NICE National Institute for Health and Care Excellence

Medical technologies advisory committee (MTAC)

17th November 2023

Information pack for draft guidance considerations on

GID-HTE10019 Digital pulmonary rehabilitation technologies for adults with chronic obstructive pulmonary disease: early value assessment

This product was selected for early value assessment in 2022. Clinical and economic evidence has been submitted to NICE by the company, and an external assessment centre report has been completed.

This pack presents the information required for the MTAC to make draft recommendations on this topic. The consultation period on these draft recommendations is scheduled to take place between 20 December 2023 and 10 January 2023.

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Papers included in pack:

1. Front sheet
2. Final scope
3. Assessment report (AR)
4. Assessment Report Overview (ARO)
5. Professional organisation submission from the Association of Respiratory Nurses (ARNS)
6. Professional organisation submission from the British Thoracic Society (BTS)
7. Register of interest

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical Technologies Evaluation Programme

Digital technologies to support the delivery of pulmonary rehabilitation for adults with chronic obstructive pulmonary disease: early value assessment

Scope

August 2023

1 Introduction

The topic has been identified by NICE for early value assessment (EVA). The objective of EVA is to identify promising technologies in health and social care where there is greatest need and enable earlier conditional access while informing further evidence generation. The evidence developed will demonstrate if the expected benefits of the technologies are realised and inform a final NICE evaluation and decision on the routine use of the technology in the NHS.

2 Description of the technologies

This section describes the properties of digital technologies to support pulmonary rehabilitation based on information provided to NICE by companies and experts, and information available in the public domain. NICE has not carried out an independent evaluation of this description.

2.1 Purpose of the medical technology

In the UK, an estimated 1.2 million people are living with chronic obstructive pulmonary disease (COPD). COPD exacerbations are the second most common cause of emergency hospital admissions, accounting for 1 in 8 of all UK hospital admissions. Exacerbations requiring hospital treatment are associated with poorer prognosis and an increased risk of death (NICE Clinical Knowledge Summaries, 2023). CORE20PLUS5 lists the prevention of exacerbations and hospital admission in people with COPD a key priority.

Pulmonary rehabilitation is an exercise and education programme for people with lung disease, including COPD, who experience breathlessness. Evidence

suggests that 90% of patients who complete a pulmonary rehabilitation programme experience increased exercise capacity and improved quality of life. However, it is currently only offered to 13% of eligible COPD patients, with a focus on those with more severe COPD. Clinical experts state that limitations in workforce and service funding restrict the ability of the NHS to provide pulmonary rehabilitation to all patients who may benefit.

The NHS Long-Term Plan includes commitments related to respiratory disease, including the need to increase access to pulmonary rehabilitation. It also highlights that new models of providing rehabilitation to people with mild COPD, including digital tools, should be offered to provide support to a wider group of patients with rehabilitation and self-management support.

Digital technologies to support pulmonary rehabilitation are a possible treatment option for adults with COPD. Delivering digitally supported pulmonary rehabilitation could improve access, engagement and adherence to pulmonary rehabilitation programmes. These technologies could also reduce unplanned hospital admissions, reduce exacerbations, prevent deterioration of a person's condition and reduce health inequalities by reducing variations in access to and outcomes of care. But some people with COPD may need support in accessing and using digital technologies.

2.2 Product properties

This scope focuses on digital technologies to support pulmonary rehabilitation for adults with COPD. Following referral and an initial in-person assessment, digital technologies can be used to deliver aspects of pulmonary rehabilitation programmes remotely, allowing people with COPD to self-manage their care at home at a time that is convenient to their lifestyle. Digital technologies to support pulmonary rehabilitation can be accessed online or via an app. NICE's guideline for the diagnosis and management of COPD in over 16s recommends that pulmonary rehabilitation programmes should include multicomponent, multidisciplinary interventions that are tailored to the individual person's needs. Pulmonary rehabilitation programmes should last a minimum of 6 weeks (British Thoracic Society Quality Standards for Pulmonary Rehabilitation in Adults) and include an in-person assessment before starting and after completion, physical training, disease education, and nutritional, psychological and behavioural interventions.

For this EVA, NICE will consider digital pulmonary rehabilitation technologies that:

- are intended for use by adults with COPD

- include at least one digital component of pulmonary rehabilitation: physical training; disease education; nutritional, psychological or behavioural intervention
- have a minimum duration of at least 6 weeks
- meet the standards within the digital technology assessment criteria (DTAC), and have a CE or UKCA mark where required. Products may also be considered if they are actively working towards required CE or UKCA mark and meet all other standards within the DTAC
- are available for use in the NHS.

For this EVA, NICE will not consider digital pulmonary rehabilitation technologies that:

- replace the before and after in-person assessment
- are solely tele-rehab i.e. live pulmonary rehabilitation delivered remotely

Seven digital pulmonary rehabilitation technologies for adults with COPD are included in the scope.

Active+me REMOTE

Active+me REMOTE (Aseptika) is a cloud-based platform that supports the hybrid delivery of pulmonary rehabilitation and remote monitoring of adults with COPD at home. The Active+ REMOTE app includes an education programme delivered in small lessons and interactive exercise videos that increase in difficulty as a person's fitness and strength improves. The technology also collects patient generated data via an add-on pulse oximeter, spirometer and smart inhaler. The technology can be accessed via a mobile phone, tablet or desktop.

CliniTouch

CliniTouch (Spirit Health) is an online platform that supports the delivery of a 6-week digital pulmonary rehabilitation programme and facilitates remote monitoring of adults with COPD and other conditions. The digital pulmonary rehabilitation programme can be accessed via a mobile phone, tablet or desktop. The programme includes exercise sessions 3 times a week and users are asked to complete questionnaires before and after each session. Users are also contacted weekly by local healthcare professionals to monitor their progress and increase the complexity of exercises.

Kaia Health COPD

Kaia Health COPD (Kaia Health) facilitates the delivery of a personalised pulmonary rehabilitation programme. The technology includes educational modules, customisable daily training sessions and mindfulness exercises. It also facilitates communication with health coaches. The technology can be accessed via a mobile phone or tablet.

MyCOPD

myCOPD (my mhealth Ltd) is an online education, self-management, symptom reporting and pulmonary rehabilitation system. The myCOPD app includes a 6-week pulmonary rehabilitation course consisting of an incremental exercise programme with education sessions to help promote self-management of COPD. The app also has a dashboard of self-care tools and educational resources for people with all stages of COPD. The app can be accessed via a mobile phone or tablet.

Rehab Guru

Rehab Guru (Rehab Guru) is a digital exercise programme management software. Clinicians can use the technology to prescribe a personalised digital pulmonary rehabilitation programme. The technology includes exercise videos and users can share feedback with their clinician after each exercise and each session. Exercises are adjusted depending on a person's ability and goals. The technology can be accessed via a mobile phone, tablet or desktop.

Space for COPD

Space for COPD (University Hospitals of Leicester NHS Trust) is a digital self-management programme designed to help people with COPD manage their condition more effectively. The programme contains educational topics including information about medication, breathing control, exercise and nutritional advice. Users are encouraged to set goals, progress through a prescribed exercise programme and achieve weekly targets. The technology can be accessed via a mobile phone, tablet or desktop.

Wellinks

Wellinks (Wellinks) is an online platform that supports the delivery of a digital pulmonary rehabilitation programme and facilitates remote monitoring of adults with COPD. The programme includes tailored exercises, education, and motivational support. It also collects patient generated data via an add-on

pulse oximeter and spirometer. Wellinks can be accessed via a mobile phone or tablet.

3 Target condition

COPD is a long-term and progressive respiratory condition that causes breathlessness, a persistent chesty cough, persistent wheezing and frequent chest infections. The term 'COPD' includes chronic bronchitis and emphysema. COPD mainly affects older adults who smoke, and many people do not realise they have it. The breathing problems experienced with COPD tend to get worse over time and can limit a person's ability to undertake daily activities. Treatment can help keep the condition under control and includes stopping smoking, using inhalers and tablets, pulmonary rehabilitation, and surgery.

In 2020 to 2021, NHS Digital reported that approximately 1.17 million people (1.9% of the population) in England have been diagnosed with COPD and it is estimated that a further 2 million remain undiagnosed. Incidence of diagnosed COPD has risen from 1.7% to 1.9% of the population over the last 10 years. Chronic lower respiratory diseases were reported as the 3rd most common cause of mortality in England and Wales in 2023 (Office for National Statistics, 2023). COPD is much more common in areas of high deprivation. People living in these areas have a lower life expectancy than the general population, and COPD is responsible for 8% of this difference in men and 12% in women. Managing COPD in the UK costs the NHS over £800 million a year.

4 Care pathway

NICE's guideline for the diagnosis and management of COPD in over 16s (2019) states that COPD care should be delivered by a multidisciplinary team that includes respiratory nurse specialists. Pulmonary rehabilitation is defined as a multidisciplinary programme of care for people with chronic respiratory impairment. It should be individually tailored and designed to optimise each person's physical and social performance and autonomy.

The NHS service guidance for pulmonary rehabilitation (2020) says that services should be offered to all patients with a confirmed diagnosis of COPD or other chronic respiratory diseases. NICE's guideline for the diagnosis and management of COPD in over 16s (2019) recommends pulmonary rehabilitation to help better manage symptoms and improve exercise capacity and quality of life for people with COPD who are functionally breathless or those who have had a recent hospitalisation because of an acute exacerbation. NICE's guideline also says that pulmonary rehabilitation should

be offered to all people who view themselves as functionally disabled by COPD (usually Medical Research Council [MRC] dyspnoea scale grade 3 and above). However, the current NHS Long-Term Plan (2023) recommends that pulmonary rehabilitation should offered to people with mild COPD and above (MRC dyspnoea scale 2 and above).

Pulmonary rehabilitation programmes should last at least 6 weeks and include a minimum of 2 sessions per week. Programmes should include individually tailored and prescribed progressive exercise training, including both aerobic and resistance training, as well as a structured education programme. The British Thoracic Society Quality Standard for Pulmonary Rehabilitation in Adults (2014) recommends that pulmonary rehabilitation is delivered in face-to-face appointments. But clinical experts note that these standards are due to be reviewed and updated, and the Cochrane review of pulmonary rehabilitation (2015) that underpins the intervention includes a mixture of home-based methods.

Potential place of digital technologies to support pulmonary rehabilitation in the care pathway

Digital technologies to support pulmonary rehabilitation programmes would be offered as an option to adults with COPD that are referred for a pulmonary rehabilitation course. This could be at the time of diagnosis or following hospitalisation for an acute exacerbation, for example.

Pulmonary rehabilitation courses are typically delivered in groups of 8 to 16 people. They may be held in local hospitals or a range of accessible venues such as community halls, health centres and leisure centres. Pulmonary rehabilitation teams typically include trained healthcare professionals such as physiotherapists, nurses and occupational therapists.

Digital technologies to support pulmonary rehabilitation could be offered to facilitate the delivery of pulmonary rehabilitation in a person's home environment. People using digital technologies that support their pulmonary rehabilitation would still need to attend in-person appointments for their initial and end assessments. Digitally supported pulmonary rehabilitation would be delivered as part of a wider respiratory pathway where people can access several parts of the pathway at the same time. Referrals may come from a broad range of sources where an accurate diagnosis of COPD has been made. This may include, but is not limited to, primary care, intermediate care, secondary care, tertiary care, occupational health, private health or self-referrals for people who have an accurate diagnosis. Patient preference and engagement should be considered when helping people make decisions about the care that they want to receive.

5 Patient issues and preferences

The NHS service guidance for pulmonary rehabilitation lists a number of ways to improve accessibility to pulmonary rehabilitation services. This includes finding a suitable venue with adequate parking and transport links, delivering programmes at a suitable time, and making accommodations for those who are working where possible. Digital technologies to support pulmonary rehabilitation can be used via mobile phones, tablets or computers and can be accessed remotely in a person's home environment. For people struggling to access face-to-face pulmonary rehabilitation courses due to lack of available services, long waiting lists or inability to attend regular in person sessions (which could be due to travel or mobility restrictions, and other time commitments), digital technologies could improve access and engagement. Digitally supported pulmonary rehabilitation could also appeal to regular users of digital technologies, people who prefer to access healthcare remotely or people who are housebound due to illness.

Some people may not choose to use a digital technology to support their pulmonary rehabilitation and may prefer in-person clinician led treatment if this is available.

People may have some of the following concerns when considering whether they want to use a digital technology as part of their pulmonary rehabilitation:

- ability to use the technology
- fear of breathlessness from exercise (not knowing that some types of breathlessness are acceptable during the exercise)
- unpredictable nature of their co-morbidities
- possible costs incurred from using digital technologies, for example mobile data charges
- level of human support provided during digitally supported pulmonary rehab
- data security and quality control

People should be supported by healthcare professionals to make informed decisions about their care, including the use of digital technologies. Shared decision making should be supported so that people are fully involved throughout their care (see the NICE guideline for shared decision making).

6 Comparator

The comparator for this assessment is standard care for adults with COPD. Standard care consists of face-to-face pulmonary rehabilitation programmes. Access to pulmonary rehabilitation courses varies depending on location, and

some people are on waiting lists to access services. So, no or delayed treatment is also a relevant comparator.

During the COVID-19 pandemic, many areas provided pulmonary rehabilitation via paper 'manuals' of exercises for people with COPD to follow from home, as face to face classes were unavailable in many areas, and this may still be an option in some services (but with face to face assessment before and after the programme). Some areas provide hybrid programmes comprising face-to-face and live sessions delivered remotely (as opposed to a purpose-designed digital technology for pulmonary rehabilitation).

7 Scope of the assessment

Table 1 Scope of the assessment

Populations	Adults with a confirmed diagnosis of COPD who: • Have had a recent hospitalisation because of an acute exacerbation, or whose functional baseline has greatly changed and is not following the expected recovery path or • Have a MRC dyspnoea score of 2 or above or • Have decreased exercise capacity as measured by a validated outcome measure such as the 6-minute walk test
Subgroups	If the evidence allows the following subgroups will be considered: • Level of breathlessness (MRC dyspnoea score) • Having or not having comorbidities (including frailty) • Living in a rural or urban setting • Having had an exacerbation which required hospitalisation in the previous 12 months
Interventions (proposed technologies)	Digital pulmonary rehabilitation technologies for adults with COPD. This includes: • Active+me REMOTE • CliniTouch • Kaia Health COPD • myCOPD • Rehab Guru • SPACE for COPD • Wellinks

Comparators	• Standard care face-to-face pulmonary rehabilitation, either in a clinical or home-based setting • No treatment, or waiting list If data is available: • Hybrid of face-to-face and remote live pulmonary rehabilitation • Non-digital non-face-to-face options for components of pulmonary rehabilitation, for example printed exercise sheets
Healthcare setting	Secondary or community care
Outcomes	Outcomes for consideration may include: <u>High priority</u> • Exercise capacity measured by a validated outcome measure • Health-related quality of life • Other measures of respiratory function (including but not limited to the COPD assessment test [CAT] score, the MRC and the modified MRC dyspnoea score) • Intervention completion (receiving a final assessment), adherence, rates of attrition (dropouts) • Intervention-related adverse events • Acute exacerbations, hospital admissions, readmissions or emergency admissions <u>Other (if data available)</u> • Intervention uptake from those offered the technologies • Daily activity • Patient experience, technology usability and acceptability • Healthcare professional experience
Costs	Costs will be considered from an NHS and Person Social Services perspective. Costs for consideration may include: <u>High priority</u> • Costs of healthcare professional time (various grades) to deliver digitally supported pulmonary rehabilitation • Costs of healthcare professional time (various grades) to deliver standard care • Cost of the digital technologies including license fees and staff training <u>Other (if data are available)</u> • Cost to healthcare system of device acquisition, if relevant

	• Cost of other resource use (e.g. associated with managing COPD, adverse events, or complications):
	  ○ Healthcare appointments in primary, secondary and community care
	  ○ Cost of emergency department attendance, and length of stay if admitted to hospital
	  ○ Medication use and adverse events

Time horizon	The time horizon for estimating the clinical and cost effectiveness should be at least a year. This is to reflect any differences in costs or outcomes between the technologies such as the impact on hospital admissions. One year is also the typical length of time before someone is eligible to repeat a course of pulmonary rehabilitation.

8 Other issues for consideration

Characteristics of digitally enabled programmes

The digital technologies to support pulmonary rehabilitation included in the scope may have differences in terms of mode of delivery (computer, app), length of programme, and the frequency and intensity of support from a range of healthcare professionals. Some technologies solely provide aspects of pulmonary rehabilitation, and some technologies have additional functions, including symptom tracking and medication monitoring.

9 Potential equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

COPD is most common in people over 50. Men tend to be at higher risk of developing COPD than women. There is a higher prevalence of respiratory diseases in people from a lower socioeconomic background due to poorer living conditions and higher rates of smoking. People living in more disadvantaged areas also have a lower life expectancy than the general population. COPD is responsible for 8% of this difference in men and for 12% of this difference in women.

Digital technologies to support pulmonary rehabilitation are accessed via a mobile phone, tablet, or computer. People will need regular access to a device with internet access to use the technologies. Additional support and resources may therefore be needed for people who are unfamiliar with digital technologies or people who do not have access to smart devices or the

internet. People with a visual, hearing, or cognitive impairment, problems with manual dexterity, a learning disability, or who are unable to read or understand health-related information (including people who cannot read English) or neurodivergent people may need additional support to use digital technologies. Some people would benefit to receive their digitally supported pulmonary rehabilitation in a language other than English. People's ethnic, religious, and cultural background may affect their views of digital pulmonary rehabilitation interventions. For example, some people may not want to attend a mixed gender exercise class. Healthcare professionals should discuss the language and cultural content of digitally enabled programmes with patients before use.

In addition, there are groups of people who may struggle to access digitally supported pulmonary rehabilitation, these include people who are homeless, people living in homes of multiple occupancy, people living in residential care and people with mental health conditions.

Age, sex, disability, race, and religion or belief are protected characteristics under the Equality Act 2010.

10 Potential implementation issues

Equity of access

Digital technologies to support pulmonary rehabilitation may not be suitable for some people. COPD is most common in people over 50 and there is a higher prevalence of respiratory diseases in people from a lower socioeconomic background. Some people may be less comfortable or skilled at using digital technologies or may not have access to appropriate equipment, the internet, and may prefer another treatment option.

Capacity limitations

Implementation of digital technologies to support pulmonary rehabilitation may initially increase staff workload to set up new pathways and become familiar with new systems. Staff may need to spend additional time attending training courses or watching training videos. Additional time may also be needed for staff to train patients to use the digital technologies. Some companies may offer patient training, and some may expect local clinicians to provide this to patients.

Costs

Costs of technologies may differ. Implementation of digital pulmonary rehabilitation technologies may initially increase costs to set up new pathways

and change service delivery. These could include training, hardware and internet access costs. Smaller service areas may have higher costs per user due to not needing as many licences for the technology. Digital technologies may be chosen based on the balance between costs and expected outcomes.

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Digital technologies to deliver pulmonary rehabilitation programmes for adults with COPD [GID-HTE10019]

External Assessment Group report

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Early Value Assessment Programme

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Contains confidential information: Yes

Number of attached appendices: 5

Purpose of the assessment report

The purpose of this External Assessment Group (EAG) report is to review the evidence currently available for included technologies and advise what further evidence should be collected to help inform decisions on whether the technologies should be widely adopted in the NHS. The report may also include additional analysis of the submitted evidence or new clinical and/or economic evidence. NICE has commissioned this work and the report forms part of the papers considered by the Medical Technologies Advisory Committee when it is making decisions about the early value assessment.

Declared interests of the authors

Description of any declared interests with related companies, and the matter under consideration. See NICE's Policy on managing interests for board members and employees.

None.

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Responsibility for report

The views expressed in this report are those of the authors and not those of NICE. Any errors are the responsibility of the authors.

Contents

Abbreviations

Term	Definition
6MWT	Six-Minute Walk Test
AHP	Allied health professional
AIC	Academic-in-confidence
BCKQ	Bristol COPD Knowledge Questionnaire
CAT	COPD Assessment Test
CCA	Cost-consequences analysis
CE mark	*Conformité européenne* (European conformity) marking
CEA	Cost-effectiveness analysis
CIC	Commercial-in-confidence
COPD	Chronic Obstructive Pulmonary Disease
CRD	Chronic refractory dyspnoea
CRQ	Chronic Respiratory Questionnaire
DPA	Data Protection Agreement
DPIA	Data Protection Impact Assessment
DTAC	Digital Technology Assessment Criteria
EAG	External assessment group
ED	Emergency department
ESF	Evidence Standards Framework
ESWT	Endurance Shuttle Walk Test
EVA	Early value assessment
F2F	Face to face
FEV	Forced expiratory volume
GB	Great Britain
GBP	British Pound
GOLD	Global Initiative for Chronic Obstructive Lung Disease
GP	General Practitioner
HADS	Hospital Anxiety and Depression Scale
HCP	Healthcare professional
HRQoL	Health-related quality of life
ICTRP	International Registry Platform
INAHTA	International Network of Agencies for Health Technology Assessment

ISWT	Incremental Shuttle Walk Test
MAUDE	Manufacturer and User Facility Device Experience
MCID	Minimal clinically important difference
MDD	Medical devices directive
MeSH	Medical subject headings
MHRA	Medicines & Healthcare products Regulatory Agency
MRC	Medical Research Council
mMRC	Modified Medical Research Council
N/A	Not applicable
NPS	Net Promoter Score
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
NLM	National Library of Medicine
NR	Not reported
PAM	Patient activation measure
PenTAG	Peninsula Technology Assessment Group
PR	Pulmonary rehabilitation
PRAISE	PR Adapted Index of Self-Efficacy
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PSS	Personal Social Services
PSSRU	Personal Social Services Research Unit
RCT	Randomised controlled trial
RWE	Real world evidence
ScHARR	School of Health and Related Research
SEAMS	Self-efficacy for appropriate medication use scale
SCM	Specialist Committee Member
SGRQ	St. George's Respiratory Questionnaire
SIGN	Scottish Intercollegiate Guidelines Network
TIDieR	Template for Intervention Description and Replication
UK	United Kingdom
UKCA	United Kingdom Conformity Assessed marking
USA	United States of America
VAT	Value added tax

VSAQ	Veteran specific activity questionnaire
WD	Walking distance
∆WD	Change in walking distance
WHO	World Health Organization
WPAI	Work productivity activity impairment

1. EXECUTIVE SUMMARY

Quality and relevance of clinical evidence

Digitally supported pulmonary rehabilitation are digital technologies that replace part of conventional face-to-face pulmonary rehabilitation. The NICE scope defines eligible technologies as ones that include at least one digital component of pulmonary rehabilitation: physical training; disease education; nutritional, psychological or behavioural intervention. Technologies that replace the before and after in person assessment or are solely tele-rehab, such as live pulmonary rehabilitation delivered virtually, were not considered eligible.

The findings of this rapid appraisal suggested that there is some evidence that digitally supported pulmonary rehabilitation may be a potentially promising treatment option for people with COPD. However, there are limitations in the evidence base that mean this finding is uncertain and more evidence generation is required. Notably, the evidence is not distributed evenly across technologies or outcomes. Most evidence was available for exercise capacity and respiratory function. There was relatively limited evidence for health-related quality of life, intervention-related adverse events and outcomes related to exacerbations and hospitalisation.

There were two technologies, myCOPD and SPACE for COPD, for which there was more than one eligible RCT and a range of other supporting evidence, reflecting a more advanced evidence base. Evidence for other technologies was fairly limited, although prioritised evidence was able to be identified for all technologies except Active+me REMOTE.

The evidence – in particular for myCOPD and SPACE for COPD – from a research perspective generally supports the concept of non-inferiority between digitally supported and face-to-face pulmonary rehabilitation, in terms of exercise capacity and respiratory function. The clinical evidence for the other technologies is weaker and often too limited to assess the promise these technologies offer.

However, when applying to clinical practice, it is important to interpret this conclusion with considerable caution and critique whether it truly holds, due to several generalisability concerns, which the EAG explore in more detail in the main report:

- UK studies are not UK wide and have a bias towards urban areas. Digital access and literacy may vary in different areas. No studies presented subgroup data for included rural areas.
- Clinical advice and comparisons to UK COPD audit reference standards suggested that control arms representing traditional face to face pulmonary rehabilitation underperformed in at least some of the included studies.
- Reporting clarity of the details of interventions and comparators was limited and does not conform to TIDieR reporting guidelines for interventions and comparators.[1]
- Clinical expert advice to the EAG was that people who choose to participate in trials for digitally supported therapies are likely to not favour face-to-face pulmonary rehabilitation to the same extent as the typical person with COPD and to also have much greater digital literacy, digital access and interest and familiarity with digital technologies. These factors are likely to lead to considerable outperformance in the digitally supported arm. If digitally supported pulmonary rehabilitation is rolled out in routine practice, a proportion of people with COPD with lower digital literacy may access this treatment option, although some may still opt out depending on what other treatment options are available.

Quality and relevance of economic evidence

The findings of the *de novo* economic analysis conducted by the EAG suggested that the digital technologies supporting the delivery of PR (as defined above), may possibly be cost saving when compared to face-to-face pulmonary rehabilitation (using data derived from the UK COPD PR audit). This finding was mainly driven by the reduction in costs associated with healthcare staff time.

Based on the EAG's reference case cost-consequence analysis (CCA), digital technologies were likely to be either on par or less effective compared to face-to-face pulmonary rehabilitation. However, as noted in the clinical evidence summary, caution needs to be exercised where the results were found to be at par based on trial data. The digital technologies appear to be cost saving when considering annual costs per participant based on license fee, staff time costs and training costs. However, there is high heterogeneity in costing model across digital technologies.

The EAG also performed a complementary and exploratory cost-effectiveness analysis (CEA) for the technologies for which the data were available: Clinitouch, myCOPD, Rehab Guru, and SPACE for COPD. It showed that the digital technologies included are likely to be less costly and less effective compared to face-to-face pulmonary rehabilitation, especially when using data from the UK COPD pulmonary rehabilitation audit. The deterministic threshold analysis identified threshold values for change in walking distance (6MWD/ISWD), below or above which the digital technologies could offer good value for money compared to face-to-face pulmonary rehabilitation.

Results of both the analyses (especially that of the exploratory CEA), need to be interpreted with caution as they are only indicative given the evolving evidence base.

Finally, it was noted by the EAG that a direct comparison with either no pulmonary rehabilitation or waitlist was not possible owing to sparsity of such data in the intervention trials. However, based on information sourced from wider literature, EAG incorporated the costs for no pulmonary rehabilitation or waitlist in addition to face-to face pulmonary rehabilitation to aid decision making. Subgroup analyses were also not viable owing to unavailability of effectiveness data for any subgroups.

Evidence Gap Analysis

Evidence gaps highlighted ought to be addressed to enable any definitive conclusions about the cost-effectiveness of digital interventions supporting delivery of pulmonary rehabilitation in COPD. The EAG identified several key evidence gaps, which could be addressed by future research, including:

- A need for more studies to assess wider outcomes including quality of life– beyond exercise capacity and respiratory function – and provide EQ-5D-3L-based utility values.
- A need for studies compared to no pulmonary rehabilitation to demonstrate the benefit of digitally supported pulmonary rehabilitation for use during wait lists for face-to-face pulmonary rehabilitation, in light of long waiting lists for this treatment.
- A need for consistently capturing the impact of digitally supported pulmonary rehabilitation technologies on health care resource use associated with emergency department (ED) visits or hospital admissions for exacerbations, in trials or follow up studies.

- A need for long-term follow up studies assessing the sustained impact of digitally supported pulmonary rehabilitation technologies.
- A need for studies or subgroup analyses with rural populations.
- Trials should include consideration of selection biases in favour of more digitally literate participants found in research studies of digitally supported pulmonary rehabilitation.

2. DECISION PROBLEM

Table 1 details the final scope issued by NICE for this early value assessment (EVA). Given the large volume of evidence for some technologies, the EAG identified priority studies for each technology, where available, based on relevance of population, study location and study design, with a preference for RCTs where possible.

Table 1: Summary scope of the assessment

Population	Adults with a confirmed diagnosis of COPD who: • Have had a recent hospitalisation because of an acute exacerbation, or whose functional baseline has greatly changed and is not following the expected recovery path or • Have a MRC dyspnoea score of 2 or above or • Have decreased exercise capacity as measured by a validated outcome measure such as the 6-minute walk test
Subgroups	If the evidence allows the following subgroups will be considered: • Level of breathlessness (MRC dyspnoea score) • Having or not having comorbidities (including frailty) • Living in a rural or urban setting • Having had an exacerbation which required hospitalisation in the previous 12 months
Interventions (proposed technologies)	Digitally supported pulmonary rehabilitation technologies for adults with COPD. This includes: • Active+me REMOTE • Clinitouch • Kaia Health COPD • myCOPD • Rehab Guru • SPACE for COPD • Wellinks

Comparators	• Standard care face-to-face pulmonary rehabilitation, either in a clinical or home-based setting • No treatment, or waiting list If data are available: • Hybrid of face-to-face and remote live pulmonary rehabilitation • Non-digital non-face-to-face options for components of pulmonary rehabilitation, for example printed exercise sheets
Healthcare setting	Secondary or community care
Outcomes	Outcomes for consideration may include: <u>High priority</u> • Exercise capacity measured by a validated outcome measure* • Health-related quality of life* • Other measures of respiratory function (including but not limited to the COPD assessment test [CAT] score, the MRC and the modified MRC dyspnoea score) • Intervention completion (receiving a final assessment), adherence, rates of attrition (dropouts) • Intervention-related adverse events • Acute exacerbations, hospital admissions, readmissions or emergency admissions <u>Other (if data available)</u> • Intervention uptake from those offered the technologies • Daily activity • Patient experience, technology usability and acceptability • Healthcare professional experience
	Costs will be considered from an NHS and Person Social Services perspective. Costs for consideration may include: <u>High priority</u> • Costs of healthcare professional time (various grades) to deliver digitally supported pulmonary rehabilitation

	• Costs of healthcare professional time (various grades) to deliver standard care
	• Cost of the digital technologies including license fees and staff training
	<u>Other (if data are available)</u>
	• Cost to healthcare system of device acquisition, if relevant
	• Cost of other resource use (e.g. associated with managing COPD, adverse events, or complications):
	  o Healthcare appointments in primary, secondary and community care
	  o Cost of emergency department attendance, and length of stay if admitted to hospital
	  o Medication use and adverse events

Time horizon	The time horizon for estimating the clinical and cost effectiveness should be at least a year. This is to reflect any differences in costs or outcomes between the technologies such as the impact on hospital admissions. One year is also the typical length of time before someone is eligible to repeat a course of pulmonary rehabilitation.

Abbreviations: CAT = COPD Assessment Test; COPD = Chronic Obstructive Pulmonary Disease; MRC = Medical Research Council; NHS = National Health Service.

Note: * these outcomes were classified as 'highly prioritised' in the EAG protocol.

3. OVERVIEW OF THE TECHNOLOGY

3.1. Purpose of the medical technology

In the UK, 1.2 million people are estimated to have COPD. COPD exacerbations are considered to be the second most common cause of UK emergency hospital admissions, accounting for 1 in 8 of all UK hospital admissions. Exacerbations requiring hospitalisation are associated with poorer prognosis and increased risk of death.[2]

Pulmonary rehabilitation is an exercise and education programme for people with lung disease, including COPD, who experience breathlessness. Evidence suggests that 90% of patients who complete a face-to-face pulmonary rehabilitation programme experience increased exercise capacity and improved quality of life. However, it is currently only offered to 13% of eligible COPD patients, with a focus on those with more severe COPD.[3] Clinical experts consulted by NICE during scoping for this EVA stated that limitations in workforce and service funding restrict the ability of the NHS to provide pulmonary rehabilitation to everyone who may benefit.[3] Table 2 sets out an overview of product properties, and Table 3 offers a top-level features profile of them. There are some limitations regarding the level of detail available on the intervention content.

Commitments to addressing respiratory disease, including increasing access to pulmonary rehabilitation, are included in the NHS Long-Term Plan.[4] The Plan also highlights the need to introduce new models of delivering pulmonary rehabilitation care, including digitally supported treatments, to increase access to appropriate rehabilitation treatments.

Digitally supported pulmonary rehabilitation has been identified as a potential treatment option for people with COPD, and a way to increase access, engagement, and adherence to pulmonary rehabilitation programmes. The final scope for this EVA[3] stated that these technologies could reduce unplanned hospital admissions, reduce exacerbations, prevent deterioration and reduce health inequalities in access to and outcomes of care. Although the scope also noted that some people with COPD may need support in accessing and using digital technologies.

3.2. Product properties

This EVA includes seven technologies that:

- are intended for use by adults with COPD;
- include at least one digital component of pulmonary rehabilitation: physical training; disease education; nutritional, psychological or behavioural intervention;
- have a minimum course duration of at least 6 weeks;
- meet the standards within the digital technology assessment criteria (DTAC) and have a CE or UKCA mark where required (products may also be considered if they are actively working towards required CE or UKCA mark and meet all other standards within the DTAC); and
- are available for use in the NHS.

For this EVA, NICE will not consider digitally supported pulmonary rehabilitation technologies that:

- replace the before and after in-person assessment; or
- are solely tele-rehab i.e. live pulmonary rehabilitation delivered remotely

The following technologies were included in the assessment:

- Active + me REMOTE
- Clinitouch
- Kaia Health COPD
- myCOPD
- Rehab Guru
- SPACE for COPD
- Wellinks

Technologies are summarised in Table 2 and their main features in Table 3, with information obtained from company submissions and company website(s). Further information can be found in the final scope.[3]

Table 2: Description of the technologies

Full technology name and manufacturer	Description	Access	Health professional involvement	CE mark and DTAC status
Active+me REMOTE (Aseptika)	Cloud-based platform that supports the hybrid delivery of pulmonary rehabilitation and remote monitoring of adults with COPD at home.	Smartphone, tablet or computer	Not stated	CE marked under MDD as a Class I Medical Device. Undergoing reclassification as class IIa. DTAC certification has been issued.
Clinitouch (Spirit Health)	Online platform that supports the delivery of a 6-week digitally supported pulmonary rehabilitation programme and facilitates remote monitoring of adults with COPD and other conditions	Smartphone, tablet or computer	Users are also contacted weekly by local healthcare professionals to monitor their progress and increase the complexity of exercises	Self-registered as a class I medical device in GB. DTAC certification has been issued.
Kaia Health COPD (Kaia Health)	Online platform that supports the delivery of a 6-week digitally supported pulmonary rehabilitation programme and facilitates remote monitoring of adults with COPD and other conditions	Smartphone or tablet	Facilitates communication with health coaches	CE Marked in Europe as a class 1 medical device. No DTAC submission.
myCOPD (my mhealth Ltd)	Online education, self-management, symptom reporting and pulmonary rehabilitation system.	Smartphone, tablet, or computer (as advised by company)	Health professional involvement is delivered through an optional clinical dashboard, where the patient data can be reviewed, prioritised, and managed by the health professional.	The platform is UKCA marked as a class 1 medical device. DTAC certification has been issued.

Full technology name and manufacturer	Description	Access	Health professional involvement	CE mark and DTAC status
Rehab Guru (Rehab Guru)	Digital exercise programme management software.	Smartphone, tablet or computer	Clinicians can use the technology to prescribe a personalised digitally supported pulmonary rehabilitation programme	No CE marking – company claims not to be a medical device. No DTAC submission.
SPACE for COPD (University Hospitals of Leicester NHS Trust)	Digitally supported self-management programme designed to help people with COPD manage their condition more effectively	Smartphone, tablet or computer	Throughout the duration of the web-based programme the patient's progress was reviewed online and there was weekly contact between the patient and the rehabilitation specialist via email or telephone using a standardised proforma"; HCP's are able to monitor patient progress via the admin site and can contact the patient via email; patients are able to message the HCP with concerns/questions from the site;	No CE marking – company claims to be exempt. No DTAC submission. The company states it has "a DPA in place that trusts sign as part of their contract, as well as a DPIA"
Wellinks (Wellinks)	Online platform that supports the delivery of a digital pulmonary rehabilitation programme and facilitates remote monitoring of adults with COPD.	Smartphone or tablet	Not stated	No information available about CE marking. No DTAC submission.

Abbreviations: CE mark = Conformité européenne (European conformity) marking, COPD = Chronic Obstructive Pulmonary Disease, DPA = Data Protection Agreement, DPIA = Data Protection Impact Assessment, DTAC = Digital Technology Assessment Criteria, GB = Great Britain, HCP = healthcare professional, MDD = Medical Devices Directive, UKCA = United Kingdom Conformity Assessed

Table 3. Feature profile of the technologies

Technology	Exercise	Education	Psychological intervention	In-app communication with AHP	Communication external to app with AHP	Patient reported symptom tracker	Objective symptom tracker	Remote monitoring
Active+me REMOTE	✓	✓		✓	✓	✓	✓	✓
Clinitouch	✓	✓		✓	✓		✓	✓
Kaia Health COPD	✓	✓						
myCOPD	✓	✓	✓	✓	✓	✓	✓	✓
Rehab Guru	✓			✓		✓	✓	
SPACE for COPD	✓	✓	✓	✓	✓	✓		
Wellinks	✓	✓	✓				✓	✓

Abbreviation: AHP = Allied Health Professional

4. CLINICAL CONTEXT

The target population for this assessment is people recommended for pulmonary rehabilitation for COPD.

4.1. Care pathway

The NICE guideline for the diagnosis and management of COPD in over 16s[5] states that COPD care should be delivered by a multidisciplinary team that includes respiratory nurse specialists. Pulmonary rehabilitation is defined as a multidisciplinary programme of care for people with chronic respiratory impairment. It should be individually tailored and designed to optimise each person's physical and social performance and autonomy. The NHS service guidance for pulmonary rehabilitation[6] says that services should be offered to all people with a confirmed diagnosis of COPD or other chronic respiratory diseases. According to these guidelines, pulmonary rehabilitation programmes should last at least six weeks and include a minimum of two sessions per week. Programmes should include individually tailored and prescribed progressive exercise training, including both aerobic and resistance training, as well as a structured education programme.

Clinical advice to the EAG was that usual care or the standard of care – as described in the literature – would be face-to-face pulmonary rehabilitation, although long waiting lists and resource limitations means that in practice only a minority of people receive the recommended treatment. This leads to uncertainty – when assessing the literature – as to what is actually being delivered both in current practice and in comparator interventions described as usual care. Where face-to-face pulmonary rehabilitation is delivered, this would typically be in secondary or community care settings. This necessitates patients travelling to clinics to participate in sessions; the convenience of this is likely to differ between urban and rural settings.

4.1.1. Current use of digitally supported pulmonary rehabilitation.

Digitally supported pulmonary rehabilitation is currently used in the NHS. Submissions were received from four out of the seven included technologies: Active+me REMOTE, Clinitouch, myCOPD and SPACE for COPD.

- Active+me REMOTE is being used within a clinical trial in Harefield Hospital, London.

- Clinitouch is being used in Staffordshire and its use evaluated alongside clinical practice.

- myCOPD has been used in the NHS since 2017, and been implemented in both primary care and rehabilitation services across 30 Integrated Care Boards. This includes, but is not limited to, [redacted] pulmonary rehabilitation services.

- SPACE for COPD was first used in the NHS in 2018 and was used by 73 trusts during the COVID-19 pandemic. There are currently two active contracts with NHS trusts.

Clinical advisers to the EAG were aware of the use of myCOPD and SPACE for COPD, along with videoconference-delivered conventional pulmonary rehabilitation. Some advisers indicated that interest in and use of digitally supported pulmonary rehabilitation had declined since the resumption of normal services following the COVID-19 pandemic.

4.2. User issues and preferences

Digitally supported pulmonary rehabilitation may improve access to pulmonary rehabilitation services in the context of long waiting lists and only a minority of people receiving the recommended treatment of face-to-face pulmonary rehabilitation.

The EAG noted that digitally supported pulmonary rehabilitation may in some cases be an add-on treatment rather than a direct comparator to face-to-face pulmonary rehabilitation. Therefore, no pulmonary rehabilitation or digitally supported pulmonary rehabilitation *followed by* face-to-face pulmonary rehabilitation (as a treatment bundle) could be valid comparators.

Digitally supported therapy may not be suitable for all people with COPD and some people will choose not to use digitally supported therapy, preferring face-to-face approaches. Some considerations about the suitability of digitally supported pulmonary rehabilitation noted in the final scope[3] include:

- individual ability to use the technology (e.g. familiarity with digital technology and access to the internet),

- fear of breathlessness from exercise (not knowing that some types of breathlessness are acceptable during the exercise),

- unpredictable nature of their co-morbidities,

- possible costs incurred from using digital technologies, for example mobile data charges,
- level of human support provided during digitally supported pulmonary rehabilitation,
- data security and quality control.

Clinical advice provided to the EAG suggested that digitally supported pulmonary rehabilitation is likely to offer some benefit over no treatment or waitlist. However, it would not be expected to be as effective as face-to-face pulmonary rehabilitation, as face-to-face treatment offers better tailoring to individual needs and address motivational challenges faced by people with COPD.

5. SPECIAL CONSIDERATIONS, INCLUDING ISSUES RELATED TO EQUALITY

The following issues were highlighted during the scoping process. No new issues were identified during the EAG assessment.

- COPD prevalence is associated with older age, male sex and lower socioeconomic status – the latter likely due to higher smoking rates and poorer living conditions.[7]
- People will need regular access to an internet-enabled device – such as a smartphone, computer or tablet – in order to access digitally supported therapies. Additional support may be needed for individuals unfamiliar with or with limited access to such devices.
- Certain conditions, of combinations of conditions, such as visual, hearing or cognitive impairment, as well as difficulties with manual dexterity, learning disability, neurodivergence, reading difficulties or low levels of English literacy may necessitate additional support to access digitally supported therapies.
- People with mental health conditions or who are living in houses of multiple occupancy, living in residential care or who have no fixed abode, may face challenges in accessing digitally supported pulmonary rehabilitation.
- Cultural, religious, and ethnic backgrounds may influence people's views on the suitability of pulmonary rehabilitation treatment options.

6. POTENTIAL IMPLEMENTATION ISSUES

Several potential implementation issues were noted during the scoping process:

- Equity of access (see Section 5)
- Capacity limitations – increasing training requirements and staff workload due to introduction of new treatment pathways.
- Cost – each technology may be associated with different costs. The introduction of digitally supported technologies may introduce additional costs related to training, hardware, and internet access in the establishment of new treatment pathways. Smaller service areas may have higher per patient costs due to requiring fewer licences.

Clinical advice to the EAG indicated that there could be significant implementation challenges for digitally supported pulmonary rehabilitation within NHS settings. Issues with digital literacy, digital hesitancy (by NHS staff as well as people with COPD) and access to digital technologies may be among the greatest challenges. COPD prevalence and social deprivation are significantly correlated, which in turn is associated with digital awareness and access, possibly suggesting that digitally supported pulmonary rehabilitation could worsen already existing inequities in outcomes and service access.

Furthermore, provision of digitally supported pulmonary rehabilitation to people on the waitlist for face-to-face pulmonary rehabilitation could have unanticipated implications for the waitlist itself. If digitally supported pulmonary rehabilitation were effective, it could reduce waiting times as only people who did not respond satisfactorily to digitally supported therapy would go on to receive face-to-face treatment. However, if most people still need to receive face-to-face pulmonary rehabilitation, the introduction of digitally supported therapy could make waitlists for face-to-face pulmonary rehabilitation longer due to diversion of staff resource to delivering digitally supported pulmonary rehabilitation.

7. CLINICAL EVIDENCE SELECTION

7.1. Search strategy

Search strategies were based on those devised during the initial scoping searches by NICE Information Services with minor adjustments. The search strategies used relevant search terms, comprising a combination of indexed keywords (e.g., Medical Subject Headings, MeSH) and free-text terms appearing in the titles and/or abstracts of database records and were adapted according to the configuration of each database. The NICE health apps filter was used, with the addition of “Digital Technology/” and also adding “enable*” to capture digitally enabled. No date, language, or publication status (published, unpublished, in-press, and in-progress) limits were applied. Searches for clinical and cost-effectiveness were combined and carried out in one search strategy.

Databases searched were Medline (including Medline in Process), Embase, Cochrane, INAHTA, CEA Registry and ScharrHUD. The trial registries searched were Clinicaltrials.gov (NLM) and ICTRP (WHO). The websites of the individual companies were searched, as well as the NICE and SIGN websites for related guidelines, and MAUDE and MHRA for adverse events data. Following deduplication (in Endnote), a total of 712 records of potentially relevant evidence on clinical and/or cost effectiveness were retrieved. The company submission references were also scanned for additional references—from which two new articles were identified.

The search strategies are presented in Appendix A.

7.2. Study selection

The abstracts and titles of references retrieved by the searches were screened for relevance (facilitated by the Rayyan platform). Full paper copies of potentially relevant studies were obtained. The retrieved articles were assessed for inclusion against pre-specified inclusion/exclusion criteria. All duplicate papers were excluded. Screening was performed initially by one reviewer (MSB). This defined the list of eligible studies, from which priority studies were selected by one reviewer (GJMT) and discussed with another reviewer (MSB).

This assessment looked across a range of evidence types, including RCTs and real-world evidence, to inform clinical effectiveness.

The following study types were excluded:

- Animal models
- Pre-clinical and biological studies
- Narrative reviews, editorials, opinion pieces
- Meeting abstracts for studies where full-text papers were available. If studies were only available as meeting abstracts, inclusion depended on sufficient information being available to offer meaningful critique.
- Studies not available in the English language.
- Studies relating to non-respiratory rehabilitation populations, for example cardiac rehabilitation.

Eligible studies assessed digitally supported pulmonary rehabilitation for people with COPD. The full decision problem is outlined in Section 2.

Studies could still be included if the comparator or the outcomes did not match the scope provided the outcomes appeared reasonable and could offer useful information in the context of the appraisal. No studies were identified where this applied. An initial large evidence base was identified for this appraisal, and within the timeframe available, between one and three studies were included for each technology. The EAG's general approach was one of 'best evidence synthesis', focusing on the most useful and rigorous evidence available over all possible included studies.

Randomised controlled trials were prioritised for inclusion where they were available. This was supplemented with additional data from other studies where it was considered appropriate. Where no prospective studies were available for a given technology, the most relevant retrospective studies were sought. If no retrospective studies were available, then conference abstracts were reviewed. If retrospective studies were available for a technology with one or more prospective studies, a brief commentary on these were provided. Studies were prioritised based on a) study design (RCT or observational), b) recency and c) population. Blinding was also noted, where applicable (depending on the study design and outcomes assessed). Qualitative studies were not prioritised when quantitative studies were available, in order to give the clearest insight into effectiveness.

A PRISMA flow diagram is provided as Appendix B.

Data were extracted from included studies by one reviewer (MSB) into a bespoke database and a sample of at least 10% was checked by another reviewer (GJMT). Due to time and resource constraints associated with conducting an EVA, the EAG did not conduct formal risk of bias assessment of the included studies.

8. CLINICAL EVIDENCE REVIEW

The EAG identified a total of 44 reports that were potentially relevant to the present decision problem, of which 9 were prioritised for inclusion in the review. Relevant information provided by companies was also considered for inclusion. Prioritised evidence was available for all studies except Active+me REMOTE, for which there was no evidence relevant to the appraisal scope. It should be noted that some studies for SPACE for COPD used a different mode of delivery, which included the use of the manual as well as or instead of the website. However, these studies were considered eligible for inclusion given how the inclusion criteria were phrased.

The majority of the evidence comprised small-scale observational studies, pilot feasibility trials and conference abstracts. Table 4 presents an overview of the evidence landscape, in which the priority studies are underlined and in bold.

The nine prioritised studies included:

- One unpublished report on Clinitouch
- One full-text RCT on Kaia Health[8]
- One conference abstract on Rehab Guru[9]
- Two full-text RCTs on SPACE for COPD[10-12]
- Three full-text RCTs on myCOPD[13-15]
- One full-text observational study on Wellinks[16]

Table 5 presents a detailed overview of the study design, characteristics, and limitations of each prioritised study.

Table 4: Evidence landscape

Technology	Randomised controlled trials (full-text)	Non-randomised trials and observational studies (full-text)	Qualitative studies	Conference abstracts	Unpublished reports
Active+me REMOTE		Frith et al., 2021[17]			[redacted]
Clinitouch					[redacted]
Kaia Health	**Spielmanns et al., 2023**[8]	Rassouli et al., 2018[22]		Gloeckl et al., 2022[23]	
myCOPD	**Bourne et al., 2017**[15]**; Crooks et al., 2020**[13]**; North et al., 2020**[14]	Chmiel et al., 2022[24]; Cooper et al., 2022[25]; Platt & Jackson, 2022[26]		Cooper et al., 2021[27]; North et al., 2014[28]; North et al., 2015[29]; O'Sullivan et al., 2021[30]; Roberts et al., 2022[31]; Stokes & Savage, 2021[32]; Wilkinson et al., 2017[33]	
Rehab Guru				**Pilsworth et al., 2021**[9]	
SPACE for COPD	**Chaplin et al., 2017**[12]; **Bourne et al.,**	Blackmore et al., 2017[34]; Bourne et al.,	Apps et al., 2017[38]; Apps	Apps et al., 2013[40]; Apps et al., 2009[41];	

Technology	Randomised controlled trials (full-text)	Non-randomised trials and observational studies (full-text)	Qualitative studies	Conference abstracts	Unpublished reports
	2022[10]; **Chaplin et al., 2022**[11]; Johnson-Warrington et al., 2016; Mitchell et al., 2014	2020[35]; Hewitt et al., 2015[36]; Houchen-Wolloff et al., 2021[37]	et al., 2013[39];	Barradell et al., 2018[42]; Chaplin et al., 2021[43]; Chaplin et al., 2016[44]; Horton et al., 2013[45], Horton et al., 2014[46]; Houchen-Wolloff et al., 2021[47]; Johnson-Warrington et al., 2015[48]; Mitchell et al., 2013[49]; Mitchell-Wagg et al., 2012[50]; Wagg et al., 2012[51]; Wagg et al., 2009[52]	
Wellinks		**Gelbman & Reed, 2022**[16]			

Bold and underlined text = extracted priority study (see Table 5)

Frith et al. (2021) study was not extracted because it was conducted in a cardiac rather than COPD population. The Gloeckl et al. (2022) study is a subgroup analysis of the Spielmanns et al. (2023) study and is included in the EAG's broader commentary on the evidence. Bourne et al. (2022) also includes qualitative evidence.

Table 5: Study design and characteristics of prioritised clinical effectiveness studies

Reference	Study design & country	Population	Intervention	Comparator(s)	Outcomes	Study limitations
Active+me REMOTE (number of prioritised studies = 0) – there were no studies in a COPD population with clinical effectiveness data						
Clinitouch (number of prioritised studies = 1)						
Staffordshire Report[21] [AIC]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Kaia Health (number of prioritised studies = 1)						
Spielmanns et al. 2023[8]	Parallel group RCT; Germany and Switzerland.	67 participants with Global Initiative for Obstructive Lung Disease (GOLD) stage II-IV COPD were randomised 1:1.	6-months of daily physical exercise training sessions conducted via the Kaia COPD app. App consisted of an exercise training programme, breathing	Exercise and lifestyle intervention (no pulmonary rehabilitation mentioned). Control group wore an activity tracker but did	Primary: change in steps per day after 6 months as measured by the POLAR A370; Polar Electro Europe AG, Steinhausen, Switzerland	Small sample size (though sufficient for statistical considerations based on primary endpoint) At least three other sites were asked to participate in the

Reference	Study design & country	Population	Intervention	Comparator(s)	Outcomes	Study limitations
		Aged (mean±sd) 64±8 years, severe airflow obstruction (severe COPD) with a mean FEV_1% predicted of 44%±16%. 33 (49.3%) female. Follow-up data available for 60 participants.	exercises, and an educational programme. Regular contacts via telephone with trained healthcare professionals to assess adherence (minimum adherence criteria: exercising with the app at least 4 out of 7 days per week). Exercise training programme consisted of 15-20 minutes whole-body exercises, with focus on compound movements. Each session began with a whole-body warm-up and ended with 2-3 stretching exercises. All exercises were performed without the need for specialised exercise equipment. Intensity increased dynamically based on feedback provided by	not have access to the Kaia COPD app. Both the intervention and the comparator groups received a leaflet to encourage an active lifestyle, as well as individual exercise recommendations, as part of their discharge instructions to reflect standard care.	Secondary: change in functional exercise capacity (60-second sit-to-stand test); Health Related Quality of Life and patient-reported health status (Chronic Respiratory Questionnaire (CRQ) and COPD Assessment Test (CAT)); number of exacerbations (defined as an increase in symptoms and an increase in dosage of or a new prescription of systemic corticosteroids and/or antibiotics); and depression and anxiety (Hospital Anxiety and Depression Scale (HADS)) Additional: compliance,	study but were not eligible due to insufficient inpatient PR case load in COPD and/or no adequate research infrastructure. Only two sites were eligible. Due to preselection of patients with sufficient literacy in mobile technology, results may not be generalisable to a broader population of people with COPD. This could also increase potential for selection bias and a subsequent effect on adherence and engagement. Due to the nature of the intervention, blinding of study participants and

Reference	Study design & country	Population	Intervention	Comparator(s)	Outcomes	Study limitations
			the participant at the end of each session. Participants also wore activity trackers and reported steps per day within the app.		adherence, facilitators, and safety.	study staff was not possible. No observations were made past 6 months.
myCOPD (number of prioritised studies = 3)						
Bourne et al. 2017[15]	Two-arm, parallel, single-blind RCT; United Kingdom.	90 participants with COPD (mMRC score of ≥2) referred for PR were randomised 2:1 (n=64 online PR; n=26 face-to-face PR). Aged (mean±sd) 70±8.2 years, moderate airflow obstruction with a mean FEV_1% predicted of 59%±22%. 31 (34.4%) female.	6 weeks of physical exercise training conducted via myPR (myCOPD). App consisted of a progressive exercise training programme and educational sessions (three educational sessions per week). Participants were given a 5–10-minute introductory session (face-to-face) to convey basic instructions on how to use the app. Participants were asked to use the app a minimum of 2 and a	Face-to-face PR (explicitly stated) Participants attended two supervised physical exercise sessions per week for 6 weeks and were asked to carry out three additional sessions at home. The programme consisted of 10 exercises (identical to those given to the online PR group). These sessions also included a warm-up and cool-down.	Primary: between group difference in best performance 6MWT and CAT score. Secondary: between group difference in respiratory quality of life (St Georges Respiratory Questionnaire (SGRQ)); anxiety and depression (HADS). Additional: adverse events (captured during weekly phones calls with the study team in	Short study duration. Single centre trial. Double blinding not possible.

Reference	Study design & country	Population	Intervention	Comparator(s)	Outcomes	Study limitations
			maximum of 5 times per week. Exercise training consisted of 10 exercises. Exercises were 1 minute each in Week 1, increasing by 30 seconds each week (up to 3 minutes 30 seconds in Week 6). Between exercises, participants were given a 1-minute rest period. All sessions included a warm-up and cool-down.	The same educational sessions as on myPR were delivered but were presented and discussed orally.	the online PR group and twice weekly at in-person meetings in the face-to-face PR group).	
Crooks et al. 2020[13]	Open-label, parallel-group, RCT; United Kingdom.	60 participants with either mild-moderate COPD (FEV_1 >50% predicted and FEV_1/forced vital capacity ratio <70%) or COPD of any severity diagnosed within the past 12 months were randomised 1:1 (n=29 myCOPD;	12 weeks of physical exercise training conducted via myCOPD. Participants were given a link to self-activate the app. This was followed by a "how to use" video which provided information of app usage and content.	Usual care. Usual care participants were asked to continue with usual COPD management for the study duration. No details as to what this comprised. After completion, they were offered life-long app access.	Primary: between group difference in mean CAT score change and proportion of participants with ≥1 critical inhaler error at 90 days. Secondary: between group difference in change in patient activation measure (PAM) score; self-	Marked phenotypic difference between groups. More participants from the usual care group volunteered for activity tracking. The usual care group were also more active than the myCOPD group.

Reference	Study design & country	Population	Intervention	Comparator(s)	Outcomes	Study limitations
		n=31 usual care). Aged (mean±sd) 66.1±7.1 years, mild COPD (n=14 (23.3%)) and moderate COPD (n=46 (76.7%)). 29 (48.3%) female.			efficacy for appropriate medication use scale (SEAMS); EQ-5D-5L. Additional: activity tracking was done in a subgroup for 7 days at baseline and prior to the end study visit.	
North et al. 2020[14]	Single blind acceptability and feasibility RCT; United Kingdom	41 participants with COPD (34% moderate and 41% severe) were randomised 1:1 (n=20 myCOPD; n=21 usual care). Aged (mean±sd) 66.6±7.0 years. 17 female (41%).	12 weeks of physical exercise training conducted via myCOPD. Participants were given a link to self-activate the app. This was followed by a "how to use" video which provided information of app usage and content.	Usual care Treatment as usual participants received usual care and were given a written self-management plan. It is not stated if any or how many participants received face-to-face pulmonary rehabilitation as usual care.	Primary: CAT score Secondary: Exacerbations, inhaler technique, readmission, respiratory quality of life (SGRQ), patient activation (PAM), depression and anxiety (HAD), veteran specific activity questionnaire (VSAQ), work	Limited in power to demonstrate effects on all measured outcomes. Study unable to capture all indices of app usage. Single centre UK trial.

Reference	Study design & country	Population	Intervention	Comparator(s)	Outcomes	Study limitations
		Complete data for treatment as usual (n=18) and myCOPD (n=17).			productivity activity impairment (WPAI).	
Rehab Guru (number of prioritised studies = 1).						
Pilsworth et al. 2021[9]	Single-arm pilot study; United Kingdom	Pilot study UK – Liverpool Thirty three people with a diagnosis of COPD	Rehab Guru over a seven month time period. A home exercise prescribing platform with larger numbers of built-in exercises and templates and facilities for treatment notes, patient forms, outcome measures, telehealth, patient monitoring and diary management	No comparator	6MWT, MRC dyspnoea and CRD dyspnoea	Conference abstract only Pilot study No comparator
SPACE for COPD (number of prioritised studies = 2)						
Bourne et al., 2022[10]	Prospective single blind RCT; United Kingdom	193 participants with established diagnosis of COPD (GOLD criteria) and had median MRC grade of 2. Recruited from 7 GP practices in Leicester,	Participants in the intervention group received a SPACE for COPD manual and attended the SPACE for COPD group-based self-management programme (SMP) usually within 1month of	Usual care Usual care participants continued with any usual check-ups/reviews—no additional care was provided or removed from their current	Change in CAT score at 6 months (primary). Bristol COPD knowledge questionnaire, EQ-5D-3L, Chronic Respiratory Questionnaire, HADS, Patient Activation Measure,	Adherence was not measured. Distance from group venues was a challenge for some participants leading to withdrawal. Some participants dislike group formats. CAT

Reference	Study design & country	Population	Intervention	Comparator(s)	Outcomes	Study limitations
		Leicestershire and Rutland.	their baseline appointment.	access. It is not stated if any or how many received face-to-face pulmonary rehabilitation as usual care.	ISWT and ESWT exercise capacity, qualitative focus group analysis	may not have been to most suitable primary outcome for participants with milder COPD.
Chaplin et al. 2017[12], 2022[11]	Feasibility RCT; United Kingdom	103 participants with COPD (FEV_1%, post-bronchodilation of <80%, predicted ratio of FEV_1 to forced vital capacity of 0.70 and MRC dyspnoea score of between 2 and 5) were randomised 1:1 (n=51 web-based PR; n=52 usual care). Aged (mean±sd) 66.1±8.1 years (web-based PR); 66.4±10.1 (usual care).	Web-based exercise and education programme (around 11-12 weeks to complete). Participants were given a standardised introductory session. Platform encouraged participants to exercise daily at home and to record progress in an online diary. The exercise programme consisted of aerobic and strength training. The intensity of the walking was based on their performance on the baseline maximal shuttle walking exercise tests and prescribed at	Usual care. (advised by the company to be face-to-face pulmonary rehabilitation) Usual care based on the site the participant was being treated at. Hospital programme (7 weeks; 4 supervised and 3 unsupervised) or 12 total session within the community. Typically twice weekly 2-hour exercise and education sessions. It is not stated if any or how many participants received face-to-face pulmonary rehabilitation as usual care.	Physical activity pattern of accumulation, number of steps per day, incremental shuttle walk test (ISWT) and endurance shuttle walk test (ESWT); CRQ-SR; HADS; CAT; PR Adapted Index of Self-Efficacy (PRAISE); Bristol COPD Knowledge Questionnaire (BCKQ); EQ-5D-5L; patient cost questionnaire.	A limitation to the study was a lack of engagement despite patient involvement in the site development. Limitations were identified when recruiting people to a technology-based intervention, in that participants needed to be competent users with an in-depth, specific web-based knowledge.

Reference	Study design & country	Population	Intervention	Comparator(s)	Outcomes	Study limitations
		36.5% female (web-based PR); 25.5% female (usual care).	85% of baseline performance. Motivational interviewing techniques were used by healthcare professionals to help participants to progress their exercise programme in the aerobic and strength training appropriately and to answer any queries that arose. Motivational interviewing is an additional behaviour change intervention and it should be considered whether this will be included in the basic technology offering. Educational content of the web-based programme was based on the 'SPACE for COPD' manual. Participants worked through the website			

Reference	Study design & country	Population	Intervention	Comparator(s)	Outcomes	Study limitations
			content at their own pace.			
Wellinks (number of prioritised studies = 1)						
Gelbman & Reed 2022[16]	A single-site, observational, prospective pilot study USA	(N=19) was conducted using the Wellinks platform in adults with COPD. All patients were aged over 30 years at screening, owned an iPhone, and were currently undergoing a treatment regimen that included nebulized therapy. 10 female, 9 male	8 weeks Enrolled patients received a study kit consisting of the Flyp nebulizer, Smart One spirometer, the Nonin pulse oximeter, plus the Wellinks mHealth app, and training for all devices. Data were sent to the attending physician in a monthly report.	No comparator	For 8 weeks, participants were to enter daily symptoms and medication use manually; spirometry, nebulizer, and pulse oximeter data were automatically recorded. Patient satisfaction was measured via a 5-point scale and the Net Promoter Score (NPS) captured in interviews at the end of the observation period.	Decline in use of spirometry and oximetry over study period This study was a small pilot with all patients selected by 1 physician at 1 pulmonology practice. Patient engagement may be artificially higher than expected in a real-world situation due to the Hawthorne effect There were no interventions taken, and the study was not powered to show improvement in clinical outcomes or

Reference	Study design & country	Population	Intervention	Comparator(s)	Outcomes	Study limitations
						pharmacoeconomic impact.

Abbreviations: 6MWT = 6-minute walk test; BCKQ = Bristol COPD Knowledge Questionnaire; CAT = COPD Assessment Test; CRD = chronic refractory dyspnoea; CRQ = Chronic Respiratory Questionnaire; CRQ-SR = Chronic Respiratory Questionnaire - Self Reported; ESWT = endurance shuttle walk test; FEV = forced expiratory volume; GOLD = Global Initiative for Chronic Obstructive Lung Disease; GP = general practitioner; HADS = Hospital Anxiety and Depression Scale; ISWT = incremental shuttle walk test; mMRC = modified Medical Research Council; MRC = Medical Research Council; PAM = patient activation measure; PR = pulmonary rehabilitation; PRAISE = PR Adapted Index of Self-Efficacy; RCT = randomised controlled trial; SEAMS = self-efficacy for appropriate medication use scale; SGRQ = St Georges Respiratory Questionnaire; SMP = self-management programme; UK = United Kingdom; USA = United States of America

8.1. Overview of methodologies of all included studies

All studies described in Table 5 had some methodological limitations or misalignment with the NICE decision problem for this appraisal.

8.2. Study design, intervention and comparator

The search identified evidence for all scoped interventions, but no studies were prioritised for Active+me REMOTE as the evidence available was not relevant to the appraisal scope. This was because Frith et al.[17] was conducted in a population of people with cardiac problems who did not have COPD. The EAG did not consider evidence in this population to be generalisable to a COPD population.

With regard to the other technologies, full-text published randomised controlled trial evidence was available for Kaia Health[13-15] (mixed Germany and Switzerland), myCOPD[10-12] (UK) and SPACE for COPD[10-12] (UK). For Wellinks, the available evidence was a full-text single-site observational pilot study from the USA without a comparator arm.[16] Finally, no full-text published relevant evidence was available for Clinitouch or Rehab Guru; therefore the EAG prioritised a company report for Clinitouch and a conference abstract for Rehab Guru.

Face-to-face pulmonary rehabilitation was explicitly the comparator in three studies: the Staffordshire report for Clinitouch , the Bourne et al.[15] study for myCOPD, and Chaplin et al[12] (as advised by the company). For most other studies, where there was a comparator, this was usual care and was not defined clearly in the study reports. According to UK practice guidelines, usual care in the UK would be face-to-face pulmonary rehabilitation. However, studies using usual care in a UK context did not provide details as to how many, if any, participants actually received face-to-face pulmonary rehabilitation. Therefore, it is unknown to what extent this usual care comparator reflected reality. It is possible that studies using usual care as the comparator were comparing digitally supported pulmonary rehabilitation with less intensive management strategies, such as self-care and the provision of patient information. The issue is that some of the usual care arms may be less effective than face-to-face pulmonary rehabilitation. For example, in the Spielmanns et al. study[8] for Kaia Health, conducted in a mixed German and Swiss population, usual care is described as a leaflet to encourage an active lifestyle, as well as individual exercise

recommendations. Participants in the control group in this study also wore an activity tracker.

Clinical expert advice to the EAG expressed concern that control arms representing face-to-face pulmonary rehabilitation in the included trials were not 'gold standard' and represented sub-par intervention delivery. Typically, for example, participants in the control arm for myCOPD did not meet the minimally clinically important difference for a change in exercise capacity, Reasons for this underperformance may vary. Usual care, while ideally face-to-face pulmonary rehabilitation, may in practice be waitlist control, GP management or other non-gold standard treatment for a proportion of patients due to resource challenges. Furthermore, in the Bourne et al. study[15] (for myCOPD) the control arm was designed to provide a non-digital close equivalent of digitally supported pulmonary rehabilitation rather than gold standard face-to-face pulmonary rehabilitation.

Selection bias is also a concern. Clinical expert advice indicates that those who want face-to-face pulmonary rehabilitation or are not confident with digital technologies do not consent to trials of digitally supported pulmonary rehabilitation. Therefore, digitally supported arms are likely to overperform. If digitally supported pulmonary rehabilitation is rolled out in routine practice, some people with COPD who have lower digital literacy or lower interest in digital technologies may choose to access this option if appropriate support is offered. However, others may not. Therefore, it is likely there will still be a selection bias in trials compared to routine practice.

Clinical experts also expressed concern about the absence of the social component in digitally supported pulmonary rehabilitation (although the EAG notes that the Bourne study for SPACE for COPD[10] did include group sessions run at community venues).

Intervention reporting across trials was generally limited and did not offer insight into the fine details of the intervention components, the order in which they would occur, how flexible the delivery would be, and what time each component would be expected to take. Intervention reporting did not meet TIDieR guidelines.[1]

> ***Evidence gap:*** *Randomised controlled trials were not available for all scoped interventions in a relevant population. Multiple RCTs were available for SPACE*

for COPD and myCOPD, but the evidence for other interventions was more limited.

Evidence gap: *Details of usual care were not generally adequately reported.*

Evidence gap: *There are also no head-to-head or indirect comparison of the different digital technologies supporting pulmonary rehabilitation delivery.*

8.3. Population

Sample sizes were generally small – two of the studies were classed as feasibility trials and much of the rest of the evidence was early stage or exploratory in nature. Understandably, therefore, studies may not be intended to be optimally powered. However, the available study for Wellinks[16] was particularly small (n=19). Furthermore, the inclusion criteria for this study required participants to have access to an iPhone running iOS version 13.4 or later. This requirement for a specific brand adds further to the potential selection bias resulting from requiring access to smart devices.

There were two prioritised studies not conducted in the UK – the study for Wellinks[16] was conducted in a USA population, while the study for Kaia Health[8] was conducted in a mixed Swiss and German population. The remaining prioritised evidence came from the UK, which may benefit generalisability. However, UK studies generally focused on urban areas, meaning that the studied population may not generalise to the broader UK population. The Clinitouch study was conducted in Staffordshire – a mixed urban and rural county. Two of the three trials for myCOPD[14,15] were based in Portsmouth, while the other trial for this intervention[13] did not specify its geographical base in the published evidence, although the company said it was conducted in Basingstoke, Hull and Hemel Hempstead, which are all urban areas. The study for Rehab Guru[9] was conducted in Liverpool. For SPACE for COPD, one study[11,12] was conducted in Leicester, while the other[10] was conducted across Leicester (a large urban area) as well as the largely rural counties of Leicestershire and Rutland. This bias towards urban settings could be important given the socioeconomic determinants of COPD and how social and geographical factors may influence ease of access to face-to-face pulmonary rehabilitation.

Evidence gap: *The available study for Wellinks was single-arm and only included 19 participants.*

Evidence gap: *Samples were often not adequately powered for appropriate clinical outcome measures.*

Generalisability gap: *While most priority studies were UK-based, there was not UK-based evidence available for Kaia Health and Wellinks.*

Generalisability gap: *UK-based studies were geographically specific rather than UK-wide, leading to potential generalisability challenges due to the socioeconomic pattern of COPD prevalence and differences in accessibility of care and digital access between urban and rural areas.*

8.4. Reported outcomes

Outcomes were classified into six categories, based on the final scope: 1) exercise capacity measured by a validated outcome measure, 2) health-related quality of life, 3) other measures of respiratory function, 4) intervention completion, 5) intervention-related adverse events, and 6) acute exacerbations, hospital admissions, readmissions or emergency admissions.

The outcome domains for which most evidence was available were exercise capacity, respiratory function and intervention completion. There were some differences in the measures used for these concepts, but the EAG considered these to be generally comparable. Intervention completion was considered a fairly limited outcome due to the lack of detail available and differences in how studies assessed completion. Measures based purely on having used the app during the study period are particularly limited and do not tell us what content participants accessed.

Exercise capacity was the clinical outcome that was of greatest relevance for the economic model (see section 11.2.1). Two principal measures were used for exercise capacity: the six-minute walk test (6MWT) and the endurance shuttle walk test (ESWT).

There are multiple estimates of what constitutes an MCID for some outcomes. Within the timeframe of this EVA, it was not feasible for the EAG to conduct a systematic literature review of MCIDs for scoped outcomes. In order to provide some

interpretation of the reported outcomes, the EAG selected MCIDs from published literature (Table 6). Where possible, MCIDs in a UK COPD population were used.

Table 6: MCIDs used for key outcomes

Outcome	MCID	Source
6MWT	54m	Redelmeier et al.[54]
ISWT	48m	Singh et al.[55]
1-MSTST	3 repetitions	Vaidya et al.[56]
CAT	2 points	Schultz et al.[57]
ESWT	174 to 279 seconds	Zatloukal et al.[58]
Used in the Staffordshire report (for Clinitouch)[21]		
6MWT	>30m	Unreferenced
5XSST	>1.7 seconds	Unreferenced
1-MSTST	>3 repetitions	Unreferenced

Abbreviations: 1-MSTST = 1-Minute Sit-to-Stand Test; 5XSST = five times sit to stand test; 6MWT = six-minute walk test; CAT = COPD Assessment Test, ISWT = incremental shuttle walk test

Data were not available for all technologies for quality of life, intervention-related adverse events, and acute exacerbations, hospital admissions, readmissions or emergency admissions.

Quality of life, when assessed, was done so using different tools. For example, by EQ-5D-5L for Clinitouch and myCOPD (Crooks et al.[13]), or with disease-specific tools – such as CRQ and SGRQ – for myCOPD (Bourne et al.[15] and North et al.[14]).

> ***Evidence gap:*** *Evidence was not available for each technology for each priority scoped outcome domain. In particular, data were limited for quality of life, intervention-related adverse events, and exacerbation and hospitalisation outcomes.*

> ***Evidence gap:*** *Utility data were only available for two technologies.*

Evidence gap: *Intervention completion was defined in heterogenous ways. Measures that are based on whether participants used the app during the study period do not offer insight into what content participants accessed.*

8.5. Results from the evidence base

Short narrative summaries of the evidence base for each technology are provided, including a brief mention of studies not prioritised for inclusion. Table 5 gives study characteristics for the prioritised studies. In the appendices, Table 29 offers a detailed breakdown of the results and Table 30 presents a summary table of some of the main outcomes across trials, including where they met MCID. At the end of this section, Table 7 summarises the statistical differences between trial arms for the main outcome categories in the comparative prioritised studies.

Following this results section is the EAG's interpretation of the clinical evidence (section 9). Overall, the EAG drew the following conclusions about the evidence base available for digitally supported pulmonary rehabilitation:

- There were two technologies – myCOPD and SPACE for COPD – for which there was more than one eligible RCT and a range of other supporting evidence, reflecting a more advanced evidence base.
- The evidence, in particular for the two technologies with a more developed evidence base, generally supports the concept of non-inferiority between digitally supported and face-to-face pulmonary rehabilitation across available measures.
- However, based on clinical expert advice, caution should be taken about accepting clinical equivalence due to the potential of selection bias. People who choose to take part in trials of digital technologies are likely to have greater digital access, digital literacy and enthusiasm for digital technologies than the general clinical population. Also, there was evidence and clinical expert opinion, to suggest that face to face pulmonary rehabilitation as evaluated in control arms may have underperformed in comparison with reference standards and other published trials.

8.5.1. Active+me REMOTE

Priority evidence

Digital technologies to deliver pulmonary rehabilitation programmes for adults with COPD [GID-HTE10019]

No priority evidence could be identified for Active+me REMOTE.

Additional evidence

One published study was available for Active+me REMOTE. Frith et al.[17] was an observational cohort study conducted in the context of cardiac rehabilitation among people who did not have COPD. Due to the mismatch in population between this paper and the scope for the present appraisal, the EAG did not consider it appropriate to extract this paper as a priority study. The Frith et al.[17] study found that adding Active+me REMOTE to standard cardiac rehabilitation was associated with increased patient skill, knowledge, and confidence to manage their condition.

The available evidence for Active+me REMOTE in a pulmonary rehabilitation context in COPD came from two unpublished reports on the Liverpool[19] and Tallaght[20] studies. While of interest, these studies did not report clinical effectiveness outcomes in a usable format, so could not be designated as priority studies. It was agreed that the key clinical effectiveness evidence on Active+me REMOTE in this population will come from the Harefield study, data from which are expected to be available in December 2023.

8.5.2. Clinitouch

Priority evidence

The priority evidence for Clinitouch was an unpublished clinical evaluation report submitted by the company.

[redacted]

Additional evidence

Digital technologies to deliver pulmonary rehabilitation programmes for adults with COPD [GID-HTE10019]

No further evidence was identified for Clinitouch.

8.5.3. Kaia Health

Priority evidence

The priority evidence for Kaia Health was an RCT[8] in a mixed Swiss and German population as compared against no pulmonary rehab (although the comparator included a leaflet to encourage an active lifestyle and individual exercise recommendations). Evidence was presented within this trial for all six outcome domains.

The arms were stated not to be statistically different in terms of adverse events (data were not provided to the EAG for validation) or exacerbations, while no evidence was available for hospitalisations. Adherence to digitally supported pulmonary rehabilitation was moderate, with 67% using the app on at least 90 days. This showed that most people were using the app fairly frequently, but over 30% were not frequently actively engaged. It was not stated clearly what would count as app usage.

There was no statistically significant difference in disease-specific quality of life between groups at baseline or follow-up. Superior performance on 60 second sit-to-stand test was shown for Kaia Health versus usual care control at 3 months post intervention (mean±sd 22.87±8.00 vs 16.83±7.64 repetitions, p=0.004), but this difference was not sustained at 6 months (22.66±7.23 vs 19.45±9.09 repetitions, p=0.143), but neither was inferiority observed. Changes in the intervention group just exceeded the MCID of 3 repetitions at both 3 and 6 months. CAT scores did not differ statistically between groups at 3 months (15.53±8.26 vs 18.70±6.71 points; p=0.109), with a statistically significant difference in favour of the intervention group emerging by 6 months (15.13±8.58 vs 19.72±6.42, p=0.024, lower scores indicating less impact of COPD). CAT scores change did not meet the MCID threshold in either arm.

Additional evidence

A subgroup analysis within this same trial population was conducted by Gloeckl et al.[23] and was presented as a symposium abstract. From the limited information available, this subgroup analysis showed that observed benefits only occurred in participants with good adherence to app usage.

An observational study by Rassouli et al.[22] provides additional evidence that use of the Kaia Health app may offer a short-term benefit in quality of life, but that this depends on the feasibility and acceptability of the use of digitally supported pulmonary rehabilitation using a smartphone app for the individual participant.

8.5.4. MyCOPD

Priority evidence

Prioritised evidence for myCOPD came from three RCTs: Bourne et al., 2017[15], Crooks et al., 2020[13], and North et al., 2020[14]. Detailed results at the study level can be found in Table 29.

One of the myCOPD trials explicitly used a comparator of face-to-face pulmonary rehabilitation,[15] while the other two trials used a usual care comparator. While clinical guidelines say this should be face-to-face pulmonary rehabilitation, there were no details provided in the reports as to whether participants in the studies actually received this.

Across the three trials, results from the intervention and control arms were comparable for the exercise capacity, health-related quality of life, and respiratory function. Both arms improved and were not statistically significantly different. Changes in CAT scores met the MCID (of 2 points) in the intervention arm in all three trials.

It should be noted that there was a large difference in baseline step count between the groups in the Crooks et al. study[13] (myCOPD group (n=5) (mean±sd), 4948.7±1667.6 steps; usual care group (n=9), 9060±5135.1)), so a much lower step count at follow-up in the myCOPD group should not be interpreted as poorer performance of the myCOPD group.

Intervention completion, engagement and adherence were mixed for myCOPD across all three studies[13-15]: North et al. found that 40% of participants used the app every week (which the EAG considered low) and 85% activated the app during the study; Crooks et al. found that 72% of participants registered and activated the app, of whom 86% were still using the app during the last month of the trial, although there was still over 30% non-engagement; Bourne et al.[15] found that mean online session

attendance dropped slightly from 3.9 sessions per participant in week one to 2.5 sessions per participant in week six. No details were provided on what counted as app usage.

Adverse events across studies were largely comparable between arms and generally not of particular concern. However, in the Crooks et al. study[13], there were more exacerbations during the study in the myCOPD group than the control group (18 (62%) vs 11 (35%)), though it should be noted that, despite randomisation, there were also more exacerbations in the myCOPD group than the control group in the three months prior to the study (12 (41%) vs 3 (10%)). This baseline imbalance should be considered as a potential limitation to the study.

Additional evidence

Additional evidence from three non-randomised studies[24-26] was consistent with evidence from the pivotal trials. Due to the large number of full-text papers for this technology, the EAG does not offer a commentary on identified conference abstracts.

8.5.5. Rehab Guru

Priority evidence

The only evidence identified for Rehab Guru comes from a conference abstract by Pilsworth et al.[9] This reported a single-arm observational pilot study. Six-minute walk test scores improved by an average of 45 metres – below the MCID – between pre- and post-test assessments. Average CRD dyspnoea scores improved by 0.68 points (from 2.69 to 3.37), while average MRC dyspnoea scores improved from 4 (“I am too breathless to leave the house” or “I am breathless when dressing/undressing”) to 3 (“I stop for breath after walking about 100 yards or after a few minutes on level ground”). 81% of participants completed the 6-8 week intervention. The interpretation of these findings is limited by the lack of a control arm. No evidence was available for other key scoped outcomes.

Additional evidence

None.

8.5.6. SPACE for COPD

Priority evidence

Prioritised evidence for SPACE for COPD comes from two RCTs. Across both studies, performance on exercise capacity, quality of life, and respiratory function was comparable across the web-based and face-to-face pulmonary rehabilitation arms, with both arms showing improvements. Change exceeded the MCID for Chaplin et al.[11,12] for ESWT, but not for Bourne et al. (2022)[10] Neither did changes in the CAT score exceed the MCID threshold in Bourne et al.

Available information on intervention completion was limited. In Bourne et al.[10] completion was not reported but it is stated that six out of 97 dropped out due to inability to attend group sessions and two dropped out as the intervention was too similar to face-to-face pulmonary rehabilitation. It is not clear how drop out was defined – for example, whether was there a threshold of sessions after which a participant was considered to have completed. In Chaplin et al.,[11] 29 (56%) participants from the web-based arm dropped out. The average number of weeks to complete the website was 11±4 with an average number of four logins per week. No specific weekly target was stated. Adverse events were only reported by Bourne et al (2022)[10] – none were deemed to be attributable to the intervention. Details of the adverse event profile were not reported. Neither study reported data on hospitalisations or exacerbations.

Additional evidence

Additional evidence from a range of non-randomised studies[34,36-39] did not provide any evidence that contradicted the findings of the pivotal trials. Apps et al.[38] provide additional qualitative insight into usability and participant experiences with the technology. Due to the large number of full-text papers for this technology, the EAG does not offer a commentary on identified conference abstracts.

8.5.7. Wellinks

Priority evidence

The priority evidence for Wellinks comes from a single-arm, single-site, observational prospective pilot study in the USA.[16] All participants were reported to have completed

the intervention. Clinical advice to the EAG was that this sounds unrealistic, raising questions about how completion was defined and whether there was substantial selection bias in the sample.

Participants had an average forced expiratory volume in one second of 56.2% of predicted (range 23%-113%) and most participants (11/19) had severe or very severe COPD according to GOLD classification criteria. The interpretation of this information is limited by the single-arm nature of the study. No evidence was available for the other key scoped outcome domains. The data were a cross-sectional snapshot as the study was looking at the ability of people with COPD to use the Wellinks platform, rather than specifically looking at the clinical effectiveness of Wellinks on COPD over time. Therefore, no measure of change in score is provided. These findings therefore cannot show whether or not people with COPD improved while using Wellinks. The EAG was advised that the key clinical effectiveness results for Wellinks are forthcoming.

Additional evidence

No further evidence was identified for Wellinks.

8.5.8. Multiple technology comparison

There were no included studies that compared multiple scoped interventions.

8.5.9. Comparative outcomes summary

Table 7 shows a top-level summary of statistical measurements of differences in outcome categories between the intervention and control arms in the prioritised studies.

Cells shaded in grey represent one of two things. First, they show where there are no comparative studies available (this is the case for Active+me REMOTE, Rehab Guru and Wellinks); in this case they are marked up as not available (N/A). Second, in the case where comparative studies do exist, they show where no statistical analyses between groups were reported for that category; in this case they are marked up as not reported (NR). The light green cells with the horizonal arrow represent where there was no statistically significant difference in outcome between intervention and control. Finally, the darker green cells with a slanting arrow represent instances

where a statistically significant difference was seen for the intervention over control for at least one, but not necessarily all, follow up timepoints.

The table provides an overall representation of the findings. The only trial for which some outcomes showed a statistically significant improvement against control was in Spielmanns et al., 2023[8], in which case the control arm included no pulmonary rehabilitation. When compared to face-to-face or usual care in this trial, no significance difference was observed between arms.

Table 7: comparison between digitally supported PR vs control for prioritised studies

Technology	Study	Control	Exercise capacity	HRQoL	Respiratory function	Adverse effects	Exacerbations etc
Active+me REMOTE	N/A	None	N/A	N/A	N/A	N/A	N/A
Clinitouch	Staffordshire Report[21] [AIC]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Kaia Health	Spielmanns et al., 2023[8]	No PR	↗[a]	↔	↗ [b]	↔	↔
myCOPD	Bourne et al., 2017[15]	F2F	↔	↔	↔	↔	NR
	Crooks et al., 2020[13]	UC	↔	↔	↔	↔	NR
	North et al., 2020[14]	UC	↔	↔	↔	↔	NR
Rehab Guru	Pilsworth et al. 2021[9]	None	N/A	N/A	N/A	N/A	N/A
SPACE for COPD	Bourne et al., 2022[10]	UC	↔	↔	↔	NR	NR
	Chaplin et al., 2017[12]; Chaplin et al., 2022[11]	F2F	↔	↔	↔	NR	NR
Wellinks	Gelbman & Reed, 2022[16]	None	N/A	N/A	N/A	N/A	N/A

Abbreviations and key: ↔ = no significant difference between intervention and control, ↗ = significant improvement was seen for the invention vs control in at least one (but not all) follow up timepoint, F2F = face-to-face, N/A = not applicable, NR = not reported, PR = pulmonary rehabilitation, UC = usual care. Two trials were non-inferiority studies against face-to-face pulmonary rehabilitation explicitly.[15,21]

[a] The exercise capacity outcome (60-second Sit-to-Stand Test) for the Kaia intervention arm reached a statistically significant difference at three months, but this was not maintained at six months.

[b] The respiratory function outcome (CAT score) for the Kaia intervention arm did not reach statistically significant difference at three months, but did at six months.

9. INTERPRETATION OF THE CLINICAL EVIDENCE

There were two technologies – myCOPD and SPACE for COPD – for which there was more than one eligible RCT and a range of other supporting evidence, reflecting a more developed evidence base. The evidence for these two technologies generally supports the concept of non-inferiority between digitally supported and face-to-face pulmonary rehabilitation, in terms of exercise capacity and respiratory function. However, there are concerns about the generalisability of this evidence, and clinical expert advice suggested that we should be cautious about accepting clinical equivalence between traditional face-to-face pulmonary rehabilitation for COPD and digitally supported pulmonary rehabilitation. As previously discussed, there are particular concerns about: underperforming control arms, socioeconomic and geographic bias, and selection bias.

The clinical evidence for the remaining technologies – Active+me REMOTE, Clinitouch, Kaia Health, Rehab Guru and Wellinks – was more limited. There is some evidence from usual care trials that digitally supported pulmonary rehabilitation may be superior to no treatment, but the generalisability of the control arms to NHS care is unclear. It was noted by clinical experts that in the UK usual care may be much more likely to be GP management or waitlist control than the recommended face-to-face pulmonary rehabilitation.

10. ADVERSE EVENTS AND TECHNOLOGY CONSIDERATIONS

Adverse events are described above under clinical effectiveness outcomes, as they represented one of the key scoped clinical outcome domains.

In summary, data for adverse events were available for Kaia Health, myCOPD and SPACE for COPD. These data did not show any particular concerns about the adverse event profile of these technologies.

There are no specific technology considerations besides those already described regarding digital literacy, digital confidence and access to relevant devices and network infrastructure, such as data signal and Wi-Fi access.

> ***Evidence gap****: Adverse event data were only available for three of the scoped technologies.*

11. ECONOMIC EVIDENCE

11.1. Published economic evidence

The EAG did not identify any published cost effectiveness evidence – such as cost utility analyses, cost effectiveness analyses, cost minimisation analyses or cost consequences analyses – that compared any of the included digital supported pulmonary rehabilitation technologies against each other. As a consequence, specific inputs were selected from existing evaluations that compared individual digital technologies against either face-to-face pulmonary rehabilitation or no pulmonary rehabilitation. These sources were identified from supplementary searches and are listed in Table 8. The specific inputs used are detailed later in Sections 11.2.2 and 11.2.3.

Table 8. Economic evaluations consulted from the literature.

	Economic evaluations consulted	Details of key inputs derived for the EAG model	Study details
1	Davies et al. 2023[59] and EAG report received from NICE for MTG68[60]	Cost assumptions for myCOPD and PR waitlist	Davies et al. 2023 is based on MTG68 (published 2022), which evaluated myCOPD. Data on PR waitlist and the associated waiting times were adopted from these sources to inform the current analyses.
2	Dritsaki et al. 2016[61]	Resource use and cost items derived for 'no PR'	Dritsaki et al 2016 is a UK based economic evaluation of a self-management programme in COPD using digital technology ("SPACE") vs TAU. TAU specifically excluded PR but healthcare resource utilisation was measured which made it a suitable proxy for the costs of no PR.
3	Griffiths et al. 2001[62]	Resource use components and assumptions derived for 'face-to-face PR'	Griffiths et al. 2001 is a UK based economic evaluation of outpatient PR vs TAU in people with COPD. The study provided a detailed breakdown of resources used to deliver F2F PR. After checking with SCM to make sure that the structure of the intervention in the study still matches the usual care in the NHS at present, the adjusted costs were used to represent the F2F PR.

Abbreviations: F2F = face-to-face; PR = pulmonary rehabilitation; SCM = specialist committee member; TAU = treatment as usual

***Evidence gap**: There is currently a lack of published cost effectiveness evidence comparing the included digital technologies to either face-to-face or no pulmonary rehabilitation/waitlist in adults with COPD. There are also no head-to-head or indirect comparison of the different digital technologies.*

11.2. Economic evaluation

The primary purpose of this analysis was to collate and summarise the existing economic evidence for the technologies supporting the digital delivery of PR. The secondary purpose was to assess whether there is a plausible *prima facie* case for any of the digitally supported pulmonary rehabilitation technologies to be cost-effective and identify any relevant evidence gaps to guide future data collection.

Due to the high-level exploratory nature of the modelling, the current analyses should be considered broadly indicative and not definitive.

11.2.1. Overall modelling approach

There are many challenges in modelling digital health interventions, compared to drugs and medical devices. Digital health interventions evolve over time, dynamically interact with both the user and the environment, and often have associated non-health impacts.[63] Given these challenges, the EAG opted for a disaggregated cost-consequences analysis (CCA) as the primary analysis, complemented with exploratory cost-effectiveness analyses (CEA).

There are many reasons for proceeding with a CCA approach. It not only allows for a transparent and holistic assessment of all the relevant costs and consequences of the technologies under consideration, but also provides the evidence currently available in a manner similar to an 'impact inventory'.[64] This approach enables decision makers to derive their own value judgements where needed so as to decide whether the cost-benefit ratios offered by the digital interventions are favourable, rather than collating them all into an overall measure of quantity of life years accrued (i.e. QALYs). The CCA approach is also supported by the NICE evidence standards framework (ESF) for digital health technologies[65] when a cost-utility analysis is not possible. Likewise, the NIHR recommends[66] CCA as a useful way to present results from feasibility trials with small sample sizes – which happens to be the case for some of the digitally supported pulmonary rehabilitation interventions under consideration in this EVA.

For example, the RCT examining the feasibility of SPACE for COPD[12] featured 52 participants in the intervention group. In another instance, the non-inferiority RCT assessing myCOPD[15] enrolled 64 participants. The feasibility RCT for the same technology, conducted by North et al. in 2020[14], included 21 people with COPD assigned to the digital technology group and 20 to the face-to-face group. Additionally, the RCT conducted by Kaia Health[8] included 33 participants in the intervention arm and the study that explored the efficacy of Clinitouch[21] involved 27 patients accessing PR through guided digital technology.

In addition to the CCA, the EAG performed a complementary exploratory cost-effectiveness analysis, expressed as cost per unit change in functional exercise capacity (measured in terms of 6MWD or ISWD) of the digital technologies compared to standard care or face-to-face pulmonary rehabilitation from a health service perspective. The EAG notes that results of this analysis should be interpreted with caution owing to their indicative nature and associated high levels of uncertainty.

Despite the evidence base being suggestive of non-inferiority between digitally supported and face-to-face pulmonary rehabilitation (see Table 7), the EAG did not consider a cost-minimisation approach (CMA) to be appropriate. This is because small sample sizes and short follow-up poses substantial challenges for CMA. Even if a non-inferiority claim is established for one specific endpoint, the potential for discovering differences in treatment effects between the interventions may arise during longer follow-up periods. In addition, clinical expert advice to the EAG indicated that often the face-to-face or centre-based pulmonary rehabilitation arm in non-inferiority studies underperforms (as described in more detail in the clinical section). Therefore, the trials could only demonstrate equivalence to a “sub-par” or “sub-optimal” intervention.

11.2.2. Reference case analysis: Cost-consequences analysis

Digital technologies were compared (where feasible) with face-to-face pulmonary rehabilitation from the NHS and PSS perspective, over a time horizon of one year. Costs were presented in 2022 GBP, but not discounted owing to the short time horizon. Unit costs were sourced from NHS reference costs 2021/22[67] and PSSRU 2022[68].

The EAG noted that none of the studies compared a digital technology to ‘no treatment’ or ‘no pulmonary rehabilitation’. However, as the scope mentioned ‘no treatment’ as a

comparator (see Table 1), the EAG extracted the costs reported for the usual care arm from Dritsaki et al.[61] The study's comparison involved self-management using SPACE for COPD, which encompasses educational materials, exercise recommendations, follow-up calls, and related components, against standard care that was managed by their GP practice. The control group (where no participants received pulmonary rehabilitation), was used as a proxy for 'no treatment'. Dritsaki et al. was chosen because its definition of the control arm was as close as possible to no treatment or no pulmonary rehabilitation. Also, the costs of face-to-face pulmonary rehabilitation were derived primarily based on the COPD PRIME tool.

All the costs and consequences reported in included studies were extracted along with their respective control arms, typically standard-of-care or usual care. However, as noted in the clinical section, there was considerable heterogeneity in the definition of control arms, and it did not always clearly refer to face-to-face pulmonary rehabilitation. For instance, the control arms in Bourne et study for myCOPD[15] referred to a combination of home-based pulmonary rehabilitation with a few supervised sessions while Chaplin et al. study for SPACE for COPD[12] referred to hospital or community-based pulmonary rehabilitation at a referral site.

As previously described, clinical outcomes considered in the studies included metrics for exercise capacity, respiratory function, health-related quality of life, along with other outcomes such as, number of adverse events and events related to hospitalisation or ED visit. These outcomes have been presented in a disaggregated form in Table 9. The incremental consequences for digital technologies versus their respective control arms have also been calculated where feasible. Results are reported as mean difference in the change over time between intervention and control, unless otherwise stated. Note that for Active+me REMOTE the results from the study are expected only in December 2023, and hence the technology has not been included in the table.

The costs considered for digital technologies primarily involved 1) licensing costs for technologies, 2) health care professional (HCP) costs, and 3) training or any other additional costs. There was heterogeneity in the cost components considered across the digital technologies. This was primarily due to different pricing models used by the included technologies. For example, myCOPD provided an annual license determined by number of COPD patients registered to that service (with fixed year 1 costs and

subsequent year costs based on number of user registrations and engagements achieved in previous year(s)), Clinitouch charged a cost per clinician, SPACE for COPD had an annual cost per trust along with an additional cost to add patients to be managed by the clinician through their platform, and Rehab Guru provided a cost per trust and a cost per clinician.

To compare the costs of these technologies in terms of cost per patient, the EAG considered data on caseload per clinician (based on clinical opinion to EAG), uptake levels for the technologies, and the number of patients who have registered and completed pulmonary rehabilitation. This allowed for a more comprehensive analysis of the cost the NHS is expected to pay per patient.

All costs have been presented in a disaggregated form in Table 10.

Table 9. Disaggregated consequences or effects

	Clinitouch vs F2F PR			MyCOPD vs F2F PR			SPACE for COPD vs TAU[a]			Kaia Health vs TAU[b]			Rehab Guru[c]		
Consequences (disaggregated)	**N (I,C)**	**Diff**	**P**	**N (I,C)**	**Diff**	**P**	**N (I,C)**	**Diff**	**P**	**N (I,C)**	**Diff**	**P**	**N (I,C)**	**Diff**	**P**
Exercise capacity															
6MWT, m	[redacted]	[redacted]	[redacted]	(64, 26)	23.8[d]	0.098							45		
ISWT, m							?<(52, 70)[e]	24.8[f]	NS						
EWST, s							?<(52, 70)[g]	40.6[h]	NS						
STST										<(33, 34)[i]	0.390	0.143			
HRQoL															
EQ-5D-5L, mean difference (%)	[redacted]	[redacted]	[redacted]						NS[j]						
EQ-5D VAS, mean difference in change	[redacted]	[redacted]	[redacted]						NS[j]						
SGRQ				(64, 26)	-3.72[k]	0.291									
CRQ (dyspnoea)							?<(52, 70)[l]	0.0[m]	NS	<(33, 34)[n]	0.570	0.033			
CRQ (total)										<(33, 34)[o]	0.508	0.056			
Respiratory function															
CAT[p]	[redacted]	[redacted]	[redacted]	(64, 26)	-1.0[q]	0.373	?(52, 70)[r]	0.511[s]	0.575	<(33, 34)[t]	-0.605	0.024			
MRC dyspnoea	[redacted]	[redacted]	[redacted]	(64, 26)	0.03[u]	0.909							-1		
AE (number of events)				(64, 26)	3	2	11 (however, none due to treatment)	7							
ED or resulting in Hospitalisation				1.88[v]	1.06[v]	0.82[v]				1.08[w]	1.23[w]	-0.15[w]			
Source(s)	Staffordshire report by Clinitouch [21]			Bourne et al. 2017[15] and hospitalisation data from North et al. 2020[14]			Bourne et al., 2022[10] except Chaplin et al. 2017[12] where stated.			Spielmanns et al. 2023[8]			Rehab Guru poster by Pilsworth et al.[9] & CS		

Abbreviations: 6MWT = 6-minute walk test; AE = adverse events; C = comparator; CAT = COPD Assessment Test; CRQ = Chronic Respiratory Disease Questionnaire; CS = company submission; Diff = difference; ED = emergency department; ESWT = endurance shuttle walk test; I = intervention; ISWT = incremental shuttle walk test; m = metres; MRC, Medical Research Council; s = seconds; SGRQ, Saint George's Respiratory Questionnaire; STST = sit-to-stand test

[a] TAU could include PR.

[b] Unknown whether TAU included PR.

[c] No comparative data available for Rehab Guru

[d] Adjusted, ITT population.

[e] Sample sizes for individual outcomes not reported explicitly reported, but primary outcome (CAT) data availability was (52,70), with between 2.6% and 52.3% of data missing for others.

[f] Baseline ISWT and ESWT in control group not reported. Details of statistical tests not reported. Figures shown are difference in metres between intervention and control at 9m

[g] Sample sizes for individual outcomes not reported explicitly reported, but primary outcome (CAT) data availability was (52,70), with between 2.6% and 52.3% of data missing for others.

[h] Baseline ISWT and ESWT in control group not reported. Details of statistical tests not reported. Figures shown are difference in metres between intervention and control at 9m

[i] 60 of 67 patients completed the study but data missingness not reported.

[j] Source: Chaplain 2017. Data not reported, but declared NS

[k] Adjusted, ITT population.

[l] Sample sizes for individual outcomes not reported explicitly reported, but primary outcome (CAT) data availability was (52,70), with between 2.6% and 52.3% of data missing for others.

[m] Difference in change from BL to 9m. 6m figures: 0.0, NS

[n] 60 of 67 patients completed the study but data missingness not reported.

[o] 60 of 67 patients completed the study but data missingness not reported.

[p] As CAT represents the impact of the disease on patient life a negative value in the table represents a decrease in that impact and an improvement in patient health

[q] Adjusted, ITT population

[r] Sample sizes for individual outcomes not reported explicitly reported, but primary outcome (CAT) data availability was (52,70), with between 2.6% and 52.3% of data missing for others.

[s] At 9m FU. 6m mean difference 1.70, p=0.135

[t] 60 of 67 patients completed the study but data missingness not reported.

[u] adjusted, ITT population.

[v] Mean in-patient treated

[w] Mean exacerbations treated

Table 10. Disaggregated costs (per patient)

	Active +me	Clinitouch	SPACE for COPD	myCOPD	Rehab Guru	Waitlist (without exacerbations)	Waitlist (with exacerbations)	F2F PR
License cost	£89	[redacted] £26.67[k]	£57[b]	yr1: [redacted][c] yr2: [redacted][c] [redacted][o]	£33[d]	-	-	-
Staff training	£42[e]	-	£12.5[f]	-	-	-	-	-
Participant training	£60 (ex VAT) [g]	-	-	-	-	-	-	-
Staff time	£144	£144[h]	£144	£144	£144			£432
Expected annual cost per patient	£335	[redacted] £171	£ 272	[redacted]	£177	£164[i]	£402[j]	£432
Uptake rate, %	-	10%[p] 30%[l]	10%[p] 5%	10%[p] (first year) 20% (Second year)	10%[p] 5%[m]	-	-	85%
Completion rate, %	-	76.6%	47%	62%	68%[n]	-	-	71%
Source(s)	Active+me company submission (request for information: Active+me ATT7-A~1)	[CIC] Email from Jim Swift from Spirit Health Att 7 -Spirit Dig_PR PR_Staffs_COPD_ PR_NICE_July_23 (includes company's HE analysis)	Att 7 - Company - request for information v2	Email from NICE : Updated pricing information from myCOPD [CIC] myCOPD pricing model	Email from NICE : FW_ URGENT AND TIME SENSITIVE - information required for NICE evaluation	Melina Dritsaki 2016, costs updated as per 2021/2022 NHS reference costs and PSSRU 2022	previous report on myCOPD DHT001 YHEC Assessment Report 18.08.2021 V5.0 post fact check CLEAN cost updated to 2022 PSSRU	COPD PRIME 2017 with costs adjusted using PSSRU 2022 Uptake and completion rates from UK COPD PR audit

[a] £1200 license cost per clinician, assuming a health care professional manages an average of 30 cases of PR annually based on SCM advice = 1200/30 = £40

[b] £500 license cost per trust and £50 for each patient added to a maximum of 30 patients per clinician. There are a total of 217 NHS trusts in the UK. According to the NACAP PR benchmark report, there are 15,713 people registered to the audit and attending PR programs. Assuming that each clinician sees 30 patients based on clinical opinion to EAG, the cost per patient can be calculated as follows: = ((500 * 217/15,713)+50*30)/30 = £57

[c] License costs corresponding to 10% uptake rate in first year and 20% uptake rate in second year sourced from myCOPD pricing model.

[d] A license for £2,000 per NHS trust, along with an additional charge of £150 per clinician to use the technology. There are a total of 217 NHS trusts in the UK. According to the NACAP PR benchmark report, there are 15,713 people registered to the audit and attending PR programs. Assuming that each clinician sees 30 patients based on clinical opinion to EAG, the cost per patient can be calculated as follows:(£2,000 * 217 / 15,713) + (£150 / 30) = £32.62 per patient.

[e] £1250 to train a clinician to use the technology, SCM advised the EAG that all clinicians would likely need training before managing their patients through the technology. And assuming a Clinician manages 30 patients = 1250/30 = £41.6

[f] The company submission- reports a cost of £375 to train a HCP and support the delivery of tech = 375/30 = £12.5

[g] The company a training cost of £150 per patient to instruct them on the usage of the technology. According to a study conducted on digitally supported pulmonary rehabilitation during the COVID-19 pandemic, it was found that 40% of the patients require assistance or lack confidence in their internet usage skills. Therefore, it can be estimated that these patients would necessitate training, resulting in a cost of £60 per patient (150 * 0.4 = £60).

[h] The Staffordshire study conducted on CliniTouch provides a detailed breakdown of the staff time required for delivering their intervention. Since other technologies did not provide the same data, a similar cost of £143.88 per patient was assumed for other technologies given the similarities in mode of delivery.

[i] Resource utilisation reported by Dritsaki et al., 2016 (adjusted for 2022 NHS cost reference) provided an annual cost of £372. The average waiting time for PR is 160.7 days. Average cost per patient on the waiting list (stable patient) = 372*(160.7/365) = £163.78

[j] Previous NICE report for MTG68 used the cost of 13 days on wating list at £40 (cost adjusted for 2022). The average waiting time for PR is 130.8 days. Average cost per patient on the waiting list (people with unstable COPD) = 40*(130.8/13) = £402.46

[k] £26.67 license cost based on company HE analysis presented in the Staffordshire report

[l] Normalised estimate so the overall proportion add up to 100% : (28%/94%)*100

[m] Assumed same as myCOPD and SPACE for COPD i.e., 5%

[n] Aggregate data from 3 sites as reported in submission file. Note, however, as per the poster submitted it is 80%

[0] myCOPD pricing based on 'legacy' contract which is a per patient fee structure starting from approximately [redacted]. Current users may remain on this fee structure in perpetuity if the contract is not reviewed.

[p] Based on the NHS England data from COPD PRIME tool, proportion who starts PR out of COPD population with MRC3 and above = 59,033/667,040 ~ 9% which aligns closely with 10%

11.2.2.1. Cost-consequences balance sheet (in terms of walking distance)

Based on the disaggregated costs and consequences presented in Section 11.2.2, a cost-consequence balance sheet was prepared (Table 11). The balance sheet specifically compares the efficacy of the included technologies to UK national COPD PR audit data, which included outcomes for 6MWT and ISWT. The sheet therefore only includes technologies for which 6MWT and ISWT outcomes were available (namely, Clinitouch, myCOPD, SPACE for COPD and Rehab Guru).

The absolute change in 6MWD from baseline was [redacted]m for Clinitouch[21], 44.9m for myCOPD[15], and 45m for Rehab Guru.[9] For SPACE for COPD[12], the absolute change in incremental shuttle walking distance (ISWD), based on Chaplin 2017, was less than 48m (45m assumed for calculation). Based on the UK COPD PR audit data for face-face pulmonary rehabilitation, the change from baseline was 63.4m for ISWD and 59m for 6MWD, derived as the weighted average of the practice and no practice cohorts.[69]

Comparison with the UK COPD PR audit therefore resulted in a difference of [redacted] for Clinitouch, -14.1 for myCOPD, and -14m for Rehab Guru (in terms of 6MWD) and -18.4m for SPACE for COPD (in terms of ISWD), as presented in Table 11.

Table 11. Cost-consequences balance sheet

	Clinitouch vs F2F PR (UK COPD PR audit)	myCOPD vs F2F PR (UK COPD PR audit)	SPACE for COPD vs F2F PR (UK COPD PR audit)	Rehab Guru vs F2F PR (UK COPD PR audit)
Difference in treatment effect, 6MWD in m	[redacted]	-14.1	NR	-14.0
Difference in treatment effect, ISWD in m	NR	NR	-18.4	NR
Annual cost savings per participant	[redacted] [redacted]	[redacted] first year[b] [redacted] second year[b]	-£218	-£255

Abbreviations: 6MWD = 6-min walking distance; ISWD = incremental shuttle walking distance; m = metres; F2F = face-to-face; NR = not reported.

[a] per participant license fee based on 'legacy' contract

[b] per participant license fee based on pricing model with 10% uptake rate at first year and 20% in the following years

The technologies supporting the digital delivery of PR were therefore slightly less effective compared to face-to-face pulmonary rehabilitation in terms of absolute change in walking distance from baseline (for both 6MWD and ISWD), as they resulted in relatively lower improvements in walking distance post baseline than that observed in the UK COPD PR audit data.

However, all of the technologies resulted in cost savings compared to face-to-face pulmonary rehabilitation as per UK COPD audit. Please note that a 10% uptake rate has been used for myCOPD based on the proportion of COPD population with MRC3 and above who start pulmonary rehabilitation in England (= 59,033/667,040 ~ 9%), as per COPD PRIME tool. Per participant costs of other technologies (namely, Clinitouch, SPACE for COPD and Rehab guru) were assumed not to be impacted by uptake rates. Annual savings per participant were:

- [redacted] based on 'legacy' contract per participant fee and [redacted] in the first year and [redacted] in the following years based on uptake rate linked pricing model provided, for myCOPD
- [redacted] based on per clinician per year cost, and £261 based on per participant license cost of £26.67, for Clinitouch
- £218 for SPACE for COPD
- £255 for Rehab Guru

The primary factor contributing to cost savings is the reduction in staff time required for delivery. The EAG also noted that the cost per patient is influenced by the pricing model for the technology. For instance, in the case of myCOPD, the higher the population covered at trust or service level (owing to higher uptake), then the lower the per participant cost. In contrast, a pricing model based on licenses per patient or clinician, as in Clinitouch and SPACE for COPD, tends to be less sensitive to low uptake rates. It is worth noting that while the cost per patient (without adjustment for uptake and completion rates) for Rehab Guru is relatively low at £177, because of which it could save £254 cost, the efficacy data are premature, as the only study for this technology has not yet reported its final results. The situation is similar with Clinitouch, where the main source of efficacy data relies on the Staffordshire study,

the results of which have not yet undergone peer review (see Section 9 for an interpretation of the clinical evidence).

To enhance the precision of this analysis, it is important to address specific knowledge gaps. For instance, uptake rates informed by real world data will lead to more robust estimations. Exacerbation rates are another key cost driver, as evidenced by the difference in costs between people with stable and unstable COPD (based on the likelihood of having exacerbations) on the waiting list. While the effectiveness evidence for face-to-face pulmonary rehabilitation interventions in reducing exacerbations is mature, there is currently a lack of data on how digital technologies compare in this regard. Closing this knowledge gap is key for a more comprehensive evaluation (see Section 13 for more details).

11.2.3. Complementary analysis: Exploratory cost-effectiveness analysis

An exploratory cost-effectiveness analysis was performed in addition to the reference case analysis. The perspective, time horizon and the source of unit costs were the same as that of the reference case CCA. Cost-effectiveness was expressed as cost per change in functional exercise capacity, as it was one of the outcomes that was reported consistently across digital technology studies (as described in Section 9). Holland et al. 2014[70] described how field walk tests, such as 6MWT, ISWT and ESWT, have demonstrated validity and reliability. They are also strongly associated with measures of exercise performance and physical activity in people with COPD undergoing pulmonary rehabilitation. Previous economic analysis such as Burge et al. 2020[71] also used change in functional exercise capacity – measured as distance walked on 6-min walk test – as their second preferred outcome measure (after health-related quality of life utility scores).

Only four technologies were included in the cost-effectiveness analysis: Clinitouch, myCOPD, Rehab Guru and SPACE for COPD. These were the only technologies for which 1) at least one of the exercise capacity measures was reported and 2) the calculation of cost per participant was feasible (as the outcomes reported were per participant). For myCOPD, Bourne et al. 2017[15] was used as the primary data source, as it was the only study which reported a validated exercise capacity measure, i.e., 6MWT (Crooks et al. 2020[13] reported only number of steps per day

and North et al. 2020[14] reported Veterans Specific Activity Questionnaire (VSAQ), neither of which were validated measures).

Key model inputs and the associated assumptions have been provided in Table 12. Please note that the change from baseline in terms of MCID units were calculated as follows: absolute change from baseline measured through 6MWT or ISWT in metres divided by the MCID for 6MWT or ISWT (54m for 6MWT[54] and 48m for ISWT[55]). As an example, for myCOPD this was calculated as: 44.9/54 = 0.831.

This decision analytic framework used enabled a threshold analysis for the four included technologies. The approach allowed identification of threshold values of key variables – such as change in functional exercise capacity (measured in terms of change in walking distance through 6MWT and ISWT), license fee for digital technologies, uptake rates etc. – above or below which the digital technologies are likely to offer good value for money compared to face-to-face pulmonary rehabilitation. Conducting a threshold analysis was considered appropriate at this stage, given that estimates of cost-effectiveness are unlikely to be definitive owing to the evidence base consisting of a small number of relatively under-powered trials (as discussed in section 8.3).[72]

Deterministic sensitivity and scenario analyses to test the impact of different sources of inputs and assumptions were also performed (Section 11.2.3.2). However, given the sparse availability of measures of parameter variability from trials and the need for several arbitrary assumptions, a probabilistic sensitivity analysis was not performed (as it may cause pseudo-certainty of the results generated which could be misleading[73]).

Table 12. Model inputs CEA

	Annual per participant costs (£)	Uptake, %	Completion, %	Per participant effects (measured as change in functional exercise capacity)		
				Absolute mean change from baseline (6MWD or ISWD in metres)	% change from baseline	Change from baseline measured as MCID units
Digitally supported pulmonary rehabilitation technologies (considering license fee, staff time and training costs)						
Clinitouch (CT)	[redacted] £170.55[b]	10%[f]	[redacted]	[redacted]	[redacted]	[redacted]
myCOPD (MC)	[redacted] (using license fee corresponding to 10% uptake)[e]	10%[f]	62%	44.9[c]	12%	0.831
Rehab Guru	£177	10%[f]	68%	45[c]	18%	0.833
SPACE for COPD	£213.29	10%[f]	47%	45[d]	15%	0.947
Face-to-face pulmonary rehabilitation						
F2F PR – 6MWD based on UK COPD PR audit (without exacerbation costs)	£432	85%	71%	59	22%	1.092
F2F PR – ISWD based on UK COPD PR audit (without exacerbation costs)				63.4	31%	1.320
F2F PR CT control arm	£272.83	70%	55.63%	[redacted]	[redacted]	[redacted]

	Annual per participant costs (£)	Uptake, %	Completion, %	Per participant effects (measured as change in functional exercise capacity)		
				Absolute mean change from baseline (6MWD or ISWD in metres)	% change from baseline	Change from baseline measured as MCID units
F2F PR myCOPD control arm	Assumed same as UK COPD PR audit	95%	72%	28.6	7%	0.530
F2F PR SPACE control arm	Assumed same as UK COPD PR audit	95%	67%	Assumed same as UK COPD PR audit		

Abbreviations: 6MWD = 6-min walking distance; F2F = face-to-face; PR = pulmonary rehabilitation; HCP = health care professional; ISWD = incremental shuttle walk distance; UK = United Kingdom. Note: As F2F arm was not available in the Rehab Guru study, it was assumed to be the same as UK COPD PR audit.

[a] Cost based on confidential per clinical per annum price reported in the company submission.

[b] Cost based on publishable license fee of £26.67.

[c] Clinitouch, Rehab Guru and myCOPD results are expressed as 6MWD.

[d] SPACE for COPD results are expressed as ISWD.

[e] Calculated as: 144+64 (license fee for 10% uptake)

[f] Based on the NHS England data from COPD PRIME tool, proportion who starts PR out of COPD population with MRC3 and above = 59,003/667,040 ~ 9%, rounded up to 10%

11.2.3.1. Key model assumptions

Related to effects:

- Reported exercise capacity outcomes were assumed to be for participants who completed the full digital or face-to-face pulmonary rehabilitation course (i.e. not those participants who did not complete the full course).
- ISWT effects for SPACE for COPD were assumed to be the same as that of the face-to-face arm of the UK COPD pulmonary rehabilitation audit, as Chaplin et al.[12] only reported the baseline data for the control arm. However, ISWT data from Bourne et al. 2022[10] have been tested in a scenario analysis.
- For Rehab Guru, as there was no control arm in its study, it was assumed to be the same as UK COPD PR audit.
- If uptake rates for the trial control arms were not provided, they were calculated as 1 minus the uptake rate in the digital arm. This assumes that there are only two arms in each trial, and if participants are not signed up for the digital arm, then the only choice available is the control arm.
- The completion rate for the control arm in the Staffordshire Clinitouch study was not reported – it was therefore assumed to be the same as that of the intervention arm.
- Mortality and other long-term outcomes (especially in terms of impact on COPD, such as changes in COPD severity) have not been captured owing to the 1-year time horizon of the model and the short follow up in the available clinical evidence.

Related to costs:

- The healthcare professional costs from Staffordshire Clinitouch study were assumed to be the same for all included technologies.
- Where licensing costs were provided per clinician (for instance, for SPACE for COPD), to enable the calculation of per participant costs, 30 patients per clinician was assumed based on clinical opinion to EAG (which itself was based

on NACAP pulmonary rehabilitation benchmark[74], assuming 3 clinicians per site: 15,713 people registered/180 sites*3 clinicians per site ~ 30). The cost per participant calculated for Clinitouch based on this assumption was tested as part of a scenario analysis, as the base case value is drawn from a company submitted economic analysis which included a publishable license fee.

- For deriving myCOPD costs per participant, based on the company provided pricing tool, an uptake rate of approximately 10% for the first year was assumed in the base case. The 10% also aligned with the proportion who starts PR out of the COPD population with MRC score of 3 and above – as per the COPD PRIME tool.). However, myCOPD' s pricing has been offered in two ways to the NHS. One considered to be a 'legacy' pricing with the starting cost per participant of [redacted], while the current approach is based on trust level pricing, where the per participant cost is linked to agreed uptake levels. Owing to this variation in pricing model, a range of pricing as low as the per participant 'legacy' contract fee ([redacted]) reflecting best case scenario and as high as [redacted] corresponding to an uptake rate of 5% reflecting worst case scenario, as per the pricing model provided, was tested in scenario analysis.

- For technologies with no uptake rate linked pricing model (namely, Clinitouch, SPACE for COPD and Rehab guru), per participant costs were assumed not to be impacted by the uptake rates.

- The costs for face-to-face pulmonary rehabilitation were sourced from the literature (see Table 13Table 13). It is to be noted that the costs based on the COPD PRIME tool[76] have been considered in base case following clinical advice to the EAG. Other costs were explored in scenario analyses.

Table 13. Face-to-face PR costs

Source and details	F2F PR costs
Griffiths et al.., 2001[62] costs updated using PSSRU 2022[68]	£1,066 per 6 weeks PR programme per patient for 12 sessions aligned with clinical advice to EAG
PR costs based on COPD PRIME[76] (without exacerbation related costs) and staff costs updated using Agenda for change 2023/24 pay scales[77]	£432 per patient

Source and details	F2F PR costs
PR costs based on COPD PRIME[76] (with exacerbation related costs) and staff costs updated using Agenda for change 2023/24 pay scales[77]	£908 per patient (£432+Average exacerbation cost including hospital admission and primary care £477)

Abbreviations: EAG = External assessment group; PR = Pulmonary rehabilitation; PRIME = Pulmonary Rehabilitation Impact Model on Exacerbations; PSSRU = Personal Social Services Research Unit

11.2.3.2. Model results (base case)

Table 14 to Table 16 present the base case results of the CEA. Results are shown for the following outcomes: 1) absolute change from baseline in exercise capacity, measured as walking distance in metres, 2) percentage change from baseline in exercise capacity, measured as walking distance, and 3) unit change from baseline in MCID of exercise capacity, measured as MCID units (calculated as described in Section 11.2.3). Mean differences in absolute change from baseline between digital and face-to-face pulmonary rehabilitation did not reach MCID for any technology in their respective trials, indicating potential non-inferiority.

The EAG considered that the face-to-face pulmonary rehabilitation data from the UK COPD PR audit are closer to real clinical practice than the control arms of the included studies (see Section 8.2), and hence only the results comparing digital technologies to that of UK COPD PR audit have been presented here. The results using the trial control arms have been presented in the Appendices (Appendix E).

When UK COPD pulmonary rehabilitation audit data were used for the face-to-face pulmonary rehabilitation arm the incremental effects ranged from:

- -18.38 to -0.11 in terms of difference in walking distance from baseline
- -0.387 to -0.002 in terms of difference in MCID units
- -15% to -2% in terms of difference in percentage change in walking distance

The incremental costs ranged from [redacted] to -£261 across the technologies, with SPACE for COPD producing the least savings.

Please note that the results have been presented in terms of cost per outcome of interest. Net benefit measures (INMB/INHB) have not been used as the outcome

here is change in walking distance, for which the willingness to pay threshold is unknown.

Table 14. Cost per change in walking distance – F2F PR UK COPD PR audit

	Costs (per annum per participant)	Effect (Change in walking distance, m)	Digital vs F2F PR		
			Incremental costs	Incremental effect	Cost per ΔWD(m)
Clinitouch (CT)	£170.55	[redacted]	-£261	[redacted]	[redacted]
F2F PR	£431.55	59.01	-	-	-
myCOPD (MC)	[redacted]	44.90	[redacted]	-14.11	[redacted]
F2F PR	£431.55	59.01	-	-	-
SPACE for COPD	£213.29	45.00	-£218	-18.38	£12
F2F PR	£431.55	63.38	-	-	-
Rehab Guru	£176.50	45.00	-£255	-14.01	£18
F2F PR	£431.55	59.01	-	-	

Abbreviations: F2F = Face-to-face; MCID = minimal clinically important difference; PR = Pulmonary rehabilitation; WD = walking distance in meters

MCID reached MCID not reached

Table 15. Cost per unit change in MCID[a] – F2F arm as per UK COPD PR audit

	Costs (per annum per participant)	Effect (change in MCID units)	Digital vs F2F PR		
			Incremental costs	Incremental effect	Cost per unit ΔMCID
Clinitouch (CT)	£170.55	[redacted]	-£261	[redacted]	[redacted]
F2F PR	£431.55	1.093	-	-	-
myCOPD (MC)	[redacted]	0.831	[redacted]	-0.261	[redacted]
F2F PR	£431.55	1.093	-	-	-
SPACE for COPD	£213.29	0.947	-£218	-0.387	£564
F2F PR	£431.55	1.334	-	-	-
Rehab Guru	£176.50	0.833	-£255	-0.259	£983
F2F PR	£431.55	1.093	-	-	-

Abbreviations: F2F = Face-to-face; MCID = minimal clinically important difference; PR = Pulmonary rehabilitation; WD = walking distance in meters [a]1 MCID for 6MWD = 54m and ISWD = 48 m.

MCID reached MCID not reached

Table 16. Cost per % change in walking distance – F2F arm as per UK COPD PR audit

	Costs (per annum per participant)	Effect (% change in walking distance)	Digital vs F2F PR		
			Incremental costs	Incremental effect	Cost per % ΔWD
Clinitouch (CT)	£170.55	[redacted]	-£261	[redacted]	[redacted]
F2F PR	£431.55	22%	-	-	-
myCOPD (MC)	[redacted]	12%	[redacted]	-11%	[redacted]
F2F PR	£431.55	22%	-	-	-
SPACE for COPD	£213.29	15%	-£218	-15%	£1,416
F2F PR	£431.55	31%	-	-	-
Rehab Guru	£176.50	18%	-£255	-4%	£5,902
F2F PR	£431.55	22%	-	-	-

Abbreviations: F2F = Face-to-face; MCID = minimal clinically important difference; PR = Pulmonary rehabilitation; WD = walking distance in meters

MCID reached MCID not reached

11.2.3.3. Sensitivity and scenario analyses

Deterministic sensitivity analyses, including one-way and two-way analysis were, performed to assess the impact of uncertainty associated with the model parameters. Face-to-face pulmonary rehabilitation data from the UK COPD PR audit has been used for all the sensitivity and scenario analysis, as it was found to reflect clinical practice more closely than the control arms in the prioritised studies.

Threshold analysis of change from baseline 6MWD indicated that when a treatment effect of around 60m and above was tested, Clinitouch, myCOPD and Rehab Guru were found to be cost saving as well as more effective compared to face-to-face pulmonary rehabilitation based on UK COPD PR audit (Table 17). Similarly, in terms of change in ISWD, when a threshold value of 65m and above was tested, SPACE for COPD was cost saving and more effective. Below these threshold values (both for 6MWD and ISWD), all the technologies considered were cost saving but less effective compared to UK COPD PR audit based face-to-face PR. Therefore, for these digital technologies to be cost saving as well as more effective compared to

face-to-face pulmonary rehabilitation, a treatment effect of at least 60m (in terms of change in walking distance) may need to be achieved. However, these threshold values are subject to uncertainty based on the change from baseline values in the face-to-face arm. This has been explored further in the sensitivity analysis. As shown in Table 18, Clinitouch would be cost saving and more effective if the change from baseline in the face-to-face arm would have been less than 60m. Similarly, if the change from baseline in the face-to-face arm would have been less than 45m, myCOPD, SPACE for COPD and Rehab guru would be cost saving and more effective.

One-way sensitivity analysis of uptake rates of the digital technologies was also performed, which indicated the uncertainty in costs savings for myCOPD, owing to its uptake rate linked pricing model. As shown in Table 19, the costs savings achieved with myCOPD were relatively more sensitive to uptake rates of up to 15%, compared to more than 15% (with the highest sensitivity noted when the uptake rate was changed to 2.5% from 5%, which reduced the cost savings from [redacted] to [redacted]. However, this was not the case for other digital technologies, as their pricing models were not directly linked to uptake rates.

To explore further the uncertainty of results, while simultaneously varying the change in walking distance (effect) and the per participant cost of the digital technologies (cost), the EAG conducted a two-way analysis for all digital technologies exploring the impact of change in their effects on their respective costs. Results of the two-way sensitivity analysis are presented in Table 20 to Table 23, which indicated that, except for myCOPD, the results were similar for all digital technologies.

In addition, scenario analyses were also carried out to explore the alternative inputs on both costs and effects. The impact of these scenarios on the base case results are shown in Table 24. In terms of scenarios evaluating alternative outcomes used for measuring the effect of treatment, using ISWD from Bourne et al 2022 (for SPACE for COPD) decreased the cost per change of walking distance by 59%. Also, using an alternative MCID cut-off for 6MWT, based on the Clinitouch Staffordshire study, decreased the cost per change in walking distance measured as MCID units by 80%. From the point of view of costs, using the first year price based on 5% uptake rate, as per the pricing model for myCOPD, decreased the cost per change in

walking distance by 40%, owing to reduced savings with a lower uptake rate than base case (10%), which aligns with the similar findings from the one-way sensitivity analysis (Table 19). On the other hand, using the legacy contract pricing increased the cost per change in walking distance by 16%, owing to the associated higher savings compared to base case. It is to be noted that the impact of alternative per participant costs (derived from per clinician costs), for Clinitouch, seem to have only marginal impact on the results (with cost per ΔWD decreasing by 5%).

Table 17. OWSA – Impact of change in walking distance on cost per ΔWD

	Cost per ΔWD			
Change from baseline WD, m	CT	myCOPD	SPACE	Rehab Guru
0	£4	£4	£3	£4
5	£5	£4	£4	£5
10	£5	£5	£4	£5
15	£6	£5	£5	£6
20	£7	£6	£5	£7
25	£8	£7	£6	£7
30	£9	£8	£7	£9
35	£11	£9	£8	£11
40	£14	£12	£9	£13
45	£19	£16	£12	£18
50	£30	£26	£17	£30
55	£65	£56	£26	£64
60	-£264	-£226	£64	-£258
65	-£44	-£37	-£135	-£43
70	-£24	-£20	-£33	-£23
75	-£16	-£14	-£19	-£16
80	-£12	-£11	-£13	-£12
85	-£10	-£9	-£10	-£10
90	-£8	-£7	-£8	-£8
95	-£7	-£6	-£7	-£7
100	-£6	-£5	-£6	-£6

Abbreviations: CT = Clinitouch; OWSA = One-way sensitivity analysis; WD = walking distance

Less costly-less effective vs F2F PR UK COPD audit

Less costly-more effective vs F2F PR UK COPD audit

Table 18. OWSA – Impact of change in walking distance in the F2F PR arm on cost per ΔWD for the technologies

	Cost per ΔWD			
Change from baseline WD F2F, m	CT	myCOPD	SPACE	Rehab Guru
0	-£4	-£5	-£5	-£6
5	-£5	-£6	-£5	-£6
10	-£5	-£6	-£6	-£7
15	-£6	-£7	-£7	-£9
20	-£7	-£9	-£9	-£10
25	-£8	-£11	-£11	-£13
30	-£9	-£15	-£15	-£17
35	-£11	-£23	-£22	-£26
40	-£14	-£46	-£44	-£51
45	-£19	£407	£485	£567
50	-£31	£40	£40	£47
55	-£76	£21	£21	£24
60	£168	£14	£14	£17
65	£40	£11	£11	£12
70	£23	£9	£9	£10
75	£16	£7	£7	£8
80	£12	£6	£6	£7
85	£10	£6	£5	£6
90	£8	£5	£5	£6
95	£7	£4	£4	£5
100	£6	£4	£4	£5

Abbreviations: CT = Clinitouch; OWSA = One-way sensitivity analysis; WD = walking distance

Less costly-less effective vs F2F PR UK COPD audit

Less costly-more effective vs F2F PR UK COPD audit

Table 19. OWSA – impact of uptake rates on cost savings

Uptake rates, %	Cost savings vs F2F PR (UK COPD PR audit)			
	myCOPD (first year)	Clinitouch	SPACE	Rehab Guru
2.5%	[redacted]	£261	£218	£255
5%	[redacted]	£261	£218	£255
10%	[redacted]	£261	£218	£255
15%	[redacted]	£261	£218	£255
20%	[redacted]	£261	£218	£255
25%	[redacted]	£261	£218	£255
30%	[redacted]	£261	£218	£255
35%	[redacted]	£261	£218	£255
40%	[redacted]	£261	£218	£255
45%	[redacted]	£261	£218	£255
50%	[redacted]	£261	£218	£255
55%	[redacted]	£261	£218	£255
60%	[redacted]	£261	£218	£255
65%	[redacted]	£261	£218	£255
70%	[redacted]	£261	£218	£255
75%	[redacted]	£261	£218	£255
80%	[redacted]	£261	£218	£255
85%	[redacted]	£261	£218	£255
90%	[redacted]	£261	£218	£255
95%	[redacted]	£261	£218	£255
100%	[redacted]	£261	£218	£255

Abbreviations: OWSA = One-way sensitivity analysis; WD = walking distance; F2F= face-to-face, PR= Pulmonary rehabilitation;

Table 20. TWSA – Impact of ΔWD versus license fee per participant on cost per ΔWD (Clinitouch)

	Change from baseline WD, m	0	10	20	30	40	50	60	70	80	90	100
Per participant annual technology cost (includes license fee, staff time and training costs)	**£0**	£7	£9	£11	£15	£23	£48	-£436	-£39	-£21	-£14	-£11
	£50	£6	£8	£10	£13	£20	£42	-£386	-£35	-£18	-£12	-£9
	£100	£6	£7	£9	£11	£17	£37	-£335	-£30	-£16	-£11	-£8
	£150	£5	£6	£7	£10	£15	£31	-£285	-£26	-£13	-£9	-£7
	£200	£4	£5	£6	£8	£12	£26	-£234	-£21	-£11	-£7	-£6
	£250	£3	£4	£5	£6	£10	£20	-£184	-£17	-£9	-£6	-£4
	£300	£2	£3	£3	£5	£7	£15	-£133	-£12	-£6	-£4	-£3
	£350	£1	£2	£2	£3	£4	£9	-£82	-£7	-£4	-£3	-£2
	£400	£1	£1	£1	£1	£2	£4	-£32	-£3	-£2	-£1	-£1
	£450	-£0	-£0	-£0	-£1	-£1	-£2	£19	£2	£1	£1	£0
	£500	-£1	-£1	-£2	-£2	-£4	-£8	£69	£6	£3	£2	£2

Abbreviations: TWSA = Two-way sensitivity analysis; WD = walking distance

Less costly-less effective vs F2F PR UK COPD audit Less costly-more effective vs F2F PR UK COPD audit More costly-less effective vs F2F PR UK COPD audit More costly-More effective vs F2F PR UK COPD audit

Table 21. TWSA – Impact of ΔWD versus license fee per participant on cost per ΔWD (SPACE for COPD)

	Change from baseline WD, m	0	10	20	30	40	50	60	70	80	90	100
Per participant annual technology cost (includes license fee, staff time and training costs)	**£0**	£7	£8	£10	£13	£18	£32	£128	-£65	-£26	-£16	-£12
	£50	£6	£7	£9	£11	£16	£29	£113	-£58	-£23	-£14	-£10
	£100	£5	£6	£8	£10	£14	£25	£98	-£50	-£20	-£12	-£9
	£150	£4	£5	£6	£8	£12	£21	£83	-£43	-£17	-£11	-£8
	£200	£4	£4	£5	£7	£10	£17	£68	-£35	-£14	-£9	-£6
	£250	£3	£3	£4	£5	£8	£14	£54	-£27	-£11	-£7	-£5
	£300	£2	£2	£3	£4	£6	£10	£39	-£20	-£8	-£5	-£4
	£350	£1	£2	£2	£2	£3	£6	£24	-£12	-£5	-£3	-£2
	£400	£1	£1	£1	£1	£1	£2	£9	-£5	-£2	-£1	-£1
	£450	-£0	-£0	-£0	-£1	-£1	-£1	-£5	£3	£1	£1	£1
	£500	-£1	-£1	-£2	-£2	-£3	-£5	-£20	£10	£4	£3	£2

Abbreviations: TWSA = Two-way sensitivity analysis; WD = walking distance

Less costly-less effective vs F2F PR UK COPD audit Less costly-more effective vs F2F PR UK COPD audit More costly-less effective vs F2F PR UK COPD audit

More costly-More effective vs F2F PR UK COPD audit

Table 22. TWSA – Impact of ΔWD versus license fee per participant on cost per ΔWD (myCOPD)

	Change from baseline WD, m	0	10	20	30	40	50	60	70	80	90	100
Per participant annual technology cost (includes license fee, staff time and training costs)	**£0**	[redacted]										
	£50	[redacted]										
	£100	[redacted]										
	£150	[redacted]										
	£200	[redacted]										
	£250	[redacted]										
	£300	[redacted]										
	£350	[redacted]										
	£400	[redacted]										
	£450	[redacted]										
	£500	[redacted]										

Abbreviations: TWSA = Two-way sensitivity analysis; WD = walking distance

Less costly-less effective vs F2F PR UK COPD audit More costly-less effective vs F2F PR UK COPD audit Less costly-more effective vs F2F PR UK COPD audit

More costly-More effective vs F2F PR UK COPD audit

Table 23. TWSA – Impact of ΔWD versus license fee per participant on cost per ΔWD (Rehab Guru)

	Change from baseline WD, m	0	10	20	30	40	50	60	70	80	90	100
Per participant annual technology cost (includes license fee, staff time and training costs)	**£0**	£7	£9	£11	£15	£23	£48	-£436	-£39	-£21	-£14	-£11
	£50	£6	£8	£10	£13	£20	£42	-£386	-£35	-£18	-£12	-£9
	£100	£6	£7	£9	£11	£17	£37	-£335	-£30	-£16	-£11	-£8
	£150	£5	£6	£7	£10	£15	£31	-£285	-£26	-£13	-£9	-£7
	£200	£4	£5	£6	£8	£12	£26	-£234	-£21	-£11	-£7	-£6
	£250	£3	£4	£5	£6	£10	£20	-£184	-£17	-£9	-£6	-£4
	£300	£2	£3	£3	£5	£7	£15	-£133	-£12	-£6	-£4	-£3
	£350	£1	£2	£2	£3	£4	£9	-£82	-£7	-£4	-£3	-£2
	£400	£1	£1	£1	£1	£2	£4	-£32	-£3	-£2	-£1	-£1
	£450	-£0	-£0	-£0	-£1	-£1	-£2	£19	£2	£1	£1	£0
	£500	-£1	-£1	-£2	-£2	-£4	-£8	£69	£6	£3	£2	£2

Abbreviations: TWSA = Two-way sensitivity analysis; WD = walking distance

Less costly-less effective vs F2F PR UK COPD audit More costly-less effective vs F2F PR UK COPD audit Less costly-more effective vs F2F PR UK COPD audit

More costly-More effective vs F2F PR UK COPD audit

Table 24. Scenario analysis

	Incremental effect (ΔWD, m)	Incremental effect (ΔWD, MCID units)	Incremental effect (%ΔWD)	Incremental costs, £	Cost per ΔWD, m	Cost per ΔWD, MCID units	Cost per %ΔWD	Change from base case value, %		
								Cost per ΔWD, m	Cost per ΔWD, MCID units	Cost per %ΔWD
Alternative effectiveness data source for SPACE for COPD										
SPACE for COPD (ISWD data source Bourne et al 2022)	-39.18	-0.825	-25%	Same as base case	£6	£265	£889	-59%	-113%	-113%
Alternative 6MWT MCID cut-off										
Clinitouch	Same as base case	[redacted]	Same as base case			[redacted]	Same as base case	-	-80%	-
myCOPD		-0.470				£476				
Rehab Guru		-0.467				£546				
myCOPD annual per participant total cost based on 5% uptake (first year cost)										
myCOPD	Same as base case			[redacted]	[redacted]	[redacted]	[redacted]	-40%		
myCOPD annual per participant total cost based on 'legacy' contract per participant fee										
myCOPD	Same as base case			[redacted]	[redacted]	[redacted]	[redacted]	16%		
Clinitouch per participant costs derived based on per clinician per year										
Clinitouch	Same as base case			[redacted]	[redacted]	[redacted]	[redacted]	-5%		

Abbreviations: WD, walking distance; MCID, Minimal clinically important difference; m, metres; 6MWT, 6-min walk test

12. INTERPRETATION OF THE ECONOMIC EVIDENCE

12.1. Reference case (cost-consequence analysis)

The cost-consequences balance sheet produced for walking distance outcome indicated that though Clinitouch, myCOPD, SPACE for COPD and Rehab Guru were slightly less effective compared to face-to-face pulmonary rehabilitation, they could offer potential cost savings due to reduced healthcare professional time. This finding is also in line with the NICE MTG68,[78] which suggested that the use of myCOPD may result in cost savings (though, subject to high uncertainty).

However, such a comparison was not possible for Active+me REMOTE, Kaia Health and Wellinks, as there were no walking distance outcome data available for these technologies. Though it could be noted that the annual per participant cost of Active+me REMOTE was comparable to other technologies and indicated potential cost savings compared to face-to-face pulmonary rehabilitation, when compared solely based on costs. For Kaia Health and Wellinks, however, the costs of the technologies were not available to derive any inference.

No direct comparison could be made of the included technologies to waitlist or no pulmonary rehabilitation. Cost per participant for waitlist or no pulmonary rehabilitation was found to be generally lower than that of the digital technologies, though it is worth noting that Dritsaki et al. 2016 showed that SPACE for COPD is likely to be more costly and more effective than no pulmonary rehabilitation (over a 6-month study period).

In terms of the costs of digital technologies, EAG would like to highlight that there was high heterogeneity about how the different components were costed. Although, EAG calculated the total costs of the technologies per participant considering as many components as possible such as the license fee, training costs and healthcare staff time, the underlying heterogeneity might still impact the cost savings indicated.

12.2. Complementary analysis (exploratory cost-effectiveness analysis)

The exploratory CEA was performed only for Clinitouch, myCOPD, Rehab Guru and SPACE for COPD. The deterministic base case showed that when trial control arm data were used for face-to-face pulmonary rehabilitation, myCOPD was cost saving and more effective than face-to-face pulmonary rehabilitation. Clinitouch, though, was found to be cost saving and less effective. However, when the UK COPD pulmonary rehabilitation audit data was used for face-to-face pulmonary rehabilitation, all four of the digital technologies considered were found to be cost saving and less effective than face-to-face pulmonary rehabilitation.

Subsequent deterministic threshold analysis also indicated that Clinitouch, myCOPD, Rehab Guru and SPACE for COPD were likely to be cost saving but less effective than face-to-face rehabilitation below the respective threshold values identified for 6MWD (60m) and ISWD (65m). Whereas, above the threshold values the technologies were likely to be cost saving as well as more effective. It is to be noted, however, that the threshold values provided are subject to change based on the observed change from baseline in face-to-face pulmonary rehabilitation arms. For instance, if the observed change from baseline in the face-to-face arm is lower than that of the digital arm, then the threshold values would decrease – otherwise, they would increase.

In terms of uptake rates, myCOPD results were found to be relatively more sensitive to the technology costs per annum as its pricing model has been linked to the uptake rates.

13. EVIDENCE GAP ANALYSIS AND FUTURE RESEARCH

13.1. Evidence gap analysis

Table 25 presents a summary of evidence gaps, focusing on outcomes. The table was populated based on prioritised evidence. Therefore, Active+me REMOTE does not feature as no priority evidence was identified. Narrative commentary on other evidence gaps is provided below the table.

Table 25: Evidence Gap Analysis (based on prioritised evidence only)

	Active +me	Clini-touch	Kaia Health	my COPD	Rehab Guru	SPACE for COPD	Wellinks
Key outcomes							
Exercise capacity measured by a validated outcome measure	Red	[redacted]	Amber	Green	Amber	Green	Red
Health-related quality of life	Red	[redacted]	Amber	Green	Red	Green	Red
Other measures of respiratory function	Red	[redacted]	Amber	Green	Amber	Green	Amber
Intervention completion	Red	[redacted]	Amber	Green	Amber	Amber	Amber
Intervention-related adverse events	Red	[redacted]	Amber	Green	Red	Amber	Red
Acute exacerbations, hospital admissions, readmissions or emergency admissions	Red	[redacted]	Amber	Green	Red	Red	Red
Modelling and economic outcomes							
Effectiveness evidence: Populations/subgroups	Effectiveness data for the digital PR technologies has not been split up by subgroups (for instance by level of breathlessness, rural/urban settings, or with/without comorbidities) and the evidence in this regard is weak currently across all PR technologies. Red						
Effectiveness evidence: Comparative data	Randomised evidence on the effectiveness of digital technologies supporting delivery of PR compared to no PR or waiting list is not consistently available for all the scoped technologies. Red						
Effectiveness evidence: Comparative data	There is currently no evidence on the comparative efficacy of digital PR technologies and there are no head-to head trials which limits the conduct of incremental analysis. Red						
Effectiveness evidence: Long-term effect of PR	Though some studies reported the outcomes beyond duration of PR programme (for instance, at 9 months), robust evidence of sustained efficacy of digital PR is currently unavailable. Red						

Costs/Resource use: Exacerbations	Data on exacerbation related events (ED visits, hospital admissions etc.) pre and post pulmonary rehabilitation were limited and not reported consistently. Amber
HRQoL: Health state utilities	Evidence on health state utilities is currently weak limiting the conduct of a cost-utility analysis. Amber
Costs: Lost productivity	Is there a case for including time off work within economic evaluations of digital PR technologies (outside NICE reference case)? The evidence base contains no data on lost productivity, currently. Red

Green = clear evidence of effectiveness from more than one study; Amber = some evidence but unclear or inconsistent; Red = no or negative evidence. It should be noted that the primary clinical claim for this appraisal is non-inferiority rather than superiority.

There are a number of evidence gaps in respect of the clinical evidence base as it pertains to the decision problem. Key gaps included:

Population gaps

- While most studies were conducted in the UK, studies were not UK-wide and generally focused more on urban areas.
- There were no subgroup analyses presented on rural communities, which may face particular challenges with regard to access to digital technologies.
- Participants in studies on digitally supported technologies are likely to have greater digital literacy, digital access and interest in digital technologies, and be less keen on receiving face-to-face pulmonary rehabilitation than the general clinical population.

Intervention gaps

- There was no published full-text evidence in a population relevant to the decision problem available for Active+me REMOTE, Clinitouch and Rehab Guru.

Comparator gaps

- No studies were conducted which explicitly compared to no pulmonary rehabilitation.
- There is no evidence comparing any of the included technologies against each other.

- Usual care as a comparator may differ between countries and also between NHS trusts. Due to resource limitations and long waiting lists, usual care in NHS settings may not always be face-to-face pulmonary rehabilitation as recommended by guidelines.
- Control arms for myCOPD did not perform at the level of gold-standard face-to-face pulmonary rehabilitation as per the National COPD audit.

Outcome gaps

- Relatively limited information was available for health-reality quality of life, adverse event and hospitalisation or exacerbation outcomes.
- Health-related quality of life was only assessed for some technologies. For other technologies, only disease specific quality of life, not utilities, were presented. Though mapping studies exist for SGRQ to EQ-5D in COPD[79], direct inclusion of EQ-5D in the technology trials would be preferable.
- Many studies did not use validated exercise capacity outcome measures with MCID, such as 6MWT.

13.2. Integration into the NHS

The broader implementation and integration of digitally supported therapies may pose challenges relating to a variety of technical, human, and operational factors. Clinical advice and EAG considerations revealed the following challenges: 1) acquisition of technology and relevant licences, 2) data security, 3) staff attitude to and awareness of digitally supported therapies, 4) staff training requirements including cost and time implications, 5) inertia and changing established treatment pathways, 6) waiting lists, 7) patient preferences, 8) patient digital literacy, 9) patient digital access, and 10) any requirements to provide additional support for those with additional needs or limited access to digital devices. It also needs to be taken into account that treatment protocols and equipment can differ significantly between hospitals and trusts.

13.3. Ongoing studies

Ongoing studies provided in company submissions and correspondence are listed below Table 26. The EAG considers these studies may partially address some of the clinical uncertainties.

Table 26: Ongoing studies from company submissions

Active+me REMOTE	Clinitouch	MyCOPD
A real-world evaluation of Active+me REMOTE at Harefield Hospital, sponsored by Anglia Ruskin University ARU/Chelmsford – data due March 2024[80]	Pulmonary Rehabilitation in Staffordshire – an open service evaluation collecting data on clinical outcomes (such as 6MWT). Data due December 2023, with further analysis of unscheduled admissions likely 2025[81]	PROPEL myCOPD – a RWE study on clinical and cost effectiveness of myCOPD as part of the respiratory discharge bundle, with a primary endpoint of hospital readmissions – data due 2025[82]
A first, full, research ethics committee approved and registered clinical trial of Active+me REMOVE at Harefield – data due December 2023[80]	An analysis of digital and face-to-face pulmonary rehabilitation in participants with respiratory diseases (not just COPD) – same endpoints as above with with an expanded patient base Interim endpoints late 2023[81]	

The EAG additionally identified an RCT for Kaia Health in people self-managing COPD at home (uncertain due date)[83], and two observational studies on Wellinks, one looking at clinical outcomes and quality of life in people with COPD[84], the other looking at hospital readmissions[85] – both studies were predicted to have completed in December 2022.

13.4. Key areas for evidence generation

Given the gaps and issues raised in this section, the EAG presents some specific evidence generation recommendations in Table 27.

Table 27: Evidence generation recommendations

Research question	Possible study design	Outcomes
1. Which technology or technologies are most suitable for NHS use?	Comparative cohort studies of two or more included technologies in a prospective	Exercise capacity, respiratory function, hospitalisation and

	RWE setting; qualitative focus group or interview study	exacerbations, health-related quality of life; patient and clinician perspectives
2. What is the real-world safety profile of scoped interventions?	Observational safety monitoring study in RWE setting	Adverse event frequency, severity and event type profile
3. How long will the effect of PR delivered through digital technologies be sustained?	Longer term follow-up of studies including RCTs	Disease severity, exercise capacity, disease specific and generic HRQoL tools
4. What are the factors which impact participant preferences and the uptake of digital PR technologies?	Preference elicitation from participants (using methods such as discrete choice experiments)	Preferred attributes from the study

Abbreviations: NHS = National Health Service; PR = pulmonary rehabilitation; RWE = real world evidence

13.5. Potential considerations for future economic models

Once the current evidence gaps on digital technologies supporting the delivery of PR highlighted in Section 13.1 have been addressed, a mature model concept could enable a robust full economic evaluation of the digital technologies. Here, the EAG sets out a few considerations in this regard:

- **Model approach/structure**: In terms of a potentially suitable model approach and structure, EAG considers that a cost utility analysis using a long-term Markov cohort model stratified based on subgroups, or a Markov microsimulation model simulating individual patients based on their baseline characteristics and disease severity (preferably defined based on GOLD stages[86]), could adequately capture the long-term effects of PR on adults with COPD. This is because COPD is heterogeneous in nature, and people with the condition are often impacted by a range of related comorbidities, even though pulmonary rehabilitation is a short-term intervention (typically, lasting 6-8 weeks with 2 sessions of 2 hours each week[6]), whether delivered face-to face or supported digitally. Also, a similar approach has been described in Atsou et al. 2016[87] (using the model detailed in Atsou et al. 2011[88]) for a French cohort of COPD patients with and without pulmonary rehabilitation, assessed over their remaining lifespan from a societal perspective. Likewise, Mosher et al. 2022[89] performed an economic evaluation from a societal perspective, comparing

COPD patients undergoing pulmonary rehabilitation to no pulmonary rehabilitation after COPD hospitalisation. This was within the US health care system for a lifetime horizon (though no effect of pulmonary rehabilitation was assumed beyond first year).

- **Consideration of impact of pulmonary rehabilitation on disease severity and mortality**: In order to consider how pulmonary rehabilitation might affect long-term outcomes for people with COPD, especially in terms of their disease severity and mortality (ideally linked to exacerbations), it might be necessary to incorporate lifetime costs. For instance, Mosher et al. 2022[89] considered readmission and death probabilities, conditioned on receiving pulmonary rehabilitation in the first year, and estimated follow-up of COPD population mortality in the subsequent years (based on age, sex, and COPD GOLD disease stages).

- **Time horizon:** In order to capture the long-term effects of pulmonary rehabilitation on disease outcomes, it might again be beneficial to consider a lifetime horizon, although assumptions related to long terms effects of pulmonary rehabilitation may need to be made (informed by expert opinion if otherwise unavailable).

- **Perspective:** A healthcare payer perspective might be able to capture the direct costs of the digital technologies to the health care system. However, a societal perspective would enable consideration of non-health benefits and costs (such as the productivity gains in relatively younger cohorts).

- **Uptake rates for digital technologies:** As the pricing for some of the digital technologies seem to be linked to its uptake rate, it might be beneficial to use real-world utilisation data for the respective technologies where available to reflect the technology costs as accurately as possible.

14. CONCLUSIONS

The two technologies for which the most clinical evidence was available were myCOPD and SPACE for COPD. Trial evidence supports the concept of non-inferiority between digitally supported and face-to-face pulmonary rehabilitation in terms of exercise capacity and respiratory function for these technologies. Therefore, they appear to offer promise as digitally supported pulmonary rehabilitation technologies for COPD. Evidence was more limited for Active+me REMOTE, Clinitouch, Kaia Health, Rehab Guru and Wellinks, and there was insufficient evidence to assess whether they are likely to offer promise. However, across all technologies, it is important to consider whether these findings are generalisable. Trial evidence was focused mainly on urban areas which may have greater access to digital technologies. No subgroup data for rural areas were available.

Clinical expert advice was that there is likely substantial selection bias in favour of participants with greater digital literacy, greater digital access and those who did not favour face-to-face pulmonary rehabilitation. There was also concern about the sub-par performance of control arms. Control groups for myCOPD did not reach gold standard reference values for key outcomes, while in Bourne et al. (2017),[15,21] the control group was designed to provide a non-digital equivalent of the digitally supported intervention rather than gold standard face-to-face pulmonary rehabilitation. In other trials, usual care was the comparator, and some participants are likely to have received waitlist control or GP management rather than the recommended face-to-face pulmonary rehabilitation, due to long waiting lists and resource challenges. Only two trials explicitly used face-to-face pulmonary rehabilitation as the comparator.

Therefore, it is possible that intervention groups over-performed and the control arms under-performed, biasing the observed results in favour of digitally supported therapy. The EAG thought this to be an important consideration.

This weakness in the clinical evidence base impacted the interpretation of the EAG economic analysis. For example, based on the reference case CCA performed using trial data, myCOPD performed better than face-to-face. However, this should be interpreted with caution because the face-to-face control arm is likely to be sub-

optimal. Other digital technologies were found to be either at par or less effective compared to face-to-face pulmonary rehabilitation in terms of consequences, especially when exercise capacity is expressed in terms of walking distance. Given such limitations with the trial control arms, the EAG produced a CCA balance sheet considering the UK COPD PR audit data for face-to-face pulmonary rehabilitation. This exercise indicated lower effectiveness for Clinitouch, myCOPD, SPACE for COPD and Rehab Guru, in terms of walking distance, than that observed in the UK COPD PR audit.

When considering the per participant licence fee, staff time costs and training costs, the included technologies have the potential to be cost saving, compared to face-to-face pulmonary rehabilitation. However, the technology costs were likely to be slightly higher compared to waitlist or no PR, though this should be carefully considered alongside the underlying assumptions in terms of waiting time, associated exacerbation costs etc.

The complementary CEA similarly indicated that the digital technologies are likely to be cost saving but less effective compared to face-to-face pulmonary rehabilitation, derived from the UK COPD PR audit, in terms of cost per change in walking distance. Deterministic threshold analysis performed also confirmed this finding, indicating a threshold value of approximately 60m for 6MWD and 65m for ISWD, below which the technologies are likely to be cost saving but less effective. Above this threshold all technologies considered in the CEA were cost saving as well as more effective. It is worth noting, however, that the threshold values provided are subject to change based on the observed change from baseline in the face-to-face arm. In addition, sensitivity analysis also indicated that myCOPD was found to be relatively more sensitive to its uptake rate as its pricing model was directly linked to uptake rates achieved. However, these findings should only be treated as indicative.

In conclusion, there remains a strong need for addressing the existing evidence gaps for digital technologies supporting the delivery of pulmonary rehabilitation in COPD to enable the conduct of a fully definitive economic evaluation.

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16. APPENDICES

Appendix A: Searches for clinical and cost effectiveness evidence

Table 28: Resources searched for clinical and cost effectiveness studies

Database Name*	Host	Date searched	Results
Medline ALL	Ovid	01/08/23	146
Embase	Ovid	01/08/23	338
Cochrane Database of Systematic Reviews	Cochrane Library: Wiley	01/08/23	9
Cochrane CENTRAL	Cochrane Library: Wiley	01/08/23	157
INHATA	https://database.inahta.org/	01/08/23	11
company websites	Various	01/08/23	11
NICE	https://www.nice.org.uk/guidance	04/08/23	7
SIGN	https://www.sign.ac.uk/our-guidelines/	04/08/23	0
MHRA	https://www.gov.uk/drug-device-alerts	04/08/23	0
MAUDE	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm	04/08/23	0
Clinical Trials.gov	http://www.clinicaltrials.gov/	03/08/23	9
ICTRP	https://trialsearch.who.int/	03/08/23	17
ScharrHUD	https://www.scharrhud.org/	03/08/23	0
CEA Registry	https://cear.tuftsmedicalcenter.org/	03/08/23	9
Records imported			**712**
Final no of records (after dedupe)			**528**

Ovid MEDLINE(R) ALL

#	Searches	Results
1	exp Pulmonary Disease, Chronic Obstructive/	67012

2	(chronic adj4 obstruct* adj4 (lung* or pulmonar*) adj4 (disease* or disorder*)).ti,kw,ab.	64447
3	1 or 2	96774
4	Rehabilitation/	18690
5	exp Exercise Therapy/	63477
6	Physical Therapy Modalities/	40854
7	Exercise Movement Techniques/	872
8	(pulmonar* adj4 rehab*).ti,ab.	5115
9	or/4-8	123134
10	Digital Technology/	719
11	Mobile Applications/	11550
12	exp Internet/	97734
13	exp Cell Phone/	22449
14	exp Computers, Handheld/	13081
15	Medical Informatics Applications/	2551
16	Therapy, Computer-Assisted/	6973
17	(app or apps).ti,ab.	43223
18	(online or web or internet or digital*).ti.	138461
19	((online or web or internet or digital*) adj3 (based or application* or intervention* or program* or therap* or enabl*)).ab.	81394
20	(phone* or telephone* or smartphone* or cellphone* or smartwatch*).ti.	27106
21	((phone* or telephone* or smartphone* or cellphone* or smartwatch*) adj3 (based or application* or intervention* or program* or therap*)).ab.	16923
22	(mobile health or mhealth or m-health or ehealth or e-health or emental or e-mental).ti.	8503
23	((mobile health or mhealth or m-health or ehealth or e-health or emental or e-mental) adj3 (based or application* or intervention* or program* or therap*)).ab.	5889
24	(mobile* adj3 (based or application* or intervention* or device* or technolog*)).ti,ab.	21800
25	or/10-24	344806
26	3 and 9 and 25	123
27	("Active+me" or "Active + Me").af.	4
28	clinitouch.af.	0
29	("Kaia COPD" or "Kaia Health COPD").af.	3
30	"myCOPD".af.	6

31	"Rehab Guru".af.	1
32	"Space for COPD".af.	17
33	"Wellinks".af.	1
34	or/26-33	146

Embase

#	Searches	Results
1	exp chronic obstructive lung disease/	173358
2	(chronic adj4 obstruct* adj4 (lung* or pulmonar*) adj4 (disease* or disorder*)).ti,kw,ab.	93842
3	1 or 2	184452
4	pulmonary rehabilitation/	9291
5	exp kinesiotherapy/	99228
6	physiotherapy/	104987
7	(pulmonar* adj4 rehab*).ti,ab.	9221
8	or/4-7	203902
9	Digital Technology/	4079
10	exp mobile application/	25229
11	exp Internet/	129040
12	exp mobile phone/	47084
13	computer assisted therapy/	4858
14	personal digital assistant/	1826
15	text messaging/	7617
16	(app or apps).ti,ab.	58589
17	(online or web or internet or digital*).ti.	158232
18	((online or web or internet or digital*) adj3 (based or application* or intervention* or program* or therap* or enabl*)).ab.	108839
19	(phone* or telephone* or smartphone* or cellphone* or smartwatch*).ti.	32084
20	((phone* or telephone* or smartphone* or cellphone* or smartwatch*) adj3 (based or application* or intervention* or program* or therap*)).ab.	22539
21	(mobile health or mhealth or m-health or ehealth or e-health or emental or e-mental).ti.	9326

22	((mobile health or mhealth or m-health or ehealth or e-health or emental or e-mental) adj3 (based or application* or intervention* or program* or therap*)).ab.	6411
23	(mobile* adj3 (based or application* or intervention* or device* or technolog*)).ti,ab.	26751
24	or/9-23	443859
25	3 and 8 and 24	274
26	("Active+me" or "Active + Me").af.	7
27	clinitouch.af.	0
28	("Kaia COPD" or "Kaia Health COPD").af.	5
29	"myCOPD".af.	20
30	"Rehab Guru".af.	1
31	"Space for COPD".af.	39
32	"Wellinks".af.	10
33	or/25-32	338

Cochrane Library

#1 [mh "Pulmonary Disease, Chronic Obstructive"] 7267
#2 (chronic near/4 obstruct* near/4 (lung* or pulmonar*) near/4 (disease* or disorder*)):ti,ab 13903
#3 #1 or #2 16259
#4 [mh ^Rehabilitation] 1344
#5 [mh "Exercise Therapy"] 19663
#6 [mh ^"Physical Therapy Modalities"] 4759
#7 [mh ^"Exercise Movement Techniques"] 326
#8 (pulmonar* near/4 rehab*):ti,ab 2646
#9 #4 or #5 or #6 or #7 or #8 27298
#10 [mh ^"Digital Technology"] 30
#11 [mh ^"Mobile Applications"] 1580
#12 [mh Internet] 6200
#13 [mh "Cell Phone"] 3146
#14 [mh "Computers, Handheld"] 1375
#15 [mh ^"Medical Informatics Applications"] 38
#16 [mh ^"Therapy, Computer-Assisted"] 1478
#17 (app or apps):ti,ab 9550
#18 (online or web or internet or digital*):ti 16962
#19 ((online or web or internet or digital*) near/3 (based or application* or intervention* or program* or therap* or enabl*)):ab 19822

#20 (phone* or telephone* or smartphone* or cellphone* or smartwatch*):ti 6915
#21 ((phone* or telephone* or smartphone* or cellphone* or smartwatch*) near/3 (based or application* or intervention* or program* or therap*)):ab 9105
#22 (mobile health or mhealth or m-health or ehealth or e-health or emental or e-mental):ti 2769
#23 ((mobile health or mhealth or m-health or ehealth or e-health or emental or e-mental) near/3 (based or application* or intervention* or program* or therap*)):ab 29087
#24 (mobile* near/3 (based or application* or intervention* or device* or technolog*)):ti,ab 6461
#25 #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 71825
#26 #3 AND #9 AND #25 144
#27 ("Active+me" or "active + me"):ti,ab,kw 280
#28 clinitouch:ti,ab,kw 0
#29 ("Kaia COPD" or "Kaia Health COPD"):ti,ab,kw 7
#30 "myCOPD":ti,ab,kw 5
#31 "Rehab Guru":ti,ab,kw 1
#32 "Space for COPD":ti,ab,kw 29
#33 "Wellinks":ti,ab,kw 1
#34 #27 or #28 or #29 or #30 or #31 or #32 or #33 323
#35 #34 and #3 28
#36 #26 or #35 166

= 9 reviews and 157 trials

INAHTA

("Wellinks") OR ("Space for COPD") OR ("Rehab Guru") OR ("myCOPD") OR ("Kaia COPD" or "Kaia Health COPD") OR (clinitouch) OR ("Active+me" or "Active + Me") OR (((((mobile* AND (based or application* or intervention* or device* or technolog*)):)[Title] OR ((mobile* AND (based or application* or intervention* or device* or technolog*)):)[abs]) OR ((((mobile health or mhealth or m-health or ehealth or e-health or emental or e-mental) AND (based or application* or intervention* or program* or therap*)))[abs]) OR (((mobile health or mhealth or m-health or ehealth or e-health or emental or e-mental))[title]) OR ((((phone* or telephone* or smartphone* or cellphone* or smartwatch*) AND (based or application* or intervention* or program* or therap*)):ab)[abs]) OR (((phone* or telephone* or smartphone* or cellphone* or smartwatch*))[title]) OR ((((online or web or internet or digital*) AND (based or application* or intervention* or program* or therap* or enabl*)))[abs]) OR (((online or web or internet or digital*))[title]) OR (((app or apps))[Title] OR ((app or apps))[abs]) OR ("Therapy, Computer-Assisted"[mh]) OR ("Medical Informatics Applications"[mh]) OR ("Computers, Handheld"[mhe]) OR ("Cell Phone"[mhe]) OR ("Internet"[mhe]) OR ("Mobile Applications"[mh]) OR ("Digital Technology"[mh]))

AND ((((pulmonar* AND rehab*))[Title] OR ((pulmonar* AND rehab*))[abs]) OR ("Exercise Movement Techniques"[mh]) OR ("Physical Therapy Modalities"[mh]) OR ("Exercise Therapy"[mhe]) OR ("Rehabilitation"[mh])) AND ((((chronic AND obstruct* AND (lung* or pulmonar*) AND (disease* or disorder*)))[Title] OR ((chronic AND obstruct* AND (lung* or pulmonar*) AND (disease* or disorder*)))[abs]) OR ("Pulmonary Disease, Chronic Obstructive"[mhe])))

= 11 hits

ClinicalTrials.gov

Search string	Results
“Active+me”/all studies	0
Aseptika/all studies	1
“Clinitouch Vie”/all studies	0
“Spirit Health” AND “Chronic Obstructive Pulmonary Disease” (condition) /all studies	0
“Kaia Health” AND “Chronic Obstructive Pulmonary Disease” (condition) /all studies	2
myCOPD/all studies	4
myHealth AND “Chronic Obstructive Pulmonary Disease” (condition) /all studies	0
“Rehab Guru” /all studies	0
“Space for COPD” /all studies	0
Wellinks AND “Chronic Obstructive Pulmonary Disease” (condition) /all studies	2
Total	9

ICTRP (basic search)

Search string	Results
“Active+me”/all studies	0
Aseptika/all studies	0
“Clinitouch Vie”/all studies	0
“Spirit Health” AND “Chronic Obstructive Pulmonary Disease” (condition) /all studies	0
“Kaia Health” AND “Chronic Obstructive Pulmonary Disease” (condition) /all studies	3
myCOPD/all studies	3
myHealth AND “Chronic Obstructive Pulmonary Disease” (condition) /all studies	0
“Rehab Guru” /all studies	1
“Space for COPD” /all studies	9
Wellinks AND “Chronic Obstructive Pulmonary Disease” (condition) /all studies	1
Total	17

CEA Registry

Search string	Results	Searcher
COPD and rehabilitation	9	AL
pulmonary and chronic and rehabilitation	9	AL

ScharrHUD

Digital technologies to deliver pulmonary rehabilitation programmes for adults with COPD [GID-HTE10019]

Search string	Results	Searcher
COPD and rehabilitation	0	AL
pulmonary and chronic and rehabilitation	0	AL

NICE

chronic obstructive pulmonary disease

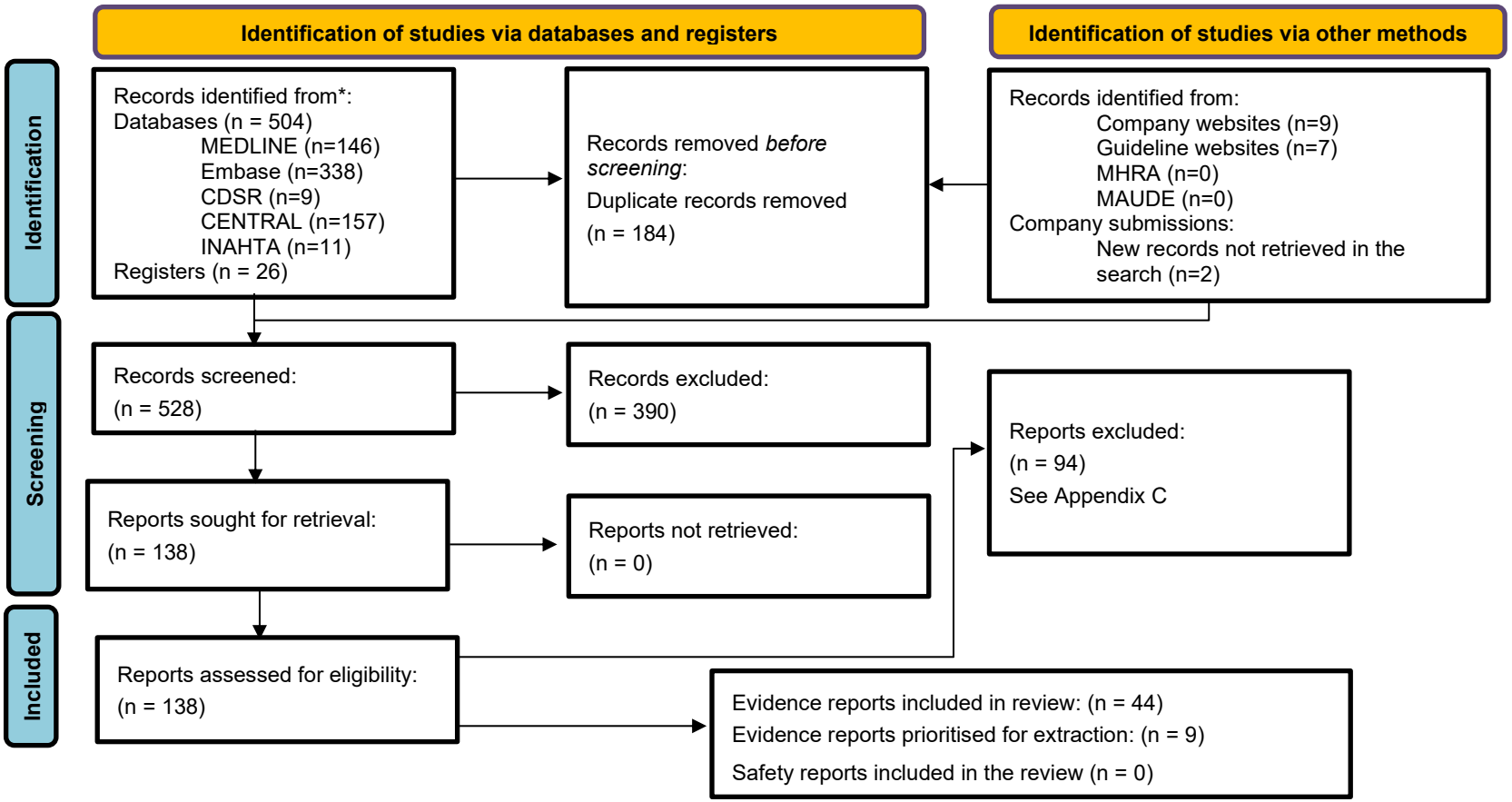
= 162, 7 added to Endnote

SIGN

chronic obstructive pulmonary disease

= **0**

Appendix B: PRISMA flow diagram



From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al.. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71. For more information, visit: http://www.prisma-statement.org/

Appendix C: List of excluded studies

This refers to the exclusion of studies from the full-text screen to reach the list of 44 relevant studies rather than the selection of priority studies. Accordingly, there were 95 excluded publications.

Author	Reason for exclusion
Alqahtani 2021[90]	Study design
Alqahtani 2022[91]	Publication type
Alwashmi[92]	Intervention
Bahadori[93]	Intervention
Barata[94]	Intervention
Barbosa[95]	Publication type
Barnes[96]	Intervention
Bentley[97]	Intervention
Bhatt 2019[98]	Duplicate
Bhatt 2019[98]	Intervention
Bhatt 2022[99]	Intervention
Biset[100]	Intervention
Candy[101]	Intervention
Cerdan-de-las-Heras[102]	Intervention
Chen[103]	Intervention
Chung[104]	Study design
ClinicalTrials.gov [105]	Publication type
ClinicalTrials.gov [106]	Publication type
ClinicalTrials.gov [107]	Publication type
ClinicalTrials.gov [84]	Publication type
ClinicalTrials.gov [108]	Publication type
ClinicalTrials.gov [85]	Publication type
ClinicalTrials.gov [109]	Duplicate
ClinicalTrials.gov [109]	Publication type
ClinicalTrials.gov[110]	Publication type
Cox 2021[111]	Publication type
Cox 2023[112]	Intervention
Davies[59]	Publication type
Demeyer[113]	Intervention

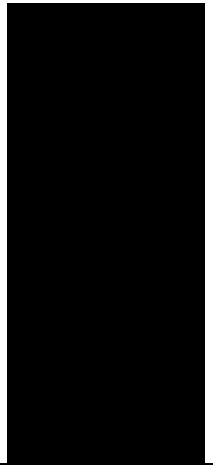
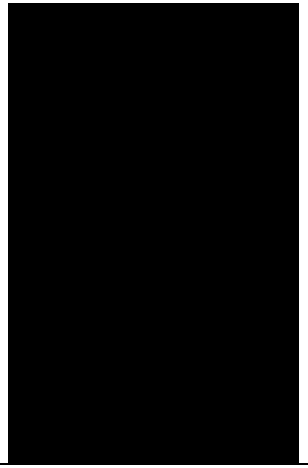
Donner[114]	Publication type
Dos Santos[115]	Intervention
Fekete[116]	Study design
Finkelstein[117]	Intervention
Flynn[118]	Intervention
Frith[17]	Population
Gabriel[119]	Intervention
Galdiz[120]	Intervention
German Clinical Trials Register[83]	Publication type
Ghosh 2016[121]	Study design
Ghosh 2018[122]	Population
Glyde[123]	Outcome
Gotfredson[124]	Intervention
Hoaas[125]	Intervention
Huang[126]	Intervention
Irina[127]	Intervention
ISRCTN[128]	Publication type
ISRCTN[129]	Publication type
ISRCTN[130]	Publication type
ISRCTN[131]	Publication type
ISRCTN[132]	Duplicate
ISRCTN[132]	Publication type
ISRCTN[133]	Publication type
ISRCTN[134]	Duplicate
ISRCTN[134]	Publication type
ISRCTN[135]	Duplicate
ISRCTN[135]	Publication type
ISRCTN[136]	Duplicate
ISRCTN[136]	Publication type
Janjua[137]	Study design
Kiani[138]	Study design
Leal[139]	Intervention
Legaspi[140]	Intervention
Lippi[141]	Study design
Lopez-Lopez[142]	Intervention

Lundell[143]	Study design
Michaelchuk[144]	Study design
Mongiardo[145]	Intervention
Morton-Holtham[146]	Outcome
Nguyen[147]	Intervention
NICE[78]	Duplicate
NICE[78]	Publication type
Park[148]	Intervention
Patil[149]	Intervention
Polgar[150]	Intervention
Raleigh[151]	Population
Robinson 2019[152]	Intervention
Robinson 2020[153]	Intervention
Robinson 2021[154]	Intervention
Saini[155]	Intervention
Santos[156]	Intervention
Slevin[157]	Intervention
Sonnerfors[158]	Intervention
Spielmanns 2021[159]	Publication type
Spielmanns[160]	Duplicate
Spielmanns[160]	Publication type
Threadgold[161]	Intervention
Tsai[162]	Intervention
Vilarinho[163]	Intervention
Vorrink[164]	Intervention
Whittaker[165]	Intervention
Wilcock[166]	Intervention
Williams[167]	Intervention
Winship[168]	Intervention
Wootton[169]	Intervention
Zhang[170]	Study design

Appendix D: Additional study results

Table 29 presents results for clinical effectiveness outcomes. Further details compared to the results presented in the main clinical section are provided where relevant. However, there has been a focus on making the results understandable rather than presenting all minutiae.

Table 29: Study results for clinical effectiveness

Reference	Exercise capacity measured by a validated outcome measure	Health-related quality of life	Other measures of respiratory function	Intervention completion	Intervention-related adverse events	Acute exacerbations, hospital admissions, readmissions or emergency admissions
Active+me REMOTE (number of prioritised studies = 0)						
Clinitouch (number of prioritised studies = 1)						
Staffordshire Report[21] [AIC]						

Reference	Exercise capacity measured by a validated outcome measure	Health-related quality of life	Other measures of respiratory function	Intervention completion	Intervention-related adverse events	Acute exacerbations, hospital admissions, readmissions or emergency admissions
	[redacted]	[redacted]	[redacted]			
Kaia Health (number of prioritised studies = 1)						
Spielmanns et al. 2023[8]	**(60-second Sit-to-Stand Test)**	**(CRQ - Total)** No significant difference	**(CAT)** No significant difference between groups at	67 participants randomised (33 to the intervention group and	No significant difference between groups regarding the number of	No significant difference between groups regarding the number of

Reference	Exercise capacity measured by a validated outcome measure	Health-related quality of life	Other measures of respiratory function	Intervention completion	Intervention-related adverse events	Acute exacerbations, hospital admissions, readmissions or emergency admissions
	No significant difference between groups at baseline (Intervention group (mean±sd), 19.07±5.77; Control group 16.87±7.07 repetitions; p=0.196). Effect size (95% CI) 0.341 (0.175, 0.853). Significant difference between groups at 3 months (Intervention group (mean±sd), 22.87±8.00;	between groups at baseline (Intervention group (mean±sd), 4.95±1.07; Control group 4.82±0.97 points; p=0.618. Effect size (95% CI) 0.129 (-0.378, 0.636). No significant difference between groups at 3 months (Intervention group (mean±sd), 4.72±1.31; Control group 4.19±1.18 points; p=0.102). Effect size (95% CI)	baseline (Intervention group (mean±sd), 16.53±7.15; Control group 16.00±7.12 points; p=0.773). Effect size (95% CI) 0.075 (-0.432, 0.581). No significant difference between groups at 3 months (Intervention group (mean±sd), 15.53±8.26; Control group 18.70±6.71 points; p=0.109). Effect size (95% CI) -0.421 (-0.931, 0.093). Significant difference between groups at 6 months (Intervention group (mean±sd), 15.13±8.58; Control group 19.72±6.42 points; p=0.024). Effect	34 to the control group). 60 participants included in the analysis (30 in intervention group, 30 in control group). Usage of Kaia app in intervention group [n (%)]: - Total use - activated the app and at least one activity; 29 (97) - training on the app on at least 30 days; 26 (87) - training on the app on at least 60 days; 24 (80) - training on the app on at least 90 days; 20 (67)	adverse events (data not reported).	exacerbations (data not reported). Exacerbation data at baseline: - Exacerbation in the last 12 months [n (%)]: overall, 53 (79.1); intervention group, 29 (87.9); control group, 24 (70.6) - Number of exacerbations treated as outpatient in the past 12 months [mean (SD)]: overall, 1.19 (1.14); intervention group,1.19 (1.33), control group, 1.19 (0.87) - Number of exacerbations treated as inpatient

Reference	Exercise capacity measured by a validated outcome measure	Health-related quality of life	Other measures of respiratory function	Intervention completion	Intervention-related adverse events	Acute exacerbations, hospital admissions, readmissions or emergency admissions
	Control group 16.83±7.64 repetitions; p=0.004). Effect size (95% CI) 0.771 (0.243, 1.293). No significant difference between groups at 6 months (Intervention group (mean±sd), 22.66±7.23; Control group 19.45±9.09 repetitions; p=0.143). Effect size (95% CI) 0.390 (0.131, 0.908).	0.429 (0.085, 0.940). No significant difference between groups at 6 months (Intervention group (mean±sd), 4.76±1.30; Control group 4.11±1.26 points; p=0.056). Effect size (95% CI) 0.508 (-0.013, 1.024). **Significant differences between groups at 6 months for dyspnoea points (Intervention group (mean±sd),	size (95% CI) -0.605 (-1.124, 0.080).	- training on the app on at least 120 days; 13 (43) - Sustained use: - an activity in the app in at least 50% of trial weeks; 79% - an activity in the app in at least 75% of trial weeks; 61% - number of active days in the final week of the study; (SD) 3.51 (2.71)		in the past 12 months [mean (SD)]: overall, 1.08 (1.23); intervention group, 1.21 (1.50); control group, 0.91 (0.79). No report on hospital admissions, readmissions, or emergency admissions.

Reference	Exercise capacity measured by a validated outcome measure	Health-related quality of life	Other measures of respiratory function	Intervention completion	Intervention-related adverse events	Acute exacerbations, hospital admissions, readmissions or emergency admissions
		4.54±1.65; Control group 3.69±1.31 points; p=0.033). Effect size (95% CI) 0.570 (0.047, 1.089) and fatigue points (Intervention group (mean±sd), 4.50±1.28; Control group 3.72±1.36 points; p=0.028). Effect size (95% CI) 0.508 (0.586, 1.105).				
myCOPD (number of prioritised studies = 3)						
Bourne et al. 2017[15]	**(6MWT)** No significant difference	**(SGRQ)** No significant difference between groups.	**(CAT)** No significant difference between groups.	90 participants randomised (64 to the Online PR group and 26 to the Face-to-Face PR group).	Online PR: back pain (n=1); muscular skeletal chest pain (n=0); inguinal pain (n=1);	Three participants from the Online PR group withdrew due to exacerbations.

Reference	Exercise capacity measured by a validated outcome measure	Health-related quality of life	Other measures of respiratory function	Intervention completion	Intervention-related adverse events	Acute exacerbations, hospital admissions, readmissions or emergency admissions
	between groups. (Baseline: Face-to-Face group (mean±sd), 416.5±118.3; Online group, 388.7±104.4 metres; 7 weeks: Face-to-Face group, 445.1±124.9; Online group, 433.6±102.9). Regression analysis [intention to treat population], adjusted difference (95% CI) 23.8 (-4.5, 52.2); p=0.098.	Baseline: Face-to-Face group (mean±sd), 37.7±17.2; Online group, 42.4±18.6 points; 7 weeks: Face-to-Face group, 39.3±18.5; Online group, 39.3±18.5. Regression analysis [intention to treat population], adjusted difference (95% CI) −3.72 (−10.7, 3.3); p=0.291. Regression analysis [per participant	(Baseline: Face-to-Face group (mean±sd), 17.3±6.7; Online group, 18.1±7.9 points; 7 weeks: Face-to-Face group, 16.2±6.7; Online group, 14.9±7.0). Regression analysis [intention to treat population], adjusted difference (95% CI) −1.0 (−2.9, 0.86); p=0.373 Regression analysis [per participant population], adjusted difference (95% CI) −0.64 (−2.5, 1.2); p=0.569 **(mMRC dyspnoea)** No significant difference between groups.	Online PR: lost to follow-up (n=4); exacerbation (n=3). Face-to-Face PR: lost to follow-up (n=2); exacerbation (n=0); withdrawn (n=3). Online PR attendance: mean 3.9 sessions per participant in week 1; mean 2.5 sessions per participant in week 6. Face-to-Face PR: mean 1.6 sessions per participant in week 1; mean 1.4 sessions per participant in week 6.	common cold (n=1). Face-to-Face PR: back pain (n=1); muscular skeletal chest pain (n=1); inguinal pain (n=0); common cold (n=0).	Data not reported.

Reference	Exercise capacity measured by a validated outcome measure	Health-related quality of life	Other measures of respiratory function	Intervention completion	Intervention-related adverse events	Acute exacerbations, hospital admissions, readmissions or emergency admissions
	Regression analysis [per participant population], adjusted difference (95% CI) 15.0 (-13.7, 43.8); p=0.300.	population], adjusted difference (95% CI) −2.5 (−9.3, 4.4); p=0.474.	(Baseline: Face-to-Face group (mean±sd), 2.0 (1.0–2.0); Online group, 2.0 (1.0–3.0); 7 weeks: Face-to-Face group: 1.5 (1.0, 2.0); Online group, 1.0 (1.0, 2.0). Regression analysis [intention to treat population], adjusted difference (95% CI) 0.03 (−0.56, 0.63); p=0.909. Regression analysis [per participant population], adjusted difference (95% CI) 0.04 (−0.54, 0.63); p=0.885.			
Crooks et al. 2020[c13]	**(Steps per day)** Number of steps per day at baseline: myCOPD	**(EQ-5D)** Adjusted mean group difference at 90 days (myCOPD to usual care) -	**(CAT)** Adjusted mean group difference at 90 days (myCOPD to usual care)	60 participants were randomised (n=29 myCOPD; n=31 usual care). Of 29 participants randomised to the	15 adverse events reported by 12 (20%) participants (5 from myCOPD group and 7 from usual care) over the	15 exacerbations were recorded in the 3 months prior to study baseline (12 myCOPD and 3 usual care).

Reference	Exercise capacity measured by a validated outcome measure	Health-related quality of life	Other measures of respiratory function	Intervention completion	Intervention-related adverse events	Acute exacerbations, hospital admissions, readmissions or emergency admissions
	group (n=5) (mean±sd), 4948.7±1667.6 steps; usual care group (n=9), 9060±5135.1. Follow-up: myCOPD group (n=4), 5458.3±2266.4 ; usual care group (n=9), 10762±7199.2. Adjusted mean daily step count in the myCOPD group was 2252 steps lower (−10 433.8, 5927.9).	0.04 (95% CI -0.12, 0.05). **(EQ VAS)** Adjusted mean group difference (myCOPD to usual care) 0.86 (-9.46, 11.18).	-1.27 (95% CI -4.47, 1.92); p=0.44 [n=58]. Mean CAT score reduced from 21.5±8.0 at baseline to 19.2±9.0 at 90 days in the myCOPD arm (unadjusted change at 90 days −1.8±5.8, [n=24]). Mean CAT score changed from 19.8±5.4 at baseline to 19.8±7.5 at 90 days in the usual care arm (unadjusted change at 90 days 0.03± 5.5, [n=30]).	myCOPD group, 26 (89.7%) were registered but of those 26, 5 (17.2%) did not activate the app. Of 21 activated users, 18 (86%) were still using the app during the last month of the trial. The app was used (mean±sd) on 44±31.6 days. A total of 87.8±118.7 app activities were recorded. 42.5 were for recording clinical scores and 45.3 for accessing educational videos.	duration of the study. Two participants from usual care reported multiple adverse events. No serious adverse events were reported.	29 exacerbations were recorded during the study (18 myCOPD group and 11 usual care). 3 (10.3%) exacerbation events required emergency department attendance (2 myCOPD and 1 usual care) and 3 (10.3%) required hospitalisation (1 myCOPD and 2 usual care).

Reference	Exercise capacity measured by a validated outcome measure	Health-related quality of life	Other measures of respiratory function	Intervention completion	Intervention-related adverse events	Acute exacerbations, hospital admissions, readmissions or emergency admissions
North et al. 2020[c14]	**(VSAQ)** Baseline (mean±sd): treatment as usual, 1.7±0.8 METS; myCOPD, 2.2±2.6. 90 days: treatment as usual, 2.95±2.43; myCOPD, 2.94±1.54 3-month adjusted between arm difference (95% CI): −0.163 (−1.40, 1.07).	**(SGRQ)** Baseline (mean±sd): treatment as usual, 68.1±13.7 points; myCOPD, 66.4±16.6. 90 days: treatment as usual, 64.1±15.94; myCOPD, 61.9±14.93 3-month adjusted between arm difference (95% CI): −1.48 (−7.82, 4.86).	**(CAT)** Baseline (mean±sd): treatment as usual, 28.0±13.7 points; myCOPD, 26.0±8.5. 90 days: treatment as usual, 25.1±7.24; myCOPD, 20.7±7.35 3-month adjusted between arm difference (95% CI): −2.94 (−6.92, 1.04). **(mMRC dyspnoea scale)** Baseline (mean±sd): treatment as usual, 3.1±1.1 points; myCOPD, 2.9±1.3.	Of the 20 participants randomised to the myCOPD group, 17 (85%) activated the app – all in the first week. Proportion of useds was highest in the first week and lowest in the last week – 8 users (40%). Weekly usage was 4.9 days, which did not significantly change over the course of the study. Highest weekly usage was in week 8; 10 (50%) of users accessed the app 6 out of 7 days.	Treatment as usual (SAEs): respiratory infection other than AECOPD (n=1). myCOPD (AEs): constipation (n=1) myCOPD (SAEs): constipation (n=1), medication side effect (n=1).	**(Number of recorded exacerbations)** Baseline (mean±sd): treatment as usual, 3.2±2.0; myCOPD, 2.9±1.6. 90 days: treatment as usual, 1.88±1.84; myCOPD, 1.06±0.83. 3-month adjusted between arm difference (95% CI): 0.581 (0.315, 1.07). Treatment as usual readmissions (n=7; 33%). myCOPD

Reference	Exercise capacity measured by a validated outcome measure	Health-related quality of life	Other measures of respiratory function	Intervention completion	Intervention-related adverse events	Acute exacerbations, hospital admissions, readmissions or emergency admissions
			90 days: treatment as usual, 2.78±1.11; myCOPD, 2.76±1.35 3-month adjusted between arm difference (95% CI): 0.0183 (−0.759, 0.796).	Lowest weekly usage was in week 6; 11 (55%) of users accessed the app 4.2 out of 7 days. 8 (40%) of users used the app at least once per week throughout the study.		readmissions (n=4; 20%).
Rehab Guru (number of prioritised studies = 1)						
Pilsworth et al. 2021[9]	6MWT: Pre digital PR average 251 metres Post-digital PR average 296 metres Change = +45 metres	Not reported	MRC dyspnoea Pre digital PR average: 4 Post-digital PR average: 3 Change: -1 CRD dyspnoea Pre digital PR average: 2.69 Post-digital PR average:	6–8-week programme completion rates were 81%	Not reported	Not reported

Reference	Exercise capacity measured by a validated outcome measure	Health-related quality of life	Other measures of respiratory function	Intervention completion	Intervention-related adverse events	Acute exacerbations, hospital admissions, readmissions or emergency admissions
			3.37 Change: +0.68			
SPACE for COPD (number of prioritised studies = 2)						
Bourne et al., 2022[10]	**(ESWT)** (mean, 95% CI) 6 months: not significant SPACE: 596.6 (491.1, 702.0) TAU: 467.0 (376.2, 557.7) 9 months: not significant SPACE: 524.4 (417.4, 631.4) TAU: 483.8 (389.3, 578.2) **(ISWT)** (mean, 95% CI) 6 months: not significant	**(EuroQoL)** Data not presented **(CRQ dyspnoea)** (mean, 95% CI) 6 months: not significant SPACE: 3.9 (3.5 to 4.2) TAU: 3.8 (3.5 to 4.2) 9 months: not significant SPACE: 4.0 (3.6 to 4.4) TAU: 3.9 (3.6 to 4.2) **(CRQ fatigue)** (mean, 95% CI)	(**CAT)** (mean, 95% CI) 6 months: p=0.135 SPACE: 16.9 (12.0 to 21.7) TAU: 15.9 (14.4 to 17.4) 9 months: p=0.575 SPACE: 15.8 (12.8 to 18.7) TAU: 14.7 (13.2 to 16.3)	Not reported; however, 6 of 97 dropped out due to inability to attend group sessions, and 2 dropped out as too similar to PR	18 serious adverse events (11 intervention, 7 control); none related to the intervention	Not reported

Reference	Exercise capacity measured by a validated outcome measure	Health-related quality of life	Other measures of respiratory function	Intervention completion	Intervention-related adverse events	Acute exacerbations, hospital admissions, readmissions or emergency admissions
	SPACE: 424.9 (380.8, 469.0) TAU: 395.1 (352.8, 437.3) 9 months: not significant SPACE: 401.1 (359.0, 443.1) TAU: 376.3 (335.8, 416.7	6 months: p=0.035 SPACE: 4.8 (4.4 to 5.1) TAU: 4.4 (4.2 to 4.7) 9 months: not significant SPACE: 4.6 (4.3 to 5.0) TAU: 4.5 (4.2 to 4.8) **(CRQ emotion)** (mean, 95% CI) 6 months: not significant SPACE: 5.3 (5.0 to 5.6) TAU: 5.2 (5.0 to 5.5) 9 months: not significant SPACE: 5.3 (5.0 to 5.6)				

Reference	Exercise capacity measured by a validated outcome measure	Health-related quality of life	Other measures of respiratory function	Intervention completion	Intervention-related adverse events	Acute exacerbations, hospital admissions, readmissions or emergency admissions
		TAU: 5.2 (5.0 to 5.5) **(CRQ mastery)** (mean, 95% CI) 6 months: p=0.015 SPACE: 5.9 (5.6 to 6.3) TAU: 5.8 (5.5 to 6.0) 9 months: p=0.011 SPACE: 6.0 (5.7 to 6.3) TAU: 5.8 (5.6 to 6.1)				
Chaplin et al. 2017[12], 2022[11]	**(ESWT)** (mean change±sd) - Web-based: 189±211.1 seconds; usual care:184.5 ±247.4	**(CRQ-D)** (mean change±sd) - Web-based: 0.7 ±1.2 points; usual care: 0.8±1.0	No other statistically significant change.	Over the course of the intervention, 29 participants from the web-based intervention group dropped-out. The average number of weeks to complete	Not reported.	Not reported.

Reference	Exercise capacity measured by a validated outcome measure	Health-related quality of life	Other measures of respiratory function	Intervention completion	Intervention-related adverse events	Acute exacerbations, hospital admissions, readmissions or emergency admissions
	P<0.001 for both. Increase in number of steps per day was greater in web-based PR group than the conventional PR group (12% vs 2%), but this was not statistically significant (p=0.2). The pattern of accumulation of physical activity was numerically different between the groups – mainly through 2-minute bouts	P<0.001 for both.		the website was 11±4 with an average number of four logins per week. Participants drop-out at different stages: No WEB introduction completed (n=5); Not registered (n=7); Stage 1 – Introduction to exercising and goal setting, exercise safety quiz, read educational material (n=4); Stage 2 – Introduction of aerobic exercise programme, set walking target, read educational material (n=11); Stage 3 - Introduction of strength training programme, set strength target, continuation of aerobic training and read education material		

Reference	Exercise capacity measured by a validated outcome measure	Health-related quality of life	Other measures of respiratory function	Intervention completion	Intervention-related adverse events	Acute exacerbations, hospital admissions, readmissions or emergency admissions
	of activity in the web-based group and 20-minute bouts in the conventional group, although this difference was not statistically significant (p=0.07).			(n=2); Stage 4 – Maintain strength and aerobic training, review educational material, knowledge quiz (n=0).		
Wellinks (number of prioritised studies = 1)						
Gelbman & Reed 2022[16]	Not reported	Not reported	Participants had an average FEV1% (forced expiratory volume in 1 second as % of predicted for the patient) of 56.2% of predicted (range 23%-113%) and FEV1/forced vital capacity of 65%.	All completed	Not reported	Not reported

Reference	Exercise capacity measured by a validated outcome measure	Health-related quality of life	Other measures of respiratory function	Intervention completion	Intervention-related adverse events	Acute exacerbations, hospital admissions, readmissions or emergency admissions
			COPD severity, as assessed by the Global Initiative for Chronic Obstructive Lung Disease (GOLD) classification, was mild in 2 patients, moderate in 6, and severe/very severe in 11; 9 patients were on home oxygen. During this 8-week study, average use of the spirometer was 2.5 times/week, and the pulse oximeter 4.2 times/week, nebulizer use 1.9 times/week, There was a strong correlation between the FEV1 (r=0.96) and peak flow (r=0.94) measurements recorded by the spirometer compared with the measurements recorded			

Reference	Exercise capacity measured by a validated outcome measure	Health-related quality of life	Other measures of respiratory function	Intervention completion	Intervention-related adverse events	Acute exacerbations, hospital admissions, readmissions or emergency admissions
			by the physician during the office visit closest in time to the at-home collected information			

Table 30: Clinical evidence direction of effect summary table

		Exercise capacity		HRQoL			Respiratory function
Technology	**Study**	**6MWT**	**ESWT**	**EQ-5D-5L**	**CRQ-D**	**SGRQ**	**CAT score**
Active+me REMOTE		–	–	–	–	–	–
Clinitouch	Staffordshire Report[21] [AIC]	[redacted]	[redacted]	[redacted]	–	–	–
Kaia Health	Spielmanns et al., 2023[8]	–	–	–	*Dig: -0.2* *No PR: -0.7*		**Dig: -1.4** *No PR: +3.7*
myCOPD	Bourne et al., 2017[15]	**Dig: +45m** **F2F: +29m**	–	–	–	**Dig: -3.1** *F2F: +1.6*	**Dig: -3.2** **F2F: -1.1**
	Crooks et al., 2020[13]	–	–	**Dig: +0.04** *UC: 0.00*	–	–	**Dig: -2.3** *UC: 0*
	North et al., 2020[14]	–	–	–	–	**Dig: -4.5** **UC: -4**	**Dig: -5.3** **UC: -2.9**
Rehab Guru	Pilsworth et al. 2021[9]	**Dig: +45m** (no control)	–	–	–	–	–
SPACE for COPD	Bourne et al., 2022[10]	–	*Dig: -72m* **UC +16m**	–	**Dig: +0.1** **UC: +0.1**	–	**Dig: -1.1** **UC: -1.2**
	Chaplin et al., 2017[12]; Chaplin et al., 2022[11]	–	**Dig: +189** **UC: +184**	–	**Dig: +0.7** **UC: +0.8**	–	–
Wellinks	Gelbman & Reed, 2022[16]	–	–	–	–	–	–

Abbreviations and key: **bold** = clinical improvement, *italicised* = no improvement or clinical worsening, green = MCID reached, Dig = digitally supported pulmonary rehabilitation, F2F = face-to-face, UC = usual care

Appendix E: Additional trial control arm-based results (CEA)

Table 31-Table 33, presents the cost per outcome results for the digital technologies when trial control arm data have been used for F2F PR.

When using the trial control arm data for face-to-face pulmonary rehabilitation, the incremental effects of digital technologies ranged from:

- -20.7 to +16.3 in terms of difference in walking distance from baseline
- -0.387 to +0.302 in terms of difference in MCID units
- -15% to +5% in terms of difference in percentage change in walking distance

Table 31. Cost per change in walking distance (m) – F2F PR as per trial control arm

	Costs (per annum per participant)	Effect (Change in walking distance, m)	Digital vs F2F PR		
			Incremental costs	Incremental effect	Cost per ΔWD(m)
Clinitouch	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
F2F PR	£272.83	[redacted]	-	-	-
myCOPD	[redacted]	44.90	[redacted]	16.31	[redacted]
F2F PR	£294.25	28.60	-	-	-
SPACE for COPD	£213.29	45.00	-£218	-18.38	£12
F2F PR	£275.26	63.38	-	-	-
Rehab guru	£176.50	45.00	-£255	-14.01	£18
F2F PR	£431.55	59.01	-	-	-

Abbreviations: F2F = Face-to-face; MCID = minimal clinically important difference; PR = Pulmonary rehabilitation; WD = walking distance in metres

MCID reached MCID not reached

Table 32. Cost per unit change in MCID* – F2F PR as per trial control arm

	Costs (per annum per participant)	Effect (change in MCID units)	Digital vs F2F PR		
			Incremental costs	Incremental effect	Cost per unit ΔMCID
Clinitouch	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
F2F PR	£272.83	[redacted]	-	-	-
myCOPD	[redacted]	0.831	[redacted]	0.302	[redacted]
F2F PR	£294.25	0.530	-	-	-
SPACE for COPD	£213.29	0.947	-£218	-0.387	£564
F2F PR	£275.26	1.334	-	-	-
Rehab guru	£176.50	0.833	-£255	-0.259	£983
F2F PR	£431.55	1.093		-	-

Abbreviations: F2F = Face-to-face; MCID = minimal clinically important difference; PR = Pulmonary rehabilitation; WD = walking distance in metres: *1 MCID for 6MWD = 54m and ISWD = 48 m.

Table 33. Cost per % change in walking distance – F2F PR as per trial control arm

	Costs (per annum per participant)	Effect (% change in walking distance)	Digital vs F2F PR		
			Incremental costs	Incremental effect	Cost per % ΔWD
Clinitouch	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
F2F PR	£272.83	[redacted]	-	-	-
myCOPD	[redacted]	12%	[redacted]	5%	[redacted]
F2F PR	£294.25	7%	-	-	-

	Costs (per annum per participant)	Effect (% change in walking distance)	Digital vs F2F PR			
			Incremental costs	Incremental effect	Cost per % ΔWD	
SPACE for COPD	£213.29	15%	-£218	-15%	£1,416	
F2F PR	£275.26	31%	-	-	-	
Rehab guru	£176.50	18%	-£255	-4%	£5,902	
F2F PR	£431.55	22%	-	-	-	

Abbreviations: F2F = Face-to-face; MCID = minimal clinically important difference; PR = Pulmonary rehabilitation; WD = walking distance in meters

GID-HTE1001921 Digital technologies to support the delivery of pulmonary rehabilitation for adults with chronic obstructive pulmonary disease

EVA guidance recommendations

Medical technologies advisory committee: 17 Nov 2023

Introducers: Dr Enya Daynes, Dr Avril McCarthy

Lay SCMs: Alan Thomas, Tessa Jelen

External assessment group: Max Barnish, Madhu Muthukumar

Technical team: Evan Campbell, Xia Li, Amy Crossley

NICE National Institute for Health and Care Excellence

Unmet need and pulmonary rehabilitation

- Chronic obstructive pulmonary disease (COPD) is a long-term and progressive respiratory condition that causes breathlessness, a persistent chesty cough, persistent wheezing and frequent chest infections. ~1.17 million people (1.9% of population) in England have a diagnosis of COPD, with an estimated 2 million undiagnosed

- Despite the fact that 90% of people with COPD who complete pulmonary rehabilitation see an improvement in exercise capacity and quality of life, and it being recommended by NICE CG115, **pulmonary rehabilitation is only *offered* to 13% of those eligible,** highlighting an unmet need

- NICE CG115 (2019) defines pulmonary rehabilitation as a multidisciplinary programme that is individually tailored to optimise physical and social performance and autonomy

- Pulmonary rehabilitation programmes should: last at least 6 weeks, include a minimum of 2 sessions per week, include individually tailored and prescribed progressive aerobic and resistance exercise training, include a structured programme of disease education, and a nutritional, psychological and behavioural intervention

NICE

COPD: chronic obstructive pulmonary disease

Digitally supported pulmonary rehabilitation

- Digital technologies to support pulmonary rehabilitation will replace at least one of the components of pulmonary rehabilitation, e.g. exercise or educational sessions
- But digital technologies will **not** replace the pre and post in-person face to face assessment
- Digitally supported pulmonary rehabilitation is intended to be an extra option for clinicians and people with COPD who are eligible for pulmonary rehabilitation. It is not intended to replace face-to-face pulmonary rehabilitation in the pathway outright.
- Tele-rehab or virtual pulmonary rehabilitation e.g. zoom exercise sessions, are a different type of intervention and technology, and have not been considered as part of this early value assessment.

Decision problem

PICO	
Population	Adults with a diagnosis of COPD who are eligible for pulmonary rehabilitation
Subgroups	• Level of breathlessness (MRC dyspnoea score) • Having or not having comorbidities (including frailty) • Living in a rural or urban setting • Having an exacerbation which required hospitalisation in the previous 12 months
Intervention	Technologies to deliver digitally supported pulmonary rehabilitation
Comparator	Face to face pulmonary rehabilitation No treatment, or waiting list
Key Outcomes	• Exercise capacity, respiratory function, HRQoL, • Intervention completion, adherence, adverse events, acute exacerbations

For full decision problem see the final scope

HRQoL: health related quality of life; MRC: Medical Research Council

Features of included technologies

Technology	Exercise	Education	Psychological intervention	In-app communication with AHP	Communication external to app with AHP	Patient reported symptom tracker	Objective symptom tracker	Remote monitoring
Active+me REMOTE	✓	✓		✓	✓	✓	✓	✓
Clinitouch	✓	✓		✓	✓		✓	✓
Kaia COPD	✓	✓			✓		✓	✓
myCOPD	✓	✓	✓	✓	✓	✓	✓	✓
Rehab Guru	✓			✓		✓	✓	
SPACE for COPD*	✓	✓	✓	✓	✓	✓		
Wellinks	✓	✓	✓				✓	✓

- All included technologies provide a different suite of features
- All technologies offer to replace exercise component of face-to-face pulmonary rehabilitation
- Some also offer to replace educational aspect and a psychological intervention

*SPACE for COPD will cease to be available in the first quarter of 2024 but will be replaced with a new website combining pulmonary and cardiac rehabilitation

NICE

AHP: allied health professional

COPD and pulmonary rehabilitation

- Chronic obstructive pulmonary disease (COPD) is a long-term and progressive respiratory condition that causes breathlessness, a persistent chesty cough, persistent wheezing and frequent chest infections. COPD includes chronic bronchitis and emphysema. COPD mainly affects older adults who smoke. Breathing problems tend to worsen over time and limit ability to undertake daily activities and people with COPD have a lower life expectancy
- ~1.17 million people (1.9% of the population) in England have a diagnosis of COPD with an estimated 2 million undiagnosed
- COPD is more common in areas with higher deprivation and more common in men than in women
- Treatment can help keep the condition under control and includes stopping smoking, inhalers and tablets, pulmonary rehabilitation, and surgery
- COPD management costs NHSE £800 million per year

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Current management overview

- NICE CG115 (2019) states that pulmonary rehabilitation should be offered to all people who view themselves as functionally disabled by COPD (usually MRC dyspnoea scale grade ≥3)
- However, the current NHS Long-Term Plan (2023) recommends that pulmonary rehabilitation should offered to people with mild COPD and above (MRC dyspnoea scale grade ≥2)
- Despite 90% of people who complete pulmonary rehabilitation see an improvement in exercise capacity and quality of life, **pulmonary rehabilitation is only offered to 13% of those eligible,** highlighting an unmet need
- NICE CG115 (2019) defines pulmonary rehabilitation as a multidisciplinary programme that is individually tailored to optimise physical and social performance and autonomy
- Pulmonary rehabilitation programmes should: last at least 6 weeks, include a minimum of 2 sessions per week, include individually tailored and prescribed progressive aerobic and resistance exercise training, include a structured programme of disease education, and nutritional, psychological and behavioural intervention

NICE

Digitally supported pulmonary rehabilitation

- Digitally supported pulmonary rehabilitation could facilitate the delivery of pulmonary rehabilitation in a person's home environment
- Digitally supported pulmonary rehabilitation would be delivered as part of a wider respiratory pathway where people can access several parts of the pathway at the same time
- Offering digitally supported pulmonary rehabilitation as an option to adults with COPD could improve access, engagement and adherence to pulmonary rehabilitation programmes
- These technologies may reduce primary and secondary care resource use

Technologies must:	Technologies must not:
be intended for adults with COPD	replace the pre and post in person assessment
include at least one digital component of pulmonary rehabilitation: physical training; disease education; nutritional, psychological or behavioural intervention	offer solely tele-rehab e.g. live sessions delivered remotely
have a minimum duration of 6 weeks	
have appropriate regulatory and DTAC approval*	

* or be working towards gaining necessary regulatory or DTAC status

Included technologies and intended benefit

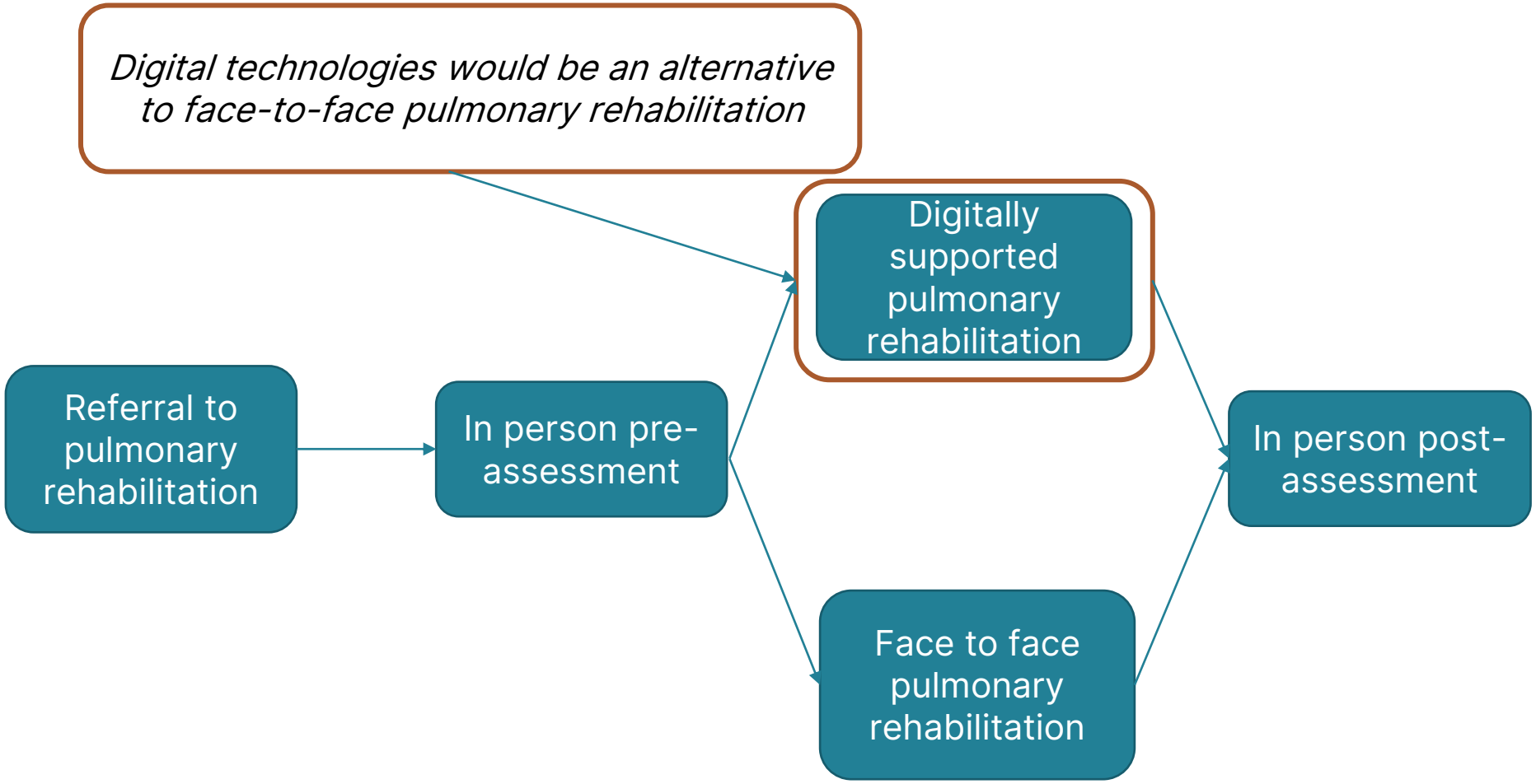
7 technologies for digitally supported pulmonary rehabilitation were included in the assessment:

- Active+me REMOTE
- Clinitouch
- Kaia COPD
- myCOPD
- Rehab Guru
- SPACE for COPD*
- Wellinks

Submissions were received from all companies apart from Wellinks who did not respond to requests. SPACE for COPD will cease to be available in the first quarter of 2024 but will be replaced with a new website. It has been included in this evaluation because the technology is within scope

All included technologies are intended to be an additional option for people with COPD who are eligible for pulmonary rehabilitation and not to replace standard care outright

Proposed care pathway



Equality considerations

- COPD is most common in people over 50, more common in men, and people from more deprived socioeconomic backgrounds
- Additional support and resources may be needed for people who are unfamiliar with digital technologies or people who do not have access to smart devices or the internet
- People with visual, hearing, or cognitive impairment; problems with manual dexterity; learning disability; mental health condition; or reading ability (including unable to read English) may need additional support
- People who are homeless, living in multiple occupancy, residential care may struggle to access digitally support pulmonary rehabilitation
- Cultural, ethnic or religious backgrounds may affect views of different types of pulmonary rehabilitation. For example, some people may not want to attend a mixed sex exercise class

Perspective of people with lived experience (1)

- No differentiation in literature between people with COPD who are dependent on oxygen and those who are not oxygen dependent. People who are dependent on oxygen generally have less energy and may not want to go to face-to-face pulmonary rehabilitation because:
    - it will use up their energy which they may prefer to use spending time with family, or on other interests (opportunity cost of patient time)
    - they might run out of oxygen while there
- Where a person lives can also affect the above points, for example rurally or having to use public transport
- No differentiation between newly diagnosed vs later stages of COPD in the evidence. Digitally supported pulmonary rehabilitation could be useful at all stages

Perspective of people with lived experience (2)

- As a person living with COPD, very much want to use digital technologies and online technologies to self-manage COPD (ownership of treatment)
- Patient benefits of pulmonary rehabilitation predominantly relate to quality of life. Even just being able to do a little more can give a big boost. This doesn't seem to have been captured in the literature
- Feels strongly that any intervention for people with COPD will have some sort of benefit, so it should be offered to them if possible
- As a someone who has experienced it (Alan), don't see why the pre and post assessment can not be done online via tele-rehab. This was managed well from both the staff and the patient side. And felt very well cared for when this happened

Professional organisation submissions (1) Association of Respiratory Nurses (ARNS)

Submission from the Association of Respiratory Nurses stated that digitally supported pulmonary rehabilitation:

- can provide access to those who are isolated, housebound or in residential settings
- can increase patient choice
- can offer more personalised care

But it:

- could exclude people who are digitally illiterate
- should not yet replace face to face groups but can be a useful adjunct

For further details see the full ARNS submission included in the pack

Professional organisation submissions (2) British Thoracic Society (BTS)

Submission from the British Thoracic Society stated that:

- Digital technologies may provide a suitable option for some patients and increase access to pulmonary rehabilitation
- Face to face assessment would be required to maintain the standards of pulmonary rehabilitation and to assess safety
- Digital exclusion may widen the health inequality/disparities for people with COPD
- Evidence is required to ensure that digital technologies are equivalent to gold standard treatment and to identify patients that may benefit
- Training for staff and infrastructure support is vital for the success of digital technologies within pulmonary rehabilitation

For further details see the full BTS submission included in the pack

Clinical evidence review

Clinical evidence summary

- 44 studies were identified as relevant and 9 were prioritised for inclusion in the review for 6 technologies:
  - Clinitouch: 1 non-randomised comparative study
  - Kaia COPD: 1 RCT
  - myCOPD: 3 RCTs (including 1 feasibility RCT)
  - Rehab Guru: 1 single-arm pilot study (conference abstract)
  - SPACE for COPD: 2 RCTs (including 1 feasibility RCT)
  - Wellinks: 1 observational pilot study
- Active+me REMOTE: no prioritised studies
- The common features across at least 5 technologies: exercise, education, in-app communication with AHP, communication external to app with AHP, objective symptom tracker, and remote monitoring
- Outcomes reported: exercise capacity, health-related quality of life, respiratory function, intervention completion, intervention-related adverse events, and acute exacerbations, hospital admissions, readmissions or emergency admissions

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AHP: allied health professional

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Characteristics of prioritised studies (1)

	Study design, country	Population	Intervention	Comparator	Key study limitations
Clinitouch	Non-randomised comparative study (Staffordshire report); UK – Staffordshire	[redacted]	Digitally supported PR using Clinitouch	[redacted]	[redacted]
Kaia COPD	RCT (Spielmanns et al. 2023); Germany and Switzerland (2 sites)	67	6-months of daily physical exercise training conducted via Kaia COPD app	Exercise and lifestyle intervention	Small sample (although sufficient for statistical considerations based on primary endpoint), no blinding to participants and staff
myCOPD	Single-blind RCT (Bourne et al. 2017); UK (single site)	90 (myCOPD, n=64; F2F, n=26)	6 weeks of physical exercise training conducted via myPR (myCOPD)	F2F PR (explicitly stated)	Short study duration
	Open-label RCT (Crooks et al. 2020); UK (3 sites)	60 (myCOPD, n=29; UC, n=31)	12 weeks of physical exercise training conducted via myCOPD	Usual care	Not powered statistically, marked phenotypic difference between groups, the control group more active than the myCOPD group
	Single-blind, feasibility RCT (North et al. 2020); UK (single site)	41 (myCOPD, n=20; UC, n=20)	12 weeks of physical exercise training conducted via myCOPD	Usual care	Not powered statistically, unable to capture all indices of app usage

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Characteristics of prioritised studies (2)

	Study design, country	Population	Intervention	Comparator	Key study limitations
Rehab Guru	Single-arm pilot study (Pilsworth et al. 2021); UK - Liverpool	33	7 months. A home exercise prescribing platform	No	Conference abstract only, pilot study with a small sample
SPACE for COPD	Signal-blind RCT (Bourne et al. 2022); UK – Leicester (7 GP practices)	193	Received a SPACE for COPD manual and attended the SPACE for COPD group-based self-management programme	Usual care	Drop out in the intervention group: n=8 due to inability to attend group sessions or similar to PR. CAT might not be the most suitable primary outcome for people with milder COPD
	Feasibility RCT (Chaplin et al. 2017; Chaplin et al. 2022); UK	103 (SPACE, n=51; UC, n=52)	Web-based exercise and education programme (mean 11 weeks)	Usual care	High dropout rate in the intervention group: 56% (n=29)
Wellinks	Prospective, observational pilot study (Gelbman & Reed 2022); USA (single cite)	19	8 weeks of physical exercise training conducted via Wellinks mHealth app	No	Small sample, decline in the use of spirometry and oximetry, and selection bias

CAT: COPD Assessment Test

Characteristics of prioritised studies

	Study design, country	Country	Sample	Comparator	Key study limitations from the EAG
Clinitouch	Non-randomised comparative study (Staffordshire report)	UK	[redacted]	[redacted]	[redacted]
Kaia COPD	RCT (Spielmanns et al. 2023)	Germany & Switzerland	67 I: n=33, C: n=34	Exercise and lifestyle intervention	Small sample
myCOPD	RCT (Bourne et al. 2017)	UK	90 I: n=64, C: n=26	Face-to-face pulmonary rehabilitation	Short study duration (6 weeks)
	RCT (Crooks et al. 2020)	UK	60 I: n=29, C: n=31	Usual care	Not powered statistically Marked phenotypic difference between groups at baseline
	Feasibility RCT (North et al. 2020)	UK	41 I: n=21, C: n=20	Usual care	Not powered statistically Unable to capture all indices of app usage
Rehab Guru	Single-arm pilot study (Pilsworth et al. 2021)	UK	33	-	Conference abstract Small sample
SPACE for COPD	RCT (Bourne et al. 2022)	UK	193 I: n=97, C: n=96	Usual care	CAT might not be suitable primary outcome for people with milder COPD
	Feasibility RCT (Chaplin et al. 2017; Chaplin et al. 2022)	UK	103 I: n=51, C: n=52	Usual care	High dropout rate in intervention group: 56% (n=29)
Wellinks	Single-arm, pilot study (Gelbman & Reed 2022)	USA	19	-	Small sample Selection bias

I: intervention; C: control; CAT: COPD Assessment Test

Clinical evidence: EAG critique

- RCTs were not available for 3 technologies (Clinitouch, Rehab Guru, Wellinks)
- There were no included studies that compared multiple scoped technologies
- Details of usual care were not generally adequately reported
- Samples were often not adequately powered for appropriate clinical outcome measures, with short follow ups
- 7 studies were conducted in UK, 1 in USA (Wellinks), 1 in Germany and Switzerland (Kaia Health)
- UK-based studies were geographically specific rather than UK-wide, leading to potential generalisability challenges due to the socioeconomic pattern of COPD prevalence and differences in accessibility of care and digital access between urban and rural areas
- Evidence was not available for each technology for each priority scoped outcome domain. In particular, data was limited for quality of life, intervention-related adverse events, and exacerbation and hospitalisation outcomes

For further details see AR pages 31 to 49

Outcome measures used in prioritised studies

Minimal clinically important difference (MCID) is the smallest change in an outcome measure that a person identifies as important, and which indicates a clinical improvement

	Measure		MCID
Exercise capacity	6MWT	6-minute walk test	54 metres
	ISWT	Incremental shuttle walk test	48 metres
	ESWT	Endurance shuttle walk test	174 to 279 seconds
	60-second STST	60-second sit to stand test	3 repetitions
	5XSTST	5 times sit to stand test	1.7 seconds
	VSAQ	Veterans Specific Activity Questionnaire	-
	Steps per day	-	-
Health-related quality of life	EQ-5D VAS	EuroQol-5 dimension visual analog scale	-
	EQ-5D-5L	5-level EQ-5D	-
	CRQ	Chronic respiratory questionnaire	-
	SGRQ	St. George's respiratory questionnaire	-
Respiratory function	CAT	COPD assessment test	-2 points
	CRD	Chronic refractory dyspnoea	-
	MRC dyspnoea	Medical research council dyspnoea scale	-
	mMRC dyspnoea	Modified Medical Research Council dyspnoea scale	-
	FEV1	Forced exploratory volume in one second	-

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Clinical evidence (1): results across all technologies

- Exercise capacity (Clinitouch, Kaia COPD, myCOPD, Rehab Guru, and SPACE for COPD):
  - 6MWT, ESWT, ISWT, 5 times STS, 60-second STS: improved after digitally supported PR, with most improvements being statistically significant
  - 6MWT, ESWT, ISWT, 60-second STS, 5 times STS, steps per day, VSAQ: no statistically significant difference between groups, except for 60-second STS for Kaia Health (a statistically significant difference in favour of intervention at 3 months but not at 6 months)
- Health-related quality of life (Clinitouch, Kaia COPD, myCOPD, Rehab Guru, and SPACE for COPD):
  - EQ-5D VAS, EQ-5D-5L, CRQ, SGRQ: generally improved after digitally supported PR
  - EQ-5D VAS, EQ-5D-5L, CRQ, SGRQ: in general, no statistically significant difference between groups
- Respiratory function (Clinitouch, Kaia COPD, myCOPD, Rehab Guru, SPACE for COPD, and Wellinks):
  - CAT, CRD, MRC, mMRC: most changes after digitally supported PR not statistically significant
  - CAT, MRC, mMRC: no statistically significant differences between groups, except for CAT for Kaia Health (a significant difference in favour of the intervention group at 6 months but not at 3 months)
  - FEV: no measure of change in score was provided for Wellinks

For further details see AR table 29: pages 124 to 141

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Clinical evidence (2): results across all technologies

- Adherence (Kaia COPD): 67%
- Intervention completion (Clinitouch, myCOPD, Rehab Guru, and Wellinks): 47% or above
- Adverse events (Kaia COPD, myCOPD and SPACE for COPD): data did not show any significant concerns
- Exacerbations (myCOPD and SPACE for COPD): largely comparable between arms and generally not of particular concern. However, Crooks et al. (2020) reported:
    - Exacerbations 3 months prior to study baseline: n=15 (myCOPD, n=12; usual care, n=3)
    - Exacerbation during the study: n=29 (myCOPD, n=18; usual care, n=11)

For further details see AR table 29: pages 124 to 141

Clinical evidence: results across all technologies

- Exercise capacity (5 technologies):
  - Before and after intervention: improved after digitally supported PR, with most improvements being statistically significant
  - Between-group comparison: no statistically significant differences (non-inferiority), except for 60-second STST for Kaia Health (a statistically significant difference in favour of intervention at 3 months)
- Health-related quality of life (5 technologies):
  - Before and after intervention: generally improved after digitally supported PR
  - Between-group comparison: in general, no statistically significant differences
- Respiratory function (6 technologies):
  - Before and after intervention: most changes after digitally supported PR not statistically significant
  - Between-group comparison: no statistically significant differences (non-inferiority), except for CAT for Kaia Health (a significant difference in favour of the intervention group at 6 months)
  - For 1 technology: no measure of change in score was provided
- Adherence (1 technology): 67%
- Intervention completion (4 technologies): 47% or above
- Adverse events (3 technologies): no particular concerns
- Exacerbations (2 technologies): largely comparable between arms and generally not of particular concern

CRD: Chronic refractory dyspnoea; EQ-5D VAS: EuroQol-5 dimension visual analog scale; PR: pulmonary rehabilitation; 60-second STST, 60-second sit to stand test

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Clinical evidence (3): key results for each technology

- myCOPD (3 RCTs):
  - Exercise capacity, health-related quality of life and respiratory function: generally comparable outcomes between groups. Exercise capacity and respiratory function improved after digitally supported pulmonary rehabilitation, with some improvements being statistically significant. Changes in CAT scores met the MCID (of -2 points) in the intervention arm in all three trials
  - Intervention completion: 62%
- SPACE for COPD (2 RCTs)
  - Exercise capacity, health-related quality of life, and respiratory function: generally comparable between groups. After digitally supported pulmonary rehabilitation, these outcomes generally showed improvements. For MCID, only the change in ESWT reached the MCID after digitally supported pulmonary rehabilitation (Chaplin et al. 2017, 2022)
  - Intervention completion: 47%

For further details see AR table 29: pages 124 to 141

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Clinical evidence (4): key results for each technology

- Clinitouch (1 non-randomised comparative study):
  - Exercise capacity: [redacted]
  - Health-related quality of life and respiratory function: [redacted]
  - Intervention completion: [redacted]
- Kaia COPD (1 RCT):
  - Disease-specific quality of life: no statistically significant difference between groups at baseline or follow ups (3 and 6 months)
  - Exercise capacity: a statistically significant difference in favour of the intervention group at 3 months but not at 6 months. Changes in 60-second STS in the intervention group just exceeded the MCID of 3 repetitions at both 3 and 6 months
  - Respiratory function: a statistically significant difference in favour of the intervention group at 6 months but not at 3 months
  - Adherence: 67% (at least 90 days)

For further details see AR table 29: pages 124 to 141

Clinical evidence (5): key results for each technology

- Rehab Guru (1 single-arm pilot study):
  - Exercise capacity: 6MWT improved by 45 metres after digitally supported PR
  - Health-related quality of life: CRD dyspnoea changed 0.68 after digitally supported PR
  - Respiratory function: MRC dyspnoea changed -1 after digitally supported PR
  - Intervention completion: 68%
- Wellinks (1 single-arm pilot study):
  - Respiratory function:
    - FEV1%: 56.2% of predicted (range 23% to 113%)
    - FEV1/forced vital capacity: 65%
  - Severe or very severe COPD: 11/19
  - Intervention completion: 100%

For further details see AR table 29: pages 124 to 141

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Clinical evidence (6): Adverse events, exacerbations and readmissions

- Kaia Health: no significant difference in the number of AEs or exacerbations between groups
- myCOPD:
  - AE: 11 events in the intervention group (back pain, n=1; inguinal pain, n=1; common cold, n=1; constipation, n=2 (1 SAE) medical side effect, n=1 (SAE); unspecified AE, n=5)
  - Exacerbations:
    - Bourne et al. (2017): n=3 (withdrew due to exacerbations)
    - Crooks et al. (2020): n=29 (myCOPD, n=18 [2 required emergency department attendance and 1 hospitalisation]; usual care, n=11 [1 required emergency attendance and 2 hospitalisation])
    - North et al. (2020): 3-month adjusted between arm difference: 0.581 (95% CI 0.315 to 1.07)
  - Readmissions: myCOPD, n=4 (20%); usual care, n=7 (33%)
- SPACE for COPD: 11 SAEs in the intervention group, and none related to the intervention

For further details see AR table 29: pages 124 to 141

AE: adverse event; SAE: serious adverse event

Clinical evidence: summary of results

Abbreviations and key: **bold** = improvement, *italicised* = no improvement or worsening, green = MCID reached, Dig = digitally supported pulmonary rehabilitation, F2F = face-to-face, UC = usual care

		Exercise capacity		HRQoL			Respiratory function
Technology	Study	6MWT	ESWT	EQ-5D-5L	CRQ-D	SGRQ	CAT score
Active+me REMOTE		–	–	–	–	–	–
Clinitouch	Staffordshire Report	[redacted]	[redacted]	[redacted]	–	–	–
Kaia COPD	Spielmanns et al., 2023	–	–	–	*Dig: -0.2* *No PR: -0.7*		**Dig: -1.4** No PR: +3.7
myCOPD	Bourne et al., 2017	**Dig: +45m** **F2F: +29m**	–	–	–	**Dig: -3.1** *F2F: +1.6*	Dig: -3.2 **F2F: -1.1**
	Crooks et al., 2020	–	–	**Dig: +0.04** *UC: 0.00*	–	–	Dig: -2.3 UC: 0
	North et al., 2020	–	–	–	–	**Dig: -4.5** **UC: -4**	Dig: -5.3 UC: -2.9
Rehab Guru	Pilsworth et al. 2021	**Dig: +45m** (no control)	–	–	–	–	–
SPACE for COPD	Bourne et al., 2022	–	*Dig: -72m* **UC +16m**	–	**Dig: +0.1** **UC: +0.1**	–	**Dig: -1.1** **UC: -1.2**
	Chaplin et al., 2017; Chaplin et al., 2022	–	Dig: +189 UC: +184	–	**Dig: +0.7** **UC: +0.8**	–	–
Wellinks	Gelbman & Reed, 2022	–	–	–	–	–	–

Clinical evidence: summary of results

Comparison between digitally supported PR and control for prioritised studies

Abbreviations and key: ↔ = no statistically significant difference between intervention and control, ↗ = statistically significant improvement was seen for the invention vs control in at least one (but not all) follow-up timepoint, F2F = face-to-face, N/A = not applicable, NR = not reported, PR = pulmonary rehabilitation, UC = usual care

Technology	Study	Control	Exercise capacity	HRQoL	Respiratory function	Adverse effects	Exacerbations etc
Comparative evidence							
Clinitouch	Staffordshire Report	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Kaia COPD	Spielmanns et al., 2023	No PR	↗[a]	↔	↗[b]	↔	↔
myCOPD	Bourne et al., 2017	F2F	↔	↔	↔	↔	NR
	Crooks et al., 2020	UC	↔	↔	↔	↔	NR
	North et al., 2020	UC	↔	↔	↔	↔	NR
SPACE for COPD	Bourne et al., 2022	UC	↔	↔	↔	NR	NR
	Chaplin et al., 2017; Chaplin et al., 2022	F2F	↔	↔	↔	NR	NR
Non-comparative evidence							
Active+me REMOTE	N/A	None	N/A	N/A	N/A	N/A	N/A
Rehab Guru	Pilsworth et al. 2021	None	N/A	N/A	N/A	N/A	N/A
Wellinks	Gelbman & Reed, 2022	None	N/A	N/A	N/A	N/A	N/A

For further details see AR pages 55-57

Clinical evidence: EAG review

- Priority evidence was available for 6 out of the 7 technologies, with myCOPD and SPACE for COPD having more advanced evidence bases than other technologies
- Evidence was not evenly distributed across clinical outcomes, with the greatest evidence available for exercise capacity and respiratory function
- Evidence (in particular for myCOPD and SPACE for COPD) from a research perspective generally supports the concept of non-inferiority between digitally supported and face-to-face pulmonary rehabilitation, in terms of exercise capacity and respiratory function
- Generalisability concerns:
  - UK studies are not UK wide and have a bias towards urban areas. Digital access and literacy may vary in different areas. No studies presented subgroup data for included rural areas
  - Selection bias might lead to outperformance in the digitally supported PR arm
  - Control arms representing traditional face to face pulmonary rehabilitation underperformed in at least some of the included studies
  - Reporting clarity of the details of interventions and comparators was limited and does not conform to TIDieR reporting guidelines for interventions and comparators

Economic evaluation

Committee member: Dr Avril McCarthy

Economic evaluation

The EAG compared the cost per patient of Active+me REMOTE, Clinitouch, SPACE for COPD, myCOPD, and Rehab Guru against the cost of delivering face-to-face pulmonary rehab, and no treatment both with and without exacerbations

For Clinitouch, myCOPD, Rehab Guru and SPACE for COPD, and using improvement in exercise capacity as the outcome of interest, the EAG conducted:

- a disaggregated cost-consequence analysis compared with face-to-face pulmonary rehabilitation, waitlist/no treatment both with and without exacerbations
- an exploratory cost-effectiveness analysis expressed as cost per change in functional exercise capacity (measured in MCID 6MWT or ISWT) compared to face-to-face pulmonary rehabilitation

Due to heterogeneity in control arms, costs of face-to-face rehabilitation were sourced from the literature and performance of face-to-face rehabilitation was sourced from UK National audit data

Economic evaluation: results (1)

Comparison of cost per patient of digitally supported pulmonary rehabilitation to cost of delivering face-to-face pulmonary rehabilitation, no treatment both with and without exacerbations requiring hospitalisation:

All the technologies considered (Active+me REMOTE, Clinitouch, SPACE for COPD, myCOPD, and Rehab guru) were:

- Cheaper to provide than face-to-face pulmonary rehabilitation
- Cheaper to provide than waitlist/no treatment for people who have an exacerbation which requires hospitalisation

But,

- were more expensive to provide than no treatment/waitlist for people who *do not* have an exacerbation that requires hospitalisation

MTAC presentation – CIC will be redacted in version on screen, CIC values cannot be mentioned in part 1 of the meeting

Economic evaluation: results (2)

Results from both the cost-consequence analysis and the cost-effectiveness analysis using walking distance as the unit of interest:

- indicated that Clinitouch, myCOPD, SPACE for COPD and Rehab Guru were **cost-saving** but **less effective** than face-to-face pulmonary rehabilitation
- Some of the technologies did not reach the level of an improvement of clinical significance, indicated by red text in effect column (green text indicates an improvement greater than MCID)

	Costs (per annum per participant)	Effect (change in MCID units)	Digital vs F2F PR	
			Incremental costs	Incremental effect
Clinitouch	[redacted]	[redacted]	[redacted]	[redacted]
F2F PR	£259.58	1.093	-	-
myCOPD	[redacted]	0.831	[redacted]	-0.261
F2F PR	£259.58	1.093	-	-
SPACE for COPD	£10.02	0.947	-£250	-0.387
F2F PR	£259.58	1.334	-	-
Rehab Guru	£12.00	0.833	-£248	-0.259
F2F PR	£259.58	1.093	-	-

Overview of health economic evaluation by EAG

The EAG identified no relevant published health economic evidence for any of the technologies

Due to heterogeneity in the study design and lack of quality-of-life measures transferable to QALY the EAG conducted:

- a disaggregated cost-consequence analysis for Active+ me REMOTE, Clinitouch, SPACE for COPD, myCOPD, Rehab guru only because these were the technologies which had pricing data available
- an exploratory cost-effectiveness analysis for Clinitouch, SPACE for COPD, myCOPD, Rehab guru because these were the technologies which had outcome data for the 6minWT or the ISWT

The EAG did not pursue a cost-minimisation approach (as is common in non-inferiority value propositions) due to the small sample sizes and short follow up periods to the prioritised studies

Disaggregated Cost Consequence Analysis (1)

For both the CCA and the CEA: the Time horizon was 1 year, costs were presented in 2022 GBP, but not discounted owing to the short time horizon. Unit costs were sourced from NHS reference costs 2021/22 and PSSRU 2022

Comparators were: face-to-face pulmonary rehabilitation, waitlist without exacerbation requiring hospitalisation, waitlist with exacerbation requiring hospitalisation (waitlist was assumed to be equal to no treatment)

Clinical outcomes included: exercise capacity, respiratory function, health-related quality of life

Other outcomes included: number of adverse events and events related to hospitalisation or visits to an emergency department

These outcomes have been presented in a disaggregated form of intervention arms vs respective control arms in Table 9 on page 65 in the EAR. The EAG has not associated any costs with these consequences

Further details in the EAR pages 62 to 72

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Disaggregated Cost Consequence Analysis (2)

The costs considered for digital technologies included:

- licensing costs for technologies
- health care professional costs
- other additional costs (staff training, participant training, website construction)

There was heterogeneity in cost components considered across the digital technologies. For example, some companies reported or enabled the calculation of per participant costs, while others only reported per clinician or supplied a performance based pricing model

Costs of face-to-face pulmonary rehabilitation were derived primarily based on the COPD PRIME tool

Clinician time was assumed to be constant between the technologies

Uptake of digitally supported pulmonary rehabilitation was assumed equal across all technologies at 10%

Further details in the EAR page 90

Disaggregated Cost Consequence Analysis (3) – pricing structures

There was heterogeneity in the cost components considered across the digital technologies. This was primarily due to different pricing models. For example, myCOPD provided an annual license determined by number of patients registered to that service (with fixed year 1 costs and subsequent year costs based on number of user registrations and engagements achieved in previous year), Clinitouch charged a cost per clinician, SPACE for COPD had an annual cost per clinician along with an additional cost to add, and Rehab Guru provided a cost per trust and a cost per clinician.

To compare the costs of these technologies in terms of cost per patient, the EAG considered data on caseload per clinician (based on clinical opinion to EAG), uptake levels for the technologies, and the number of patients who have registered and completed pulmonary rehabilitation. This allowed for a more comprehensive analysis of the cost the NHS is expected to pay per patient.

As well as providing a performance based pricing model, myCOPD also has existing 'legacy' per patient users. These legacy licenses range from approximately [redacted] to [redacted]. In line with NICE's methodologies for assessing technologies available at more than one price to the NHS, myCOPD was assessed at both the minimum and maximum available.

Further details in the EAR pages 63 to 64

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Disaggregated Cost Consequence Analysis (4) – detailed results

Costs per patient for digitally supported pulmonary rehabilitation and comparators

	Active +me	Clinitouch	SPACE for COPD	myCOPD	Rehab Guru	F2F PR	Waitlist (with exacerbation)	Waitlist (without exacerbation)
license cost	£89	[redacted] £26.67[k]	£67[b]	yr1: [redacted] yr2: [redacted]	£33[d]	-	-	-
Staff training	£42[e]	-	£12.5[f]	-	-	-	-	-
Participant training	£60 (ex VAT) [g]	-	-	-	-	-	-	-
Staff time	£144	£144[h]	£144	£144	£144	£432		
Expected annual cost per patient	£335	[redacted] £171	£ 272	Yr 1: [redacted] Yr 2: ****	£177	£432	£402[j]	£164[i]
Uptake rate, %	-	30%[l]	5%	yr1 10% yr2 20%	5%[m]	85%	-	-
Completion rate, %	-	[redacted]	47%	62%	68%[n]	71%	-	-

See table 10 on page 67 of EAR for sources of data for references a-n

Disaggregated Cost Consequence Analysis (5) – detailed results

All the technologies considered (Active+ me REMOTE, Clinitouch, SPACE for COPD, myCOPD, Rehab guru) were:

- cheaper to provide compared to face-to-face pulmonary rehabilitation
- cheaper to provide compared to waitlist/no treatment when the person with COPD has an exacerbation which requires hospitalisation

But,

- were more expensive to provide than no treatment/waitlist when the person with COPD does *not* have an exacerbation that requires hospitalisation

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Disaggregated Cost Consequence Analysis (6) – detailed results

When adjusting for uptake and completion rates the EAG calculated cost savings per patient, alongside the improvement in exercise capacity, compared to National UK COPD audit data for providing face to face rehabilitation

Comparison of cost-savings of digitally supported PR to face to face pulmonary rehab as per the UK COPD PR audit

	Clinitouch vs F2F PR (UK COPD PR audit)	myCOPD vs F2F PR (UK COPD PR audit)	SPACE for COPD vs F2F PR (UK COPD PR audit)	Rehab Guru vs F2F PR (UK COPD PR audit)
Difference in treatment effect, 6MWD in m	[redacted]	-14.1	NR	-14.0
Difference in treatment effect, ISWD in m	NR	NR	-18.4	NR
Annual cost savings per participant	[redacted] [redacted]	[redacted]_first year [redacted] second year [redacted]_legacy contract	-£218	-£255

Disaggregated Cost Consequence Analysis (7) – detailed results and drivers

Cost-savings for digital technologies compared to face-to-face pulmonary rehab ranged from [redacted] (first year of myCOPD) to £255 (SPACE for COPD). Generally, the effect on exercise capacity was slightly lower than that of the UK COPD audit data. Note that differences in the clinical effect are indicative only and have not been tested for statistical significance. Data for the clinical effect of the digital technologies comes from studies, while data for the clinical effect of face-to-face pulmonary rehabilitation comes from the UK National audit data, which is real world evidence.

Drivers of cost savings

The main drivers of cost savings were the:

- per patient license fee
- resource cost of providing face to face pulmonary rehabilitation
- cost of hospitalisation following an exacerbation

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Exploratory cost-effectiveness analysis (1)

Included technologies

Four technologies were included in the cost-effectiveness analysis: Clinitouch, myCOPD, Rehab Guru and SPACE for COPD. These were the only technologies for which 1) at least one of the exercise capacity measures was reported and 2) the calculation of cost per participant was feasible (as the outcomes reported were per participant)

More detail can be found on page 72 in section 11.2.3 of the EAR

Model, inputs and assumptions

The model was a simple decision tree comparing digitally supported pulmonary rehabilitation to face-to face pulmonary rehabilitation

Exploratory cost-effectiveness analysis (2)

Analysis by the EAG comparing digitally supported pulmonary rehabilitation for each technology to face to face pulmonary rehabilitation using the UK National audit data is described here

For analysis by the EAG comparing digitally supported pulmonary rehabilitation to the respective control arms from each technology's relevant study, see section 11.2.3 from page 72 in the EAR

Model, inputs and assumptions

The perspective, time horizon and the source of unit costs were the same as that of the CCA

Cost-effectiveness was expressed as cost per change in functional exercise capacity, as it was one of the outcomes that was reported consistently across digital technology studies

A cost-utility analysis describing incremental costs per QALY, as is normally seen in health technology assessment, was not possible due to a lack of quality-of-life data. Therefore, for this exploratory evaluation the EAG used changes in functional exercise capacity to demonstrate a direction of clinical effect and comparison of cost

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Exploratory cost-effectiveness analysis (3)

Table of model inputs

	Annual per participant costs (£)	Uptake, %	Completion, %	Per participant effects (measured as change in functional exercise capacity)		
				Absolute mean change from baseline (6MWD or ISWD in metres)	% change from baseline	Change from baseline measured as MCID units
Digitally supported pulmonary rehabilitation technologies (considering license fee, staff time and training costs)						
Clinitouch	[redacted] £170.55[b]	10%	[redacted]	[redacted]	[redacted]	[redacted]
myCOPD	[redacted]	yr1 10% yr2 20%	62%	44.9[c]	12%	0.831
Rehab Guru	£177	10%	68%	45[c]	18%	0.833
SPACE for COPD	£223.05	10%	47%	45[d]	15%	0.947
Face-to-face pulmonary rehabilitation						
F2F PR – 6MWD based on UK COPD PR audit (without exacerbation costs)	£432	85%	71%	59	22%	1.092
F2F PR – ISWD based on UK COPD PR audit (without exacerbation costs)				63.4	31%	1.320

For more detail on sources and model inputs for the technology specific control arm data see table 12 on page 74 of the EAR

Exploratory cost-effectiveness analysis (4)

Key assumptions:

- Reported exercise capacity outcomes were assumed to be for participants who completed the full digital or face-to-face pulmonary rehabilitation course
- Incremental shuttle walk test effects for SPACE for COPD were assumed to be the same as that of the face-to-face arm of the UK COPD pulmonary rehabilitation audit, as Chaplin et al. 2017. only reported the baseline data for the control arm
- The healthcare professional costs from Staffordshire Clinitouch study were assumed to be the same for all included technologies
- Where licensing costs were provided per clinician (for instance, for SPACE for COPD), to enable the calculation of per participant costs, 30 patients per clinician was assumed based on clinical opinion to EAG
- Uptake of digitally supported pulmonary rehabilitation was assumed to be equal across all technologies at 10%
- The costs for face-to-face pulmonary rehabilitation were based on the COPD PRIME tool have been considered. This was following clinical advice to the EAG. Alternative costs based on other sources were explored in scenario analyses

See section 11.2.3.1 on page 76 of the EAR report for further assumptions. Assumptions related to within trial comparisons in the CEA have not been described here

See table 13 on page 77 of the EAR report for more details of alternative sources for costs of face-to-face pulmonary rehabilitation

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Exploratory cost-effectiveness analysis (5) – detailed results

The base case analysis from the EAG comparing digitally supported pulmonary rehabilitation vs face-to-face pulmonary rehabilitation, using cost per change in MCID:

- indicated that Clinitouch, myCOPD, SPACE for COPD and Rehab Guru were **cost-saving** but **less effective** than face-to-face pulmonary rehabilitation
- Some of the technologies did not reach the level of an improvement of clinical significance, indicated by red text in effect column (green text indicates an improvement greater than MCID)
- The cost per unit change in MCID is for illustrative purposes only to demonstrate costs for different levels of performance between technologies from a health service perspective

	Costs (per annum per participant)	Effect (change in MCID units)	Digital vs F2F PR		
			Incremental costs	Incremental effect	Cost per unit ΔMCID
Clinitouch	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
F2F PR	£259.58	1.093	-	-	-
myCOPD	[redacted]	0.831	[redacted]	-0.261	[redacted]
F2F PR	£259.58	1.093	-	-	-
SPACE for COPD	£10.02	0.947	-£250	-0.387	£645
F2F PR	£259.58	1.334	-	-	-
Rehab Guru	£12.00	0.833	-£248	-0.259	£954
F2F PR	£259.58	1.093	-	-	-

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Exploratory cost-effectiveness analysis (6)

Sensitivity analyses

One-way sensitivity analyses were conducted by the EAG varying:

- the size of the improvement following digitally supported pulmonary rehabilitation
- uptake rates

The EAG found that when the improvement in walking distance was about equal to that of the UK National audit data the technologies became cost-saving and more effective. When performance was under this threshold the technologies were cost-saving but less effective

The EAG found that savings generated by myCOPD were sensitive to uptake rate particularly with uptake rates being below 15%. The highest sensitivity was observed when the uptake rate was changed to 2.5% from 5%, which reduced the cost savings from [redacted] to [redacted]

A two-way sensitivity analysis was conducted varying:

- Change in walking distance (effect) and per participant cost of the digital technologies (cost)

Results of the two-way sensitivity analysis indicated that, except for myCOPD, the results were similar to the one-way sensitivity analyses for all digital technologies. For myCOPD the difference was still driven by its uptake rate linked pricing model

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Exploratory cost-effectiveness analysis (7)

Scenario analyses

The EAG conducted the following scenario analyses:

- evaluating alternative outcomes used for measuring the effect of treatment, using incremental shuttle walk test data from Bourne et al 2022 (for SPACE for COPD). This increased the cost per change of walking distance by 59%
- using an alternative MCID cut-off for 6MWT, based on the Clinitouch Staffordshire study. This increased the cost per change in walking distance measured as MCID units by 80%
- using a 5% uptake rate for myCOPD. This increased the cost per change in walking distance by 43%, which aligns with the similar findings from the one-way sensitivity analysis
- impact of alternative per participant costs (derived from per clinician costs) and an uptake rate aligned with other technologies, for Clinitouch, did not seem to have an influential impact on the results

For more detail on sensitivity and scenario analyses see section 11.2.3.3 on page 80 of the EAR

EAG interpretation and conclusions (1)

Disaggregated CCA

The disaggregated CCA using walking distance as an outcome indicated that though Clinitouch, myCOPD, SPACE for COPD and Rehab Guru were slightly less effective compared to face-to-face pulmonary rehabilitation, they could offer potential cost savings due to reduced healthcare professional time.

It was not possible to include Active+me REMOTE, Kaia COPD and Wellinks, as there were no walking distance outcome data available for these technologies. The EAG noted that the annual per participant cost of Active+me REMOTE was comparable to other technologies and indicated potential cost savings compared to face-to-face pulmonary rehabilitation, when compared solely based on costs. For Kaia Health and Wellinks, however, the costs of the technologies were not available to derive any inference.

EAG highlighted that there was high heterogeneity about how the different components were costed. Although the EAG calculated the total costs of the technologies per participant considering as many components as possible, such as the license fee, training costs and healthcare staff time, the underlying heterogeneity might still impact the cost savings indicated.

EAG interpretation and conclusions (2)

Exploratory CEA

Clinitouch, myCOPD, SPACE for COPD: when the UK COPD pulmonary rehabilitation audit data was used for face-to-face pulmonary rehabilitation, all four of the digital technologies considered were found to be cost saving and less effective than face-to-face pulmonary rehabilitation

Economic evaluation: uncertainty and applicability of results

Results from the exploratory economic evaluation by the EAG for illustrative purposes to indicate direction of effect and not represent true value for money in the NHS (applicability) and have a degree of uncertainty in the results themselves

Factors affecting uncertainty

- None of the studies that the results were taken from were statistically powered for the outcome measures in question
- The national UK Audit data only included those who completed their course pulmonary rehabilitation
- None of the data sets for the technologies have been compared statistically to the data from the national audit data. Statistical testing may reveal that there is no statistical difference between the two sets of data. This is despite initial indications that digital technologies may not perform as well clinically as face-to-face pulmonary rehabilitation

Economic considerations

- Direction of the cost-consequence analysis was that digital technologies were likely cheaper than:
    - Face to face pulmonary rehab with and without exacerbations
    - Waitlist for pulmonary rehabilitation with and without exacerbations
    - No treatment with and without exacerbations
- Exploratory cost-effective analysis indicated that digital technologies were likely to be less effective, but cheaper, than face to face pulmonary rehabilitation
- Results of both the CCA and CEA are for illustrative purposes only and the results are limited by uncertainty and applicability
- Traditional CEA was not possible due to a lack of quality-of-life data, this is why the EAG used a measure of exercise capacity for exploratory purposes to demonstrate a direction of effect

CCA: cost-consequence analysis, CEA: cost-effectiveness analysis

Implementation challenges reported by EAG

- Acquisition of technology and relevant licences
- Data security
- Staff attitude to and awareness of digitally supported therapies
- Staff training requirements including cost and time implications
- Inertia and changing established treatment pathways
- Waiting lists
- Patient preferences, digital literacy, and digital access
- Additional support for those with additional needs or limited access to digital devices

Gap analysis (1)

- No published full-text evidence in people with COPD for Active+me REMOTE, Clinitouch or Rehab Guru
- Most studies were conducted in UK but were not UK-wide and generally focused on urban areas. No sub-group analyses of rural vs urban dwelling
- Usual care as a comparator may differ between countries and also between NHS trusts, may not always be face-to-face pulmonary rehabilitation as recommended by guidelines
- Control arms did not always represent gold standard face to face pulmonary rehabilitation

Gap analysis (2)

- No evidence comparing any of the included technologies against each other
- Information available for health-related quality of life, adverse events and hospitalisation or exacerbation outcomes was relatively limited
- Health-related quality of life was often assessed using disease-specific measures, meaning utility values were not available for most interventions (precluding the use of cost-utility analysis)

Gap analysis (3) – summary

Green = clear evidence of effectiveness/non-inferiority from more than one study; amber = some evidence but unclear or inconsistent; red = no or negative evidence

Key outcomes	Clinitouch	Kaia COPD	myCOPD	Rehab Guru	Space for COPD	Wellinks	Active+me REMOTE
Exercise capacity measured by a validated outcome measure	[redacted]	Amber	Green	Amber	Green	Red	Red
Health-related quality of life	[redacted]	Amber	Green	Red	Green	Red	Red
Other measures of respiratory function	[redacted]	Amber	Green	Amber	Green	Amber	Red
Intervention completion	[redacted]	Amber	Green	Amber	Amber	Amber	Red
Intervention-related adverse events	[redacted]	Amber	Green	Red	Amber	Red	Red
Acute exacerbations, hospital admissions, readmissions or emergency admissions	[redacted]	Amber	Green	Red	Red	Red	Red

Key considerations for committee

- Unmet need in the NHS with only 13% of those eligible being offered pulmonary rehabilitation
- Evaluation of early evidence base indicates digitally supported pulmonary rehabilitation is either on par or slightly less effective than face-to-face pulmonary rehabilitation, but may also be cost saving
- Does evidence suggest a potential benefit for the use of digitally supported pulmonary rehabilitation as an option in addition to standard of care for people with COPD who are eligible for pulmonary rehabilitation?

Possible recommendations

Conditionally recommended for use while further evidence is generated

- Likely that the technology will solve the unmet need and it is acceptable for the technology to be used in practice while further evidence is generated

Recommended only in a research context

- Uncertain if the technology has the potential to solve the unmet need, or it is not acceptable to be widely used in practice while further evidence is generated

Not recommended for use

- Unlikely that a technology has the potential to meet the unmet need, or where there are concerns about the potential harms associated with using the technology even in a research context

NICE National Institute for Health and Care Excellence

Thank you

NICE National Institute for Health and Care Excellence

National Institute for Health and Care Excellence
Early value Assessment
Digital pulmonary rehabilitation technologies for chronic obstructive pulmonary disease (Provisional Title)

Professional organisation submission

Thank you for agreeing to give us your organisation's views on this technology and its possible use in the NHS.

You can provide a unique perspective on the technology in the context of current clinical practice that is not typically available from the published literature.

To help you give your views, please use this questionnaire. You do not have to answer every question – they are prompts to guide you. The text boxes will expand as you type.

Information on completing this submission

- Please do not embed documents (such as a PDF) in a submission because this may lead to the information being mislaid or make the submission unreadable
- We are committed to meeting the requirements of copyright legislation. If you intend to include **journal articles** in your submission you must have copyright clearance for these articles. We can accept journal articles in NICE Docs.
- Your response should not be longer than 13 pages.

About you

1. Your name	Elaine Bevan-Smith
2. Name of organisation	ARNS
3. Job title or position	Pulmonary rehabilitation Lead
4. Are you (please select Yes or No):	An employee or representative of a healthcare professional organisation that represents clinicians? Yes or No A specialist in the treatment of people with this condition? Yes or No A specialist in the clinical evidence base for this condition or technology? Yes or No Other (please specify):
5a. Brief description of the organisation (including who funds it).	The Association of Respiratory Nurses (ARNS) was established in 1997 as a nursing forum to champion the specialty respiratory nursing community, promote excellence in practice, and influence respiratory health policy. ARNS also works to influence the direction of respiratory nursing care.
5b. Has the organisation received any funding from any company with a technology included in the evaluation in the last 12 months? (Please refer to the final scope for a full list of technologies included. The final scope is due to be published on 28th July 2023.) **If so, please state the name of company, amount, and purpose of funding.**	No
5c. Do you have any direct or indirect links with, or funding from, the tobacco industry?	No

The aim of treatment for this condition

6. What is the main aim of these technologies? (For example, initial diagnosis, clinical monitoring, treatment triage assessing stages of disease progression or risk stratification.)	Increase access and provision to PR, improving patient outcomes as PR evidence shows Reduction in PR costs providing less face to face PR programmes. Tech will provide more face to face classes for those that require it and either don't have digital access / devices or would prefer face to face classes
7. In your view, is there an unmet need for patients and healthcare professionals in this area?	The unmet need in this area is the digitally illiterate patient group. Frail and elderly in care homes.

What is the expected place of the technologies in current practice?

8. How is chronic obstructive pulmonary disease (COPD) currently treated in the NHS?	Patients generally have face to face pulmonary rehabilitation. There is digital technology available for self management and adjunctive support to programmes. Some centres are offering a remote version of pulmonary rehabilitation.
9a. Are any relevant clinical guidelines we should be aware of, and if so, which?	BTS/NICE pulmonary rehabilitation guidelines 2013. New BTS statement on pulmonary rehabilitation (in press)
9b. Is the pathway of care well defined? Does it vary or are there differences of opinion between professionals across the NHS? (Please state if your	During Covid when face to face pulmonary rehabilitation was not possible there was a growth in digital technology. There is a difference in opinion around remote exercise testing. Some field exercise tests conducted in the home during remote pulmonary rehabilitation do not enable precise exercise prescription so there is contention from those who claim these should not be used. However patients can self monitor their exercise intensity using the borg scale which is effective.

experience is from outside England.)	
9c. What impact would these technologies have on the current pathway of care?	Improve access to PR service in timely manner PR earlier following an acute exacerbation Reduce waiting lists Remove variation or access across boundaries Technology would increase exclusion from pulmonary rehabilitation for those digitally illiterate. It would be more inclusive for those who are not keen on groups or unable to travel to centres.
10. Will the technologies be used (or are they already used) in the same way as current care in NHS clinical practice?	There are differences in staff skills, safety and delivery.
10a. How does healthcare resource use differ between the technologies and current care?	Initially remote and digital Pulmonary rehabilitation has high set up costs but once embedded is likely similar in cost.
10b. In what clinical setting should the technologies be used? (For example, primary or secondary care, specialist clinics.)	In patients homes. Remote pulmonary rehabilitation has also been delivered in a hub and spoke type model. It would be a good option for our rural populations in terms of accessibility but then they also have poor WiFi and phone signal, which could cancel that out!
10c. What investment is needed to introduce these technologies? (For example, for facilities, equipment, or training.)	Training for staff as delivery remotely is different to in person. Digital equipment including provision of laptops / tablets for patients. Many patients are not online and this would entail investment into providing connectivity. Tech enabled devices Staff time for training and set up of devices Reconditioned device access to reduce inequalities for some service users Charity based organisation to support patients with tech enablement
11. Do you expect the technologies to provide clinically meaningful benefits compared with current care?	It has already demonstrated this. In Gloucestershire outcomes were comparable to a face to face programme. Increase access to PR
11a. Do you expect the technologies to increase	No

length of life more than current care?	
11b. Do you expect the technologie to increase health-related quality of life more than current care?	No but it adds more choice to the patient journey
12. Are there any groups of people for whom these technologies would be more or less effective (or appropriate) than the general population?	More effective: people living in remote areas. People with no transport. Less effective – for those without tech enabled devices / wifi, fear of using digital solution, lack of trust. More effective – for tech savvy individuals with confidence and motivated, those of working age unable to access PR classes during working hours

The use of the technologies

13. Will the technologies be easier or more difficult to use for patients or healthcare professionals than current care? Are there any practical implications for their use (for example, additional clinical requirements, factors affecting patient acceptability or ease of use or additional tests or monitoring needed.)	It will be easier for some and more difficult for some according to the digital skills of both groups. It is difficult to perform exercise testing in remote pulmonary rehabilitation. It may be more difficult to elicit group support during remote pulmonary rehabilitation although there is no current evidence to inform us, In digital pulmonary rehabilitation patients are unable to connect with each other and personalisation is difficult. Patients even when undertaking pulmonary rehabilitation remotely need to have at least one face to face session with the therapist to conduct any assessments face to face. Would increase the initial workload of HCPs assisting with set up of technology in the first instance. Will require staff to adopt a change in current workflow / practices. Accessibility a concern for those from; poorer economic

	background / literacy challenges / digital fear Monitoring and reporting of use vital for both patient and service outcomes. Currently remote pulmonary rehabilitation can only be used as an adjunct to face to face delivery until we have better research to underpin it.
15. Do you consider that use of the technologies will result in any substantial health-related benefits that are unlikely to be included in the quality-adjusted life year (QALY) calculation?	No
16a. Do you consider the technologies to be innovative in its potential to make a significant and substantial impact on health-related benefits and how might they improve the way that current need is met?	Yes. As an adjunct to face to face pulmonary rehabilitation Yes will make a difference and reduce the post code lottery of access to PR
16b. Does the use of the technologies address any particular unmet need of the patient population?	Those who are isolated, housebound or live inrural areas.
17. Are there any side effects or adverse effects associated with the technologies and how do	Loneliness. Isolation Fear of using digital solutions. May be more isolating, particularly for those already isolated

they affect the patient's quality of life?	

Sources of evidence

18. Are you aware of any relevant data that might not be found by a systematic review of the evidence?	No
19. How do data on real-world experience compare with the available data?	Many patients have had life changing benefits from remote pulmonary rehabilitation which is not reflected in the current body of knowledge.

Equality

20. Are there any potential equality issues that should be taken into account when considering this treatment?	Digital literacy. Rural areas Patients in Residential settings Patients with no transport Potential age discrimination Lack of access to wifi / digitally enabled device
21. Consider whether these issues are different from issues with current care and why.	The above patients are not able to currently access pulmonary rehabilitation

Topic-specific questions

22. Are these technologies currently used in the NHS? How would they be used?	Yes many centres are offering remote and digital pulmonary rehabilitation
23. What features and technical and clinical requirements would digital pulmonary rehabilitation technologies for COPD need to be considered for use in the NHS?	As above
24. Would these technologies address a potential unmet clinical or system need?	As above
25. What do you consider the most relevant clinical and patient outcomes for evaluating digital pulmonary rehabilitation technologies for COPD?	Coping. Optimism. Self efficacy. Increased physical activity. Reduced sedentary time Increase quality of life. Reduced breathlessness reduced anxiety
26. What are the limitations of adopting digital pulmonary rehabilitation technologies for COPD in the NHS, if any?	Financial Digital illiteracy Connectivity
27. What level and type of support or training would be needed?	As above

Key messages

28. In up to 5 bullet points, please summarise the key messages of your submission.	• Digital and remote pulmonary rehabilitation can provide access to those who are isolated, housebound or in residential settings. • Digital and remote pulmonary rehabilitation can increase patient choice • Digital and remote pulmonary rehabilitation can offer more personalised care • Digital and remote pulmonary rehabilitation can exclude people who are digitally illiterate • Digital and remote pulmonary rehabilitation should not yet replace face to face groups but can be a useful adjunct.

Thank you for your time.

Please log in to your NICE Docs account to upload your completed submission.

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NICE National Institute for Health and Care Excellence

National Institute for Health and Care Excellence
Early value Assessment
Digital pulmonary rehabilitation technologies for chronic obstructive pulmonary disease (Provisional Title)

Professional organisation submission

Thank you for agreeing to give us your organisation's views on this technology and its possible use in the NHS.

You can provide a unique perspective on the technology in the context of current clinical practice that is not typically available from the published literature.

To help you give your views, please use this questionnaire. You do not have to answer every question – they are prompts to guide you. The text boxes will expand as you type.

Information on completing this submission

- Please do not embed documents (such as a PDF) in a submission because this may lead to the information being mislaid or make the submission unreadable
- We are committed to meeting the requirements of copyright legislation. If you intend to include **journal articles** in your submission you must have copyright clearance for these articles. We can accept journal articles in NICE Docs.
- Your response should not be longer than 13 pages.

About you

NICE National Institute for Health and Care Excellence

1. Your name	Enya Daynes
2. Name of organisation	British Thoracic Society
3. Job title or position	Clinical Academic Physiotherapist
4. Are you (please select Yes or No):	An employee or representative of a healthcare professional organisation that represents clinicians? Yes A specialist in the treatment of people with this condition? Yes A specialist in the clinical evidence base for this condition or technology? Yes Other (please specify):
5a. Brief description of the organisation (including who funds it).	The British Thoracic Society is a professional membership society representing health care professionals in respiratory. It is a charity with funding sources from membership fees, conferences and academic journals.
5b. Has the organisation received any funding from any company with a technology included in the evaluation in the last 12 months? (Please refer to the final scope for a full list of technologies included. The final scope is due to be published on 28th July 2023.) **If so, please state the name of company, amount, and purpose of funding.**	No
5c. Do you have any direct or indirect links with, or funding from, the tobacco industry?	No

The aim of treatment for this condition

6. What is the main aim of these technologies? (For example, initial diagnosis, clinical monitoring, treatment triage assessing stages of disease progression or risk stratification.)	The main aim of these technologies is improve uptake and access to pulmonary rehabilitation for those with chronic lung disease to meet the ambitions of the NHS Long Term Plan. Despite the strong evidence base for pulmonary rehabilitation there is a large disparity between the number of patients who are eligible for, who are referred for, and who go on to complete a course.
7. In your view, is there an unmet need for patients and healthcare professionals in this area?	Pulmonary rehabilitation is currently facing challenges in relation to workforce and delivery of the intervention. There are workforce shortages of suitable skilled staff, resulting in limited capacity and availability of pulmonary rehabilitation programmes mean that not all eligible patients are able to access programmes. There has also been a shortage of space to deliver rehabilitation, which has been hugely impacted by the pandemic. As a result there is a reduced access to rehabilitation, and patients have to travel further for this key intervention.

What is the expected place of the technologies in current practice?

8. How is chronic obstructive pulmonary disease (COPD) currently treated in the NHS?	A multidisciplinary approach is taken to the management of patients with COPD, involving both pharmacological and non-pharmacological interventions. Non-pharmacological interventions such as pulmonary rehabilitation have been shown to be more effective at improving quality of life and exercise capacity than inhalers. Pulmonary rehabilitation is the cornerstone of treatment in patients with COPD who are functionally limited by their symptoms. Currently pulmonary rehabilitation should be offered to patients as part of any routine review of their COPD (MRC 2-5) and also those hospitalised with an exacerbation of COPD as part of a COPD discharge bundle. Pulmonary rehabilitation is delivered by a multidisciplinary team comprised of exercise, education and self-management strategies.
9a. Are any relevant clinical guidelines we should be aware of, and if so, which?	NICE guideline for the management of COPD British Thoracic Society Quality Standards for pulmonary rehabilitation in adults British Thoracic Society Guideline on pulmonary rehabilitation in adults: accredited by NICE British Thoracic Society Clinical Statement (in progress- due to be published September 2023)

	American Thoracic Society workshop report on the key components of Pulmonary Rehabilitation.
9b. Is the pathway of care well defined? Does it vary or are there differences of opinion between professionals across the NHS? (Please state if your experience is from outside England.)	The pathway for referral to pulmonary rehabilitation is well defined with referral criteria for patients with stable COPD (MRC 2-5) and national quality improvement indicators around time from referral to enrolment on a programme and completion rates. Patients should be seen within 90days of referral if stable at the time of referral, or 30 days following hospitalisation of an acute exacerbation of COPD. Pulmonary Rehabilitation programmes are encouraged to participate in the National respiratory Audit Programme. There may be local variations in duration of programmes but are approximately 6-8 weeks (twice per week), acceptance of post exacerbations patients, delivery methods offered (e.g. inclusion of virtual offering). Digital apps are not routinely used and funding for these not established. If digital options are offered within the service the pathway remains the same.
9c. What impact would these technologies have on the current pathway of care?	The COVID 19 pandemic has exacerbated waiting lists for pulmonary rehabilitation when services suspended face to face programmes or redeployed staff. The pandemic also highlighted the potential for technology in pulmonary rehabilitation delivery including digital applications and virtual delivery. A menu of choice in pulmonary rehabilitation has also been suggested to increase uptake in hard to reach groups, those unable to access a directly supervised programme such as those with transport issues, caring or work commitments, those who drop out. Introduction of digital technologies could increase access to this gold standard treatment, reduce barriers in attending pulmonary rehabilitation and may have environmental impact by reducing travel for patients. Currently there is a huge variation in the offer of rehabilitation methods depending on location, and therefore it would be beneficial to ensure availability across regions.
10. Will the technologies be used (or are they already used) in the same way as current care in NHS clinical practice?	Digital technologies are used with a great degree of variability and with varying success, though some technologies have been available for a long period of time. There evidence base is limited to support digital pulmonary rehabilitation models. Some studies have demonstrated equitable benefit but note a reduced uptake to this intervention; however this would be suitable option for a small group of people. It is important to establish the benefits of these interventions and identify who would benefit before the scope of pulmonary rehabilitation is extended to include such alternative models. Most importantly the safety of delivered exercise remotely an unsupervised must be considered. Pulmonary rehabilitation is an individualised programme and how this can be delivered by a digital tool, and exercise incrementally tailored must be considered so that outcomes are not diminished. It is important that the face to face assessment for pulmonary rehabilitation is not lost.
10a. How does healthcare resource use differ	There is a significant concern that the COPD population includes those who are often older, and digital apps whilst complementary and offer an alternative model, may be poorly understood by such populations who may be digital excluded. In order to ensure that patients are not digitally excluded extra health resource may need to

between the technologies and current care?	be considered for staff to support these models or to provide the necessary equipment. The offer of digital technologies is currently very variable and with varying success in uptake and completion.
10b. In what clinical setting should the technologies be used? (For example, primary or secondary care, specialist clinics.)	These technologies should only be used by those with experience in delivering pulmonary rehabilitation so that safety can be ensured, and assessments made prior to the prescription of exercise. They should also only be used where the diagnosis of COPD is confirmed and not in doubt. Pulmonary Rehabilitation is often delivered in secondary care and community hospitals.
10c. What investment is needed to introduce these technologies? (For example, for facilities, equipment, or training.)	If there is a role for these technologies funding into infrastructure for implementation of digital programmes should be provided (computers, devices for patients where needed, funding for apps), including appropriate training for staff, training equipment for patients to use in homes where necessary. Guidance on safety of implementation of these measures should also be provided.
11. Do you expect the technologies to provide clinically meaningful benefits compared with current care?	Studies are limited and data heterogenous, and at present the evidence base supports centre based face to face pulmonary rehabilitation. Equivalence has been demonstrated in clinical trials but generally usual care (face to face) is sub-standard in these trials. Digital technologies may however as discussed above provide alternatives for those who are unable to access traditional programmes and therefore there is an opportunity to utilise digital technologies to enhance clinical care.
11a. Do you expect the technologies to increase length of life more than current care?	No. However potentially could be similar if digital tool designed appropriately and proven in robust trials of equivalence
11b. Do you expect the technologies to increase health-related quality of life more than current care?	No. However potentially could be similar if digital tool designed appropriately and proven in robust trials of equivalence
12. Are there any groups of people for whom these technologies would be more or less effective (or appropriate) than the general population?	It is important to pay consideration to digital literacy and digital hesitancy. These technologies have the potential to increase health inequalities through digital exclusion, in particular for those with low socioeconomic status and/or language barriers to the intervention. It may also be inappropriate in the frail population if safety for home/ unsupervised.

The use of the technologies

13. Will the technologies be easier or more difficult to use for patients or healthcare professionals than current care? Are there any practical implications for their use (for example, additional clinical requirements, and factors affecting patient acceptability or ease of use or additional tests or monitoring needed.)	Healthcare professionals will need training to use digital tools. Some patients may be digitally excluded due to lack of internet, smart devices, and confidence to use, which will be increased in those from a low socioeconomic area. Lack of supervision may mean safety is a concern in often multimorbid populations. The lack of ability to provide individualised and tailored programmes via apps may mean outcomes are less good, and therefore a face to face assessment would be required. In may be cumbersome for pulmonary rehabilitation programmes to offer many options. Unsure if apps allow clinicians to provide feedback and encouragement. For some patients digital technologies may alleviate a barrier in attending pulmonary rehabilitation, particularly if they live in rural areas or areas where pulmonary rehabilitation provision is limited due to availability of venues to deliver pulmonary rehabilitation. It is crucial that digital options still maintain the standard of pulmonary rehabilitation and meet the guidelines/ accreditation standards.
15. Do you consider that use of the technologies will result in any substantial health-related benefits that are unlikely to be included in the quality-adjusted life year (QALY) calculation?	Digital technologies allow patients to exercise in their own environment which may lead to behaviour change and increased self-efficacy, owing to the continuation of exercise programmes.
16a. Do you consider the technologies to be innovative in its potential to make a significant and substantial impact on health-related benefits and how might they improve the way that current need is met?	Digital technologies may increase access to pulmonary rehabilitation, especially in those of working age/ unable to attend centre based programmes.

16b. Does the use of the technologies address any particular unmet need of the patient population?	This may increase access for those unable to attend centre based programmes, particularly if of working age or from rural areas.
17. Are there any side effects or adverse effects associated with the technologies and how do they affect the patient's quality of life?	It is important to explore the safety concerns of unsupervised training, though currently the literature does not report excessive adverse events in these treatments.

Sources of evidence

18. Are you aware of any relevant data that might not be found by a systematic review of the evidence?	No
19. How do data on real-world experience compare with the available data?	Real world use of apps used during the COVID pandemic found that they were rarely accessed by individuals, and many had not completed registration. Others declined use. Currently there is a preference for face to face delivery and even many virtual programmes are being stood down. Additionally those that opt for digital technologies often appear less engaged than in the literature and less compliant, therefore yielding poorer outcomes.

Equality

20. Are there any potential equality issues that should be taken into account when considering this treatment?	Any digital tool needs to be simple to use, available in other languages, incorporate safety and monitoring. Those with sight or hearing issues may not be able to access. Difficult to adapt programmes for those with e.g. disabilities.
21. Consider whether these issues are different from issues with current care and why.	Adaptations in programmes and equipment often easier face to face. Motivation, encouragement, support may be less easy to provide though a digital platform.

Topic-specific questions

22. Are these technologies currently used in the NHS? How would they be used?	Digital apps are available but not widespread, due to weak evidence base, lack of funding, poor and limited experience in real world. They would be used as adjuncts rather than alternatives to gold standard pulmonary rehabilitation.
23. What features and technical and clinical requirements would digital pulmonary rehabilitation technologies for COPD need to be considered for use in the NHS?	• Face to face assessment in order to screen for safety and for exercise prescription • Ability to tailor programmes to the individual / prescribe exercise • Aerobic and resistance elements • Ability to monitor compliance and access to digital tool by patient • Dashboard of users with - ability to monitor compliance and access to digital tool by patient • Ability to onboard patients who do not have email addresses • Bluetooth monitoring facility for safety – e.g. wireless physiological monitoring • Ability for clinician to provide feedback or encouragement remotely • Be able to we used on all android/apple/PC devices • Simple to access and follow • Provision for the educational component of pulmonary rehabilitation programmes • Helpline for patients with issues with registering of app queries that cannot be dealt with by clinical teams
24. Would these technologies address a potential unmet clinical or system need?	Those unable to access pulmonary rehabilitation due to availability of centre-based programmes in their area, or if of working age and unable to take time off work. System wide, this may increase the capacity of pulmonary rehabilitation programmes, which are currently underfunded and understaffed, however staffing should consider the time taken to monitor patients on the digital platform(s).
25. What do you consider the most relevant clinical and patient outcomes for evaluating digital pulmonary rehabilitation technologies for COPD?	The most relevant clinical outcomes include showing meaningful improvements in exercise capacity and health related quality of life. Other important outcomes should include exacerbations, psychological status, uptake, and compliance and user feedback. Equivalence with traditional models should be investigated.

26. What are the limitations of adopting digital pulmonary rehabilitation technologies for COPD in the NHS, if any?	Digital literacy/digital hesitancy and access is a barrier for some patients. NHS IT infrastructure means it is often difficult to incorporate material from client based apps into NHS patient records. Currently there is limit data to support digital tools as an alternative pulmonary rehabilitation model in the NHS. Cost of access to these platforms, and subscription may be a barrier.
27. What level and type of support or training would be needed?	Training would need to be provided for staff in delivering the intervention and how to support staff/offer technical support for patients wanting to access this option. It may be necessary to provide equipment for accessing the digital platforms and to be able to exercise at home. Access to the internet will be an important consideration in order to not widen health inequality.

Key messages

28. In up to 5 bullet points, please summarise the key messages of your submission.	• Digital technologies may provide a suitable option for some patients and increase access to this key intervention • Face to face assessment would be required in order to maintain the standards of pulmonary rehabilitation and to assess safety • Digital exclusion may widen the health inequality/disparities for people with COPD • Evidence is required to ensure that digital technologies are equivalent to gold standard treatment and to identify patients that may benefit. • Training for staff and infrastructure support is vital for the success of digital technologies within pulmonary rehabilitation.

Thank you for your time.

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NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

130th MTAC meeting – Friday 17 November 2023

DECLARATIONS OF INTEREST – MTAC 17 November 2023

Declaration of interests register							
Medical Technologies Advisory Committee				**Publication Date: 07 February 2024**			
Topic: GID-HTE10019 Digital pulmonary rehabilitation technologies for adults with chronic obstructive pulmonary disease: early value assessment							
Name	**Role with NICE**	**Type of interest**	**Description of interest**	**Relevant dates**			**Comments**
				Interest arose	**Interest declared**	**Interest ceased**	
Claire Nolan	Specialist committee member	Non-Financial Professional and Personal Interest	Manuscript publication: Polgar, O., Patel, S., Walsh, J. A., Barker, R. E., Ingram, K. A., Kon, S. S., ... & Nolan, C. M. (2022). Digital habits of pulmonary rehabilitation service-users following the COVID-19 pandemic. *Chronic Respiratory Disease*, *19*, 14799731221075647.	2022	Nov 2023	Ongoing	No action other than open declaration
Claire Nolan	Specialist committee member	Non-Financial Professional and Personal Interest	British Thoracic Society Summer meeting invited presentation: Digital habits of pulmonary rehabilitation service-users: Opportunities and challenges	23/06/2023	Nov 2023	23/06/2023	No action other than open declaration
Claire Nolan	Specialist committee member	Non-Financial	Manuscript pending publication: British	Pending publication	Nov 2023	Ongoing	No action other than open declaration

Declaration of interests register

Medical Technologies Advisory Committee **Publication Date: 07 February 2024**

Topic: GID-HTE10019 Digital pulmonary rehabilitation technologies for adults with chronic obstructive pulmonary disease: early value assessment

Name	Role with NICE	Type of interest	Description of interest	Relevant dates			Comments
				Interest arose	Interest declared	Interest ceased	
		Professional and Personal Interest	Thoracic Society Clinical Statement on Pulmonary Rehabilitation				
Enya Daynes	Specialist committee member	Indirect Interest	Chair of the British Thoracic Society Pulmonary Rehabilitation Specialist Advisory Group	November 2022	Nov 2023	Ongoing	No action other than open declaration
Enya Daynes	Specialist committee member	Indirect Interest	American Thoracic Society Website committee member	2022	Nov 2023	Ongoing	No action other than open declaration
Nicholas Hopkinson	Specialist committee member	Non-Financial Professional and Personal Interest	Investigator in MOBILISE-D project (Horizon 2020) investigating digital mobility outcomes in people with long term health conditions. Does not involve pulmonary rehabilitation interventions.	April 2019	Nov 2023	June 2024	No action other than open declaration
Nicholas Hopkinson	Specialist committee member	Non-Financial Professional and Personal Interest	Medical Director, Asthma + Lung UK	December 2016	Nov 2023	Ongoing	No action other than open declaration
Nicholas Hopkinson	Specialist committee member	Non-Financial	Chair, Action on Smoking and Health ASH(UK)	December 2017	Nov 2023	Ongoing	No action other than open declaration

Declaration of interests register

Medical Technologies Advisory Committee **Publication Date: 07 February 2024**

Topic: GID-HTE10019 Digital pulmonary rehabilitation technologies for adults with chronic obstructive pulmonary disease: early value assessment

Name	Role with NICE	Type of interest	Description of interest	Relevant dates			Comments
				Interest arose	Interest declared	Interest ceased	
		Professional and Personal Interest					
Nicola Roberts	Specialist committee member	Non-Financial Professional and Personal Interest	Co-design of educational resources for children and young adults with asthma to manage their condition independently Funded Napier studentship (DOS Nicola Roberts, Janette Pow Alison Porter Armstrong)	2023	Nov 2023	2028	No action other than open declaration
Nicola Roberts	Specialist committee member	Non-Financial Professional and Personal Interest	Take Ten Scoping Study The Scottish Inward Investment Catalyst Fund Application Form Scottish Government (funded £10K) Alison Porter-Armstrong, Fintan Connolly, Nicola Roberts, Fiona Maclean, Cathal Breen	2022	Nov 2023	2023	No action other than open declaration
Nicola Roberts	Specialist committee member	Non-Financial Professional and	European Respiratory Society Clinical Research Collaborations (CRC) proposal: CRC-2022-02 -	2023	Nov 2023	ongoing	No action other than open declaration

Declaration of interests register

Medical Technologies Advisory Committee **Publication Date: 07 February 2024**

Topic: GID-HTE10019 Digital pulmonary rehabilitation technologies for adults with chronic obstructive pulmonary disease: early value assessment

Name	Role with NICE	Type of interest	Description of interest	Relevant dates			Comments
				Interest arose	Interest declared	Interest ceased	
		Personal Interest	Moving multiple digital innovations towards connected respiratory care: addressing the over-arching challenges of whole systems implementation (CONNECT) – collaborator (health literacy)				
Nicola Roberts	Specialist committee member	Indirect Interest	Co-chair of the pulmonary rehabilitation specialist advisor group at the British Thoracic Society	Dec 2022	Nov 2023	ongoing	No action other than open declaration
Nicola Roberts	Specialist committee member	Indirect Interest	Member of the Pulmonary rehabilitation pulmonary rehabilitation guidelines group, British Thoracic society	2022	Nov 2023	ongoing	No action other than open declaration
Nicola Roberts	Specialist committee member	Indirect Interest	Member of the Healthcare Technologies Research Group, School of Social and Health Care (Sighthill Campus), Edinburgh Napier University, Edinburgh	2022	Nov 2023	ongoing	No action other than open declaration
William Man	Specialist committee member	Financial Interest	Private practice – Alongside my NHS	1st April 2009	Nov 2023	Ongoing	No action other than open declaration

Declaration of interests register							
Medical Technologies Advisory Committee				**Publication Date: 07 February 2024**			
Topic: GID-HTE10019 Digital pulmonary rehabilitation technologies for adults with chronic obstructive pulmonary disease: early value assessment							
Name	**Role with NICE**	**Type of interest**	**Description of interest**	**Relevant dates**			**Comments**
				Interest arose	**Interest declared**	**Interest ceased**	
			consultant role, I deliver private outpatient respiratory services. As part of these services, I might recommend referral to pulmonary rehabilitation as part of an overall management plan. However I do not directly deliver pulmonary rehabilitation nor have any financial interest in any organization that delivers private pulmonary rehabilitation.				
William Man	Specialist committee member	Non-Financial Professional and Personal Interest	Honorary President for the Association for Respiratory Technology and Physiology (ARTP) – this is a 2 year term which will terminate in March 2024. The ARTP's interests are principally in the field of lung function and sleep services including the use of technology. The ARTP does not have pulmonary	1st May 2022	Nov 2023	Ongoing	No action other than open declaration

Declaration of interests register							
Medical Technologies Advisory Committee				**Publication Date: 07 February 2024**			
Topic: GID-HTE10019 Digital pulmonary rehabilitation technologies for adults with chronic obstructive pulmonary disease: early value assessment							
Name	**Role with NICE**	**Type of interest**	**Description of interest**	**Relevant dates**			**Comments**
				Interest arose	**Interest declared**	**Interest ceased**	
			rehabilitation This post is not renumerated.				
William Man	Specialist committee member	Non-Financial Professional and Personal Interest	Co-Chair, British Thoracic Society Clinical Statement on Pulmonary Rehabilitation. I am the co-chair of a committee that will be publishing the BTS Clinical Statement on Pulmonary Rehabilitation. This is expected in Q3 of 2023-2024. The statement will include a section on alternative methods of delivering pulmonary rehabilitation including digital pulmonary rehabilitation technologies. This post is not renumerated.	1st April 2022	Nov 2023	Ongoing	No action other than open declaration
William Man	Specialist committee member	Non-Financial Professional and Personal Interest	Research interests – I am widely published in pulmonary rehabilitation, although not specifically on digital pulmonary rehabilitation delivery. I have co-authored two publications which	January 2000	Nov 2023	Ongoing	No action other than open declaration

Declaration of interests register							
Medical Technologies Advisory Committee				**Publication Date: 07 February 2024**			
Topic: GID-HTE10019 Digital pulmonary rehabilitation technologies for adults with chronic obstructive pulmonary disease: early value assessment							
Name	**Role with NICE**	**Type of interest**	**Description of interest**	**Relevant dates**			**Comments**
				Interest arose	**Interest declared**	**Interest ceased**	
			documents the digital literacy of people referred for pulmonary rehabilitation.				
William Man	Specialist committee member	Non-Financial Professional and Personal Interest	I am a co-applicant on a SBRI grant awarded to a commercial company, Aseptika, that produces an app that supports digital delivery of pulmonary rehabilitation. I have no financial interests in Aseptika and received no payments from this company. My organisation has received research funding through this grant in order to employ research staff to manage the independent evaluation of the app.	1st December 2022	Nov 2023	Ongoing	No action other than open declaration
William Man	Specialist committee member	Non-Financial Professional and Personal Interest	I will be taking up the post of Secretary, Group 1.02 Chronic care and rehabilitation of the European Respiratory Society. This group organises sessions at the	10th September 2023	Nov 2023	Ongoing	No action other than open declaration

Declaration of interests register

Medical Technologies Advisory Committee **Publication Date: 07 February 2024**

Topic: GID-HTE10019 Digital pulmonary rehabilitation technologies for adults with chronic obstructive pulmonary disease: early value assessment

Name	Role with NICE	Type of interest	Description of interest	Relevant dates			Comments
				Interest arose	Interest declared	Interest ceased	
			European Respiratory Society congress, some of which may include pulmonary rehabilitation.				
William Man	Specialist committee member	Indirect Interest	Nothing to Declare	n/a	n/a	n/a	No action
Alan Thomas	Lay Specialist Committee Member	n/a	Nothing to Declare	n/a	n/a	n/a	No action
Tessa Jelen	Lay Specialist Committee Member	Non-Financial Professional and Personal Interest	*Volunteer Lead for Breathe Easy Westminster support group. Interest in improving self management facilities for those with respiratory conditions*	*2023*	*November 2023*	*Ongoing*	No action
Neil Hawkins	MTAC member	Non-Financial Professional & Personal Interests	*I am a director of a consultancy company providing HTA consultancy services to biomedical and pharmaceutical companies. No services have been provided to any stakeholders associated with these appraisals.*	*N/A*	*October 2023*	*ongoing*	No action other than open declaration