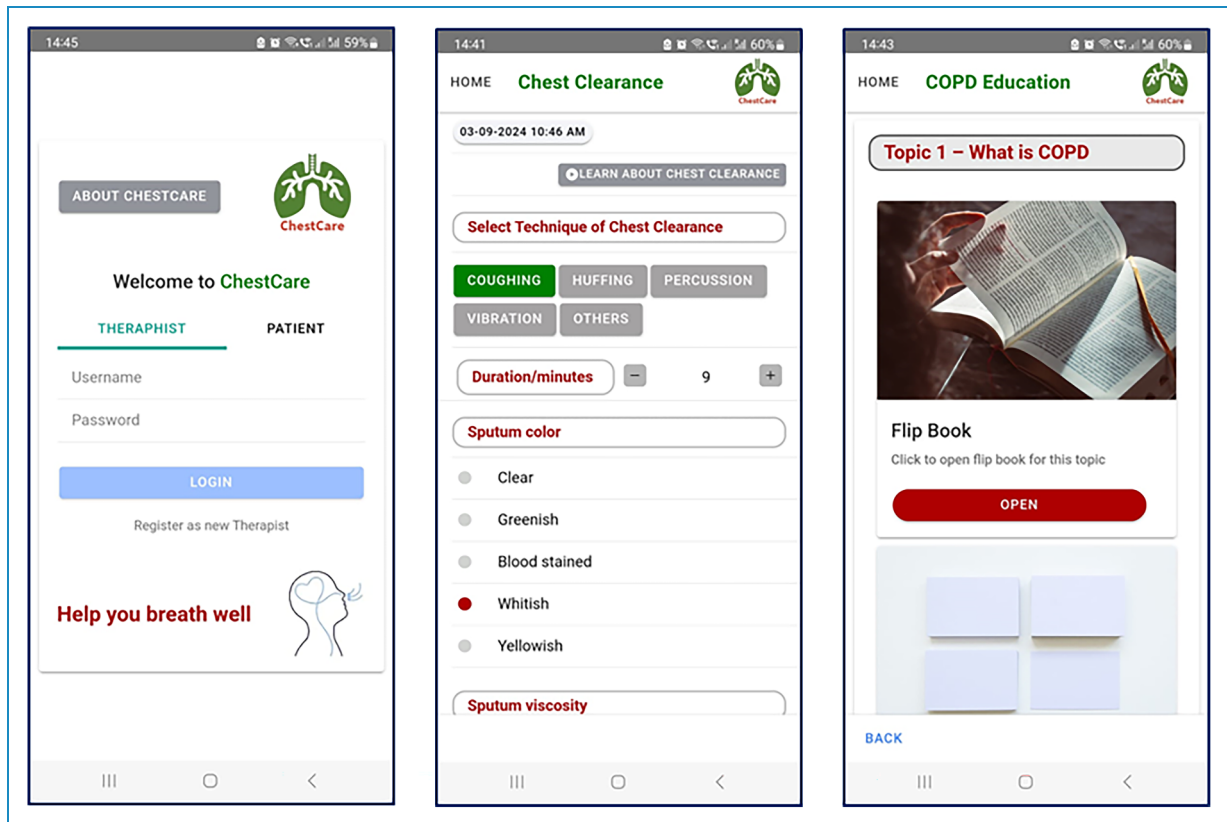


Figure 4. Screenshot from the ChestCare app: sign-up, chest clearance and COPD education modules.

The COPD community. The utilisation of mHealth apps has enhanced communications between patients and HCPs, with a high potential to enhance patients' empowerment and self-management, with an ultimate improvement of TOMs.¹⁰⁶ Communication through the mHealth app has been enhanced by launching channels between patients and HCPs,¹⁰⁷ and among patients themselves, in a peer lead form¹⁰⁸; and shown its effects on enhancing patients' engagement, facilitating the transfer of knowledge and experience and augmenting reminders to perform self-care tasks.¹⁰⁷ It also facilitated problem-solving, daily management and behavioural modifications and provided patients with social and emotional support.¹⁰⁸ The development of the COPD community has been derived from the physiotherapists' remarks on the good impact of two-way communication for patients. Besides that, patients have reported the importance of identifying each patient's condition and circumstances, which can be achieved only through two-way communication. Furthermore, the development of this module aligned with the LFA guidelines to deploy active participation through interaction and discussion.¹⁰¹ This module includes three components that allow patients to communicate with physiotherapists and other patients in the community, thus supporting each other and exchanging information and experience. The three components are as follows: (1) ask the therapist, (2) tell your story and (3)

ask your friends. All physiotherapists and patients must log into this module with their real names. Anonymous posts are not allowed, and every post has to be approved by a physiotherapist before being posted into the module. Participants are also allowed to share their contact information and arrange for shared activities, thus achieving the objectives of this module, which are to enhance communication, provide support and exchange knowledge and experience.

The risk factors monitoring module. Monitoring is an integral component of telehealth and mHealth.^{102,109} Tracking, a term used interchangeably with monitoring, is defined by the PubMed mesh as 'Information relating to itemised coding of procedures and costs associated with healthcare delivery, used as a means for tracking healthcare utilisation, patterns of care and treatment outcomes'.¹¹⁰ Although the PubMed definition highlighted three areas of monitoring: healthcare utilisation, the pattern of care and treatment outcomes, the current tracking module highlighted the pattern of care along with the treatment outcomes in addition to the risk factors. Development of this module has been derived from the UCD approach through discussion with the patients, as they implied that 'it is important to understand what is the main thing that triggers the disease and how to overcome this problem

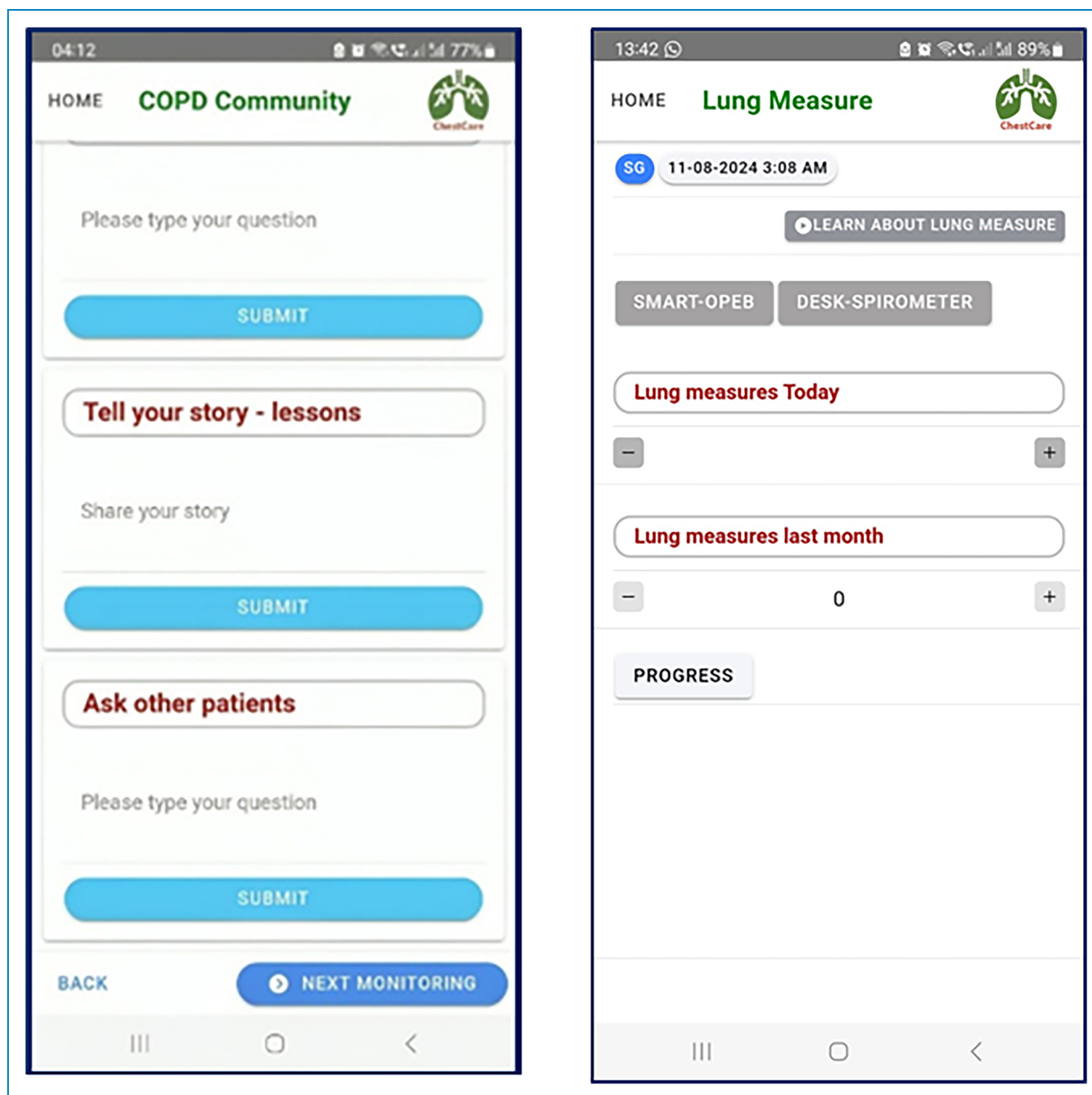


Figure 5. COPD community module and lung volume measure modules.

... and understand the place he lives in, the lifestyle'. The reminder module asks questions to the patients, about their disease, risk factors and compliance with medications and PR programs. The notifications will be sent to the patients as a push notification following their responses to the risk factors monitoring module. A total of 11 notification messages have been developed according to the LFA guidelines,¹⁰¹ the PR toolkit,¹⁰⁴ and the patient's guidance,¹⁰⁵ and have also been validated by the expert panel. The notification messages targeted monitoring of the healthy BMI, smoking, the participants' need for support to quit smoking, type of work, living situations, irritants of symptoms, exposure to irritants and air pollution, adherence to medications, vaccines and inhaler devices.

Development of the reminder module. Reminders, in variable forms, are one of the proficiency experience techniques of the mHealth apps. They enhance adherence to the intervention-targeted self-management and encourage the participants' self-efficacy, time management and motivation toward commitment.^{111–113} The reminder module has been developed based on an analysis of related apps; it was also emphasised through the UCD based on FGD discussions with patients. Reminders will be sent to the patients as a push notification following their selection of reminders. Automated push notifications are inherent functionalities that are valuable since they require minimal or no input from participants and HCPs. They enhance the likelihood of gathering necessary data and serve as an effective

tool for user engagement.^{111,112} Reminders were set to be delivered daily, weekly or monthly. Specific functions were assigned as a daily reminder, such as the CAT test, breathing exercises and staying active. Meanwhile, other functionalities were assigned for weekly reminders, such as COPD community and chest clearance. Monthly reminders include completing the QoL survey, visiting the physiotherapy department and performing the lung measure test.

Discussion

Principal findings

Under the context of this study, we outlined the fundamental functionalities of the ChestCare mHealth app that had the potential to serve patients with COPD with PR programs, thus bridging the gap of unavailable alternatives to the under-recognised, underdeveloped and underutilised PR programs. The ChestCare app ended up with 13 functionalities, including sign-up, browsing contents, symptom assessment, tracking lung volume, functional capacity test, action plan, breathing exercises, chest clearance, staying active, COPD education, COPD community, monitoring and reminders.

User-centred design and iteration

We deployed the UCD as a system design approach for ChestCare app development. User-centred design emphasised the end-users, physiotherapists and COPD patients in the case of ChestCare, along with stakeholders. Additionally, UCD adopted iteration in research, design, development and testing of the developed system.⁵⁰ The UCD allowed for translating evidence-based practice to industry along with prioritising users' needs.^{114,115} Agile or iterative development, alongside UCD, involved progressive and responsive design, development and testing for rapid learning and product adaptation.⁵¹ Agile, in contrast to the waterfall model, allowed for enhancing system features, minimising usability issues, adding new system features and responding to design changes.¹¹⁶ Through the course of ChestCare development, which lasted for 12 months, we started with the first app prototype, which encompassed 11 displays and eight simple functionalities; however, after conducting two FGDs with physiotherapists, one FGD with patients, and a series of discussions with the MDT, we ended up with the final version of the app encompassing of 30 displays, two users' pathways, with marked enhancement of the app functionalities to align with international guidelines and practice. Here, we realise that having this extent of functionalities would overwhelm users, especially old-age patients with COPD, who may have cognitive frailty. To overcome this potential challenge, we upgraded the simple messaging system of the

first prototype version to the COPD community, which allowed patients to interact with and support each other and exchange experiences and knowledge related to their disease management. Additionally, the COPD community allowed for two-way interaction with the physiotherapists, which would motivate patients and allow for more engagement.¹⁰⁷ We also considered other measures to facilitate the use of ChestCare through the development of a detailed educational module that will be displayed to users in variable and interesting formats to enhance engagement and benefits.¹⁰¹

The action plan: utilising the physiotherapists' competencies

Development of the action plan was aimed at providing patients with a written plan on what actions to take, based on assessment results, to help manage disease symptoms and avoid flare-ups. The action plan was considered one of the general practitioners' (GP) responsibilities.¹¹⁷ However, under this developmental work, physiotherapists will be the main HCPs who supervise and guide the PTR programmes. Therefore, we adapted the action plan¹¹⁷ to align with the PTs' competencies and responsibilities. Medical doctors at the hospital will refer patients with COPD to the outpatient physiotherapy department as the responsible physiotherapist will evaluate the patient and decide to refer him to the ChestCare app. The responsible PT will also decide on the embedded action plan, which does not surpass physiotherapy competencies and responsibilities. Worldwide, physiotherapy is moving toward direct access or primary contact,^{118,119} where patients directly access physiotherapy without a referral from medical doctors. Such a transition from secondary healthcare to an autonomous practice implicates several advantages, including cost-effectiveness due to the reduced time, cost and resources.^{120,121} It is associated with better outcomes in disability and QoL.¹²² The referral-based PT practice has limited physiotherapists' clinical reasoning, clinical decision-making and evidence-based practice, resulting in irresponsibility and frustration.¹²³ The physiotherapist's independent judgement under the context of ChestCare is not a transition to the autonomous practice nor a call to surpass the medical doctor, who will be making the first decision of referring patients to PR in alignment with the referral system in Malaysia. However, this is an attempt to utilise the physiotherapists' clinical reasoning, decision-making skills and responsibilities to evaluate the patient's symptoms and decide, under the context of the referral system, whether to receive PR interventions or to refer the patient back to doctors for medical attention. This also justifies why the decisions impeded in the action plan

were not automated; we rely on the physiotherapists' clinical reasoning, clinical decision-making skills and independent judgement responsibility.

Mhealth development and effectiveness: tackle the challenges

One of the key variables of providing PTR is the selection of its context; the mHealth app is preferred over other contexts due to its extensive accessibility, portability, cost-effectiveness and data resourcefulness.³⁴ However, three basic challenges may jeopardise the mHealth development and, therefore, its effectiveness; the first is the lack of rigorous evidence and guidelines for the development and evaluation of the mHealth apps by the global regularity bodies.^{30,32} The second is the high rate of attrition, with 43% drop-out in observational and experimental studies¹²⁴ and with adherence rate as low as 56%,¹¹¹ which endangers treatment effectiveness, might increase hospitalisations, and is a major mHealth development jeopardy.¹¹¹ The third is the lack of national guidelines for implementing a digital health innovation ecosystem.¹²⁵ Our endeavours to tackle the first challenge focus on the adoption of the IPO framework for the TR system development, which is supported by rigorous evidence.³¹ Hence, we followed the IPO's recommendations in conducting mixed-methods research, working in a multidisciplinary team, identifying a budget and timeline and adopting the UCD iterative design approach^{50,51,114–116} and self-management.^{17,102,103} We also addressed our previous hypothesis of TR system development and testing to invest more effort in the design and development, which lasted 12 months, thus minimising the usability issues and enhancing the user experience.³¹ Finally, we considered the STEERING model as a recommended approach to developing telemedicine, including the mHealth,¹²⁶ which emphasises self-management, tracking of TOMs, pattern of care and healthcare utilisation, education, enhanced adherence, reminders, identified usefulness, networking and generalised versus individualised features for developing mHealth that effectively enhances TOMs.¹²⁶

The reported high rate of attritions should be managed to maximise mHealth effectiveness for the NCDs management in the long term.¹²⁴ The intention to use the mHealth apps is essential to ensure adherence and maximise effectiveness. Such intention is influenced by several factors, including social encouragement, the possibility of sharing information about one's illness with a social network, concerns about patients' digital information, perceived effort in terms of time-consuming and carrying out several tasks independently, inadequate privacy and inadequate information about the provided tool, as well as the improvement of manual records.¹²⁷ Moreover, variable intervention-related factors have shown

their impact on maximising adherence, including personalisation of content to the user's need, push-up notifications, user-friendly and technically stable app design and personal support compatible with the digital intervention.¹¹¹ Social factors and gamification features have also shown their influence on adherence, patient characteristics and recruitment channels.¹¹¹ Real-time data monitoring, passive monitoring and personalised study feedback can potentially maximise long-term engagement. Other engagement strategies should incorporate technology usability, motivating elements and the necessity for personal contact with research professionals and study assistance.¹¹² A key factor that should be considered in developing mHealth is the significance of carrying out a digital health innovation ecosystem in HICs and LMICs, along with adopting the policy implementation guidelines.¹²⁵ Future upgrading of the ChestCare app would include the development of Key Performance Indicators to reflect the patient's compliance with the PR program in terms of adherence calculations and enhanced TOMs, along with the healthcare utilisation and patterns of care.^{128,129}

Commercialising potentials

Malaysia is an upper middle-income economy¹³⁰ and has developed a two-tiered healthcare system: the public sector, financed and led by the government and the well-established private industry. The two systems work in good collaboration with each other.¹³¹ Both sectors are challenged by staff shortages, along with the location of their best facilities in large cities. The public sector is equipped with excellent medical devices and diagnostic capabilities, and the cost is heavily subsidised by the government. However, it is challenged by the very long waiting time and the very basic health services provided in rural areas.¹³¹ Currently, the private sector drives the adoption of health technology. However, to offer world-class healthcare, the public and private healthcare sectors will invest more in healthcare technology, medical devices and digital health, with a special focus on monitoring and preventing NCDs.¹³² Alternatively, Malaysia aligns with the worldwide 'triple problem of COPD' exemplified by underdiagnosis,³⁸ under-recognition^{11,13} and the under-development of PR programs³⁹ as well as the restricted related database, PR programme accessibility and alternative availability⁴⁴ and low referrals along with a low commitment to implementing PR.⁴⁵ The need to develop alternatives to the challenged PR programs is obvious, and a consolidated rationale was formulated to develop the ChestCare mobile app, which took place in the public sector, where health technology adoption is not a current priority. This urges us to intensify the efforts to carry out the development process and to plan for the next usability, feasibility and validity phases. However, the main challenge seems to lie in commercialising the ChestCare app.¹³³ Considering that the public sector lacks the

commercialisation potentials, assets and means, the private sector is perfect for commercialisation due to its current adoption of health technology and the availability of assets and potential users. Therefore, the commercialisation transition,¹³³ as an essential commercialisation phase, should be planned to transition to the private sector.

Cross-cultural validation and adaptation

Cross-cultural adaptation and validation of an instrument are different. However, they are complementary in steps of conduction¹³⁴; adaptation involves selecting, translating and adjusting the instrument across languages and cultures for meaningful comparisons and appropriateness, thus providing an equivalent measure.¹³⁵ Validation determines whether instruments, usually psychological notions, from one culture are applicable, meaningful and equivalent in another in numerical values, thus confirming accuracy and reliability.¹³⁶ In that sense, we enquire whether this methodology of cross-cultural adaptation and validation of PROMs applies to mHealth; we are trying to figure out whether the mobile app that has been developed for the Malaysian population should be committed to a cross-cultural adaptation and validation when attempting to be used by non-Malaysian users. This adaptation and validation is meant to go through several steps, including translations, synthesis of the translations, back translation, six types of equivalence analysis, expert committee review to align the translated versions, pre-final version testing in pilot studies and testing for the retention of the psychometric properties, where it is essential to consider the mode and the context of administering the instrument,^{134,136} along with the conceptual, semantic, operational and equivalences of the instrument that should be verified.¹³⁴ mHealth development and testing are emerging knowledge, and non-to-limited information about cultural adaptation and validation is available. However, researchers should always consider that the mHealth app is designed for specific patient populations, age groups and literacy levels to improve patient engagement and health outcomes,¹³⁷ highlighting the necessity to consider cross-cultural adaptation and validation. To our knowledge, the only case that was located in the literature was the development and testing of the Advanced Symptom Management System (ASyMS), which was a mobile app deployed for remote monitoring of chemotherapy and was developed and tested on British patients.^{138,139} However, deploying the ASyMS for Canadian patients required conducting a new usability testing study,¹⁴⁰ clearly stated in the study rationale. Here, it is difficult to claim that the latest usability testing is equivalent to cross-cultural adaptation and validation, and it is equally difficult to argue that our enquiries about adapting and validating the mobile app in different cultures are an essential milestone. It might be reasonable, at this stage, to initiate this argument, and perhaps others can proceed with deep insights in future research.

Strengths and limitations of the study

We claim this work has undergone a robust design and development methodology as described previously. This may facilitate usability and feasibility studies, subsequent clinical efficacy and cross-cultural adaptations.

A considerable limitation of this work was the under-recognition of COPD, equally by medical and rehabilitation management. Finding databases, statistics and validated guidelines for COPD management in Malaysia was challenging. Similarly, patients' responses to our invitation for FGDs were as low as 10%; 3 out of 30 eligible participants have participated. Moreover, the potential participants of this research were elderly, and the elderly-associated frailty and grey digital divide could impose the forthcoming usability testing, feasibility and effectiveness evaluation along with the actual benefit of the app. Therefore, we considered variable inclusion criteria of those participants, such as good cognitive function and ability to use the mobile apps. Additionally, we considered several design principles to facilitate the usability of this app, such as less wordy displays, and high contrast between the white background and the applied colours.

Future work

This work is the design and development of a TR system to provide management for patients with COPD. Development of the ChestCare apps is the first stage of the forthcoming Smart OPEP project⁴⁸ as the app will be connected to the Smart OPEP device. Participants will need to deploy the entire system to carry out the PR program, adhering to the regulations and registration requirements for medical devices in Malaysia. According to the consolidated evidence of TR system development, this work should proceed with usability studies, thus identifying ease of use, possible usability difficulties and issues and patients' satisfaction. Future research should focus on testing the system's effectiveness through feasibility, disease-free cohorts and a clinical efficacy study (RCT).^{51,141} These studies should also consider the elderly-associated frailty and the grey digital divide. Cross-cultural validation would also be recommended for future research if non-Malaysian users use this system. The future inclusion of artificial intelligence is promising for monitoring and disease management.^{142,143} However, privacy, security, quality assessment, reproducibility and uncertainty related to artificial intelligence should be considered.¹⁴³

Conclusion

In this study, we identified and developed, through the UCD iterative design and by adopting the self-management theory, the essential modules and functionalities to provide PTR services for patients with COPD. We outlined the

symptom assessment, lung volume measurement and functional capacity testing. We developed the action plan, breathing exercises, chest clearance and physical activity for intervention. We also outlined the education module, the COPD community, the risk factor monitoring and the reminders. Usability and feasibility testing studies will follow this development study before being available for patients' use.

Acknowledgements: The authors would like to acknowledge all study participants for their contributions. We thank the managers at the hospital for enabling the organisation of FGDs. We would also like to thank all colleagues involved in the mobile app modules' content validity evaluation and colleagues who facilitated the discussions and data collection.

Authors' contributions: SG imported the data, analysed the data, prepared the FGD moderator guide and the app prototypes, prepared the content validity document, conducted the FGDs and the meeting with experts and was the primary writer of the manuscript. AFML, NMA and AKAS discussed and agreed on the moderator guide for the FGDs, content analysis document, and all versions of the app prototype and contributed to writing the manuscript. All authors read and approved the final manuscript.

Declaration of conflicting interests: The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethical approval: This study was approved by the Ethics and Research Committee (UKM PP1/111/8/JEP-2022–561).

Funding: The authors received no financial support for the research, authorship, and/or publication of this article.

Guarantor: AFML.

ORCID iDs: Suad J. Ghaben  <https://orcid.org/0000-0001-8653-5249>

Arimi Fitri Mat Ludin  <https://orcid.org/0000-0003-1517-2115>

Devinder Kaur Ajit Singh  <https://orcid.org/0000-0002-6551-0437>

Supplemental material: Supplemental material for this article is available online.

References

1. Agustí A, Celli BR, Criner GJ, et al. Global initiative for chronic obstructive lung disease 2023 report: GOLD executive summary. *Am J Respir Crit Care Med* 2023; 207: 819–837.
2. Global Initiative for Chronic Obstructive Lung Disease (GOLD). *Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease*. 2023. USA: GOLD, 2023.
3. Forum of International Respiratory Societies. *The global impact of respiratory disease*. Lausanne: European Respiratory Society, 2017.
4. Holland AE, Cox NS, Houchen-Wolloff L, et al. Defining modern pulmonary rehabilitation. An official American Thoracic Society Workshop Report. *Ann Am Thorac Soc* 2021; 18: e12–e29.
5. Lindenauer PK, Stefan MS, Pekow PS, et al. Association between initiation of pulmonary rehabilitation after hospitalization for COPD and 1-year survival among Medicare beneficiaries. *JAMA* 2020; 323: 1813–1823.
6. Puhan MA, Gimeno-Santos E, Cates CJ, et al. Pulmonary rehabilitation following exacerbations of chronic obstructive pulmonary disease. *Cochrane Database Syst Rev* 2016; 15: 1–85. doi:10.1002/14651858.CD005305.pub4
7. Lahham A and Holland AE. The need for expanding pulmonary rehabilitation services. *Life* 2021; 11: 1236.
8. Sami R, Salehi K, Hashemi M, et al. Exploring the barriers to pulmonary rehabilitation for patients with chronic obstructive pulmonary disease: a qualitative study. *BMC Health Serv Res* 2021; 21: 1–10.
9. Cox NS, Oliveira CC, Lahham A, et al. Pulmonary rehabilitation referral and participation are commonly influenced by environment, knowledge, and beliefs about consequences: a systematic review using the theoretical domains framework. *J Physiother* 2017; 63: 84–93.
10. Levack WM, Jones B, Grainger R, et al. Whakawhānauatanga: the importance of culturally meaningful connections to improve uptake of pulmonary rehabilitation by Māori with COPD – a qualitative study. *Int J Chron Obstruct Pulmon Dis* 2016; 11: 489–501.
11. Halpin DM, Celli BR, Criner GJ, et al. It is time for the world to take COPD seriously: a statement from the GOLD board of directors. *Eur Respir Soc* 2019; 54: 1–5. doi:10.1183/13993003.00914-2019
12. Orme MW, Free RC, Manise A, et al. Global RECHARGE: Establishing a standard international data set for pulmonary rehabilitation in low-and middle-income countries. *J Glob Health* 2020; 10: 1–5.
13. Habib GM, Uzzaman MN, Malik P, et al. Engaging with stakeholders in a research programme to promote implementation of pulmonary rehabilitation in Bangladesh: Challenges and opportunities. *J Glob Health* 2020; 10: 1–5.
14. Martz E. *Promoting self-management of chronic health conditions: theories and practice*. Oxford: Oxford University Press, 2017.
15. Mulligan H, Wilkinson A, Chen D, et al. Components of community rehabilitation programme for adults with chronic conditions: a systematic review. *Int J Nurs Stud* 2019; 97: 114–129.
16. Richardson CR, Franklin B, Moy ML, et al. Advances in rehabilitation for chronic diseases: improving health outcomes and function. *Br Med J* 2019; 365: 1–12.
17. O'Connell S, Mc Carthy VJ and Savage E. Frameworks for self-management support for chronic disease: a cross-country comparative document analysis. *BMC Health Serv Res* 2018; 18: 1–10.
18. Ryan P and Sawin KJ. The individual and family self-management theory: background and perspectives on

- context, process, and outcomes. *Nurs Outlook* 2009; 57: 217–225.e6. e216.
19. Davies A, Mueller J, Hennings J, et al. Recommendations for developing support tools with people suffering from chronic obstructive pulmonary disease: co-design and pilot testing of a mobile health prototype. *JMIR Hum Factors* 2020; 7: e16289.
 20. Deng N, Sheng L, Jiang W, et al. A home-based pulmonary rehabilitation mHealth system to enhance the exercise capacity of patients with COPD: development and evaluation. *BMC Med Inform Decis Mak* 2021; 21: 1–15.
 21. Korpershoek YJ, Hermesen S, Schoonhoven L, et al. User-centered design of a mobile health intervention to enhance exacerbation-related self-management in patients with chronic obstructive pulmonary disease (copilot): mixed methods study. *J Med Internet Res* 2020; 22: e15449.
 22. Kwon H, Lee S, Jung E, et al. An mHealth management platform for patients with chronic obstructive pulmonary disease (efil breath): randomized controlled trial. *JMIR Mhealth Uhealth*. 2018; 6: e10502.
 23. Velardo C, Shah SA, Gibson O, et al. Digital health system for personalised COPD long-term management. *BMC Med Inform Decis Mak* 2017; 17: 1–13.
 24. Hessler DM, Fisher L, Bowyer V, et al. Self-management support for chronic disease in primary care: frequency of patient self-management problems and patient reported priorities, and alignment with ultimate behavior goal selection. *BMC Fam Pract* 2019; 20: 1–10.
 25. Novak M, Costantini L, Schneider S, et al. Approaches to self-management in chronic illness. In: *Seminars in dialysis*. Oxford: Wiley Online Library, 2013, pp. 188–194.
 26. Global Initiative for Chronic Obstructive Lung Disease. *Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary diseases (2024 REPORT)*. USA: GLOD, 2024.
 27. Mubarak F and Suomi R. Elderly forgotten? Digital exclusion in the information age and the rising grey digital divide. *Inquiry* 2022; 59: 00469580221096272.
 28. Tomczyk Ł, Mascia ML, Gierszewski D, et al. Barriers to digital inclusion among older people: a intergenerational reflection on the need to develop digital competences for the group with the highest level of digital exclusion. *Innoeduca* 2023; 9: 5–26. doi:10.24310/innoeduca.2023.v9i1.16433
 29. World Health Organization. *mHealth: new horizons for health through mobile technologies*. Vol. 64, 2011, pp.5–16.
 30. Rowland SP, Fitzgerald JE, Holme T, et al. What is the clinical value of mHealth for patients? *NPJ Digit Med* 2020; 3: 4.
 31. Ghaben SJ, Mat Ludin AF, Mohamad Ali N, et al. A framework for design and usability testing of telerehabilitation system for adults with chronic diseases: a panoramic scoping review. *Digit Health* 2023; 9: 20552076231191014.
 32. Tarricone R, Petracca F, Ciani O, et al. Distinguishing features in the assessment of mHealth apps. *Expert Rev Pharmacoecon Outcomes Res* 2021; 21: 521–526.
 33. Istepanian RS and AlAnzi T. Mobile health (m-health): evidence-based progress or scientific retrogression. *Biomedical information technology*. London: Elsevier, 2020, pp. 717–733.
 34. Paglialonga A, Patel AA, Pinto E, et al. The Healthcare System Perspective in mHealth. In: Andreoni G, Perego P and Frumento E (eds) *m_Health Current and Future Applications*. Cham: Springer International Publishing, 2019, pp.127–142.
 35. Broderick A and Haque F. *Mobile health and patient engagement in the safety-net: a survey of community health centers and clinics*. Vol. 97. The Commonwealth Fund, 2015, pp.1–8.
 36. Mehl G, Tunçalp Ö, Ratanaprayul N, et al. WHO SMART guidelines: optimising country-level use of guideline recommendations in the digital age. *Lancet Digit Health* 2021; 3: e213–e216.
 37. World Health Organization. *Use of appropriate digital technologies for public health*. Geneva: World Health Organization, 2018.
 38. Carlone S, Balbi B, Bezzi M, et al. Health and social impacts of COPD and the problem of under-diagnosis. *Multidiscip Respir Med* 2014; 9: –6.
 39. Singh SJ, Halpin DM, Salvi S, et al. Exercise and pulmonary rehabilitation for people with chronic lung disease in LMICs: challenges and opportunities. *Lancet Respir Med* 2019; 7: 1002–1004.
 40. Blanco I, Diego I, Bueno P, et al. Geographic distribution of COPD prevalence in the world displayed by geographic information system maps. *Eur Respir J* 2019; 54: 1900610. doi:10.1183/13993003.00610-2019
 41. Group RCW. COPD prevalence in 12 Asia–pacific countries and regions: projections based on the COPD prevalence estimation model. *Respirology* 2003; 8: 192–198.
 42. ur Rehman A, Hassali MAA, Muhammad SA, et al. Economic burden of chronic obstructive pulmonary disease patients in Malaysia: a longitudinal study. *Pharmacoecon Open* 2021; 5: 35–44.
 43. Au R, Muhammad SA, Tasleem Z, et al. Humanistic and socioeconomic burden of COPD patients and their caregivers in Malaysia. *Sci Rep* 2021; 11: 22598.
 44. Chan SC, Engksan JP, Nathan JJ, et al. Developing a home-based pulmonary rehabilitation programme for patients with chronic respiratory diseases in Malaysia: A mixed-method feasibility study. *J Glob Health* 2023; 13: 1–7.
 45. Chan SC, Sekhon JK, Engksan JP, et al. Barriers and challenges of implementing pulmonary rehabilitation in Malaysia: Stakeholders' perspectives. *J Glob Health* 2021; 11: 1–4.
 46. Jafni TI, Bahari M, Ismail W, et al. Exploring barriers that affect telerehabilitation readiness: a case study of rehabilitation centre in Malaysia. In: *Recent Trends in Data Science and Soft Computing: Proceedings of the 3rd International Conference of Reliable Information and Communication Technology (IRICT 2018)*, 2019, pp.761–771. Springer.
 47. Jackson T, Williams S and Fernandes G. Engaging stakeholders and communities to improve respiratory health in Asia. *J Glob Health* 2022; 12: 1–3.
 48. Ghaben SJ, Aqel MO, Sama'a AB, et al. Aerobika as an evidence based physiotherapy procedure for COPD and the proposition of a smart OPEP device. In: *2020 International Conference on Assistive and Rehabilitation Technologies (iCareTech) 2020*, pp. 143–148. IEEE.

49. Creswell JW and Creswell JD. Mixed methods procedures. In: Salmon H (ed) *Research design: qualitative, quantitative, and mixed methods approaches*. Los Angeles, USA: Sage Publications, Inc., 2018, pp.294–326.
50. Cornet VP, Toscos T, Bolchini D, et al. Untold stories in user-centered design of mobile health: practical challenges and strategies learned from the design and evaluation of an app for older adults with heart failure. *JMIR Mhealth Uhealth* 2020; 8: e17703.
51. Jacobs MA and Graham AL. Iterative development and evaluation methods of mHealth behavior change interventions. *Curr Opin Psychol* 2016; 9: 33–37.
52. Fetter MD, Curry LA and Creswell JW. Achieving integration in mixed methods designs – principles and practices. *Health Serv Res* 2013; 48: 2134–2156.
53. Gale NK, Heath G, Cameron E, et al. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Med Res Methodol* 2013; 13: –8.
54. Spencer, L, Ritchie J, O'Connor W, et al. Analysis in practice. In: Nane Ritchie JL, Nicholis CM and Ormston R (eds) *Qualitative research: practice: a guide for social science students and researchers*. 2nd ed. London: Sage Publications Ltd, 2013, pp.376–433.
55. Linneberg MS and Korsgaard S. Coding qualitative data: a synthesis guiding the novice. *Qual Res J* 2019; 19: 259–270.
56. Ector GI, Westerweel PE, Hermens RP, et al. The development of a web-based, patient-centered intervention for patients with chronic myeloid leukemia (CMylife): design thinking development approach. *J Med Internet Res* 2020; 22: e15895.
57. Subramaniam A, Hensley E, Stojancic R, et al. Careful considerations for mHealth app development: lessons learned from QuestExplore. *Mhealth* 2022; 8: 1–10. doi:10.21037/mhealth-21-51
58. Alan Davies JM. Designing an mHealth intervention. *Developing medical apps and mHealth interventions: a Guide for Researchers, physicians and informaticians*. Switzerland: Springer Nature Switzerland, 2020, pp. 98–99.
59. Yusoff MSB. ABC Of content validation and content validity index calculation. *Educ Med J* 2019; 11: 49–54.
60. Rodrigues IB, Adachi JD, Beattie KA, et al. Development and validation of a new tool to measure the facilitators, barriers and preferences to exercise in people with osteoporosis. *BMC Musculoskelet Disord* 2017; 18: –9.
61. Polit DF and Beck CT. The content validity index: are you sure you know what's being reported? Critique and recommendations. *Res Nurs Health* 2006; 29: 489–497.
62. Turner SF, Cardinal LB and Burton RM. Research design for mixed methods: a triangulation-based framework and roadmap. *Organ Res Methods* 2017; 20: 243–267.
63. Dupin CM and Borglin G. Usability and application of a data integration technique (following the thread) for multi-and mixed methods research: a systematic review. *Int J Nurs Stud* 2020; 108: 103608.
64. Steinmetz-Wood M, Pluye P and Ross NA. The planning and reporting of mixed methods studies on the built environment and health. *Prev Med* 2019; 126: 105752.
65. Jones P, Harding G, Berry P, et al. Development and first validation of the COPD assessment test. *Eur Respir J* 2009; 34: 648–654.
66. Husebø G, Köll RM, Nielsen AF, et al. CAT-score is a predictor for mortality in COPD. *Eur Respir J* 2016; 48: PA3106.
67. Karloh M, Mayer AF, Maurici R, et al. The COPD assessment test: what do we know so far?: a systematic review and meta-analysis about clinical outcomes prediction and classification of patients into GOLD stages. *Chest* 2016; 149: 413–425.
68. Lee S-D, Huang M-S, Kang J, et al. The COPD assessment test (CAT) assists prediction of COPD exacerbations in high-risk patients. *Respir Med* 2014; 108: 600–608.
69. Suetomo M, Kawayama T, Kinoshita T, et al. COPD Assessment tests scores are associated with exacerbated chronic obstructive pulmonary disease in Japanese patients. *Respir Investig* 2014; 52: 288–295.
70. Dodd JW, Hogg L, Nolan J, et al. The COPD assessment test (CAT): response to pulmonary rehabilitation. A multicentre, prospective study. *Thorax* 2011; 66: 425–429.
71. Zhou A, Zhou Z, Peng Y, et al. The role of CAT in evaluating the response to treatment of patients with AECOPD. *Int J Chron Obstruct Pulmon Dis* 2018; 13: 2849–2858. doi:10.2147/COPD.S175085
72. Jones PW. COPD Assessment Test (CAT), <https://www.mdcalc.com/calc/10161/copd-assessment-test-cat#creator-insights> (2024, accessed 23 March 2024).
73. Mahler DA and Wells CK. Evaluation of clinical methods for rating dyspnea. *Chest* 1988; 93: 580–586.
74. Hajiro T, Nishimura K, Tsukino M, et al. Analysis of clinical methods used to evaluate dyspnea in patients with chronic obstructive pulmonary disease. *Am J Respir Crit Care Med* 1998; 158: 1185–1189.
75. Hensch I, Strang S, Löfdahl C-G, et al. Health-related quality of life in a nationwide cohort of patients with COPD related to other characteristics. *Eur Clin Respir J* 2016; 3: 31459.
76. Mahler DA. mMRC (Modified Medical Research Council) Dyspnea Scale, <https://www.mdcalc.com/calc/4006/mmrc-modified-medical-research-council-dyspnea-scale> (2014 accessed 23 March 2024).
77. Laboratories ACoPSfCPF. ATS statement: guidelines for the six-minute walk test. *Am J Respir Crit Care Med* 2002; 166: 111–117.
78. Enright PL and Sherrill DL. Reference equations for the six-minute walk in healthy adults. *Am J Respir Crit Care Med* 1998; 158: 1384–1387.
79. Enright PL. The six-minute walk test. *Respir Care* 2003; 48: 783–785.
80. Enright PL. 6 Minute Walk Distance. USA: MDCalc. <https://www.mdcalc.com/calc/3983/6-min-walk-distance> (2024, accessed 23 March 2024).
81. Exarchos KP, Gogali A, Sioutkou A, et al. Validation of the portable Bluetooth® Air Next spirometer in patients with different respiratory diseases. *Respir Res* 2020; 21: –7.
82. Barr RG, Stemple KJ, Mesia-Vela S, et al. Reproducibility and validity of a handheld spirometer. *Respir Care* 2008; 53: 433–441.

83. Ramos Hernández C, Núñez Fernández M, Pallares Sanmartín A, et al. Validation of the portable air-smart spirometer. *PLoS One* 2018; 13: e0192789.
84. Represas-Represas C, Fernández-Villar A, Ruano-Raviña A, et al. Screening for chronic obstructive pulmonary disease: validity and reliability of a portable device in non-specialized healthcare settings. *PLoS One* 2016; 11: e0145571.
85. Feizi H, Alizadeh M, Nejadghaderi SA, et al. The burden of chronic obstructive pulmonary disease and its attributable risk factors in the Middle East and north Africa region, 1990–2019. *Respir Res* 2022; 23: 319.
86. Labaki WW and Han MK. Chronic respiratory diseases: a global view. *Lancet Respir Med* 2020; 8: 531–533.
87. Emerman CL, Effron D and Lukens TW. Spirometric criteria for hospital admission of patients with acute exacerbation of COPD. *Chest* 1991; 99: 595–599.
88. Rea H, Kenealy T, Adair J, et al. Spirometry for patients in hospital and one month after admission with an acute exacerbation of COPD. *Int J Chron Obstruct Pulmon Dis* 2011; 6: 527–532.
89. Loh CH, Genese FA, Kannan KK, et al. Spirometry in hospitalized patients with acute exacerbation of COPD accurately predicts post discharge airflow obstruction. *Chron Obstruct Pulmon Dis* 2018; 5: 124.
90. Flattet Y, Garin N, Serratrice J, et al. Determining prognosis in acute exacerbation of COPD. *Int J Chron Obstruct Pulmon Dis* 2017; 12: 467–475. doi:10.2147/COPD.S122382
91. Celli BR, Cote CG, Marin JM, et al. The body-mass index, airflow obstruction, dyspnea, and exercise capacity index in chronic obstructive pulmonary disease. *N Engl J Med* 2004; 350: 1005–1012.
92. Ong K-C, Earnest A and Lu S-J. A multidimensional grading system (BODE index) as predictor of hospitalization for COPD. *Chest* 2005; 128: 3810–3816.
93. Marin JM, Carrizo SJ, Casanova C, et al. Prediction of risk of COPD exacerbations by the BODE index. *Respir Med* 2009; 103: 373–378.
94. Celli BR. BODE Index for COPD Survival. <https://www.mdcalc.com/calc/3916/bode-index-copd-survival> (2024, accessed 23 March 2024).
95. Committee NCE. Management of Chronic Obstructive Pulmonary Disease (COPD): National Clinical Guideline No. 27. 2021.
96. Alison JA, McKeough ZJ, Johnston K, et al. Australian and New Zealand pulmonary rehabilitation guidelines. *Respirology* 2017; 22: 800–819.
97. Borg G. BorgPerception AB, <https://borgperception.se/> (2024, 2024).
98. NCP Respiratory. *Guidance for setting up a Virtual Pulmonary Rehabilitation Programme. Guidance*. Ireland: NCP Respiratory, 2023.
99. NCP Respiratory. *A guidance document for setting up a Pulmonary Rehabilitation Programme for Healthcare Professionals*. Ireland: NCP Respiratory. 2020.
100. O'Sullivan SB and Susan B. Clinical decision making and examination. In: O'Sullivan TJS and Fulk G (eds) *Physical rehabilitation*. 7th ed. Philadelphia, USA: F.A DAVIS, 2019, pp. 1–27.
101. Lung Foundation Australia. Patient Education, <https://pulmonaryrehab.com.au/patient-education/> (2024, accessed 17 March 2024).
102. Obro LF, Heiselberg K, Krogh PG, et al. Combining mHealth and health-coaching for improving self-management in chronic care. A scoping review. *Patient Educ Couns* 2021; 104: 680–688.
103. Bashi N, Fatehi F, Fallah M, et al. Self-management education through mHealth: review of strategies and structures. *JMIR Mhealth Uhealth* 2018; 6: e10771.
104. Lung Foundation Australia. Pulmonary Rehabilitation Toolkit, <https://lungfoundation.com.au/health-professionals/clinical-information/pulmonary-rehabilitation/pr-toolkit/> (2024, accessed 17 March 2024).
105. Queensland Health and Lung Foundation Australia. *Better living with chronic obstructive pulmonary disease: A patient guide*. 3rd ed. Australia: Australia Queensland Government and Lung Foundation, 2023.
106. Qudah B and Luetsch K. The influence of mobile health applications on patient-healthcare provider relationships: a systematic, narrative review. *Patient Educ Couns* 2019; 102: 1080–1089.
107. Steinman L, Heang H, van Pelt M, et al. Facilitators and barriers to chronic disease self-management and mobile health interventions for people living with diabetes and hypertension in Cambodia: qualitative study. *JMIR Mhealth Uhealth* 2020; 8: e13536.
108. Park PH, Wambui CK, Atieno S, et al. Improving diabetes management and cardiovascular risk factors through peer-led self-management support groups in western Kenya. *Diabetes Care* 2015; 38: e110–e111.
109. Cho Y, Zhang H, Harris MR, et al. Acceptance and use of home-based electronic symptom self-reporting systems in patients with cancer: systematic review. *J Med Internet Res* 2021; 23: e24638.
110. PubMed Mesh. Administrative Claims, Healthcare, <https://www.ncbi.nlm.nih.gov/mesh/2009747> (2024, accessed 18 March 2024).
111. Jakob R, Harperink S, Rudolf AM, et al. Factors influencing adherence to mHealth apps for prevention or management of noncommunicable diseases: systematic review. *J Med Internet Res* 2022; 24: e35371.
112. Druce KL, Dixon WG and McBeth J. Maximizing engagement in mobile health studies: lessons learned and future directions. *Rheumat Dis Clin* 2019; 45: 159–172.
113. Shi N, Wong AK, Wong FK, et al. Mobile health application-based interventions to improve self-management of chemotherapy-related symptoms among people with breast cancer who are undergoing chemotherapy: a systematic review. *Oncologist* 2023; 28: e175–e182.
114. Wallisch A, Sankowski O, Krause D, et al. Overcoming fuzzy design practice: revealing potentials of user-centered design research and methodological concepts related to user involvement. In: 2019 IEEE international conference on engineering, technology and innovation (ICE/ITMC), 2019, pp.1–9: IEEE.
115. Farao J, Malila B, Conrad N, et al. A user-centred design framework for mHealth. *PLoS One* 2020; 15: e0237910.
116. Gharajeh MS. Waterative model: an integration of the waterfall and iterative software development paradigms. *Database Syst J* 2019; 10: 75–81.

117. Lung Foundation Australia. COPD Action Plan, <https://lungfoundation.com.au/resources/copd-action-plan/> (2024, accessed 26 March 2024).
118. Bury TJ and Stokes EK. A global view of direct access and patient self-referral to physical therapy: implications for the profession. *Phys Ther* 2013; 93: 449–459.
119. World Physiotherapy. Policy statement: Direct access and patient/client self-referral to physiotherapy, <https://world.physio/policy/ps-direct-access> (2023, accessed 27 March 2024).
120. Yang M, Bishop A, Sussex J, et al. Economic evaluation of patient direct access to NHS physiotherapy services. *Physiotherapy* 2021; 111: 40–47.
121. Maselli F, Piano L, Cecchetto S, et al. Direct access to physical therapy: should Italy move forward? *Int J Environ Res Public Health* 2022; 19: 555.
122. Demont A, Bourmaud A, Kechichian A, et al. The impact of direct access physiotherapy compared to primary care physician led usual care for patients with musculoskeletal disorders: a systematic review of the literature. *Disabil Rehabil* 2021; 43: 1637–1648.
123. Lim WS, Sharma S and Devan H. Physiotherapists' attitudes towards and challenges of working in a referral-based practice setting—a systematic scoping review. *Eur J Physiother* 2021; 23: 332–343.
124. Meyerowitz-Katz G, Ravi S, Arnolda L, et al. Rates of attrition and dropout in app-based interventions for chronic disease: systematic review and meta-analysis. *J Med Internet Res* 2020; 22: e20283.
125. Iyawa GE, Herselman M and Botha A. A scoping review of digital health innovation ecosystems in developed and developing countries. In: 2017 IST-Africa Week Conference (IST-Africa), 2017, pp.1–10: IEEE.
126. Ghaben SJ and Mat Ludin AF. Treatment Outcomes. In: Heston TF (ed) *A comprehensive overview of telemedicine*. 1st ed. London, UK: IntecOpen Limited, 2024, pp.120–144.
127. del Río-Lanza A-B, Suárez-Vázquez A, Suárez-Álvarez L, et al. Mobile health (mHealth): facilitators and barriers of the intention of use in patients with chronic illnesses. *J Commun Healthc* 2020; 13: 138–146.
128. Brenner M, Weir A, McCann M, et al. Development of the key performance indicators for digital health interventions: a scoping review. *Digit Health* 2023; 9: 1–7.
129. Khalifa M and Khalid P. Developing strategic health care key performance indicators: a case study on a tertiary care hospital. *Procedia Comput Sci* 2015; 63: 459–466.
130. World Bank. World Bank Country and Lending Groups: Country Classification, <https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups#:~:text=For%20the%20current%202024%20fiscal,those%20with%20a%20GNI%20per> (2024, accessed 24 March 2024).
131. International Citizens Insurance. Understanding Malaysia's Healthcare System. <https://www.internationalinsurance.com/health/systems/malaysia.php> (2024, accessed 24 March 2024).
132. International Trade Administration. Malaysia – Healthcare, <https://www.trade.gov/country-commercial-guides/malaysia-healthcare> (2024, accessed 24 March 2024).
133. Tahun Pengkomersialan Malaysia. Malaysia Commercialization Year 2.0, <https://mcyportal.mosti.gov.my/tips-panduan/technology-readiness-level-trl/> (2019–2023, accessed 24 March 2024).
134. Borsa JC, Damásio BF and Bandeira DR. Cross-cultural adaptation and validation of psychological instruments: some considerations. *Paidéia (Ribeirão Preto)* 2012; 22: 423–432.
135. Dias R. Cross-cultural adaptation. In: Maggino F (ed) *Encyclopedia of quality of life and well-being research*. 2nd ed. Switzerland: Springer Nature Switzerland AG, 2023, pp.1512–1515.
136. Wong W. Cross-cultural validation. In: Maggino F (ed) *Encyclopedia of quality of life and well-being research*. 2nd ed. Switzerland: Springer nature Switzerland, 2023, pp.1517–1520.
137. Birkhoff SD and Moriarty H. Challenges in mobile health app research: strategies for interprofessional researchers. *J Interprof Educ Pract* 2020; 19: 100325.
138. Maguire R, Miller M, Sage M, et al. Results of a UK based pilot study of a mobile phone based advanced symptom management system (ASyMS) in the remote monitoring of chemotherapy related toxicity. *Clin Eff Nurs* 2005; 9: 202–210.
139. Cowie J, McCann L, Maguire R, et al. Real-time management of chemotherapy toxicity using the advanced symptom management system (ASyMS). *J Decis Syst* 2013; 22: 43–52.
140. Moradian S, Krzyzanowska MK, Maguire R, et al. Usability evaluation of a mobile phone-based system for remote monitoring and management of chemotherapy-related side effects in cancer patients: mixed-methods study. *JMIR Cancer* 2018; 4: e10932.
141. Nickolls BJ, Relton C, Hemkens L, et al. Randomised trials conducted using cohorts: a scoping review. *BMJ Open* 2024; 14: e075601.
142. Bhatt P, Liu J, Gong Y, et al. Emerging artificial intelligence-empowered mhealth: scoping review. *JMIR Mhealth Uhealth* 2022; 10: e35053.
143. Deniz-Garcia A, Fabelo H, Rodriguez-Almeida AJ, et al. Quality, usability, and effectiveness of mHealth apps and the role of artificial intelligence: current scenario and challenges. *J Med Internet Res* 2023; 25: e44030.