NICE National Institute for Health and Care Excellence

NICE guidance

Digital technologies to deliver pulmonary rehabilitation programmes for adults with COPD: early value assessment

Health technology evaluation
Published: 30 April 2024

www.nice.org.uk/guidance/hte18

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

1 Recommendations

Can be used in the NHS while more evidence is generated

1.1 myCOPD can be used in the NHS while more evidence is generated, to deliver pulmonary rehabilitation programmes for adults with chronic obstructive pulmonary disease (COPD) who cannot have or do not want face-to-face pulmonary rehabilitation.

1.2 The company (my mhealth) must confirm that agreements are in place to generate the evidence (as outlined in NICE's evidence generation plan) and contact NICE annually to confirm that evidence is being generated and analysed as planned. NICE may withdraw the guidance if these conditions are not met.

1.3 At the end of the evidence generation period (3 years), the company should submit the evidence to NICE in a form that can be used for decision making. NICE will review the evidence and assess if the technology can be routinely adopted in the NHS.

Can only be used in research

1.4 More research is needed on 5 digital technologies to deliver pulmonary rehabilitation programmes for adults with COPD who cannot have or do not want face-to-face pulmonary rehabilitation. The technologies are:

- Active+me REMOTE
- Clinitouch
- Kaia Health COPD
- Rehab Guru, and
- Wellinks.

1.5 Access to the technologies in section 1.4 should be through company, research, or non-core NHS funding, and clinical and financial risks should be appropriately managed.

Evidence generation and more research

1.6 Evidence generation and more research is needed:

- on how well the digital technologies work compared with:
  - pulmonary rehabilitation following the British Thoracic Society's guideline on face-to-face pulmonary rehabilitation programmes (PDF)
  - not having or waiting to have a face-to-face programme
- measuring the following outcomes:
  - health-related quality of life and exercise capacity (using validated measures)
  - resource use, including technology costs, exacerbation-related costs, and implementation costs
  - uptake rates
  - intervention adherence rates
  - intervention completion rates
  - patient preference and experience
  - adverse events
  - exacerbation rate
  - hospitalisation from exacerbation
  - long-term effect up to 12 months
- on where the technologies will be used in the care pathway

- reporting outcomes in the following subgroups:
  - people living in urban areas compared with people living in rural areas
  - people with a new COPD diagnosis compared with those with an existing diagnosis
  - people who depend on supplemental oxygen to manage COPD
  - people recently discharged from hospital after an exacerbation.

    The evidence generation plan gives further information on the prioritised evidence gaps and outcomes, ongoing studies and potential real-world data sources for myCOPD. It includes how the evidence gaps (see section 3.19) could be resolved through real-world evidence studies.

    For more detail on the committee's considerations about the evidence gaps for the technologies in 1.4, see sections 3.9 and 3.10 and sections 3.19 to 3.22.

Potential benefits of use in the NHS with evidence generation

- **Access:** There is a gap in service provision for pulmonary rehabilitation (see NHS England's Quality and Outcomes Framework, 2022-23). A digital technology to deliver pulmonary rehabilitation may help people who may not be able to access face-to-face sessions. For example, when there is no face-to-face pulmonary rehabilitation programme available, for people living in rural areas where there may be limited or no face-to-face sessions, for people unable to travel because of how severe their COPD is, and for people who cannot or do not want to take time off work. A digital technology will not replace face-to-face pulmonary rehabilitation in the care pathway.
- **Clinical benefit:** Clinical evidence suggests that myCOPD may improve exercise capacity and symptoms of COPD. There are no particular safety concerns with using a digital technology to deliver pulmonary rehabilitation. The technology may address an unmet need for people with COPD who are eligible for pulmonary rehabilitation but who are not offered it.
- **Resources:** A digital technology to deliver pulmonary rehabilitation could be cheaper to provide than face-to-face sessions. This is when comparing the licence costs of the technology plus staff time with the staff time for delivery of face-to-face pulmonary rehabilitation. But this is uncertain because the training and implementation costs are not known.
- **Equality:** COPD is most common in people over 50 years old. Men tend to be at higher risk of developing COPD than women. There is a higher prevalence of respiratory diseases in people with lower socioeconomic status. This is because of the effect of living in deprived areas and higher rates of smoking. Also, people living in deprived areas have a lower life expectancy than the general population. COPD is responsible for 8% of life expectancy difference in men and for 12% of this difference in women. Widening access to pulmonary rehabilitation with alternatives to face-to-face treatment for COPD may help address some of this inequality.

Managing the risk of use in the NHS with evidence generation

- **Costs:** There may be costs associated with implementation, staff training,

integration with NHS systems such as EMIS, and providing smart devices that need an internet connection.

- **Equality:** Support and resources may be needed for people:
  - unfamiliar with digital technologies
  - without access to smart devices or the internet
  - with visual, hearing, or cognitive impairment, problems with manual dexterity or a learning disability
  - with a mental health condition
  - with a lower reading ability (including people unable to read English)
  - experiencing homelessness
  - living in a multiple occupancy household
  - having residential care
  - with cultural, ethnic or religious backgrounds that may affect whether they do pulmonary rehabilitation, for example, some people may not want to attend a mixed-sex exercise class.

2 The technologies

2.1 Digital technologies to deliver pulmonary rehabilitation for chronic obstructive pulmonary disease (COPD) provide parts of face-to-face pulmonary rehabilitation. Pulmonary rehabilitation programmes should last at least 6 weeks and include an in-person assessment before starting and after completion, physical training, disease education, and nutritional, psychological and behavioural interventions. These technologies include at least 1 component of pulmonary rehabilitation:

- physical training
- education about the condition
- nutritional, psychological or behavioural interventions.

Technologies that replace the before-and-after in-person assessment, or are tele-rehab alone ('live' pulmonary rehabilitation delivered through a mobile phone, tablet or desktop with webcam), were not included in this early value assessment (EVA).

2.2 There were 7 technologies identified for this EVA. The technologies have different features but all provide an exercise intervention. SPACE for COPD is awaiting appropriate regulatory approval so is not included in the recommendations for use section at this time.

Active+me REMOTE

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

or desktop computer.

Clinitouch

2.4 Clinitouch (Spirit Health) is an online platform that delivers a 6-week digital pulmonary rehabilitation programme and supports remote monitoring of COPD and other conditions in adults. The digital pulmonary rehabilitation programme can be accessed with a mobile phone, tablet or desktop computer. 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

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

myCOPD

2.6 myCOPD (my mhealth) is an online education, self-management, symptom reporting and pulmonary rehabilitation system. The myCOPD app includes a 6-week pulmonary rehabilitation course. This consists of an incremental exercise programme with education sessions to help with 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 with a mobile phone or tablet.

Rehab Guru

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

SPACE for COPD

2.8 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 medicine, breathing control and 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 with a mobile phone, tablet or desktop computer.

Wellinks

2.9 Wellinks (Wellinks) is an online platform that delivers a digital pulmonary rehabilitation programme and supports remote monitoring of COPD in adults. The programme includes tailored exercises, education, and motivational support. It also collects patient-generated data through an add-on pulse oximeter and spirometer. Wellinks can be accessed with a mobile phone or tablet.

Care pathway

2.10 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, and many people do not realise they have it. Breathing problems had with COPD tend to get worse over time and can limit a person's ability to do daily activities. Treatment can help keep the condition under control and includes stopping smoking, using inhalers and tablets, pulmonary rehabilitation, and surgery.

2.11 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. 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 third 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.

2.12 NICE's guideline on 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 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).

2.13 NHS's England's policy on pulmonary rehabilitation suggests that 90% of people who complete a face-to-face pulmonary rehabilitation programme have increased exercise capacity and improved quality of life. But there is a gap in service provision for offering pulmonary rehabilitation to people who are eligible for it (see NHS England's Quality and Outcomes Framework, 2022-23).

2.14 Digital technologies to deliver pulmonary rehabilitation programmes would be offered as an option to adults with COPD who are eligible for a pulmonary rehabilitation course but cannot, or do not want to, attend face-to-face sessions. They would not replace face-to-face pulmonary rehabilitation programmes.

The comparator

2.15 The comparators for this EVA were face-to-face pulmonary rehabilitation and no treatment or waitlist to have face-to-face pulmonary rehabilitation. Pulmonary rehabilitation is defined in NICE's guideline on the diagnosis and management of COPD in over 16s (2019) as a multidisciplinary programme of care for people with chronic respiratory impairment. It should be tailored for the person, in line with their physical and social needs and capacity, and follow the British Thoracic Society's 2023 clinical statement on pulmonary rehabilitation.

3 Committee discussion

NICE's medical technologies advisory committee considered evidence on digital technologies to deliver pulmonary rehabilitation programmes for people with chronic obstructive pulmonary disease (COPD) from several sources, including an early value assessment (EVA) report by the external assessment group (EAG), and an overview of that report. Full details are in the project documents for this guidance on the NICE website.

Unmet need

3.1 The 2015 National COPD Audit Programme report suggested an unmet need in the provision of face-to-face rehabilitation. The clinical experts explained that this was despite face-to-face pulmonary rehabilitation being recommended by NICE and the British Thoracic Society. The clinical experts explained that digitally supported pulmonary rehabilitation would help people who cannot, or do not want to, access face-to-face pulmonary rehabilitation. The committee defined the group of people who this guidance will apply to as those who cannot have or do not want face-to-face pulmonary rehabilitation.

Implementation

3.2 The committee considered information governance and NHS England's Digital Technology Assessment Criteria (DTAC) compliance. The companies and technology developer explained that the technologies were all compliant with GDPR. Some of the technologies that can only be used in research were not yet DTAC compliant, but the companies without DTAC approval were working towards this.

3.3 The clinical experts explained that barriers to implementation would include:

- digital literacy
- language and cultural considerations
- social and environmental factors

- staff training needed to deliver digital pulmonary rehabilitation
- additional resources needed, and
- usability of the technologies.

The clinical experts also explained that an additional barrier to implementation of these technologies is ensuring that people who are offered them adhere to the programme. They explained that monitoring COPD remotely takes significant time and resource.

Patient considerations

3.4 The patient experts explained that while improved exercise capacity is one of the key outcomes, the effect of pulmonary rehabilitation on people with COPD was far-reaching and holistic. They thought that any interventions that deliver potential benefits to people with COPD should be available. One explained based on their own experience without digital technologies they would not have been able to participate in pulmonary rehabilitation because of their dependence on supplemental oxygen. The other explained that participating in pulmonary rehabilitation provides a means of social support. They explained that digital technologies should not exclude the 'human touch' of the camaraderie and social aspect of pulmonary rehabilitation. A charity also emphasised the importance of the social aspect. They highlighted the social benefits of pulmonary rehabilitation, such as people learning about their condition, being able to meet others going through something similar, and sharing their experiences. These social aspects need to be considered when using digital technologies to deliver pulmonary rehabilitation.

3.5 Both patient experts acknowledged the constraints on capacity to deliver face-to-face pulmonary rehabilitation, and that these technologies could be useful in addressing this. An example was to provide pulmonary rehabilitation for people who were on a waiting list to start another course of pulmonary rehabilitation after completing a face-to-face programme.

3.6 Regarding exercise capacity measures, a patient expert questioned if using

validated measures such as the 6-minute walk test was appropriate for people with advanced COPD. But there was no consensus on an alternative measure that was more appropriate for these people.

Benefits of the technologies

3.7 The committee discussed the potential of digital technologies to increase access to pulmonary rehabilitation and to address the unmet need of people who are eligible for face-to-face rehabilitation but are not offered it or cannot have it. Clinical experts explained that digital technologies to deliver pulmonary rehabilitation programmes should be used to overcome barriers to participation, and not to deal with backlogs for face-to-face services. This is in line with the British Thoracic Society's 2023 clinical statement on pulmonary rehabilitation, which stated that face-to-face pulmonary rehabilitation is the preferred treatment option for people with COPD. The committee agreed that digital technologies for pulmonary rehabilitation provide another option for people with COPD, but they will not replace face-to-face pulmonary rehabilitation in the care pathway.

3.8 For SPACE for COPD, the committee was aware that this technology is being developed into a new programme that offers both pulmonary and cardiac rehabilitation. When reviewing the guidance, the committee will revisit its recommendation and assess any new evidence on the new programme.

Clinical effectiveness

Evidence from research studies

3.9 The evidence was not evenly distributed across the technologies and clinical outcomes. There were 11 studies across the 7 technologies. myCOPD and SPACE for COPD had well-designed randomised controlled trials that reported outcomes relevant to NICE's scope. The committee noted that the evidence on these 2 technologies supports the concept of non-inferiority between digitally supported pulmonary rehabilitation and face-to-face pulmonary rehabilitation, particularly in

exercise capacity. This evidence did not raise any particular concerns about adverse events and exacerbations. Overall, this evidence showed potential clinical benefits for people who are eligible for pulmonary rehabilitation, and the potential to address an unmet need (see section 3.7). There were concerns about the generalisability of the results because some effects did not reach clinical significance, and there was potential underperformance of comparators. This could be explained by the comparator arms in some of the trials being suboptimal rather than 'gold standard' pulmonary rehabilitation. The committee concluded that myCOPD and SPACE for COPD can be used in the NHS while more evidence is generated to address these concerns.

3.10 For the other 5 technologies, evidence on effectiveness or safety was limited or lacking. The evidence for Kaia Health COPD did not align with NICE's scope because it was done outside of the UK and compared the technology with standard care (not face-to-face pulmonary rehabilitation considered as standard care in the UK). For Active+me REMOTE, Clinitouch and Wellinks, the evidence was limited in quality. For Rehab Guru, there was a lack of evidence. Given the uncertainty about the potential benefits of these 5 technologies, the committee recommended more research to understand the benefits.

Comparison with national audit data

3.11 For walking distance, the trial data suggested that digital pulmonary rehabilitation was non-inferior to face-to-face pulmonary rehabilitation. But the outcomes were compared with data from the National COPD Audit Programme, which suggested that digitally supported pulmonary rehabilitation could be on par with or less effective than face-to-face pulmonary rehabilitation. The EAG explained that this could be because of a difference between some of the 'usual care' arms of the trials and the face-to-face pulmonary rehabilitation used in the audit data. They also explained that this was an observational comparison and not statistically robust. A clinical expert explained that this comparison should not be considered definitive, because of differences in how the outcome measures are generated (only people who completed a programme are included in the National COPD Audit Programme). So, more research is needed using comparators that follow the British Thoracic Society's guideline for face-to-face pulmonary rehabilitation.

Equality considerations

3.12 There were multiple equality considerations noted by the committee. These included general and digital literacy, not speaking English or having English as a second language, age, access to equipment and internet access. The committee recognised that 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. Most of the companies stated that they were either making plans to develop or had developed their technology to be available in another language. A clinical expert explained that digital technologies could actually be an enabler for those with language difficulties because it would allow people to rewatch and reread instructions as much as they wanted to.

Costs and resource use

3.13 A cost-consequences analysis was done using data from the 2015 National COPD Audit Programme, with walking distance as the outcome. It suggested that Clinitouch, myCOPD, SPACE for COPD and Rehab Guru could offer potential cost savings caused by reduced healthcare professional time. This was despite these technologies being slightly less effective than face-to-face pulmonary rehabilitation.

3.14 An exploratory cost-effectiveness analysis using 2015 National COPD Audit Programme data as the comparator, suggested that Clinitouch, myCOPD, SPACE for COPD and Rehab Guru were found to be cost saving and less effective than face-to-face pulmonary rehabilitation, when considering walking distance as the outcome.

3.15 For Active+me REMOTE, a hybrid model (offer of usual care and provision of the app) was used. Depending on the number of in-person supervised sessions assumed, both cost-consequences and exploratory-cost effectiveness analyses indicated that this technology could either be cost saving or more costly, but slightly less effective than face-to-face pulmonary rehabilitation using 2015 National COPD Audit Programme data.

3.16 Economic analysis was not possible for Kaia Health and Wellinks because of a

lack of cost information.

3.17 The committee noted that there were differences in effectiveness when using different comparators and difference sources of data (the trial data and the UK audit data [there were differences in how the outcome measures were generated for the UK audit data]). When taking into account licence costs and healthcare professional time for delivery only, the technologies appeared cheaper to provide than face-to-face pulmonary rehabilitation. But this did not take into account other potential costs related to staff training and implementation. The EAG agreed that the difference in effectiveness was uncertain and that the health economic evaluation was for exploratory purposes only. The committee recommended that data be collected, including comparisons with appropriate comparators, to enable a full, robust, health economic evaluation.

3.18 Evidence for Active+me REMOTE assessed a hybrid model of digital and face-to-face pulmonary rehabilitation. The committee understood that some people choose to attend a full course of in-person supervised sessions, as well as using the app to supplement these sessions, or for monitoring. Because of this, the intervention then may not address the unmet need in the NHS, of those who cannot have or do not want face-to-face pulmonary rehabilitation. The committee also understood that the hybrid model created uncertainty about if the technology was cost saving or cost incurring.

Evidence gap review

3.19 For all the technologies, the evidence gaps related to the population, comparator and outcomes.

Population

3.20 The patient experts highlighted that people with advanced COPD who are dependent on supplemental oxygen were underrepresented in the research. The clinical experts agreed. They also stated that people with a recent diagnosis should be considered for future research, along with those recently discharged from hospital following an exacerbation. The committee noted that there was no

comparison of outcomes for people living in urban and rural settings.

Comparator

3.21 The comparators in the research were heterogeneous. The committee agreed that all comparators of face-to-face pulmonary rehabilitation should follow the British Thoracic Society standards. The specialist committee members highlighted that there was a gap in the evidence relating to comparison against waiting lists and no treatment.

Outcomes

3.22 Gaps in the outcomes included heterogeneity in the exercise capacity outcome measures, waiting list data, health-related quality of life data (which can be translated into quality-adjusted life years), information on adverse events and hospitalisation because of an exacerbation, and exacerbation rates. The committee noted that long-term data was also needed to evaluate the true effectiveness of these technologies. The companies and technology developer agreed with this.

4 Committee members and NICE project team

Committee members

This topic was considered by NICE's medical technologies advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technologies to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of the medical technologies advisory committee meetings, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Additional specialist committee members took part in the discussions and provided expert advice for this topic:

Specialist committee members

Dr Enya Daynes
Clinical academic physiotherapist, University Hospitals of Leicester NHS Trust

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NICE project team

Each medical technologies guidance topic is assigned to a team consisting of 1 or more health technology assessment analysts (who act as technical leads for the topic), a health technology assessment adviser and a project manager.

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ISBN: 978-1-4731-6041-5

Accreditation