GID-HTE1001921 Digital technologies to deliver pulmonary rehabilitation programmes for adults with chronic obstructive pulmonary disease

EVA guidance recommendations

Medical technologies advisory committee: 17 Nov 2023

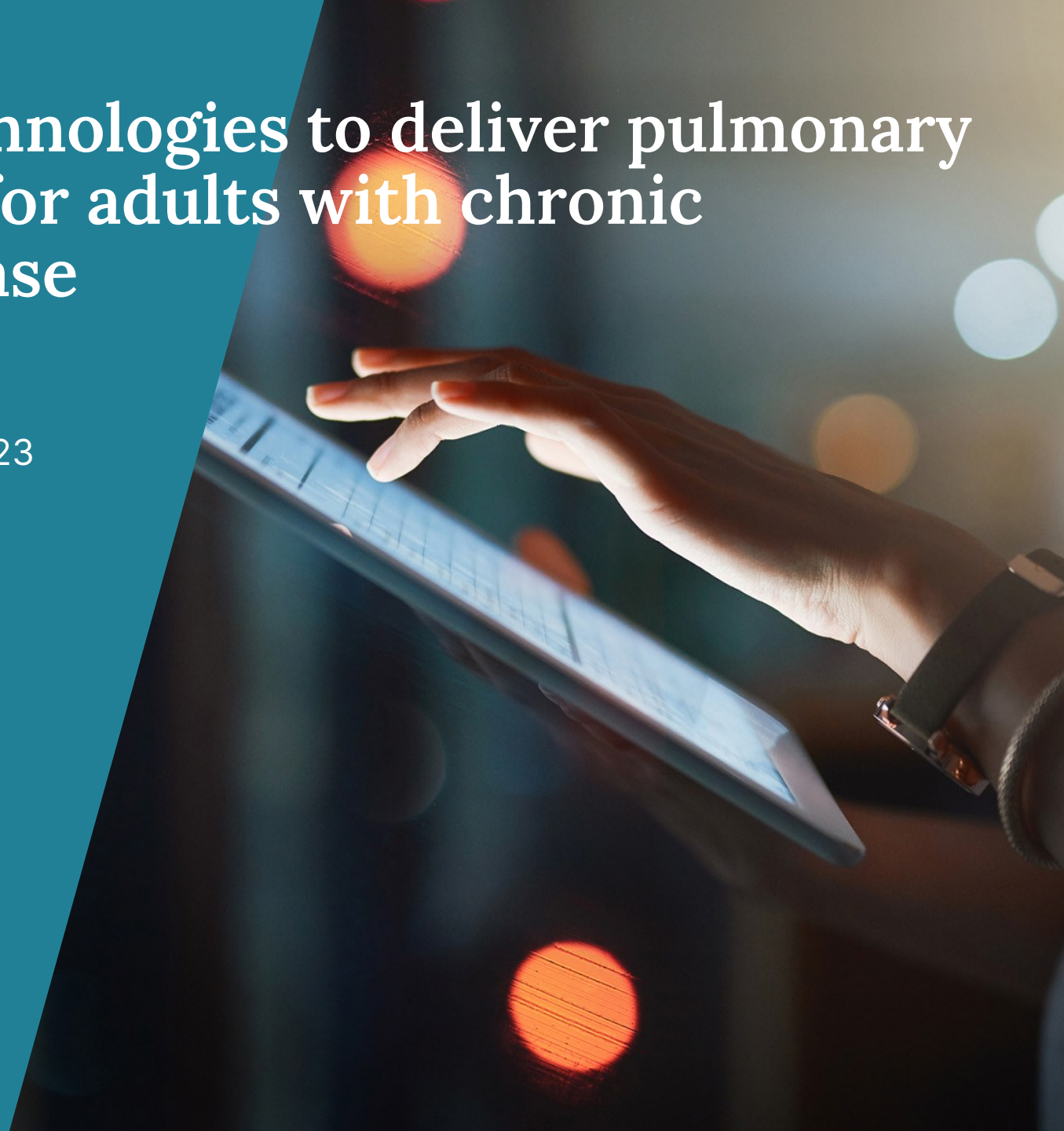
Introducers: Dr Enya Daynes, Dr Avril McCarthy

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

NICE

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

NICE

Pack only

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

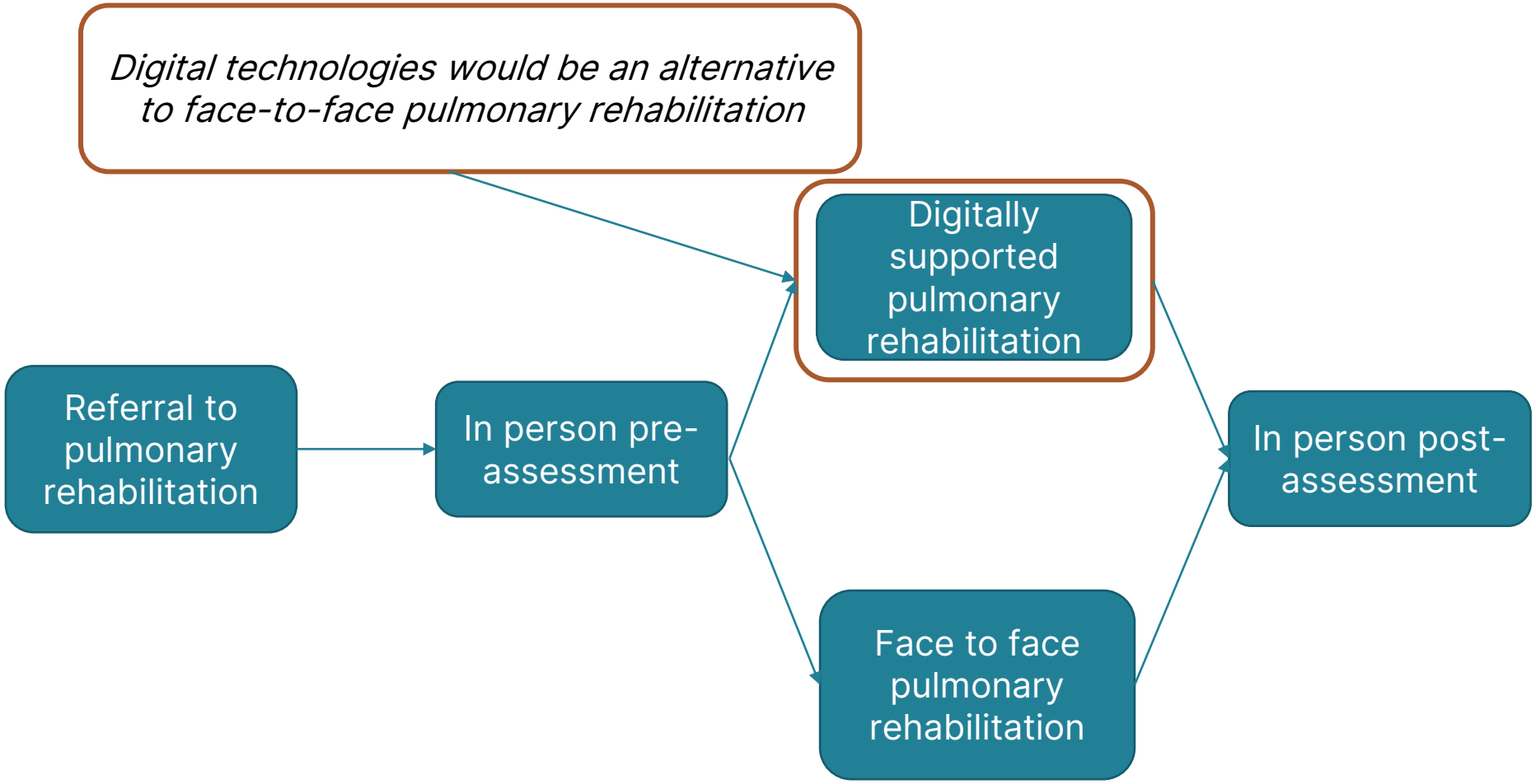
7 technologies for digitally supported pulmonary rehabilitation were included in the assessment:

- 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

NICE National Institute for Health and Care Excellence

AHP: allied health professional

Pack only

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

Pack only

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	-

Pack only

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

Pack only

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

Pack only

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

Pack only

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

Pack only

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

Pack only

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

Pack only

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

Pack only

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

Pack only

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

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

Pack only

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

Pack only

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

NICE

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

Pack only

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	-	-	-

NICE

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

Pack only

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	Amber	Amber	Green	Amber	Green	Red	Red
Health-related quality of life	Amber	Amber	Green	Red	Green	Red	Red
Other measures of respiratory function	Amber	Amber	Green	Amber	Green	Amber	Red
Intervention completion	Amber	Amber	Green	Amber	Amber	Amber	Red
Intervention-related adverse events	Red	Amber	Green	Red	Amber	Red	Red
Acute exacerbations, hospital admissions, readmissions or emergency admissions	Red	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