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Exploring participant utilisation of a novel digital support service for people with COPD using a mixed methods study

A thesis presented by

Anna Juliette Taylor

MBBCh BSc(hons)

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Summary

Background

Chronic obstructive pulmonary disease (COPD) is a significant health concern thought to affect over 4 million people in the UK. Although not curable, effective management and treatment can minimise symptom and healthcare burden. Effective self-management - empowering patients to manage their own condition, recognise changes, and seek early intervention when needed – is a key component of value-based COPD care. There is however a mismatch between guideline-based recommendation and care resources, often exacerbated by socioeconomic disparities and quality care gaps. Digital solutions offer the opportunity to overcome service inefficiencies, widen access and increase uptake of strategies known to improve healthcare outcomes in COPD. A range of digital health solutions to support COPD management have been developed and evaluated over the last 10 years, but firm evidence of their sustained usage and utility has not yet been acquired.

COPD is a major healthcare challenge in Scotland, with notable variation in health outcomes and access to guideline-based care across the country. To address this, the Innovate UK-funded DYNAMIC project was created in 2018. The project aimed to co-develop and implement a digital intervention for people with COPD, with effectiveness testing of a digital infrastructure and associated service model to support effective delivery of supported COPD management and evidence-based care. The innovation team, in collaboration with a digital agency (StormID), co-designed and developed the COPD digital support service intervention, with the overarching goal to improve patient outcomes for those with COPD, whilst also integrating remote management and data capture.

The COPD digital support service consists of a patient-facing web application (app), where users can submit daily patient reported outcomes (PRO), access self-management info and medication information, link in Fitbit wearables and home non-invasive ventilation devices, and use patient<>clinician asynchronous messaging for non-urgent advice or queries. A linked support site gives access to further self-management resources. An associated clinician dashboard displays

PRO responses and physiological data, and allows management of messaging and collated health record data.

Approach

The RECEIVER trial is the implementation and effectiveness observational cohort study that evaluated the use of the COPD digital support service alongside routine care. Its planned 1-year recruitment phase commenced in September 2019, with follow-up data censored in August 2021. Patients with COPD who had access to smartphone, tablet or computer and had had a severe COPD exacerbation requiring admission to hospital, and/or had chronic hypercapnic respiratory failure on home non-invasive ventilation were eligible for the study. The primary outcome of the trial was participant usage of the support service, measured through the submission of daily PROs. Secondary outcomes included clinical events, PRO and quality of life measures.

This research for this thesis sat within the RECEIVER trial and aimed to explore utilisation of the digital support service by people with COPD using an explanatory mixed methods study design. Study participant usage data and clinical outcomes were collated and analysed. Participant admission and occupied bed days (OBD) were compared to a matched contemporary control cohort created from a deidentified dataset of patients with COPD in NHS GGC.

The results from the quantitative evaluation that warranted further exploration were identified. Qualitative semi-structured interviews were designed and conducted in a sub-cohort of study participants who were best placed to give added insight into the findings seen. Interview transcripts were coded, and thematic analysis was undertaken to develop themes reflecting the use of the service from participant's perspectives. This sequential combining of quantitative outcome data with qualitative semi-structured interview themes provided additional perspectives and deepened the understanding of the results obtained.

Findings

81 people with high-risk COPD were recruited to the RECEIVER study. Quantitative results showed consistent utilisation of the service, with participants submitting an average of 4 sets of PROs per week over the course of the study. There were notable reductions in hospital admissions and OBDs following enrolment, along with improvements in time to readmission and survival rates among RECEIVER participants compared to the matched contemporary controls.

To better understand the reasons behind the sustained usage of the service by some participants, semi-structured interviews were conducted with a sub-cohort of those who continued to engage with the platform. 14 interviews were performed and data from these analysed. Four themes were developed; *conditions for success*, *added colour and detail*, *background care*, and *a means to help*. These themes revealed key factors that appeared to contribute to successful use of the app and highlighted the perceived benefits experienced by participants from use of the COPD digital support service components.

The combining of qualitative and quantitative results allowed conclusions to be drawn about the practical drivers behind the persisting usage seen within the trial and identified aspects and priorities to incorporate into future service iterations and other project developments. This integration also broadened the insight into motivations behind usage and mechanisms that may have led to the improved outcomes seen. Aspects of the service that warranted further evaluation were revealed, including potential value gained from analysis of messaging patterns and physiological data.

Evaluation data from the scale-up of the COPD digital service provision during the COVID-19 pandemic (out with the RECEIVER trial) is also explored. Eligibility was extended to include any patient with COPD resident in NHS GGC. Results from the evaluation confirmed sustained utilisation and reductions in clinical events for patient users, mirroring the results from the RECEIVER trial. User feedback from this scale-up cohort group also captured similar sentiments to those recorded amongst RECEIVER trial participants.

Conclusion

This mixed-methods RECEIVER trial evaluation and complementary data from the subsequent service scale-up confirms sustained patient utilisation, perceived participant benefits and positive impact on healthcare utilisation from development and deployment of a co-designed COPD digital service. The outcomes from this research project have contributed to the adoption and evaluation of the service in other organisations, the publication of a supportive NICE early value assessment and to the extension of the digital tools including development, deployment and evaluation of artificial intelligence-based risk prediction models and transformation of the COPD diagnostic pathway. This research project and its evaluations also provide exemplar insights for implementation-effectiveness evaluations of additional digital technologies for COPD and other long-term conditions.

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Statement of originality

I, Anna Taylor, confirm that the research included within this thesis is my own work.

The statistical analysis within chapters 3, 4 and 6 were undertaken in conjunction with University of Glasgow MSc precision medicine students that I co-supervised, some of whom continued in industry placement employed as analysts at StormID/Lenus Health on completion of their MSc studies.

Funding

Core funding for the DYNAMIC project and RECEIVER clinical trial was from an Innovate UK Digital Health Technology Catalyst award (grant number/project ID 104552). Subsequent continuity and scale-up evaluations of the COPD digital support service have had support from an unrestricted investigator-initiated research award from ResMed, and also as part of the 'DYNAMIC-SCOT' COVID-19 response project funding from the Scottish Government. The development of the artificial intelligence (AI) insights and the DYNAMIC-AI clinical trial are supported by an NHSX/NIHR Accelerated Access Collaborative AI in Health and Care Award.

Covid-19 Impact Statement

Recruitment to the RECEIVER trial was halted at the announcement of the UK COVID-19 lockdown on 16th March 2020. All participants who had previously been enrolled continued within the trial. The last participant was recruited on 13th March 2020. Because of the remote nature of the RECEIVER trial, I was able to continue to monitor and collate event data for the participants who had already been enrolled to the study. I undertook regular clinical shifts on the respiratory and acute medical wards at the Queen Elizabeth University Hospital and covering outpatient clinics at Gartnavel General Hospital throughout 2020, 2021 and 2022, in addition to my research commitments including work on COVID-19 related research studies.

Although lockdown restrictions had eased by the time of recruitment to the first qualitative stage of this project, caution surrounding unnecessary healthcare contact activities with vulnerable population groups (such as the high-risk individuals within the RECEIVER trial) remained. As a result, the first set of qualitative interviews were all conducted over the phone. Attitudes towards maintaining shielding precautions and minimising external contact continued during the second qualitative stage, and although in person interviews were offered, the majority of participants chose to take part via the telephone.

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My thanks must first and foremost go to the people with COPD who participated in this research. I feel very honoured to have had the opportunity to work with such a diverse and interesting group of people. Despite being challenged by their condition on a daily basis, they retained their enthusiasm and interest for the project and the goals we were striving to achieve.

I would like to thank all the members of the clinical respiratory nurse specialist team at the Queen Elizabeth University Hospital in Glasgow, who have played such an integral role in making the COPD digital support service what it is today. Especially to Lindsay and Lorna for all their RECEIVER trial recruiting; negotiating sporadic hospital Wi-Fi and tricky device connections with enthusiasm and good humour.

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Industry partner collaboration was not something that I had any experience of prior to starting on this research project. It has been a steep learning journey into the world of software design, digital development and artificial intelligence

for me, but one that I could not have successfully navigated without the enthusiasm and drive from the team at StormID and LenusHealth. It has been and continues to be a pleasure working with you all.

Thank you to Jacqueline for being the project manager powerhouse behind everything. I am very grateful for your encouragement and support keeping me, and everybody else on track.

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Finally, I would like to thank my partner Grae for his unwavering support, encouragement and belief in me throughout this research project. I promise not to do another PhD if you promise not to do one either!

List of publications

Some of the results within this thesis and subsequent work have been published, details are given below:

Full paper

Taylor A, Lowe DJ, McDowell GM, Lua S, Burns S, McGuinness P, Carlin CM. Remote-Management of COPD Evaluating the Implementation of Digital Innovation to Enable Routine Care (RECEIVER): the protocol for a feasibility and service adoption observational cohort study. BMJ Open Respir Res. August 2021. doi: 10.1136/bmjresp-2021-000905

Taylor A, Cushing A, Dow M, Anderson J, McDowell GM, Lua S, Manthe M, Padmanabhan S, Burns S, McGuiness P, Lowe DJ, Carlin CM. Long-Term Usage and Improved Outcomes with Adoption of a COPD Digital Service: Key findings from the RECEIVER trial. Int J Chron Obstruct Pulmon Dis. June 2023. doi: 10.2147/COPD.S409116

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Taylor A, Scott R, McDowell GM, McGuinness P, Lowe DJ, Carlin CM. RECEIVER trial: positive early experience and sustained patient engagement with a digital service model for COPD management. Eur Respir J. October 2020, 56 (suppl 64). doi: 10.1183/13993003.congress-2020.1365

Taylor A, Anderson J, Lowe DJ, Carlin CM. Mitigating the COVID-19 impact on COPD care: rapid development of remote recruitment processes to a digital self-management service. Thorax. February 2021, 76 (suppl 1). https://doi.org/10.1136/thorax-2020-BTSabstracts.179

Taylor A, Lowe DL, Bryson I, Murray L, McGinness P, Carlin CM. Bioplausible insights captured from COPD patients: aligning biometric data with exacerbation events and therapy changes using a commercial wearable device. Thorax. February 2021, 76 (suppl 1). https://doi.org/10.1136/thorax-2020-BTSabstracts.193.

Cox G, Burns S, **Taylor A**, McGuiness P, Lowe DJ, Carlin CM. Predicting hospital length of stay for acute admissions in patients with COPD. Thorax. November 2021, 76 (suppl 2). https://doi.org/10.1136/thorax-2021-BTSabstracts.36

Burns S, Lowe DJ, **Taylor A**, McGuiness P, Carlin CM. Predicting 12-month mortality in a Scottish COPD cohort. Eur Respir J. November 2021, 58 (suppl 65). doi: 10.1183/13993003.congress-2021.PA3827

Carlin C, **Taylor A**, Anderson J, Burns S, McGuiness P, David DJ. RECEIVER trial: sustained use and improved outcomes with digitally supported COPD co-management. Eur Respir J. November 2021, 58 (suppl 65). doi: 10.1183/13993003.congress-2021.PA3874

Taylor A, Cushing A, Dow M, Anderson J, McDowell GM, Lua S, Manthe M, Padmanabhan S, Burns S, McGuiness P, Lowe DJ, Carlin CM. Sustained patient use and improved outcomes with a COPD digital service. Thorax. November 2022, 77 (suppl 1). https://doi.org/10.1136/thorax-2022-BTSabstracts.333

Burns S, Subasic G, Dow M, **Taylor A**, McGuinness P, Lowe DJ, Carlin CM. Towards implementation of live AI-based prognostic risk-prediction scores in a COPD MDT. Thorax. November 2022, 77 (suppl 1). https://doi.org/10.1136/thorax-2022-BTSabstracts.72.

Cushing A, Burns S, **Taylor A**, Lowe DJ, Carlin CM. Co-development and operationalising machine learning models for COPD care in a clinical setting: a workflow framework. Eur Respir J. Sept 2024, 64 (suppl 68): OA2770 doi: 10.1183/13993003.congress-2024.OA2770

Taylor A, Burns S, Anderson J, Walker E, Mckinley G, McConnachie A, Lowe DJ, Carlin CM. Acceptability, feasibility and utility of presenting live AI-based risk prediction models to a COPD MDT. Eur Respir J. Sept 2024, 64 (suppl 68) doi: 10.1183/13993003.congress-2024.PA2514

Fernando N, Goldsmith K, Cushing A, **Taylor A**, Burns S, Lowe DJ, Carlin CM. From development to deployment: actionable AI models that accurately predict admission and exacerbations in patients with COPD. Thorax. (*pre-publication*; *accepted for conference presentation*, November 2024)

Other peer reviewed publications

Carlin CM, **Taylor A**, Van Loon I, McDowell GM, Burns S, McGuiness P, Lowe DJ. Review article: Role for artificial intelligence in respiratory diseases – chronic obstructive pulmonary disease. J Hosp Manag Health Policy. September 2021. doi: https://doi.org/10.21037/jhmhp-20-119

Burns S, Cushing A, **Taylor A**, Lowe DJ, Carlin CM. Supporting long-term conditions management: a workflow framework for the co-development and operationalisation of machine learning models using electronic health record data insights. Front Artif Intell, sec. Medicine and Public Health, vol 7, 2024. (*Accepted for publication October 2024*. doi: 10.3389/frai.2024.1458508*)*

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Glossary of Abbreviations

A&A	Ayrshire & Arran
ACP	Anticipatory Care Plan
AI	Artificial Intelligence
API	Application Programming Interface
CAT	COPD Assessment Tool
CNS	Clinical Nurse Specialist
COPD	Chronic Obstructive Pulmonary Disease
COVID-19	Coronavirus disease (caused by SARS-CoV-2 virus)
.csv	Comma-separated values (file)
CVD	Cardiovascular Disease
DPA	Data Processing Agreement
DPIA	Data Protection Impact Assessment
ED	Emergency Department
EHR	Electronic Healthcare Record
EMG	Electromyography
EQ-5L-5D	A brief, multi-attribute, generic health status measure
EQ-VAS	Health status measure visual analogue scale
EVA	Early Value Assessment
FEV1	Forced Expiratory Volume in 1 second
FEV1/FVC	Forced Expiratory Volume in 1 second/Forced Vital Capacity (ratio)
FOT	Forced Oscillometry Technique
FVC	Forced Vital Capacity
GG&C	Greater Glasgow & Clyde
GOLD	Global Initiative for Obstructive Lung Disease
GP	General Practitioner
HCP	Healthcare Professional
HTA	Health Technology Assessment
ICD-10	International Classification of Disease, 10th Revision
ICS	Inhaled Corticosteroids
ICU	Intensive Care Unit
LABA	Long-acting Beta Agonist
LAMA	Long-acting Muscarinic Antagonist

LPAC	Local Privacy and Advisory Committee
MDT	Multi-disciplinary team
ML	Machine learning
MCN	Managed Clinical Network
MRC	Medical Research Council dyspnoea scale
MSc	Master of Science (degree)
NA	Not applicable
NDP	National Digital Platform
NHS	National Health Service
NHSX	Joint unit of NHS England and NHS Improvement and Department of Health and Social Care
NIHR	National Institute of Health and Care Research
NICE	National Institute for Health and Care Excellence
NIV	Non-invasive Ventilation
OBD	Occupied Bed Days
PDF	Portable Document Format (Adobe Acrobat)
PHS	Public Health Scotland
PRO	Patient Reported Outcome
PPIE	Public and Patient Involvement and Engagement
QUAN	Quantitative
QUAL	Qualitative
QoL	Quality of Life
RC	RECEIVER (trial)
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
RSV	Respiratory Syncytial Virus
SD	Standard Deviation
SIMD	Scottish Index of Multiple Deprivation
SMR01	Health record code for an inpatient or day case admission
SMS	Short Message Service
TA	Thematic Analysis
WoS	West of Scotland

1 Introduction

The landscape of global health is changing. With health care advances, people are living longer, and the prevalence of long-term conditions is increasing (Hajat and Stein, 2018). Providing early accurate diagnosis and effective management and treatment for long-term conditions that often co-exist is a global healthcare challenge.

As a long-term respiratory disease, chronic obstructive pulmonary disease (COPD) causes significant physical, healthcare and economic burden at both an individual and societal level (Safiri *et al.*, 2022). Effective management and treatment can minimise the impact of COPD, however there is a mismatch between guideline-based recommendations and care resources, often exacerbated by socioeconomic disparities and quality of care gaps. Digital transformation with deployment of developed technologies offers the prospect of improving clinical workflows and addressing service inefficiencies. Thus, enabling the widening of access to and options for diagnostic pathways, increasing access and uptake of interventions known to improve healthcare outcomes, and accelerating the identification and implementation of new care pathways and new interventions. A range of digital health solutions to support COPD management have been developed and evaluated over the last 10 years, but evidence of their sustained usage, utility and impact is variable. There is a need to continue to grow and evolve the evidence base for the use of digital support solutions in the management of COPD.

This thesis will explore the use of a co-designed digital support service for people with COPD through a mixed methods study design, incorporating both quantitative and qualitative outcome data from the RECEIVER clinical trial.

1.1 Long term conditions

Long-term conditions include heart disease, diabetes, cancer and lung disease, and are responsible for 74% of all deaths globally (WHO, 2023b). Effective management of these chronic conditions is difficult. With advancements in care and treatment of many long-term conditions, larger proportions of people are

now able to live a longer, more active life. However, these evolving management and treatment requirements account for a substantial proportion of health resources. In the UK in 2014, 70% of total expenditure on health and care in England was associated with treatment of people with one or more long-term conditions (Care Quality Commission, Public Health England, and NHS Improvement, 2014). There is ongoing need to re-shape care delivery and drive down variations in quality and safety of care to address the inefficiencies and care-quality gaps that exist in the management of long-term conditions (Care Quality Commission, Public Health England, and NHS Improvement, 2014). Harnessing the potential of technology and innovation is recognised as a means to tackle such care-quality gaps through simplifying patient access to care and supporting people to manage their own health (NHS England, 2017).

COPD is a long-term respiratory condition and is a leading cause of global mortality, morbidity, and disability (Safiri *et al.*, 2022). As a heterogeneous lung condition, COPD is characterised by chronic respiratory symptoms including dyspnoea, cough, sputum production and/or exacerbations. It is the result of abnormalities in the airways (bronchitis, bronchiolitis) and/or alveoli (emphysema) and causes persistent airway obstruction that is often progressive (Celli *et al.*, 2022; GOLD, 2024). Tobacco smoking and the inhalation of toxic particles and gases from household and outdoor air pollution account for the main environmental exposures leading to COPD (Yang, Jenkins and Salvi, 2022; Sin *et al.*, 2023). Genetic-environmental interactions over the course of the lifetime of an individual are also thought to contribute to the development of COPD (Agustí *et al.*, 2022). Diagnosis of COPD is based on the presence of non-fully reversible airflow obstruction (FEV1/FVC <0.7 post bronchodilator) measured by spirometry, in conjunction with the appropriate clinical risk factors and symptomology (GOLD, 2024).

In the UK, COPD presents a significant health concern with more than 4 million people estimated to have a diagnosis and over 35,000 deaths per year attributed to COPD (Institute for Health Metrics and Evaluation, 2024). Delay in diagnosis and inconsistent delivery of optimised evidence-based COPD care contribute to adverse outcomes and are a clear example of the care-quality gaps that often exist in long-term disease management.

1.2 Challenges in COPD

COPD leads to notable morbidity and mortality, including an increasing and substantial economic and social burden (GOLD, 2024). Nine out of ten cases of COPD in the UK are caused by cigarette smoking; occupational exposure, air pollution and genetic factors are also known to be contributory factors (NHS England, 2023). People with COPD commonly experience increased levels of breathlessness, wheeze, chronic cough, and excessive mucus production. The time course of the disease is variable and often punctuated by periods of symptom worsening or exacerbations, commonly caused by viral or bacterial infections. Exacerbation events make up a significant proportion of the healthcare costs associated with COPD (Press, Konetzka and White, 2018; Gutiérrez Villegas *et al.*, 2021) and have been shown to have a negative impact on patients' lives (Anzueto, 2010; Perera *et al.*, 2012; Jones *et al.*, 2014; Qureshi, Sharafkhaneh and Hanania, 2014; Hurst *et al.*, 2020). High exacerbation rates are associated with increased disease severity and poor disease control (Anzueto, 2010). Damage associated with exacerbations extends beyond the lungs and increases the risk of cardiovascular events such as myocardial infarctions and ischaemic strokes (Donaldson *et al.*, 2010; Shrikrishna *et al.*, 2024). The mortality rate for patients with COPD following their first exacerbation requiring hospital admission is high, with one in five dying within a year of the initial admission (Ho *et al.*, 2014). Increased mortality risk is associated with moderate and severe exacerbations, with the risk increasing with exacerbation frequency (Rothnie *et al.*, 2018).

The estimated prevalence and mortality rate for COPD is higher in Scotland compared to the rest of the UK (Snell *et al.*, 2016; Stone *et al.*, 2022). Figure 1 shows the impact of COPD in Scotland (image adapted from ACT on Scotland National Working Group and AstraZeneca, 2023).

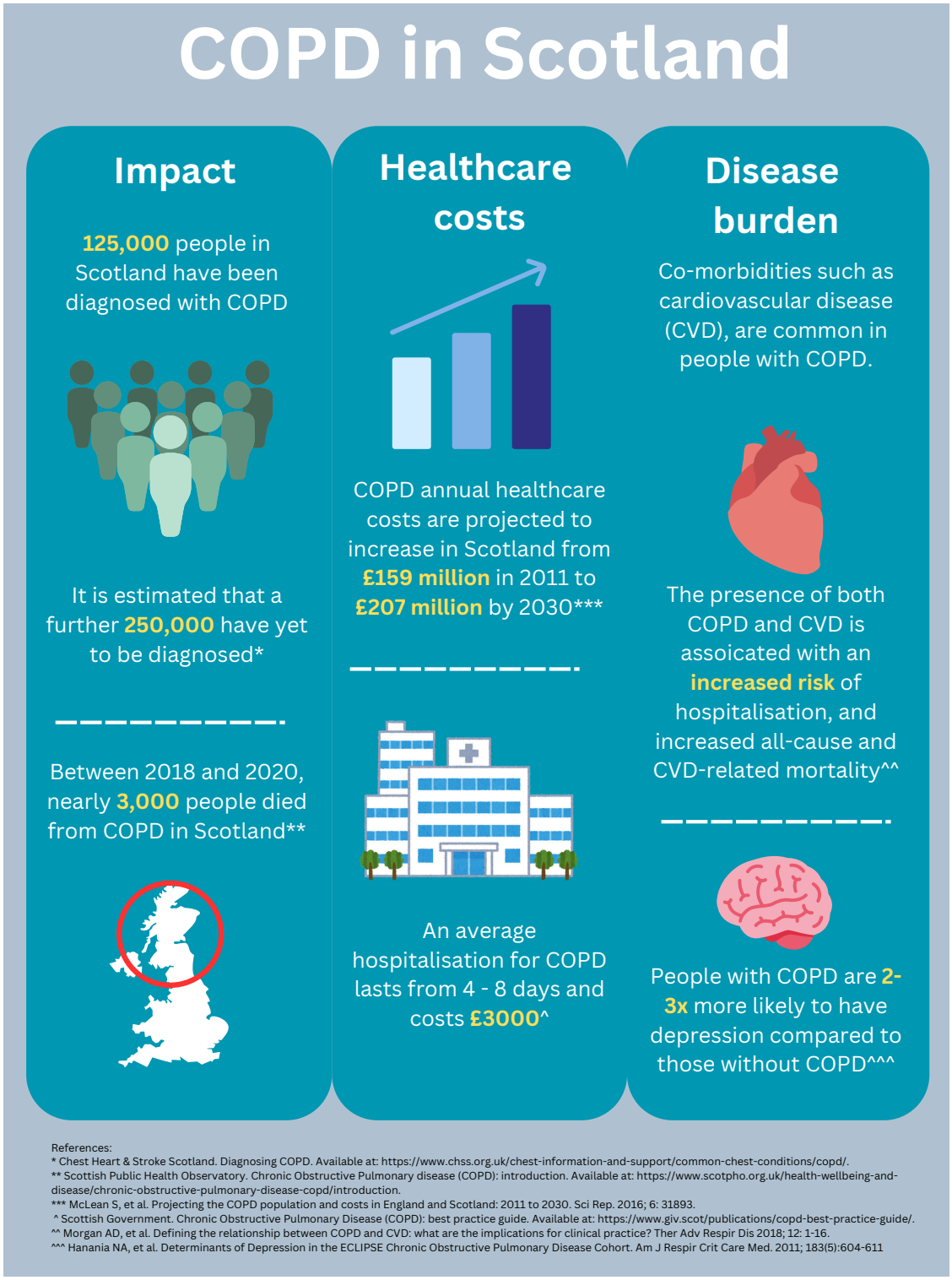


Figure 1 Infographic showing a summary of the impact of COPD in Scotland. Adapted from ACT on COPD Scotland - Pathway Best Practice Report, August 2023

Poor inhaler technique also leads to reduced disease control and is associated with an increased environmental burden; inhaler emissions account for nearly 3% of NHS carbon footprint (Public Health England, NHS England, and Sustainable Development Unit, 2018).

People with COPD prioritise the avoidance of exacerbations and resultant hospitalisations (Zhang *et al.*, 2018) and patient groups have called on the research community to address how exacerbations can be prevented (Alqahtani, Aquilina, *et al.*, 2021).

1.2.1 Key interventions for COPD

Despite not being curable, COPD is preventable and treatable. Through a combination of pharmacological and non-pharmacological treatment approaches, COPD management can be optimised, and exacerbation risk reduced (GOLD, 2024).

Non-pharmacological treatments include smoking cessation, vaccination against respiratory pathogens (influenza, coronavirus disease (COVID-19), pneumococcus, and respiratory syncytial virus (RSV)) and pulmonary rehabilitation. Pharmacological treatments included personalised inhaled therapy, with a range of devices and delivery methods available to suit patient preference and coordination ability. Patients with COPD who have symptoms should receive long-acting muscarinic antagonist (LAMA) and long-acting beta agonist (LABA) as combination long-acting bronchodilator therapy (LABA-LAMA) (GOLD, 2024). Patients who have exacerbations, particularly if there is an elevated eosinophil count, should additionally receive an inhaled corticosteroid (ICS) within a single combination inhaler (LABA-LAMA-ICS) (GOLD, 2024). This single inhaler triple therapy has been shown to reduce exacerbations, hospitalisations, cardiovascular events and mortality compared with LABA-LAMA or LABA-ICS therapy (Rabe *et al.*, 2020; Martinez *et al.*, 2021; Bardsley *et al.*, 2022). For those with more advanced disease, home oxygen therapy, home non-invasive ventilation (NIV), lung volume reduction procedures and lung transplantation are considerations.

Effective delivery of these evidence-based interventions has been shown to reduce exacerbations and hospital admissions and are recommended in national and global guidelines. Adherence to these guidelines is reduced however, with a lack of clarity in information, unfamiliarity with recommendations and inadequate implementation programmes being highlighted as barriers to uptake and delivery (Overington *et al.*, 2014; Sehl *et al.*, 2018). Care-quality gaps

further compound effective implementation and exaggerate inequalities in care provision.

Current healthcare pressures often lead to reactive unscheduled care provision and fractured care, with capacity and reimbursement not focused on preventative proactive interface or primary care resources. There is an urgent requirement for reorientation in disease management strategy and service redesign that can integrate care to deliver evidence-based interventions and achieve reductions in COPD exacerbations and admissions.

1.3 Supported self-management for COPD

Self-management strategies are recommended to people with COPD as an adjunct to other non-pharmacological treatments to help long-term management of their condition (GOLD, 2024). These approaches involve providing patients with knowledge about their illness, exercise information, education about medication and exacerbation recognition, aimed at improvement in self-help behaviours and self-management skills (Lorig and Holman, 2003; Cannon *et al.*, 2016). Self-management empowers patients to take control of their condition and develop skills to better manage their COPD with support from healthcare professions, carers and family (Chest, Heart & Stroke Scotland *et al.*, 2024).

Self-management strategies have been shown to improve health related quality of life measures for patients with COPD (Cannon *et al.*, 2016; Lenferink *et al.*, 2017; Kessler *et al.*, 2018; Rose *et al.*, 2018; Schrijver *et al.*, 2022). People who can be successfully taught and supported with COPD self-management show a significant reduction in admissions relating to their COPD (Bucknall *et al.*, 2012; Ferrone *et al.*, 2019). Clinical programmes which provide education and support patient self-management are recommended as part of routine clinical care for the long-term management of patients with COPD (GOLD, 2024). Nevertheless, availability, accessibility, and uptake of these type of programmes, particularly those provided as part of pulmonary rehabilitation, is highly variable (Early *et al.*, 2018). In their 2016 meta-analysis, Cannon et al recommended that the process of self-management becomes integrated into patient's usual care, providing patients with ongoing feedback and bolstering their support, in addition to improving their overall health and well-being (Cannon *et al.*, 2016).

Out with formal self-management education programmes, providing patients with a COPD action plan, alongside brief education around its use, has been shown to reduce hospital healthcare utilisation and increase timely treatment of exacerbations with steroids and antibiotics (Howcroft *et al.*, 2016). Action plans can improve a patient's ability to recognise and self-start treatment for worsening COPD symptoms, thus building on the ability for them to manage their own condition.

1.4 Digital technologies and healthcare transformation: overview

Digital access for the general public has been shown to be increasing. 94% of UK individuals aged 16+ now have access to the internet at home and levels of internet access have remained stable since 2021 (Ofcom, 2024). In 2020, Ofcom reported that 80% of people in the UK had access to a smart phone (Ofcom, 2020). It is predicted that the 95% of the UK population (~65 million people) will be smartphone users by 2025 (Nick Baker, 2024).

Electronic healthcare (eHealth) and digital innovations are rapidly emerging areas in medicine. Improvements in computing power have enabled evolution of healthcare systems designed to improve efficiency and reduce costs. In parallel, emerging innovations such as smart inhalers, domiciliary cough monitoring, remotely monitored home NIV machines, wearable physiology monitors, and predictive artificial intelligence (AI) models offer potential COPD care-quality improvements through providing actionable insight to clinical care teams in real time outside of traditional care settings (Nield and Hoo, 2012; Farmer *et al.*, 2017; North *et al.*, 2020; Crooks *et al.*, 2021). However, infrastructure is required to further evaluate and operationalize these tools within current treatment pathways. Advancements in secure cloud-based data storage allow connections between computer-based systems, improving data sharing infrastructure and the potential for blended care models among services, as well as facilitating interactions and support between patients and their clinicians.

Within COPD, digital innovations offer the opportunity for a more flexible, and less-burdensome service delivery strategy for patients, compared to more traditional face-to-face service model. Digital solutions have been sought to improve accessibility and uptake of strategies that are known to improve patient

outcomes, including patient education and interventions to support patient self-management (Morrison *et al.*, 2017).

In their 2017 meta ethnographic analysis of patient and health care professionals (HCP) use of digital interventions across common health conditions, Morton et al (2017) found that patients perceived closer contact with their HCP and felt better cared for. They noted that the digital interventions didn't replace professional care but rather enabled patients to attain 'best' healthcare, increasing their awareness and meant they were more likely to be motivated to engage in lifestyle behaviours to help them improve. Digital interventions were able to simultaneously support patient self-management as well as facilitate HCP control of patient health (Morton *et al.*, 2017).

1.5 Digital technologies to support COPD management: evidence to date

A continuum of digital self-management solutions exists for COPD, ranging from unsupported 'over the counter' mobile apps offering a variety of educational resources that include simple self-management information, to comprehensive supported self-management platforms that enable virtual patient-clinician interactions and adaptable educational content (Nguyen *et al.*, 2013; Sobnath *et al.*, 2017). Along with educational resources, more interactive digital self-management systems allow patients to record daily symptoms and physiological measurements with the capability for prediction of exacerbations when parameters fall outside pre-determined ranges. For some systems, patients or clinicians may be alerted to the risk of an impending exacerbation through remote monitoring mechanisms, giving scope for pro-active intervention (Farmer *et al.*, 2017; Stamenova *et al.*, 2020).

Positive results have been seen in individual studies using internet/app based digital self-management interventions for COPD. Improvements have included reductions in exacerbation frequency, reduced hospital admissions, reductions in length of stay during admissions and improvements in quality-of-life markers (Farmer *et al.*, 2017; North *et al.*, 2020; van Buul *et al.*, 2021). However, it has been noted that the format and delivery of the interventions are often highly variable, and results are not consistent or comparable between studies. Systematic reviews have been unable to collate evidence of significant or

persisting benefit due to the heterogeneity between studies and high risk of bias (Alwashmi *et al.*, 2016; McCabe, McCann and Brady, 2017; Shaw *et al.*, 2020; Janjua *et al.*, 2021).

1.6 Digital technologies to support COPD management: evidence gaps

There are recognised limitations in the current research on digital self-management interventions for people with COPD. As highlighted above, issues with heterogeneity of implementation type and outcomes measured have restricted the conclusions that can be drawn, with a need to consider standardisation of the outcomes used in this area of research (Shaw *et al.*, 2020). Previous studies evaluating remote monitoring tools have often been affected by lack of effective clinical infrastructure or installation issues (Cannon *et al.*, 2016; Rose *et al.*, 2018) and systematic reviews have been unable to draw conclusions about the use of remote monitoring alongside usual care in COPD (Janjua *et al.*, 2021).

Additionally, there is a scarcity of research investigating the mechanisms behind use and effect of digital interventions for COPD in general. Several reviewers have recommended inclusion of behavioural change measures, along with study durations of greater than a year to allow detection and comment on behaviour change (McCabe, McCann and Brady, 2017; Janjua *et al.*, 2021).

Furthermore, studies using these types of digital interventions are often performed in isolation and not evaluated within real-life service provision, with analysis of patient factors including uptake, usage and engagement, being key components that are often missed (McCabe, McCann and Brady, 2017; Janjua *et al.*, 2021). There is recognition that digital interventions are complex, and impacts are driven by more than just binary causation and interactions. Measures of utilisation and user interaction with digital interventions are often inconsistent or absent, meaning studies are unable to identify appropriate patient groups or highlight the assistance required to enable patient use in the real world (Böhm *et al.*, 2020; Madujibeya *et al.*, 2022). There is therefore a need to evaluate them from all angles, expanding investigations to seek an understanding of all aspects of the interventions and factors that may be influencing their impact (Baumel, 2022).

1.7 Digital technologies in healthcare: Patient usage as concept

For a digital intervention to be effective, it is generally agreed that some level of user engagement and use is required (Short *et al.*, 2018; Baumel, 2022). Gaining an understanding of how and why patients have used an intervention is likely to be necessary in understanding the effect an intervention has on outcomes (Donkin *et al.*, 2011; Sieverink, Kelders and van Gemert-Pijnen, 2017). Digital interventions have the advantage over traditional trial interventions through the ability to obtain more objective measures, including uptake, number of completed activities and patterns of usage (Donkin *et al.*, 2011).

1.7.1 Influences on uptake and usage

Influences on usage of a digital health intervention are multifactorial and may begin even before an individual is exposed to the intervention. Understanding the factors that can influence the initial uptake and buy-in to a digital health intervention is important during the development and evolution of a system to ensure successful adoption.

1.7.2 Known barriers to uptake and usage

A range of barriers to use of digital health interventions for COPD management from patient perspectives have been identified within the literature. These include factors surrounding digital exclusion, low digital literacy and technical confidence of participants, as well as the reliability of the technology itself and issues with it not working (Slevin *et al.*, 2019a; Alwashmi *et al.*, 2020; Ramachandran *et al.*, 2023). Motivational barriers included lack of perceived usefulness, little interest in the use of digital interventions or the lack of awareness of them (Slevin *et al.*, 2019a; Alwashmi *et al.*, 2020; Ramachandran *et al.*, 2023). People have also voiced concern with regards to fear about the nature of the data being recorded, interventions leading to impersonal care delivery, and issues surrounding privacy and confidentiality of data (Slevin *et al.*, 2019a; Alwashmi *et al.*, 2020; Ramachandran *et al.*, 2023). Older age has also been presented as a common barrier to usage of digital technology, alongside those in low socioeconomic areas, with lack of digital access creating a ‘digital divide’ (Metting *et al.*, 2023).

The extent to which a patient is required to interact with a digital intervention can cause a barrier to buy-in and persisting usage. In an observational study, Althobiani et al (2023) evaluated a remote monitoring program for respiratory diseases and looked at the feasibility and acceptability of collecting remotely monitored data and symptom questionnaires via Bluetooth enabled spirometers, pulse oximeters and smartphone app as well as long-term passive data collection (Althobiani *et al.*, 2023). Tasks requiring high levels of interaction (spirometry recording and symptom questionnaires) had the lowest levels of retention and compliance, versus much higher levels in the more passively collected data measures (via wearable).

These all represent key challenges that should be recognised and steps made to develop strategies to minimise or overcome their impact on uptake and usage of a digital intervention for COPD (Janjua *et al.*, 2021).

1.7.3 Known facilitators for uptake and usage

Several studies have identified factors that promote and facilitate the uptake and usage of digital health interventions for COPD. These include perception of ease of use, patient education, improved disease understanding and management through use of the intervention, evident value and credibility, facility for bi-directional communication with HCPs, and convenient access to health services (Korpershoek *et al.*, 2018; Slevin *et al.*, 2019b; Alwashmi *et al.*, 2020; Ramachandran *et al.*, 2023).

1.7.4 Utilisation and engagement

As previously mentioned, it is generally agreed that some level of user engagement and use of a system is required for it to be effective (Short *et al.*, 2018). However, variations in the conceptualisation of engagement exist and therefore limit the conclusions that can be drawn about strategies that promote it. Yardley et al (2016) advocated the establishment and promotion of ‘effective engagement’ as the sufficient engagement required to achieve the intended outcome (Yardley *et al.*, 2016). This can vary from patient to patient depending on their needs and motivations. Patients may value different outcomes from

those that were intended and simply having the reassurance of a fallback option in times of difficulty without any daily interaction may be adequate for some. Importance is placed on the need to understand the patient as a user of the intervention in order to refine development to ensure it meets the needs of the patient and maximise effective engagement (Yardley *et al.*, 2016). Measuring engagement is felt to require a multi-dimensional approach which present methodological challenges, including establishing valid outcome measures, intervention fidelity, varying levels of engagement, loss to follow up and need for evaluation at multiple development and implementation phases (Michie *et al.*, 2017).

Aspects of psychological and behavioural process also need to be taking into consideration when seeking to understand patient engagement with and experience of a digital solution (Short *et al.*, 2018). For remotely monitored self-management strategies, digital technology gives the opportunity to introduce immediate feedback and response to patient reported symptoms, as well as asynchronous forms of communication. This type of management brings its own challenges and implications. Provision of care through remote interactions, enhanced by continuous and unobtrusive monitoring can support and educate patients to be more aware of their health, as well as empowering them to manage their own underlying health conditions (Morton *et al.*, 2017). However, depending on the level of support and interaction provided by such digital healthcare solutions, concepts of self-management and independence can be undone by the presence and reliance of background monitoring systems (Schermer, 2009). Giving feedback to patients based on their recorded measurements can provide incentives and positive reinforcement of 'good' health behaviours (Morton *et al.*, 2017). Conversely, it also has the potential to further influence reliance on services and may in fact be detrimental to both mental and physical wellbeing (Lucivero and Jongsma, 2018). It is therefore important to gain an understanding of the potential learned behaviours that are gained using a digital tool and how its potential monitoring capabilities are perceived.

Nested qualitative studies and the use of mixed methods research designs have been suggested to provide more depth and insight into possible explanations

behind patients' uptake, use and engagement with digital interventions in COPD, alongside investigating their clinical utility (Alwashmi *et al.*, 2016; McCabe, McCann and Brady, 2017; Janjua *et al.*, 2021).

1.8 Patient reported outcomes in COPD

Patient reported outcomes (PRO) can be defined as ‘any report of the status of a patient’s health conditions that comes directly from the patient, without interpretation of the patient’s response by a clinician or anyone else’ (Centre for Drug Evaluation and Research, Centre for Devices and Radiological Health, and Centre for Biologics Evaluation and Research, 2009). PROs can provide a more complete understanding of the impact of an intervention, therapy, and/or service on the patient (Weldring and Smith, 2013). The process of completing PROs can also prompt a patient to reflect on their health and in doing so develop a deeper understanding of how their condition affects them (Greenhalgh *et al.*, 2018).

Paper-based daily symptom diaries represent one of the earliest iterations of PROs in COPD. Gaining patient perspectives on severity and change in symptoms has shown value in providing a means for both patients and clinicians to track exacerbations and symptomatology (Mackay *et al.*, 2018). PROs have been extensively used to monitor disease status, treatment response and intervention impacts within clinical trials. Uptake of PROs in routine clinical care can be limited however, with reduced awareness and difficulty incorporating questionnaires into practice flow (Vogelmeier *et al.*, 2020).

Alongside event rates, PROs provide a more accurate determinant of future COPD-related events than clinician-determined severity classifications (Reddel *et al.*, 2021). Patients themselves have endorsed the use of PROs in COPD to optimise standardised patient-centred care and facilitate multicentric data collection (Gyselinck *et al.*, 2023). Digital technology can support more efficient methods of data entry of PROs by either clinicians or direct from patients themselves. Electronic collection of PRO data alongside structured electronic healthcare record (EHR) data also offers the opportunity to enhance remote monitoring capabilities and provide enriched datasets to develop and

operationalise machine learning algorithms for earlier detection of addressable changes in a patient's condition.

1.9 Formation of the DYNAMIC project

Chronic disease management for COPD is challenging, with a high level of symptom burden and mortality within the UK population. Inefficiencies and inequalities in current services have led to care-quality gaps putting further burden on healthcare systems and patients themselves. Evidence based interventions exist but there are difficulties in effective delivery and uptake. Digital interventions combined with service transformation have the potential to help overcome some of these challenges and reduce care-quality disparity. Self-management is effective in reducing some of the considerable burdens of COPD, and there have been preliminary successes with digital interventions that promote and support self-management. There are known limitations and uncertainties to current research and there is a need to expand and build on the existing evidence base, with emphasis on real-world clinical application.

The prevalence of COPD in Scotland is notable, with disproportionately higher mortality rates compared to the rest of the UK (Snell *et al.*, 2016; Stone *et al.*, 2022). Variation in health outcomes and access to guideline-based care also exist across Scotland, with Glasgow City and the West of Scotland (WoS) having the highest rates of emergency COPD-related hospital admission, readmission and COPD-related mortality compared to other areas of the country (Public Health Scotland, 2022).

In 2018, the NHS Greater Glasgow & Clyde (NHS GG&C) WoS respiratory innovation team partnered with StormID (a digital software agency) to develop the proposed 'DYNAMIC' project. This received an Innovate UK digital technology catalyst award, to respond to a major healthcare challenge through digital innovation development. The project vision was to co-design, develop, implement and evaluate a preventative service model for people with COPD, that integrated digital health into a continuum of care, incorporating a range of innovations. This included the development and potential implementation of AI-based insights derived from continuous PRO and other monitoring data. The funding led to the creation of the "Digital Innovation with Remote Management

and Machine Learning Predictive Models to Integrate Care of High-Risk COPD" (DYNAMIC) project, designed to tackle the challenges of COPD care through digital technology.

The project built upon the team's prior experience with supported self-management clinical trials and community interventions for COPD, a pilot adoption study of remote-managed home NIV for COPD patients, and data visualisation studies demonstrating the utility of machine-learned analyses (Bucknall *et al.*, 2012; Eckert *et al.*, 2018; McDowell *et al.*, 2020).

The DYNAMIC project aimed to develop and implement a digital intervention for people with COPD, with effectiveness testing of a digital infrastructure and associated service model to support effective delivery of supported COPD management and evidence-based care. The overarching goal was to improve patient outcomes for those with COPD, whilst also integrating remote management and data capture. This approach was intended to train and validate AI-derived actionable insights, ultimately evolving into a proactive participatory preventative service model. Based on consideration of the patient and service burden, the initial development and implementation of the intervention was focused on those people at high risk for COPD-related hospitalisations.

Clinical and digital agency collaboration on the project commenced in September 2018. Initially, a literature review was conducted to identify the requirements for the intervention, and to assess which elements had proven effective and ineffective in previous research. From September 2018 to August 2019, monthly workshops brought together clinical teams, designers, and developers. Extensive on-site user research was undertaken by the digital agency with patients with COPD, family members and members of the clinical team to understand the challenges faced by people with COPD, as well as the existing service, infrastructure and pathways that the intervention would integrate into, facilitating improvement and transformation of care. Development efforts included iterative co-design and testing sessions involving patients and caregivers, with a total of 38 patients contributing to at least one one-to-one user experience design session.

The value proposition for the DYNAMIC project was developed from the Glasgow supported self-management trial (Bucknall *et al.*, 2012) and other published data. It was proposed that an intervention that facilitated the delivery of COPD care could be developed, and that if an average of 1 service interaction per patient per week could be achieved, this would translate to a reduction in COPD-related hospital admissions averaging 1 per patient per year. It was understood that any benefit would likely to be for heterogeneous reasons and there would therefore be an additional need to explore this further through a range of methodologies. It was envisaged for example that some patients may benefit from structured self-management resources, others may benefit from access to communication with the clinical team including for early support post discharge or during early adoption phase of home NIV or other advanced interventions. Additionally, some patients may benefit from the enhanced structured provision of cornerstone COPD interventions (smoking cessation, pulmonary rehabilitation, optimised inhaler therapy) facilitated by their setup 'onboarding' to the digital service.

The protocol for the clinical trial (Remote-Management of COPD: Evaluating Implementation of Digital Innovation to Enable Routine Care (RECEIVER)) in which the implementation and evaluation of the digital intervention would be undertaken was also developed across year one of the DYNAMIC project. Comprehensive governance documentation and approvals were obtained in line with NHS GG&C eHealth and Health Research Authority guidelines. These included licences for PROs, data processing agreements (DPAs), data protection impact assessments (DPIAs), system security approval, and sponsor, research ethics committee (REC) and research & development (R&D) management approval.

1.10 Description of the COPD digital support service intervention

Through the co-design process, a patient-facing web application (app) and associated clinician dashboard was developed for the DYNAMIC project. Along with a linked support website, these components formed the **COPD digital support service**.

This co-design approach mirrors that undertaken in other digital intervention studies for COPD. For example, Williams et al used patient co-design and qualitative feedback in the development of their digital self-management platform (Williams *et al.*, 2014). Successive evaluations incorporated aspects of patient engagement into subsequent developments and improvements within their system (Velardo *et al.*, 2017).

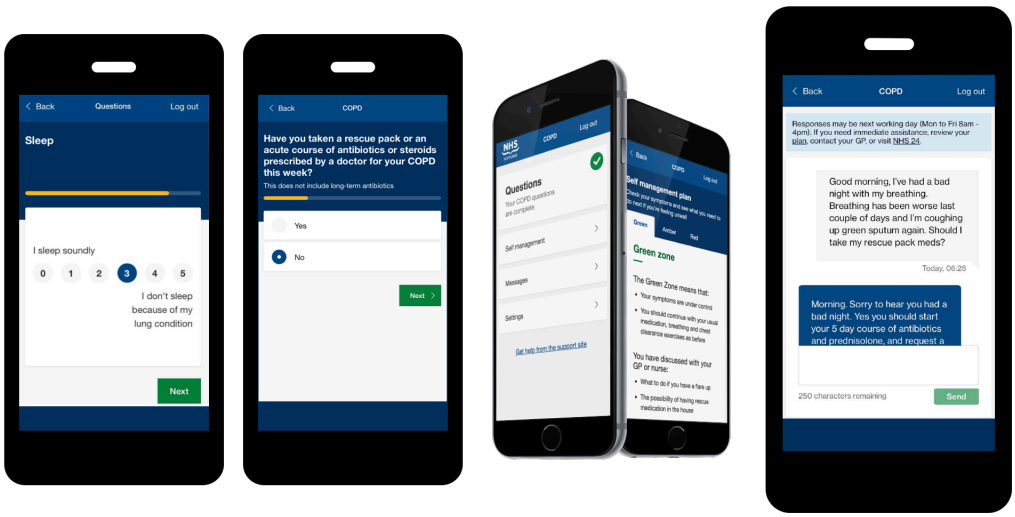
The COPD digital support service patient app is accessible via any internet-enabled device (e.g. smartphone, tablet or computer). Within the app, patient users' complete daily PRO measures and have access to standardised self-management advice with tailored medication information. There is also facility to link users own wearable devices (Fitbit) and ResMed remotely monitored NIV machines (where applicable) to allow sharing of data with the clinical team. An asynchronous messaging function allows for non-urgent patient<>clinician contact. Short message service (SMS) and email prompts are sent daily to remind patient users to complete their PROs, and alert when a new message from the clinical team has been received. Additional self-management resources are viewable through the linked COPD support website.

PROs include daily symptom questions and COPD-assessment tool (CAT) scores, weekly exacerbation history and Medical Research Council dyspnoea score (MRC) questions, and 4-weekly health-related quality of life questions (EQ-5D-5L, EQ-VAS). The full set of PROs as displayed in the patient app are included in the appendix (1).

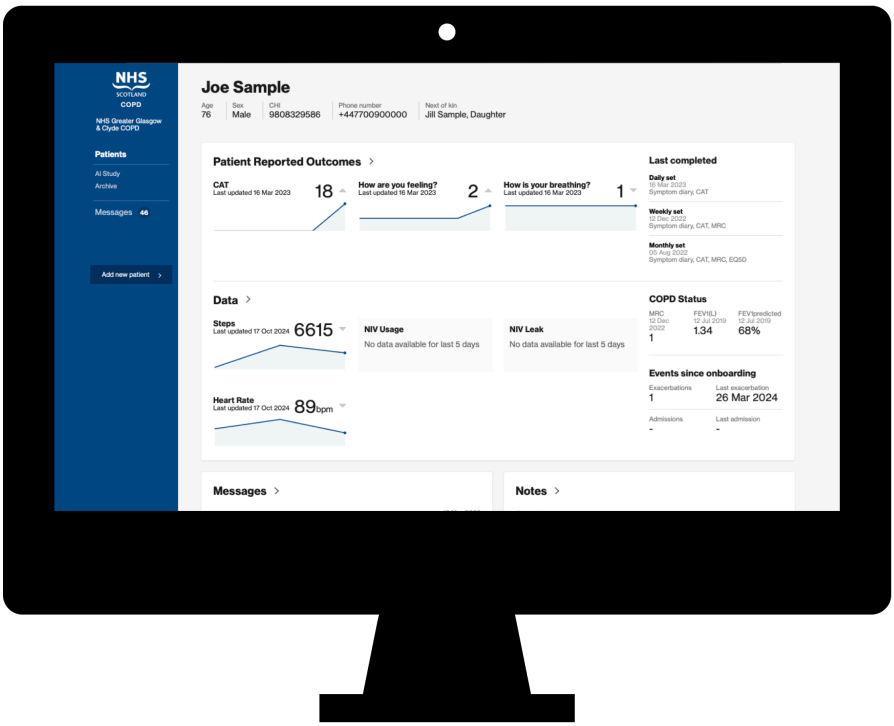
The associated clinician dashboard displays patient PRO responses and messaging, alongside structured EHR, wearable and home NIV remote monitoring data (if applicable).

Screen capture views of the intervention components are shown in figure 2. Further information about the COPD digital support service is available at http://support.nhscopd.scot

A


Back
Questions
Log out
Sleep
I sleep soundly
0 1 2 3 4 5
I don't sleep because of my lung condition
Next
Back
COPD
Have you taken a rescue pack or an acute course of antibiotics or steroids prescribed by a doctor for your COPD this week?
This does not include long-term antibiotics
Yes
No
Next
Questions
Self management
Messages
Settings
Green zone
Back
COPD
Log out
Responses may be next working day (Mon to Fri 8am - 4pm). If you need immediate assistance, review your plan, contact your GP, or visit NHS 24.
Good morning, I've had a bad night with my breathing. Breathing has been worse last couple of days and I'm coughing up green sputum again. Should I take my rescue pack meds?
Today, 06:28
Morning. Sorry to hear you had a bad night. Yes you should start your 5 day course of antibiotics and prednisolone, and request a
250 characters remaining
Send

B


NHS SCOTLAND
COPD
NHS Greater Glasgow & Clyde COPD
Patients
AI Study
Archive
Messages 46
Add new patient
Joe Sample
Age 76
Sex Male
CHI 9808329586
Phone number +447700900000
Next of kin Jill Sample, Daughter
Patient Reported Outcomes
CAT
Last updated 16 Mar 2023
18
How are you feeling?
Last updated 16 Mar 2023
2
How is your breathing?
Last updated 16 Mar 2023
1
Last completed
Daily set
16 Mar 2023
Symptom diary, CAT
Weekly set
12 Dec 2022
Symptom diary, CAT, MRC
Monthly set
05 Aug 2022
Symptom diary, CAT, MRC, EQ5D
Data
Steps
Last updated 17 Oct 2024
6615
NIV Usage
No data available for last 5 days
NIV Leak
No data available for last 5 days
Heart Rate
Last updated 17 Oct 2024
89bpm
COPD Status
MRC
12 Dec 2022
1
FEV1(L)
12 Jul 2019
1.34
FEV1predicted
12 Jul 2019
68%
Events since onboarding
Exacerbations
1
Last exacerbation
26 Mar 2024
Admissions
-
Last admission
-
Messages
Notes

C

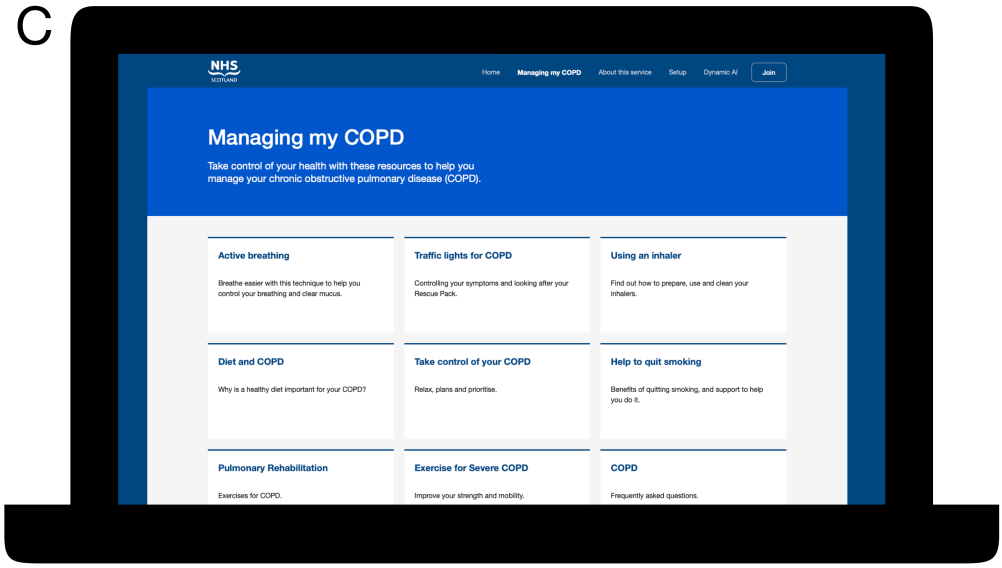


Figure 2 Screen capture views of the components of the COPD digital support service. A) patient web app with messaging and example patient reported outcome (PRO) entry screen, B) clinician dashboard, and C) additional self-management resources accessible on the support website. Synthetic patient data is shown for illustrative purposes only.

The COPD support service was designed to be utilised alongside routine clinical care, to enhance and improve the efficiency of care delivered. Table 1 summarises the additional components of the COPD digital service alongside those used in routine clinical care.

Electronic data and service digital architecture is held within NHS GG&C on the NHS GG&C Microsoft Azure cloud tenancy, with industry standard security and identity assurance processes governed by NHS GG&C eHealth systems. Data access is password protected and accessible only by authorised clinicians, with data management as per NHS GG&C and NHS Scotland data protection policies. An overview of database input, storage and output for the DYNAMIC project is shown in figure 3.

	Routine clinical care	COPD digital support service components
Symptom diary	CAT, MRC, symptom diary and generic-QOL questionnaires completed on paper at home and/or at COPD clinical reviews. Clinician aggregates and summarises data.	CAT, MRC, symptom diary and generic-QOL questionnaires completed by patient in webform. Daily reminder text/email alert to complete. Data presented unmodified to clinician in COPD dashboard.
COPD self-management, generic	Paper or digital information supports clinical explanations, including 'traffic light' system for recognising and managing exacerbations.	RECEIVER patient dashboard and linked COPD support website contains content matching paper and digital information currently provided.
COPD self-management, individualised	Clinician documents for patient on paper (then in letter or other area of electronic health record (EHR)) antibiotic and/or prednisolone dose for exacerbation. Prescription provided.	Clinician documents in RECEIVER dashboard antibiotic and/or prednisolone dose for exacerbation. This is visible at self-management section of patient dashboard and exported to GP and EHR. Prescription provided.
Patient unscheduled contact with COPD clinical team	Patient provided with leaflet and business card with answerphone/email for relevant clinical teams. Standard written text and email auto-reply on clinician availability and signposting for emergencies provided. No admin support, ad-hoc approach to managing messages by clinical team.	Patient can submit message via patient dashboard. Standard advice – identical to current clinical care – on clinician availability and signposting for emergencies provided on screen. Email and text message alerts patient to any new message from clinical team. Clinician messaging dashboard highlights new and unresolved messages. RECEIVER project manager oversees and ensures appropriate response to patient, and any escalation.
Scheduled patient reviews	Appointments made via Trakcare or telephone/paper diary by clinical team. Email and text message reminder alerts sent. Telephone calls, text or email queries, videocalls used in place of hospital or domiciliary attendance, when possible.	Current routine-clinical care supplemented by clinician-patient messaging via RECEIVER dashboards. E.g. messaging used for appointment scheduling, information gathering to add value-efficiency to telephone or face-face consultation.
Clinical documentation	Paper notes, clinical portal clinical notes (in EHR), dictated-transcribed letters. COPD shared documentation e-form in clinical portal (previously trakcare). Documentation siloed: often not visible/shared across primary- secondary care split.	Structured documentation and free text clinical notes in clinician RECEIVER dashboard. Content matches COPD shared documentation clinical portal e- form. Clinical summary, clinical notes and anticipatory care plan exported as pdf from dashboard to EHR visible to all primary and secondary care team.
Patient data storage and management	NHS GG&C eHealth systems	NHS GG&C eHealth systems

Table 1 Summary of routine clinical care available for people with COPD in NHS Greater Glasgow & Clyde (NHS GG&C) alongside COPD digital support service components. Adapted from the table in the published RECEIVER trial protocol (Taylor et al.*, 2021).*
Abbreviation: CAT, COPD assessment tool. MRC, Medical research council dyspnoea scale. QoL, Quality of Life. GP, general practitioner.

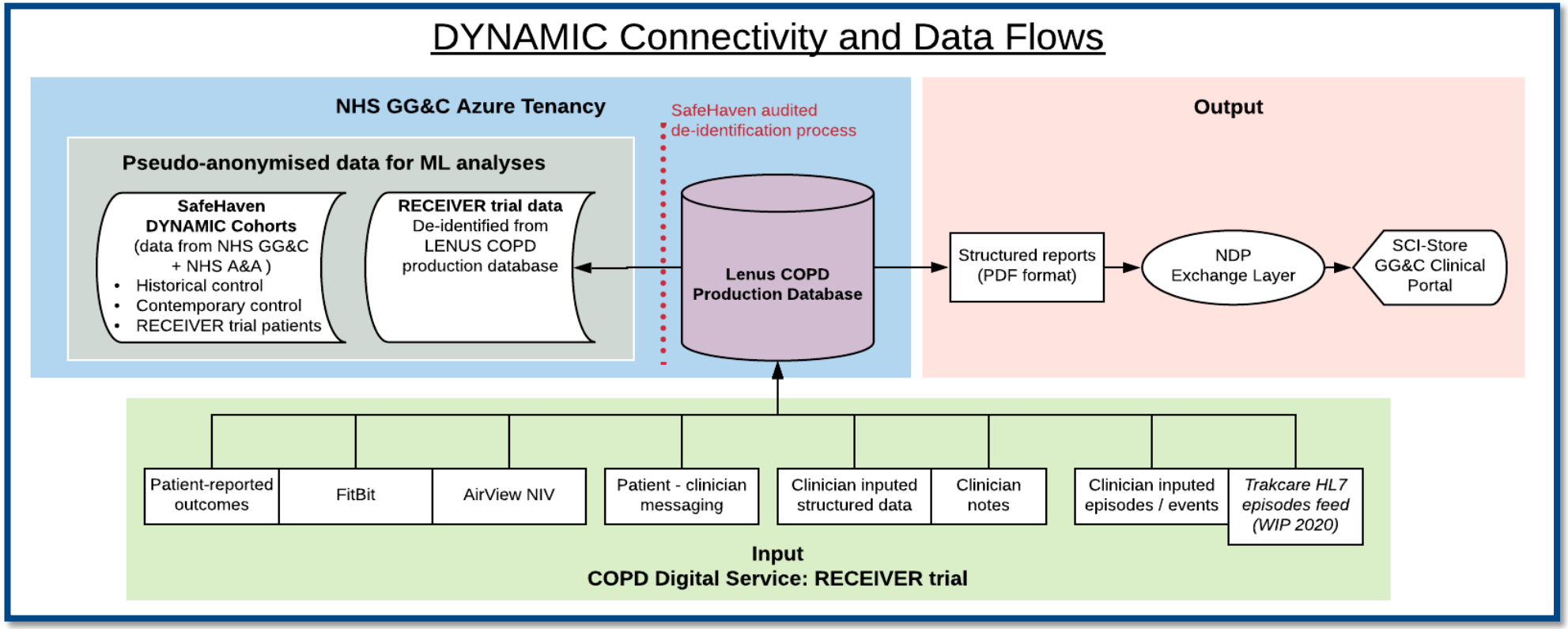


Figure 3 Overview of the database input, output and storage for the DYNAMIC project. The working components of the COPD digital service are maintained within the NHS Greater Glasgow & Clyde (NHS GG&C) Lenus account, which is held on the NHS GG&C Microsoft Azure Tenancy. There is restricted access to the cloud-based database containing the patient data. Planned analysis of these datasets is subject to local privacy and advisory committee (LPAC) approvals and SafeHaven standard operating procedures to ensure only de-identified data is shared.
Abbreviations: NHS A&A, NHS Ayrshire & Arran. PDF, Portable Document Format. NDP, National Digital Platform. NIV, non-invasive ventilation.

1.11 The RECEIVER clinical trial

Evaluation of the DYNAMIC COPD digital support service was undertaken within the Remote-Management of COPD: Evaluating Implementation of Digital Innovation to Enable Routine Care (RECEIVER) clinical trial. Recruitment to this trial commenced on 1st September 2019. As a prospective observational cohort hybrid implementation and effectiveness study, it aimed to evaluate the adoption of the digitally integrated remote-management service to support routine clinical care for people with COPD. Detailed further in Chapter 2, the study protocol included collection and analysis of primary usage and secondary clinical endpoint data, as well as the scope to obtain qualitative feedback data.

1.12 My position within the DYNAMIC project and RECEIVER clinical trial, and the foundation for this PhD thesis

The research forming this PhD thesis was nested within the RECEIVER trial.

I joined the research team as a clinical research fellow in August 2019, after the initial co-design and development of the digital service intervention and the protocol for the RECEIVER trial had been approved, but prior to the launch of the study. Since the commencement of my job, I have had an integral role in the implementation of the RECEIVER trial, including with participant recruitment and subsequent data collection and analysis, as well as being involved in the iterative development of the digital service and other DYNAMIC portfolio projects.

I focused on formulating and developing the research proposal for this thesis over the first year of my clinical fellow role. The study aims were devised through the direct experience and perspectives gained whilst working on the initial stages of the RECEIVER trial. Upon commencement of my doctoral studies, I participated in various research training opportunities, including a weeklong course on qualitative research methods at the University of Oxford. This training was designed to broaden my understanding and enhance my skills in research at the postgraduate level.

1.13 Thesis outline

A mixed methods study design was utilised within this thesis, incorporating both quantitative and qualitative findings to achieve the aims and objectives detailed below.

1.14 Research aims

The aim of this thesis is to explore participant utilisation with a novel digital support service for people with COPD.

1.15 Research objectives

This aim will be achieved through the following objectives:

1) Detail the recruitment experience and results of the primary endpoint (daily PRO completion in the app) of the RECEIVER clinical trial, including analyses of utilisation patterns and exploring correlations with other participant factors.

2) Undertaking quantitative analyses of the selected secondary outcomes from the RECEIVER trial:
   a) Explore the longitudinal changes in clinical events and acquired patient reported outcome data from RECEIVER participants.
   b) Compare RECEIVER participant event data with a contemporary matched control cohort, to investigate the potential contribution of access to a digital service has on their clinical outcomes.

3) Develop methodology and undertake RECEIVER trial qualitative analyses:
   a) Determine which quantitative findings warranted further elaboration with focused qualitative research, to add breadth and broaden understanding of the quantitative results acquired.
   b) Detail the recruitment and demographics of the qualitative research participants.

c) Generate qualitative themes exploring the use of the digital service from the participant's perspective and whether having access to the COPD digital support service had any impact on their condition.

4) Detail the scale up of the COPD digital support service as a result of the COVID-19 pandemic, and associated service evaluations across an expanded cohort of people with COPD.

5) Discuss and integrate the findings from both the quantitative and qualitative aspects of this research, and how this can contribute to further development of the digital tools, as well as the design and undertaking of future implementation-effectiveness projects.

2 General methods: RECEIVER trial protocol and development of mixed methods approach

Chapter one has given an outline of the issues facing the management of COPD as a long-term respiratory condition, which has a substantial impact on patients and healthcare resources. The potential role of the digital transformation of services and technology-driven healthcare solutions to improve the delivery of evidence-based interventions and improve clinical outcomes for people with COPD have been highlighted. Additionally, chapter one introduced the NHS GGC-based DYNAMIC project that was established with a vision to deliver these improvements through the development, implementation and evaluation of a digital technology solution for people with COPD, the COPD digital support service. The components of the digital service were outlined and the RECEIVER clinical trial evaluating the use of this service alongside routine clinical care was introduced. Chapter one concluded with the aims and objectives of the research comprising this thesis.

This chapter will 1. outline the RECEIVER implementation and effectiveness observational study that was conducted to evaluate the use of the digital service as an intervention alongside routine clinical care and 2. describe the mixed methods approach and research stance that was taken during this research project to fulfil the aims and objectives listed in chapter one.

2.1 The RECEIVER Trial

The Remote-Management of COPD: Evaluating the Implementation of Digital Innovation to Enable Routine Care (RECEIVER) study explored the implementation of a digital support service that incorporated additional," potentially assistive digital components alongside routine clinical care. Trial endpoints were selected to determine participant utilisation, clinical service impact and clinical outcomes, and to evaluate the feasibility of this approach versus current standards of care.

'Can patients use it, will they use it, does it make a difference'.
Prof. Chris Carlin (Principal Investigator)

The RECEIVER trial commenced recruitment in September 2019. Study follow up took place until 31st August 2021. Recruitment to the trial ceased in March 2020 due to UK COVID-19 restriction but follow up continued for those already enrolled.

The full protocol for the RECEIVER trial has been published (Taylor *et al.*, 2021).

2.1.1 Study design for the RECEIVER trial

A blended approach of clinical effectiveness and implementation research was taken in the study design for the RECEIVER trial. Use of this hybrid approach is thought to provide more useful information for decision makers and judicious use can speed up the translation of research findings into routine practice (Curran *et al.*, 2012). An implementation-effectiveness observational study was selected over a randomised control trial to allow evaluation within real-world conditions (Peters *et al.*, 2014). The RECEIVER trial was designed to be a real-world investigation looking at the introduction of the support service alongside routine care; it was intended to be additive and not a full replacement of the routine support provision. An overview of the study design for the RECEIVER trial is shown in Figure 4.

The capacity to collect qualitative data was included within the study protocol and consent. It was recognised that the user story would be important to include within the evaluations of the intervention, but the scope and timing of these elements was flexible to allow for their evolution within the study.

While interventions should be developed for people with all severities of COPD, at the time of designing this study, it was felt logical to target immediate efforts towards those people at the most risk of exacerbation and hospital admission; 'high-risk' patients. People with COPD who have had a severe exacerbation (one requiring emergency department (ED) attendance or admission to hospital) in the previous 12 months and/or have persisting hypercapnic respiratory failure requiring home NIV therapy fall into this high-risk category (Calverley, 2003; Piquet *et al.*, 2013). Interventions proven in this group can then be rolled out (if cost-effective) to lower risk groups of people with COPD.

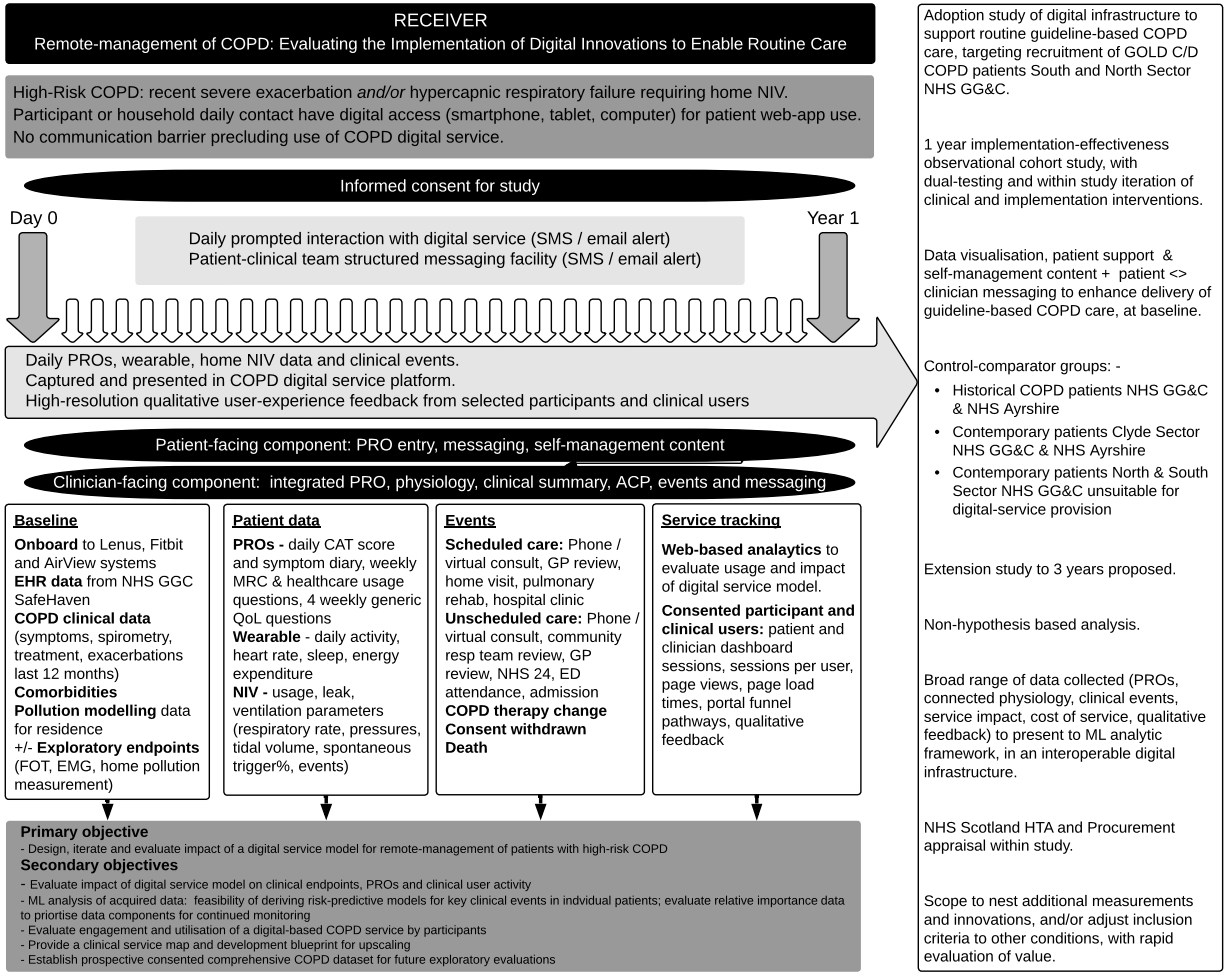


Figure 4 Diagram showing an overview of the study design for the RECEIVER trial
Abbreviations: NIV, non-invasive ventilation. PRO, patient reported outcome. SMS, short message service. ACP, anticipatory care plan. EHR, electronic health record. FOT, Forced Oscillometry Technique. EMG, electromyography. NHS GG&C, NHS Greater Glasgow & Clyde. CAT, COPD assessment tool. MRC, medical research council dyspnoea scale. QoL, Quality of Life. GP, general practitioner. ED, emergency department. ML, machine learning. GOLD, Global Initiative for Obstructive Lung Disease. NHS A&A, NHS Ayrshire & Arran. HTA, Health Technology Assessment.

2.1.2 Study outcome measures

The primary outcome measure for the RECEIVER study was the proportion of trial participants utilising the patient app as determined by completion of daily PROs. An average of one PRO set per participant per week over the trial follow up was selected as a utilisation target for success, based on expert consensus.

Secondary outcome measures included clinical events and hospital occupied bed days (OBD). Full details of the study outcome measures are given in table 2.

Primary outcome measure:	Proportion of enrolled high-risk participants with COPD who utilise remote-management in a digital service model.
Secondary outcome measures:	Clinical outcomes, comparing impact of digitally-enabled remote-management vs historical and contemporary SafeHaven cohorts): - • Clinical events: COPD exacerbations; unscheduled care contact (digital platform, COPD team visit, primary care, emergency department, hospital admission); mortality – COPD and non-COPD related. • Hospital occupied bed days preceding and subsequent 12 months (adjusted time interval if survival <12 months) • Treatment uptake (where indicated): smoking cessation; pulmonary rehabilitation; vaccination; supported self-management; home oxygen; home non-invasive ventilation (NIV). • NIV group: NIV usage, symptom change, NIV therapy parameters, blood gases during routine clinical care • Supported self-management: utilisation of self-management information (page views), number of exacerbations managed at home vs in hospital, number of rescue packs used in 12 months (captured through weekly patient reported outcomes (PRO)), utilisation of messaging (number of message threads), sputum microbiology (where available during routine clinical care), impact of patient activation measures (where measured during routine care). • Impact of demographics, physiology and patient activation measures (where measured during routine care) - deprivation category of area of residence, age and sex, number of previous admissions, smoking status, participation in pulmonary rehabilitation in previous 2 years; lung function measurements, modelled home air pollution exposure; electromyography, oscillometry and home air pollution monitoring in subset of participants where this is carried out - on outcomes, clinical events and treatment uptake. Clinical service outcomes for digital service model, remote-managed home NIV and supported self-management: - • Remote-managed home NIV: number, nature and complexity of NIV therapy reviews and interventions to provide. • Supported self-management: number, nature and complexity of reviews and interventions to provide. • Digitalised service model: user and developer time/cost required for development and modification of clinical dashboard; qualitative analysis

	(clinical user satisfaction & reflection on efficiency or additional workload); quantitative analysis (clinical dashboard utilization tracking) • Patient-portal: user and developer time/cost required for development and modification of clinical dashboard; qualitative analysis (user satisfaction) and quantitative analysis (uptake, engagement with app and wearable, successful use of digital service vs bypass to conventional healthcare contacts). Machine-learning supported exploratory analyses of associations and relative predictive importance of electronic health record, patient-reported outcomes, wearable physiology and NIV parameters: - • Associations between changes in patient-reported outcomes (Medical research council dyspnoea score, COPD Assessment Test, Symptom diary, EQ-5D-5L) with routine clinical care interventions, COPD exacerbations and other clinical events. • Associations between changes in wearable monitoring parameters (activity, sleep, heart rate variability, energy expenditure, respiratory rate) with routine clinical care interventions, COPD exacerbations and other clinical events. • Associations between changes in NIV monitored parameters (usage, leak, airway pressures, respiratory rate, tidal volume, minute ventilation, inspiratory/expiratory ratio and detected respiratory events) with routine clinical care treatment interventions, COPD exacerbations and other clinical events. • Associations between changes in clinical endpoints and relative importance plots of all remote-management acquired data (including electromyography, oscillometry and home pollution monitoring exploratory endpoints in subgroup these measured on) to determine contribution of these to outcome prediction, and therefore value of these for future prospective study. Patient-centred outcomes: - • Health-related quality of life (EQ-5D-5L) at baseline and monthly during study. • Qualitative user research (planned subset of participants, convenience sample) with semi-structured user experience interviews. • Impact of patient activation (where this is measured at baseline and/or follow up during routine clinical care) on enrolment and use of digital service model Healthcare cost analyses: - • Development and installation costs for digitalised service model for remote-management of COPD. • Recurring costs (clinical staffing, digital platform hosting, digital platform scheduled update and maintenance) for digital service model for remote-management of COPD. • Projected direct and indirect cost-savings (admission and unscheduled care reduction, travel, carer-burden impact, clinical efficiency) of high-risk COPD with digitally-enabled remote-management, compared with previous service model.

Table 2 Primary and secondary outcome measures for the RECEIVER trial.
Abbreviations: EQ-5D-5L, a brief, multi-attribute, generic health status measure.

2.1.3 Trial location and usual care context

The RECEIVER trial was sponsored by and conducted within NHS GG&C. NHS GG&C is the largest NHS organisation in Scotland and one of the largest health boards in the UK. It serves a population of 1.3 million people across the city of Glasgow and surrounding areas in the West of Scotland (NHS GG&C, 2024). Crude prevalence of COPD among all ages in NHS GGC is 2.74%, with increased rates seen amongst those living in the most deprived areas (Levin, Milligan and Anderson, 2018). Rates of COPD-related mortality are substantially higher in NHS GG&C compared to the rest of Scotland (Public Health Scotland, 2022).

Although there are primary and secondary care provisions for all people with COPD in NHS GG&C, eligible participants within the RECEIVER trial fell within the more high-risk/severe categories, who are usually managed within secondary care. The respiratory nurse specialist team, who are based at the acute hospital sites, provide individualised COPD inpatient optimisation reviews following guideline-directed care bundles, early supported discharge services, assessment and management of home oxygen therapy, and support for advanced therapies including home NIV. For the RECEIVER trial, an additional respiratory nurse specialist was recruited to the team to champion the service, lead on patient screening, recruitment and service onboarding, and to provide workforce capacity to manage the asynchronous messaging during the trial period. Table 1, in chapter one, summarises the additional components of the COPD digital service alongside routine care provision in NHS GG&C.

2.1.4 Eligibility Criteria

People with COPD at high-risk for hospital admission who were attending secondary care in North and South Sectors of NHS GG&C were screened for inclusion into the RECEIVER trial.

Inclusion criteria:

a) At least 18 years of age at enrolment
b) confirmed diagnosis of COPD (as per Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines, FEV1/FVC <0.7) (GOLD, 2020)

c) at least one severe exacerbation of COPD in preceding 12 months resulting in a hospital admission and/or chronic respiratory failure requiring home NIV treatment
d) daily access to a smartphone, tablet, or desktop computer with internet access either personally or through a close contact

Exclusion criteria

a) lack of capacity to give informed consent or having a communication barrier than precluded the use of the digital COPD support service web-app

2.1.5 Recruitment process

Study recruitment occurred during index hospital admissions and at routine follow up respiratory clinic appointments. Eligible individuals were approached by a member of the research team and provided with the study participant information sheet (appendix 2). Further follow up was then arranged with interested individuals to complete the consent process.

2.1.6 Study setup

After written consent was obtained, participants were onboarded onto the COPD digital support service. Instruction was given on how to complete the daily PROs, view the self-management information and send a message to the clinical team. Participants were encouraged to complete their PROs each day, or at a frequency that was least burdensome to them. Reminder notifications to complete daily PROs were activated to be received by either SMS, email, or both. These prompts were sent automatically at midday unless PROs had already been completed for that day.

Participants were made aware that their symptom data would not be continuously reviewed or monitored on a specific schedule but could be visible to the clinical team to assist and inform participant-initiated contacts and scheduled clinical contact (e.g. clinic appointments). They were informed that clinical team response to messaging would be within working hours and that they

should seek medical advice through usual care channels if they felt unwell. This was also visible in the messaging section of the patient app, shown in figure 5.

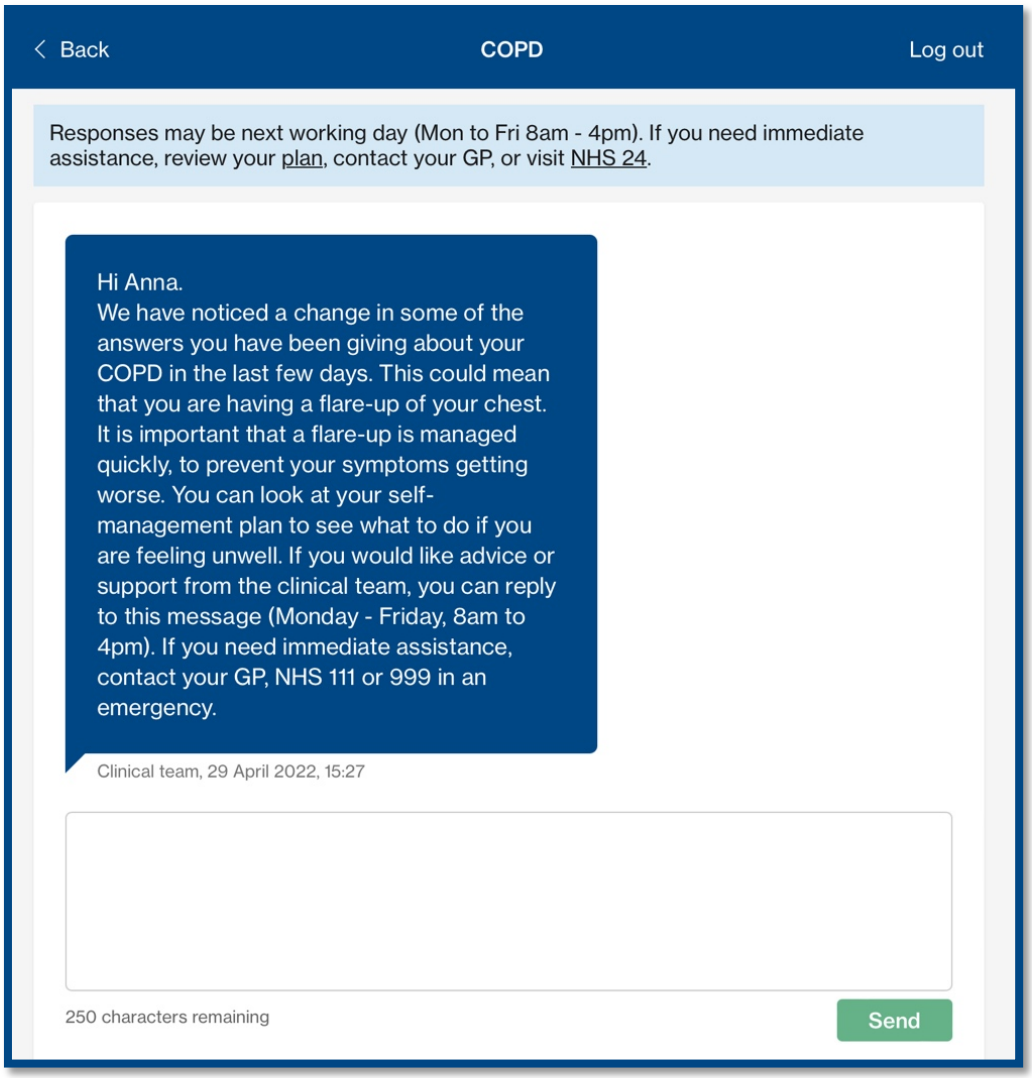


Figure 5 Screenshot of the messaging section of patient app screen, with safety net advice for urgent or out-of-hours contacts displayed at the top of the screen. Synthetic patient details are shown for illustrative purposes only.

A proportion of the participants were also setup with a Fitbit Charge 3 device that recorded heart rate, step count and sleep. This was linked to their digital service account via an application programming interface (API) with the Fitbit app. Participants with chronic hypercapnic respiratory failure who were receiving home NIV therapy treatment with remotely monitored ResMed Lumis150 devices also had their NIV data linked to their digital COPD support service account via an API with the Resmed AirView remote monitoring platform.

2.1.7 Data collection

Demographic and disease severity data was collated from participant's EHR and following consultation with the participant at enrolment into the trial. These data were recorded in the clinical details form within the clinician dashboard of the digital COPD support service. Study ID was assigned to allow data to be anonymised during analysis. PRO data were collected via the patient app.

2.1.8 Control cohort creation

A contemporary control cohort was created through the WoS SafeHaven for use in the trial outcome analysis. The WoS SafeHaven is a trusted research environment governed by the Charter for Safe Havens in Scotland (2015) (Scottish Government, 2015). Formed collaboratively between NHS GG&C Research & Innovation department and the Robertson Centre for Biostatistics, it provides a secure computing environment through which approved researchers can access de-identified data and work on approved projects deemed to be of public benefit.

The control cohort was created prospectively to match the demographic and admission history of the RECEIVER cohort. As the majority of the RECEIVER participants were recruited and enrolled on the service at a hospital admission episode, the primary matching criteria was a respiratory-related hospital admission within the date proximate to the participant's enrolment date. This, combined with a 12-month pre and 12-month post index follow up period to consider COPD exacerbations and hospitalisations mitigates any potential impact of seasonality (and also the COVID-19 pandemic) on event rates comparisons between controls and participants. Availability and constraints on the de-identified data held within the WoS SafeHaven research environment meant that there were limitations to the degree of matching possible; some desirable matching criteria such as lung function, smoking status and symptom history were not available.

2.1.9 Ethics

Ethical approval covering the RECEIVER trial and the research for this thesis was obtained from the WoS Research Ethics Service, reference 19/WS/0072. Approval for use of de-identified electronic health record data stored within WoS SafeHaven repository was granted by the Local Privacy and Advisory Committee (LPAC). The RECEIVER trial was registered prospectively at clinicaltrials.gov website (reference NCT04240353).

2.2 Mixed methodology

Acknowledging the complexities of digital interventions and the advantage of having a comprehensive understanding of their usage and impact, there is value in including both quantitative and qualitative data when undertaking evaluations of such interventions. The use of mixed methodology is recognised as a means of assessing effective engagement and potential behaviour change mechanisms within digital interventions (Yardley *et al.*, 2016; Milne-Ives *et al.*, 2023).

In simplistic terms, a mixed methods study involves the utilisation and integration of both quantitatively and qualitatively acquired data to answer a research question. Traditionally, a researcher would select either a quantitative or qualitative methodology to answer a specific research question. Combining both methods provides data and insights that can enhance and enrich the understanding of a phenomenon and provide a more complete analysis of complex scenarios, interventions or outcomes (Greene, 2007; Creswell and Plano Clark, 2018).

Greene (2007) described using mixed methods as,

> '*multiple ways of seeing and hearing, multiple ways of making sense of the world, and multiple standpoints on what is important and to be valued and cherished*' (Greene, 2007)

Mixed methods are being increasingly used in digital healthcare research and implementation. For example, Bradbury et al (2015) used qualitative interviews to refine and develop an online weight management intervention (Bradbury *et al.*, 2015). A Quantitative feasibility study of the intervention was then used to evaluate the effectiveness of different levels of support, followed by qualitative interview with participants to explore their perceptions of the nursing support. All three components were combined to evaluate the intervention and provide richer insights than use of the components alone. Within respiratory care, Alwashmi et al (2020) explored the perceptions of patients regarding mobile health interventions for the management of COPD (Alwashmi *et al.*, 2020). They collected quantitative survey data on the use of technology and mobile health use from patients attending respiratory clinics. This survey was then used to

guide further qualitative interviews with selected participants. Through this design they were able to describe demographics, use, and access to smartphones for people with COPD, and developed an understanding of the factors that may influence the use of mobile health interventions for COPD management.

2.3 Philosophical assumptions

The choice of method and methodology undertaken in research is underpinned by the theoretical perspective or worldview taken by the researcher (Crotty, 2015). Differing theoretical positions bring with them varying philosophical assumptions about the nature of data, how knowledge is gained, and what 'reality' is.

Traditionally, the methods by which data are derived and are analysed within quantitative and qualitative research differ in relation to their philosophical assumptions regarding reality (ontology) and how knowledge is gained (epistemology) (Crotty, 2015). Over the last 30 years, there has been extensive debate about the ability to undertake mixed methods study and combine these two approaches, which are based on such polar worldviews. Although this debate has never been fully resolved, more recently there has been a move away from these dichotomous viewpoints and emphasis placed on the benefits of using mixed methods study to produce more comprehensive, rounded results.

2.3.1 Reconciling opposing theoretical assumptions

Scientific and medical research traditionally use quantitative methods and sits within an objective epistemology, with a positivist theoretical perspective; there is a singular reality that exists independently, knowledge is gained through empirical observation and measurement, theories can be verified, and the researcher is unbiased and value-free.

Prior to my medical degree, I completed a BSc in Zoology. I am familiar with academia and the traditional concept of 'research', and my previous experience therefore stems from a positivist 'scientific' paradigm.

Utilisation of qualitative methods often involves adopting a research stance that incorporates a more inductive mindset to fully appreciate the advantages and scope of data that can be generated from this type of enquiry. Qualitative methods originate from a constructivist perspective; multiple realities exist and are created as a social construct unique to an individual, knowledge is subjective, theories are generated, and data is interpretated through the researcher's own perspective and standpoint.

Creswell and Plano Clark (2018) describe four research broad stances that can be adopted when approaching mixed methods research, to reconcile opposing theoretical assumptions (Creswell and Plano Clark, 2018):

1) *One 'best' worldview* – a single overarching worldview that informs mixed methods research, e.g. pragmatism or critical realism
2) Using a dialectical perspective that combines multiple worldviews - researchers can use multiple paradigms in mixed methods research but must be explicit in their use, e.g. dialectical pluralism
3) Worldview based on study context and design – flexibility to use a worldview that best fits the context of the study
4) Worldview dependent on the scholarly community

2.4 Research stance

I have chosen to use a single overarching worldview of pragmatism to inform and shape my use of mixed method in the context of this research study.

Pragmatism is a philosophical set of ideas that has been articulated throughout history by figures such as John Dewey, William James, and Charles Sanders Peirce, as well as in more contemporary literature (Cherryholmes, 1992; Morgan, 2007). As a research paradigm, it focuses on the importance of the research questions, collecting multiple forms of data that 'best' address the research aims, valuing both objective and subjective knowledge and multiple views of reality, and recognising that causal relationships exist but they are often particularistic and transitory (Fetters, 2020; Tashakkori, Johnson and Teddlie, 2021). Tashakkori and Teddlie (2003) formally linked pragmatism and mixed methods research, and it remains a dominant research philosophy used within

mixed methods studies (Johnson *et al.*, 2017). Having pragmatism as a research stance enables the adoption of a pluralistic approach of gathering all types of data to best answer the research question (Creswell and Plano Clark, 2018).

I considered the use of multiple worldviews; adopting a postpositivist orientation for the quantitative components, then shifting to more constructivist assumptions for the qualitative components, with the final interpretation of the connected results based on one set of assumptions or a dialectical perspective involving both stances. However, I felt that the real world-practice orientated focus of pragmatism was more fitting to my research aims as well as those of the RECEIVER trial and DYNAMIC project as a whole, with the ultimate goal of obtaining useful answers (Tashakkori, Johnson and Teddlie, 2021).

2.5 Mixed methods study design

Quantitative and qualitative data can be combined in a number of different ways, and study design is commonly directed by the research problem and objectives of a study.

During the development of original RECEIVER protocol, it was recognised that user perspectives were expected to be a valuable asset. The ability to capture qualitative data was included within the participant trial consent, appreciating the direction of interest and priorities were likely to evolve as the trial commenced and planned interim analysis of the quantitative effectiveness outcomes were obtained. Interim analysis conducted six months into the RECEIVER trial highlighted emerging results that warranted further investigation and directed my selection of a mixed methods research question and study design. Tashakkori et al (2021) describe the necessity of mixed methods emerging sometimes during or at the end of a project strand, transforming the initial research question into a mixed methods question, also referred to as an emergent mixed methods research question (Tashakkori, Johnson and Teddlie, 2021). This is in contrast to projects where the decision to use mixed methods is made early on in the planning process as there is a predetermined integrated research question. Creswell (2022) also notes that the choice of mixed methods study design can emerge in a study rather than always being preplanned and is

often influenced by factors such as demands of resources or shifting priorities of participants (Creswell, 2022).

Mixed methods study designs have evolved over time with maturation of the mixed methods field. Within current methodological literature, mixed methods study design approaches can be method focused, based on types (or a typology), or research-process focused. A typology-based approach was selected for this thesis as they are most commonly used within healthcare mixed methods research and is best suited to researchers who are new to designing and conducting mixed methods studies (Creswell and Plano Clark, 2018; Tashakkori, Johnson and Teddlie, 2021). Using a typology-based approach, three core mixed methods designs were developed and evolved by Creswell and Plano Clark (2018) to be bother parsimonious and practical for researchers; the convergent design, the explanatory sequential design, and the exploratory sequential design (Creswell and Plano Clark, 2018). An explanation and rationale for each design are given below, according to the descriptions given by Creswell and Plano Clark (2018).

2.5.1 Convergent design

In a convergent design, qualitative and quantitative data are brought together with the intention to combine or compare results, recognising that both types of data bring different insights. This allows the subject of study to be seen from multiple angles and perspectives. Integration occurs with merging of the two datasets, with discussion of the conclusions or inferences drawn based on the combined results (figure 6 A).

A convergent study design can be viewed as an efficient means of data collection, as both types of data are usually collected around the same time. This type of design also lends itself to team research where each set of data can be collected and analysed independently, and individuals can work within their own field of expertise. Collecting data in parallel allows for direct comparison of participants' and researchers' perspectives. This can mean that there are different sample sizes and consideration of this is needed when the two data sets are merged. Merging text and text databases in a meaningful way can also

be problematic; data transformation and joint displays are often used to overcome this.

2.5.2 Explanatory sequential design:

In an explanatory sequential design, the qualitative results are used to explain the quantitative results. This type of design can help to understand the reasons behind why certain quantitative results are obtained or understand the findings in more depth. Results that are followed up are often those that are significant, unexpected, or outliers. Integration occurs at point of selection of quantitative results that are deemed to warrant further explanation.

In this study design there are two distinct phases of data collection. In the initial phase, quantitative data is collected and analysed. The direction of the second phase is determined by the results of interest obtained in the initial phase. Specifically, the qualitative research questions, purposeful sampling procedures and data collection are developed and refined at this intermediate point. In the second phase, qualitative data is collected and analysed to help explain or expand on the results seen in the initial phase. Connection between the two phases occurs in the intermediate point of the study, with integration of the quantitative and qualitative results occurring at the study conclusion (figure 6 B).

Data collection within an explanatory sequential design is often seen as straight forward to implement with one phase following the other. Because of this, extended time is needed for completion, with complete analysis of the first phase of data collection required before moving onto the second. Additionally, the qualitative results requiring follow up need to be identified, meaning the qualitative phase cannot be fully specified in advance, although there may be an awareness of the potential questions that may arise during the conception of the study. This type of design therefore lends itself to an emergent approach.

2.5.3 Exploratory sequential design:

In an exploratory sequential design, the intent is to develop measures and instruments that are sensitive and relevant to the needs of a specific population

or sample; the approach or tool is grounded in the views of the participants. For example, there may be a need to understand the requirements or cultures of the population being studied before determining what measures are best suited, or how existing measurements can be adapted to cultural requirements.

There are three phases within an exploratory sequential design. The initial stage starts with the collection and analysis of qualitative data. This is then followed by a development phase, translating the findings into an approach or tool, which is then tested quantitatively in the third phase. Integration occurs within the development phase and conclusions drawn after quantitative testing of the approach or tool has been conducted (figure 6 C).

Strengths of this study design mirror that of the explanatory sequential design with the distinct phases aiding clear description, implementation and reporting. A new instrument or tool is also produced as a potential product of the research process. However, this approach commonly requires extended time for completion. There is also additional thought and planning required as to the need for different study samples and sizes, and which of the qualitative results to use to develop and build the new tool. Rigorous steps of instrument and scale development require researcher skill.

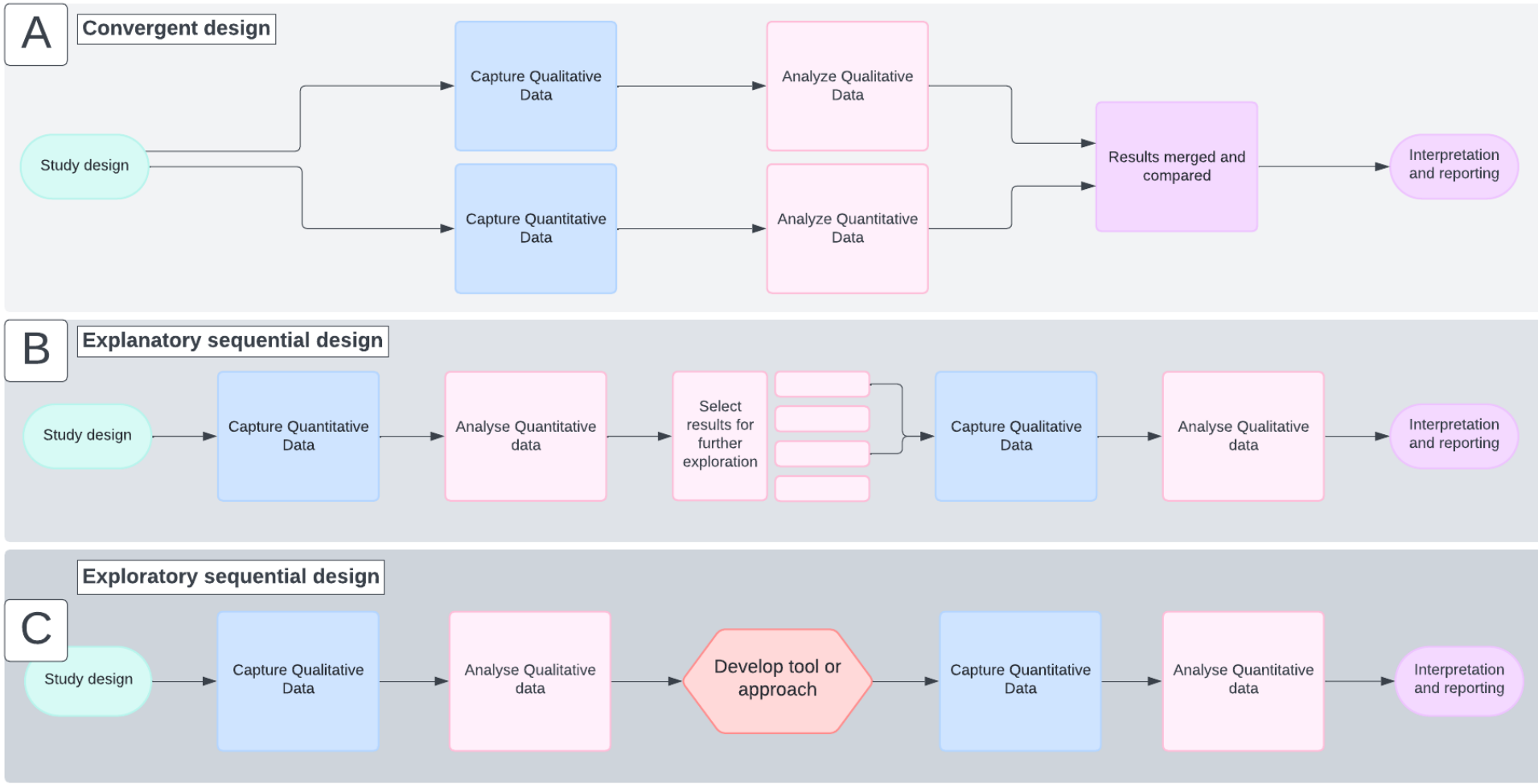


Figure 6 Diagram showing the three core mixed methods study designs developed by Creswell and Plano Clark (2018). A) Convergent study design, B) Explanatory sequential study design, C) Exploratory sequential study design

2.6 Chosen study design

An explanatory sequential mixed methods study design was used for this research project as I believed that this study design was best suited to gaining further understanding of the emerging results that were beginning to be seen from the quantitative elements of the RECEIVER study. An explanatory sequential design also allowed distinct phases of data collection to be undertaken which suited the resources and time available to me. For this study the emphasis was placed on the quantitative phase (QUAN) of the study as it addressed the main purpose of the overall RECEIVER trial, with the qualitative phase (qual) adding explanation and understanding to the quantitative results.

The following notation can be used to demonstrate this: QUAN $\rightarrow$ qual = explain quantitative results.

Further details of the quantitative results chosen to be followed up and rationale for identifying the participants that were approached for the qualitative sample is given in chapters four and five.

2.7 Qualitative methods

2.7.1 Thematic analysis

A reflexive thematic analysis (TA) approach (Braun and Clarke, 2006) was used within the qualitative elements of this research project as it allowed participant 'truths' and lived experiences to be explored. This method allowed me to be mindful of the context and understanding from which the knowledge was produced, as well as the influence and contribution I bring to the data as a researcher. Reflexive TA also allowed coding to occur inductively, from the 'bottom up', initially at a semantic (descriptive), then latent (interpretive) level. This widened the scope of understanding of the data and contribution to the research question, without being tied to a specific theoretical framework. There was an experiential focus on the explicit meaning in the data, assuming meaning and understanding is articulated through language (Potter and Wetherell, 1987).

The analysis was conducted through an experiential lens from the experiences and perspectives of participants focusing on ground-up generation of themes. The context within which participant usage and beliefs about the support service were created was also taken into consideration as the themes were developed.

Analysis was guided by the six phases of reflexive TA as outlined by Braun and Clark (2021) (summarised in table 3). This was a recursive process, with time taken to move back and forth between phases to fit with the research question and data collection.

Phase	Description of process
1. Familiarising yourself with your data:	Immersion in the dataset; listening (if applicable), reading, re-reading of the data and making (brief) notes about any analytical ideas or insights you may have.
2. Coding:	Working systematically through dataset, identifying segments that appear potentially interesting, relevant or meaningful to your research question, and applying analytically-meaningful descriptions (code labels) to them. Code labels are then collated and the relevant segments of data compiled for each code.
3. Generating initial themes:	Identification of shared patterned meaning across the dataset. Compilation of clusters of code that seem to share a core idea or concept, which might provide a meaningful 'answer' to your research question = candidate themes.
4. Developing and reviewing themes:	Development and review involve checking that candidate themes make sense in relation to both the coded extracts, and then the full dataset. Certain candidate themes may be collapsed together or split into new themes or discarded all together. In reviewing, you need to think about the character of the individual theme and its scope. You also need to start considering the relationship between the themes, and existing knowledge, and wider context of the research.
5. Refining, defining, and naming themes:	Analysis is fine-tuned, ensuring that each theme is clearly demarcated and is built around a strong core concept or essence. Key activities in this phase involve writing a brief synopsis of each theme and deciding on a concise and informative name.
6. Writing up:	Finesse and finish the writing process (often started informally in earlier phases through familiarisation notes and reflexive journaling). Aiming to weave together your analytic narrative and compelling, vivid data extracts, to tell you reader a coherent and persuasive story about the dataset that addresses your research question.

Table 3 The phases of reflexive thematic analysis - taken from Braun and Clarke, (2021)

2.8 Personal background and reflexivity

Practicing reflexivity is important not only to provide insight into how the research has been performed but also to inform the role of the researcher as an active agent in the production of knowledge (Trainor and Bundon, 2021).

Reflexivity is most associated with qualitative research where it is used to increase the integrity and trustworthiness of the research (Finlay, 2002).

My background is in hospital medicine, initially training in acute medicine and more latterly working in respiratory and sleep medicine as a clinical research fellow. I have no prior experience of qualitative data collection but have completed a formal training programme in qualitative research methods.

Whilst the high degree of involvement in both the technology unpinning the RECEIVER study and the study itself allowed for a greater understanding and awareness of the clinical context in which they sit, I recognised that I should be mindful of my influence over the data and its analysis

2.9 Chapter conclusion

The RECEIVER implementation and effectiveness observational study that was conducted to evaluate the use of the COPD digital support service has been outlined in this chapter. Additionally, the rationale behind the mixed methods approach that was taken during the research project has been described, along with the explanatory mixed method study design that was chosen and the qualitative analysis methodology that was utilised.

The next chapter will detail the quantitative recruitment experience and results of the primary outcomes of the RECEIVER trial.

3 RECEIVER trial recruitment and primary outcome results

The previous chapter has documented the initial methodology for this project and introduced the RECEIVER clinical trial and the digital COPD support service interventions that the trial has evaluated.

Self-management strategies are recommended to people with COPD to help long-term management of their condition (GOLD, 2024). Digital solutions have been sought to improve accessibility and uptake of these strategies, but there have been limitations to the comparison of evidence to support their effectiveness. Gaps exists in the research evaluating usage and engagement with these types of digital intervention, which may account for the previous variations in success.

The utilisation measures captured within the primary outcome of the RECEIVER study looked to evaluate if and how participants used the COPD support service patient app. It is no good evaluating the impact of an intervention if patients cannot or will not use it in the first place.

This chapter details the recruitment experience and results of the primary endpoint of the RECEIVER study. Content and data contained in this chapter have been published; **Taylor *et al.*, 2023. Long-Term Usage and Improved Clinical Outcomes with Adoption of a COPD Digital Support Service: Key Findings from the RECEIVER Trial.** *International Journal of Chronic Obstructive Pulmonary Disease* Volume 18, pp. 1301–1318. doi: 10.2147/COPD.S409116.

The statistical analysis for the RECEIVER study was undertaken by MSc students as part of their University of Glasgow stratified medicine project under direct supervision by me and other members of the research team.

3.1 Methods

The following methods were used to capture and evaluate patient app usage for the primary endpoint analysis.

3.1.1 Baseline data

Baseline demographic, admission history, lung function and comorbidity data were obtained from participants EHR and collated within the clinician dashboard (shown in figure 7). Baseline PRO data were taken during trial enrolment.

3.1.2 Patient reported outcome (PRO) data

Participants were prompted to input PRO responses daily through the patient app, with the response data that were collected each day counted as a PRO 'set'. These data were captured and displayed within the clinician dashboard, and data stored within a cloud-based database. De-identified PRO data, consisting of the frequency and PRO response breakdown, were aggregated from the database via the cloud data factory, and made available as a .csv file.

3.1.3 Primary outcome measures

Primary endpoint → participant utilisation of the patient app was measured by the number of PROs sets completed per week over the course of the study, with the target of completion of 1 set of PROs per participant per week.

The frequency of daily PRO submission by a participant across each week of participation was employed as a measure of usage of the patient app. Analysis of usage patterns across the whole cohort was undertaken, along with sub-group analysis of those participants resident in more deprived postcodes to allow conclusion about equality and fairness to be drawn.

3.1.3.1 Exploratory analysis derived from primary outcome

Exploratory analysis was conducted to further characterise and stratify usage patterns and determine potential participant factors associated with utilisation. Stratification of usage patterns was through 7-day rolling averages of PRO completion rates, grouped into quartiles. Kruskal-Wallis tests and chi squared tests were used to explore interactions between PRO completion and baseline characteristics and admission events over the first year of follow-up.

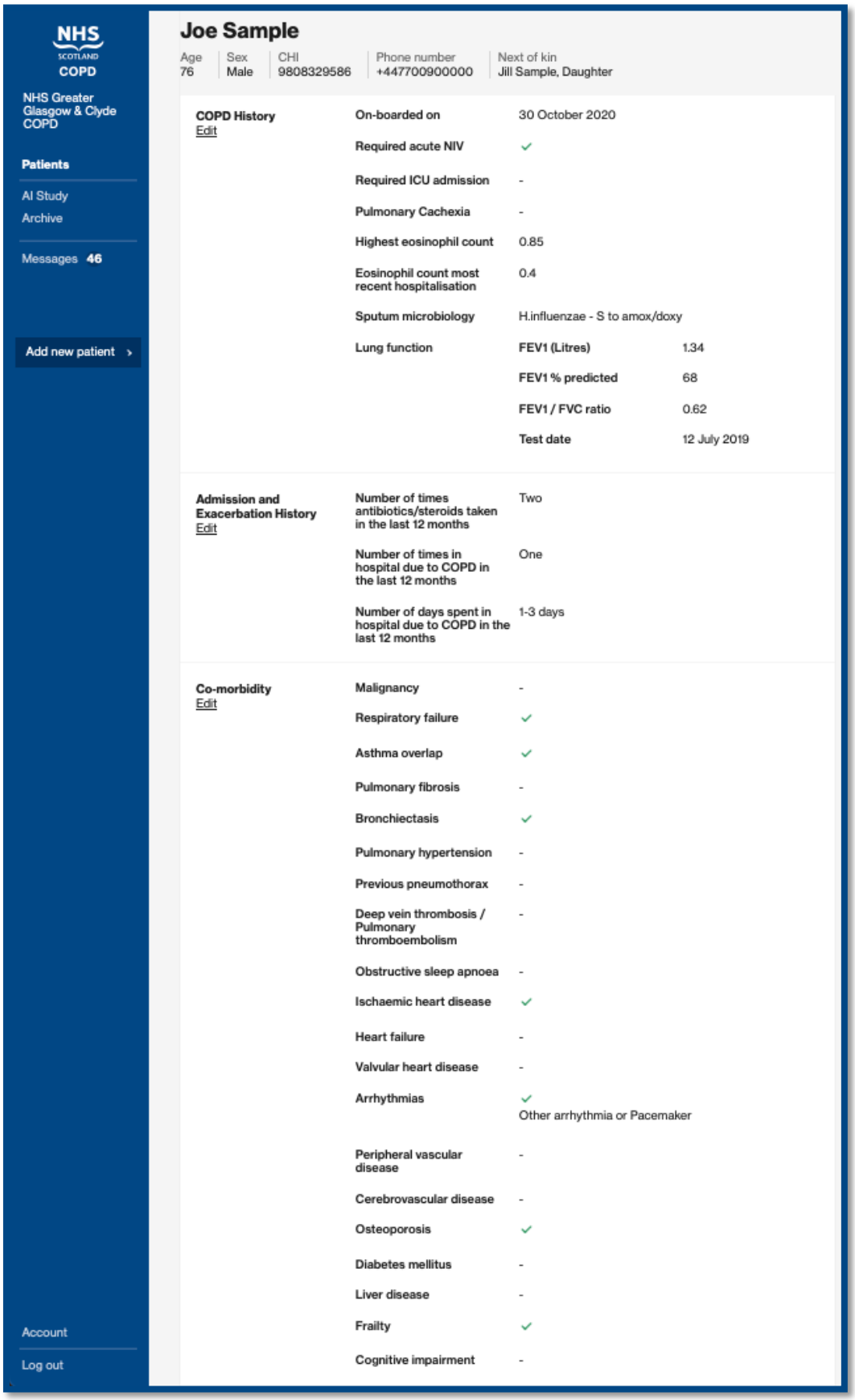


Figure 7 Screenshot showing the form used to capture baseline clinical data for participants, collated from their electronic heath records including pulmonary function tests, admission history and co-morbidities. Synthetic patient data is shown for illustrative purposes only.
Abbreviations: ICU, intensive care unit. NIV, non-invasive ventilation. FEV1, forced expiratory volume in 1 second. FVC, forced vital capacity.

3.1.4 Interim analysis and data censor

For trial safety and project monitoring, planned interim analyses of PRO submission and event rate was undertaken at three, six and 12 months from trial commencement, and once all participants had completed at least 365 days in the study (March 2021).

There were no trial safety concerns raised during the interim analysis and data censor for final study analysis took place as planned on 31st August 2021, despite the enforced early recruitment close due to the COVID-19 pandemic.

3.1.5 Data handling, aggregation and analysis

De-identified clinical data were obtained from the service database, through the cloud data factory output.

Data handling, aggregation and analysis was performed using Microsoft Excel, R version 4.0.5 and GraphPad Prism version 9.3.1.

3.2 Results

3.2.1 RECEIVER trial recruitment

Figure 8 details the RECEIVER trial recruitment experience. 283 individuals were screened to the trial. Of those excluded at screening, 41 individuals did not have access to technology. 86 people enrolled onto the RECEIVER study, with 83 participants going on to be onboarded to the service and complete follow up. Two individuals were not able to access the digital service due to technology issues and did not complete enrolment. One individual withdrew before receiving the service intervention.

54 people had been screened and were pending recruitment to the trial at the point of UK COVID-19 lockdown.

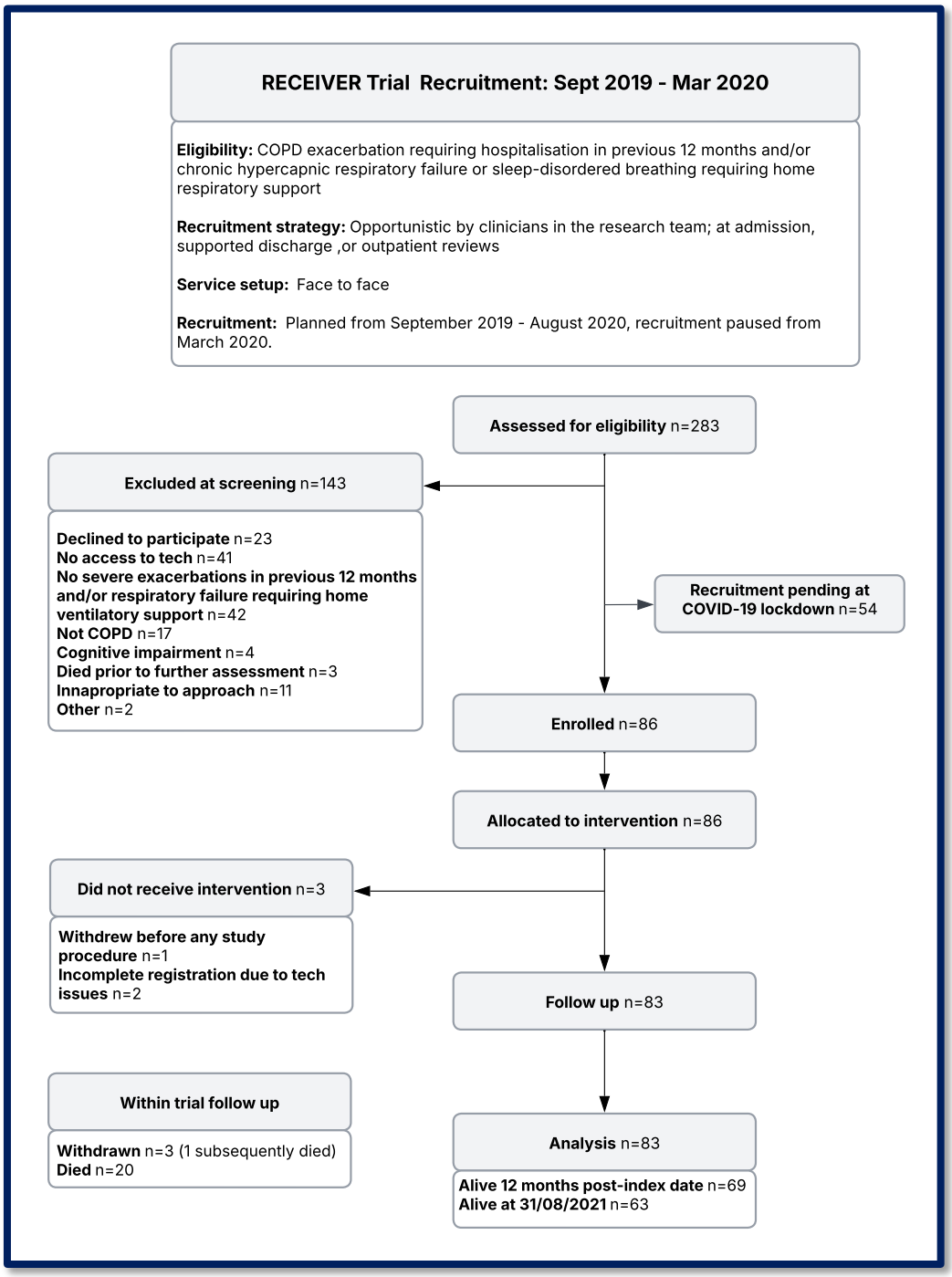


Figure 8 Flow diagram detailing the recruitment of participants to the RECEIVER trial. Abbreviations: COVID-19, coronavirus disease.

3.2.2 RECEIVER trial population characteristics

The baseline characteristics of the participants in the RECEIVER trial are summarised in table 4. On average, participants were 64.4 years old, with women making up a larger proportion of the group. Many individuals had high scores on both their CAT and MRC baseline responses, reflecting the considerable burden of their disease. About one-third of participants required either long-term oxygen therapy or home NIV to support their breathing.

Additionally, those in this subgroup had higher rates of hospital admissions in the year leading up to their enrolment in the study. Notably, 54 out of the 83 participants had at least one pre-existing additional health condition at the start of the trial.

57.8% of the RECEIVER participants were resident within postcodes in the most socioeconomically deprived quintile on the Scottish Index of Multiple Deprivation (SIMD). This proportion mirrors the typical burden of COPD in deprived areas within NHS GG&C (Public Health Scotland, 2022)(figure 9).

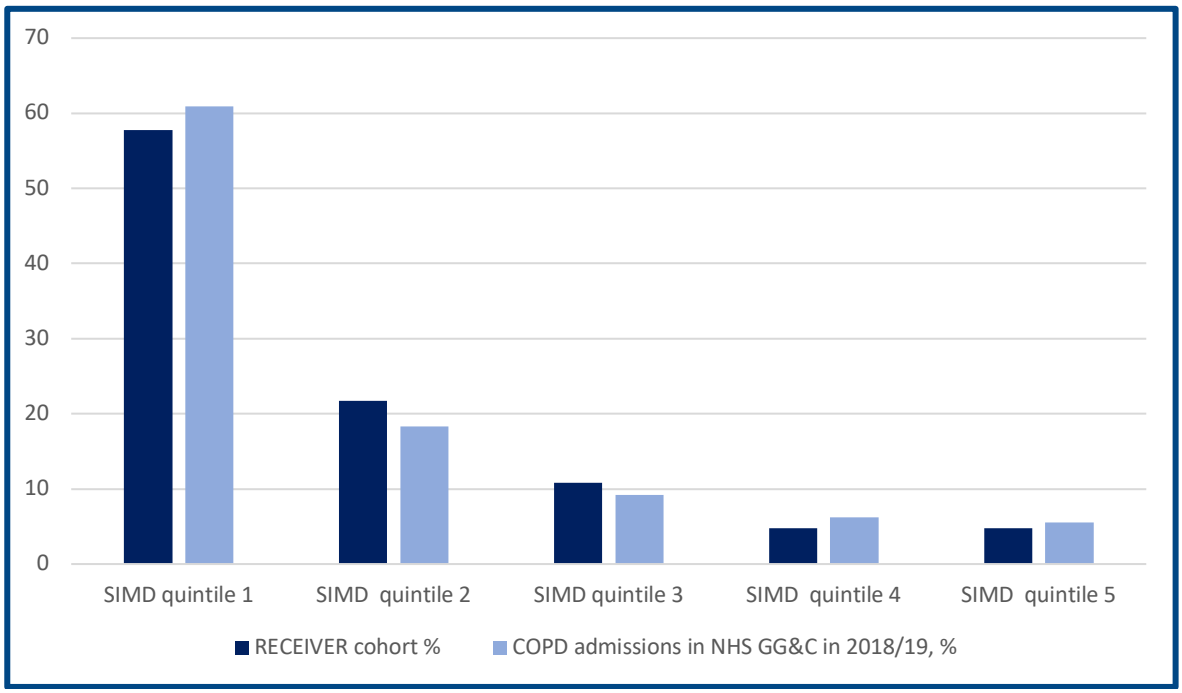


Figure 9 Graph showing the percentage of RECEIVER participants resident in each quintile of the Scottish Index of Multiple Deprivation (SIMD) compared to the overall COPD population within NHS Greater Glasgow & Clyde (NHS GG&C) (Public Health Scotland, 2022). SIMD 1 = area of most deprivation, SIMD 5 = area of least deprivation.

	RECEIVER
Number of individuals	83
Age at baseline, mean (SD), years	64.4 (9.3)
Sex, % female	63.9
COPD or respiratory-related admissions in the previous year, mean (SD)	2.5 (2.3)
Smoking status, %	
Former smoker	69.9
Current smoker	30.1
FEV1 % Predicted, mean (SD)	47.9 (20.8)
FEV1/FVC Predicted, mean (SD)	0.46 (0.1)
Baseline CAT score, mean (SD)	23 (6.6)
Baseline MRC Dyspnoea scale score, mean (SD)	4 (1.2)
Trible combination inhalers (LABA+LAMA+ICS), % users	80.7
Previous pulmonary rehabilitation, % had attended	24.1
NIV therapy, % users	28.9
Home oxygen therapy, % users	37.3
Comorbidities, % with	
Osteoporosis	13.3
Ischaemic heart disease	8.4
Obstructive sleep apnoea	12
Diabetes	10.8
Asthma	9.6
Atrial Fibrillation	9.6
Heart Failure	10.8
Deep venous thrombosis/pulmonary thromboembolism	3.6
Cerebrovascular disease	0
Bronchiectasis	2.4
Pulmonary hypertension	1.2
Pneumothorax	2.4
Pulmonary fibrosis	0
Lung cancer	1.2

Table 4 Baseline characteristics of the RECEIVER trial participants
Abbreviations: SD, standard deviation. FEV1, forced expiratory volume in 1 second. FVC, forced vital capacity. CAT, COPD assessment tool. MRC, Medical Research Council dyspnoea scale. LABA, long acting beta agonist. LAMA, long acting muscarinic antagonist. NIV, non-invasive ventilation.

3.2.3 Primary outcome: patient app utilisation based on daily patient reported outcome set completion

A high level of sustained completion of PROs by participants was noted, with 26,019 sets of daily of PROs submitted over the course of the study. More than two thirds of participants completed at least one set of PROs per week in the first year of follow up, with consistent usage noted beyond this (figure 10).

The mean number of PROs submitted per participant per week was 4.3 across the first year of follow up, with an average of 4.0 across the whole study (Figure 11).

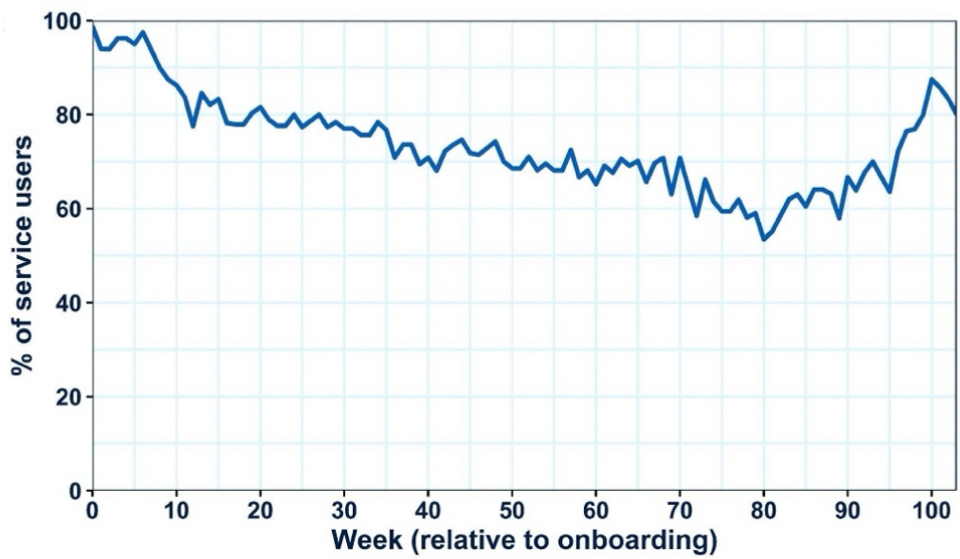


Figure 10 Graph showing percentage of participants completing at least one set of patient reported outcomes (PRO) per week across the duration of the RECEIVER trial.

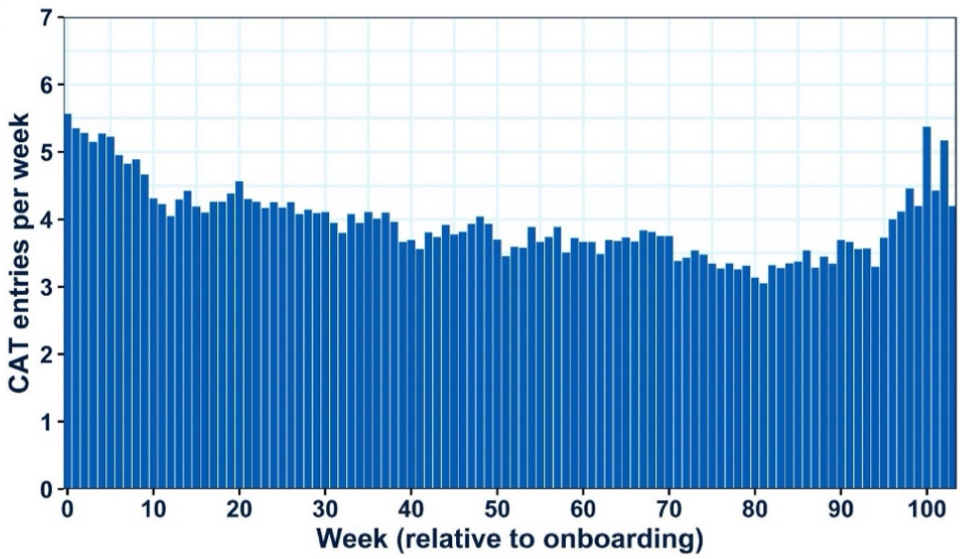


Figure 11 Graph showing mean number of patient reported outcome (PRO) sets completed per participant per week over the course of the RECEIVER trial

3.2.4 Exploratory analysis: usage patterns and stratification

The rates of completion of at least one PRO set per week were compared across the follow up period at a cohort and individual level, to show patterns of usage. These data were then stratified by usage rates and socioeconomic status to explore possible associations between different participant factors and their usage types.

3.2.4.1 *General usage patterns*

Around 77% of participants were sustained users, with completion of at least one PRO set per week on over half of the possible follow-up weeks. Completion rates varied between participants; a pause in PRO submissions for at least 1 week was observed for 39 participants, 24 of which subsequently returned to regular or intermittent use.

3.2.4.2 *Stratification by usage quartile and quartile comparison*

Usage data were stratified into four quartiles based on mean number of entries completed in previous seven days at each possible point over the first year of follow up (seven-day rolling average completion). Quartile ranges were labelled as very regular users, regular users, intermittent users and infrequent or non-users.

Figure 12 shows a heatmap visualisation of the seven-day rolling average (RA), grouped into the utilisation quartiles. From this visualisation it is possible to see the variation in usage patterns of participants both within and between quartile groups. As mentioned previously, there were several individuals who paused PRO completion for a time, and recommenced either regularly or intermittently.

Exploratory analysis found no significant differences in baseline characteristics or admission data between the four utilisation quartiles in the year post trial enrolment (comparison data shown in tables 5 and 6).

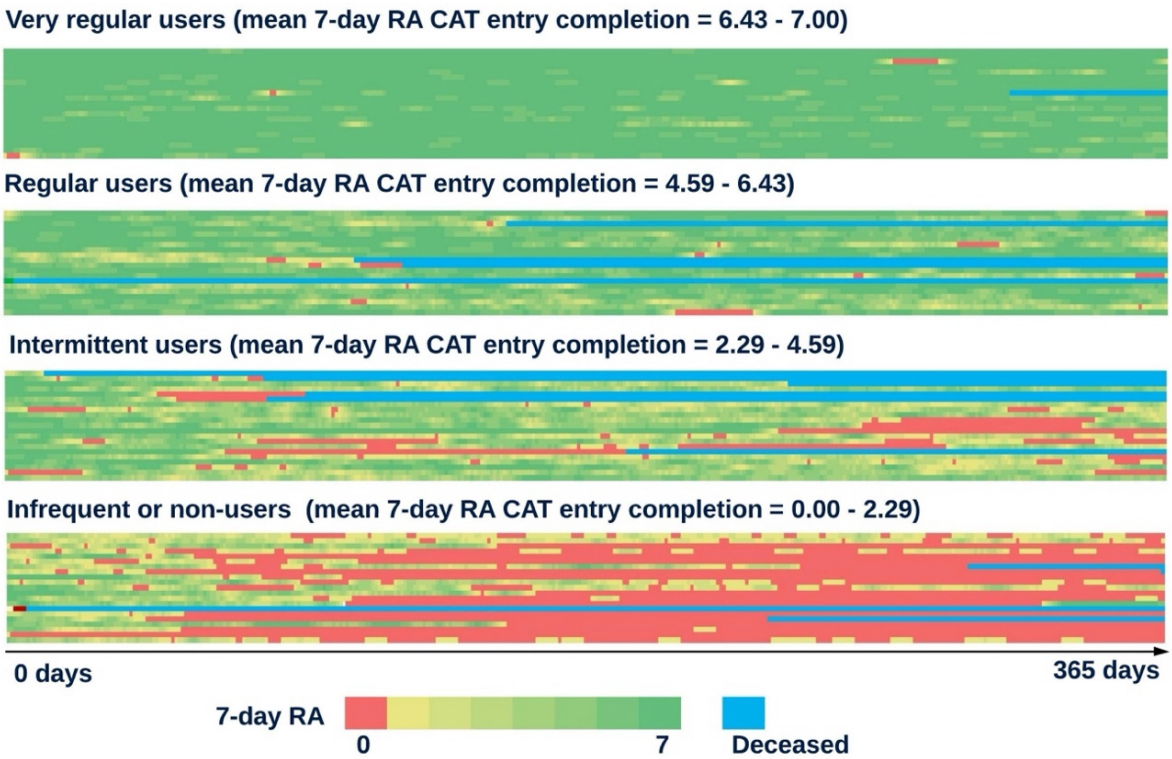


Figure 12 Heatmap visualisation showing the 7-day rolling average (RA) of patient reported outcome entry completion (shown as CAT entry in this figure) for each RECEIVER participant over the first year of follow up, segregated into utilisation quartiles. Each line represents a participant. Dark green areas represent periods of very high completion (6-7 daily PRO entries in previous seven days), whilst red areas represent periods of no recent completion (zero PRO entries in previous seven days). Continuous blue denotes when a participant has died.
Abbreviation: CAT, COPD assessment tool

	Very regular users (4), n = 20	Regular users (3), n = 16	Intermittent users (2), n = 16	Infrequent or non-users (1), n = 17	p-value
COPD or respiratory-related admission events over first year of follow-up, mean	0.85	0.625	1.31	1.18	0.5665
COPD or respiratory-related occupied bed days over first year of follow-up, mean	5.45	3.06	7.62	12.2	0.3262

Table 5 COPD or respiratory related admissions and occupied bed day count for participants in each of four utilisation quartiles, with p-value >0.05 for each, showing no significant difference between utilisation groups (Kruskal-Wallis test). Data is shown for individuals alive 12-months post index date.

	Very regular users (4) n = 21	Regular users (3), n = 20	Intermittent users (2), n = 21	Infrequent/non-users (1), n = 21	p-value
Age at baseline, mean	63.1	67.3	64	63.3	0.3318
Sex, % female	52.4	60	71.4	71.4	0.4992
Smoking Status, % current	23.8	25	38.1	33.3	0.7093
COPD or respiratory-related admissions in previous year, mean	2.7	2.5	2.4	2.3	0.9572
SIMD Quintile, mean	1.7	1.8	2	1.5	0.305
FEV1% predicted, mean	44.7	50	48	49	0.8428
FEV1 /FVC predicted, mean	0.45	0.47	0.47	0.45	0.9837
Previous pulmonary rehabilitation, %	28.6	35	19	14.3	0.4029
NIV therapy, % users	33.3	20	19	42.9	0.2665
Home Oxygen User, % users	33.3	35	33.3	47.6	0.7331
Baseline CAT, mean	21.2	23.4	24.6	23.8	0.4737
Baseline MRC, mean	3.6	3.8	4	3.3	0.2728
Highest eosinophil count, mean	0.55	0.51	0.56	0.93	0.6877
Comorbidities, % with					
Osteoporosis	28.6	5	9.5	9.5	0.1126
Ischaemic Heart Disease	4.8	5	9.5	14.3	0.6514
Obstructive Sleep Apnoea	9.5	5	9.5	23.8	0.269
Diabetes Mellitus	9.5	5	4.8	23.8	0.1578
Asthma Overlap	9.5	10	4.8	14.3	0.7777
Bronchiectasis	0	5	0	4.8	0.5515
Atrial Fibrillation	14.3	15	4.8	4.8	0.5072
Heart Failure	14.3	10	14.3	4.8	0.7213
Cerebrovascular Disease	0	0	0	0	NA
Pulmonary Fibrosis	0	0	0	0	NA
Pulmonary Hypertension	4.8	0	0	0	0.3934
Previous Pneumothorax	4.8	0	4.8	0	0.5723
Deep Vein Thrombosis or pulmonary Thromboembolism	9.5	5	0	0	0.285
Lung Cancer	4.8	0	0	0	0.3934

Table 6 Baseline characteristics for RECEIVER participants in each of the four utilisation quartiles, with p-value >0.05 for each showing no significant difference between utilisation groups. Kruskai-Wallis or Chi-square test as appropriate, NA is shown when no incidence of a binary feature were observed. Abbreviations: SIMD, Scottish Index of Multiple Deprivation. FEV1, forced expiratory volume in 1 second. FVC, forced vital capacity. NIV, non-invasive ventilation. CAT, COPD assessment tool. MRC, Medical Research Council dyspnoea scale.

3.2.4.3 *Usage stratification by socioeconomic status*

PRO submission rates for those participants resident in the most deprived postcodes (SIMD quintile 1) did not show a notable difference when compared to utilisation levels in the wider cohort (SIMD quintiles 2-5) (figure 13).

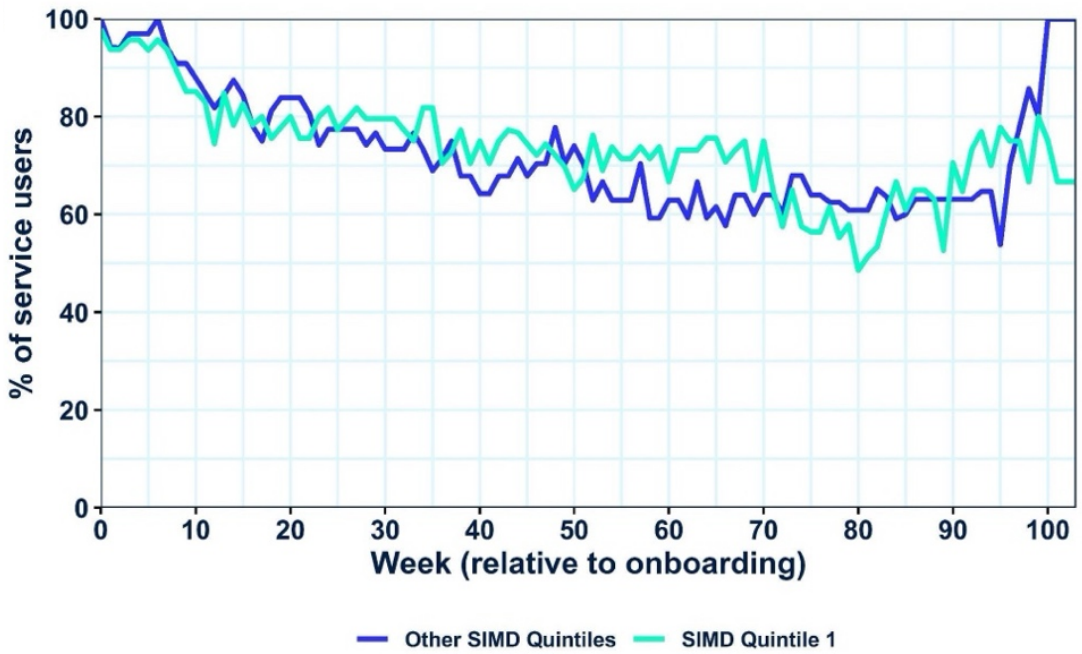


Figure 13 Graph showing percentage of participants completing at least one set of PROs per week stratified by Scottish Index of Multiple Deprivation (SIMD) quintile (SIMD 1 - most deprived vs SIMD 2-5)

3.3 Chapter discussion

A summary of the results found within the first quantitative section of this project is shown in figure 14.

There were a satisfactory number of participants recruited to the trial. The main barriers to inclusion being lack of a severe exacerbation in the preceding 12 months or not having access to suitable technology. Of the 283 people screened for recruitment to the RECEIVER trial, 41 lacked access to technology. Although this proportion was lower than levels noted in previous reports (Granger *et al.*, 2018), this still presents a barrier to usage that should be taken into consideration for ongoing service development, including exploring potential solutions to overcome digital exclusion and/or ensure adequate care delivery via equivalent non-digital service models. There were a notable number of participants ready to enrol in the RECEIVER trial at the point of cessation of recruitment in March 2020 due UK COVID-19 lockdown.

The study included a higher number of female participants. Research has shown that women are more likely than men to develop COPD. Furthermore, women with severe COPD face a greater risk of being hospitalised and of dying from the disease (Prescott *et al.*, 1997; Celli *et al.*, 2011; Goel *et al.*, 2018). However, these trends are not as noticeable in Scotland, according to data from Public Health Scotland (Public Health Scotland, 2021). In Scotland, the prevalence of COPD is particularly high among individuals aged 65 and older (Scottish Government Population Health Directorate, 2023). Interestingly, the average age of participants in the RECEIVER study was slightly younger than this age group, which may be linked to the higher than average rates of COPD incidence, hospitalisation and deaths reported in NHS GG&C compared to the national average (Scottish Public Health Observatory Collaboration, 2020).

The RECEIVER trial recruited participants with advanced COPD as evidenced by their high symptom burden (CAT and MRC scores), severe airflow obstruction, high rates of preceding hospital admissions and high proportion with established respiratory failure requiring home oxygen therapy and/or home NIV. Furthermore, collated lung function values were historical based on the last documented values within obtainable electronic healthcare records. For some individuals this potentially underestimated their spirometry-defined disease severity at the time of participation.

The frequency of co-morbidities seen within the RECEIVER cohort is slightly lower than those reported in studies of generalised COPD populations in Scotland (Chetty *et al.*, 2017). However, RECEIVER trial baseline co-morbidities were limited to those shown in table 4 and did not include mental health conditions, which may account for the difference in co-morbidity frequency noted.

High and sustained levels of patient app utilisation was achieved, with a large proportion of participants submitting at least 1 set of PROs per week over the course of the trial. Continuation of the duration of follow up beyond a year allowed detailed and extended characterisation of app usage to be undertaken; collection of longer-term usage data has been previously recommended to enhance understanding and increase the evidence base (McCabe, McCann and Brady, 2017; Janjua *et al.*, 2021).

The prevalence of COPD is disproportionately higher in more deprived communities and there is an increased risk of COPD hospitalisation and mortality associated with deprivation (Collins *et al.*, 2018). Within the UK, there is unequal access to care for those people living in more socioeconomically deprived communities, and higher levels of deprivation are associated with digital exclusion (Holmes and Burgess, 2022). It was therefore important to evaluate this aspect within the RECEIVER trial participant population. The level of deprivation within the study cohort (as measured by residence within SIMD quintile one) mirrored the proportions seen within the population of people with COPD within NHS GG&C, and usage of the app for this subgroup did not differ from the wider cohort. These data gave reassurances that socioeconomic status was not adversely affecting accessibility, uptake or utilisation of the digital service.

There was variation in usage pattern between individuals, with the measuring of the seven-day RA PRO submission rate allowing increased granularity compared to viewing overall mean completion rates alone, and the heatmap giving an effective means of visualising these data. The level of usage did not appear to be associated with any baseline demographics or clinical event data. Limited conclusions could be made as to how the frequency of usage or utilisation patterns may have impacted or be impacted by other factors (e.g. increased use around the time of an exacerbation, or lack of use during a hospital admission). These primary outcome results posed important questions for consideration within the qualitative elements of this study, highlighting the need to explore other aspects of utilisation and usage in further detail, to understand potential impact of and the mechanisms that may be driving it.

The RECEIVER study successfully recruited a sufficient number of participants to be able to demonstrate persisting usage of the patient app. However, it is not possible to draw conclusions about clinical effectiveness from this alone. As Baumel noted in their 2022 paper, the digital footprint denoting program usage is easily obtained and reported in research, however usage is not necessarily equal to the incorporation of a therapeutic activity (Baumel, 2022). Analysis of the secondary outcomes of the trial have provided additional information about

the clinical effectiveness of the support service and are detailed in the next chapter.

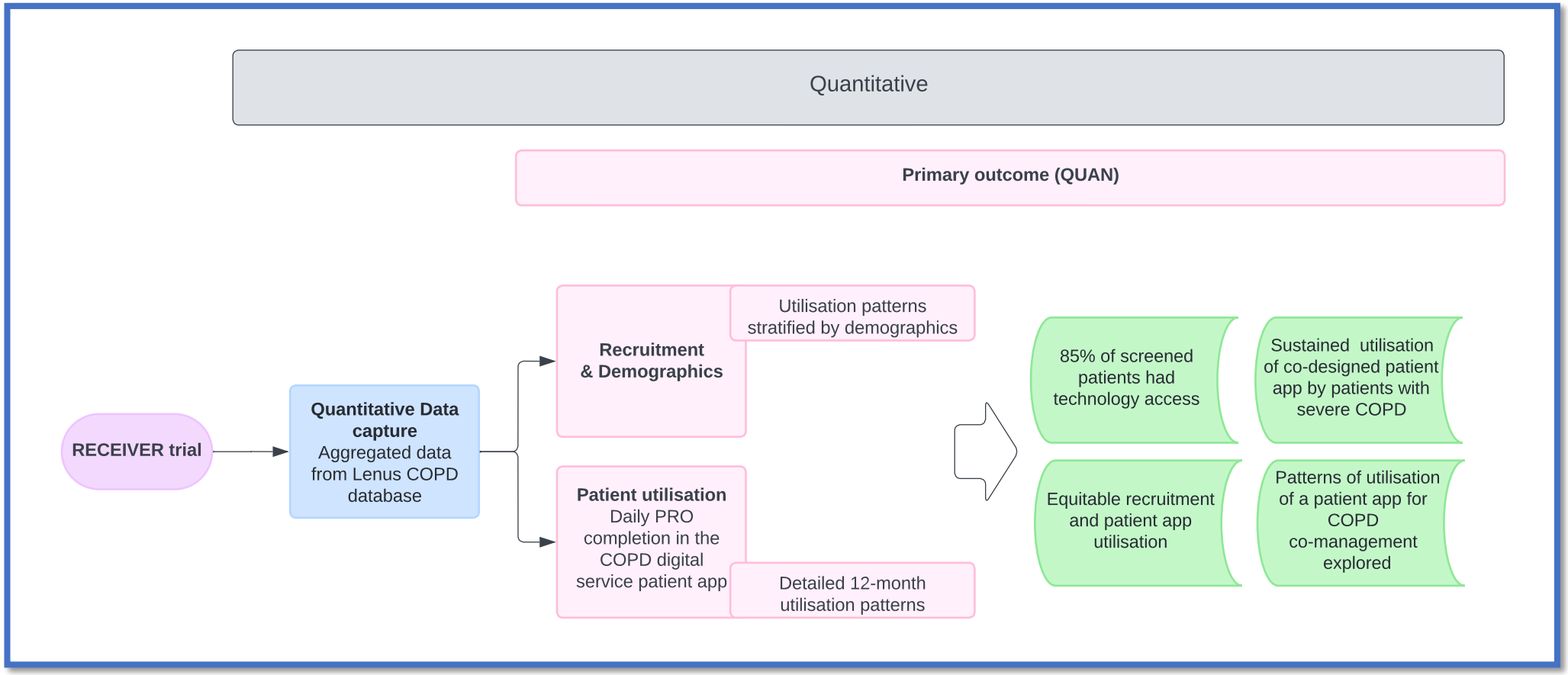


Figure 14 Summary diagram of primary outcome analysis and results from RECEIVER trial.
Abbreviations: PRO, patient reported outcome.

4 Results: RECEIVER trial key secondary outcome data

Chapter three has detailed the recruitment and primary outcomes of the RECEIVER study. This confirmed persisting utilisation of the service by participants over the course of the trial, and novel aggregation of participants into groups based on percentiles of rolling average use. Usage does not however appear to correlate with key baseline data.

Clinical trials of digital interventions that support COPD self-management have yielded variable outcomes, and systematic reviews have failed to draw firm conclusions as to significant or persisting benefit. This chapter addresses this gap. It describes the methods and results of the secondary endpoint analysis of the RECEIVER study data focusing on the impact that access to additional digital support intervention has had on clinical events for participants, in comparison to a contemporary age-gender-admission matched control cohort who did not receive the intervention.

The data, content and conclusions contained in this chapter have been published; **Taylor, A. et al. 2023. Long-Term Usage and Improved Clinical Outcomes with Adoption of a COPD Digital Support Service: Key Findings from the RECEIVER Trial.** *International Journal of Chronic Obstructive Pulmonary Disease* Volume 18, pp. 1301–1318. doi: 10.2147/COPD.S409116.

4.1 Methods

4.1.1 Secondary outcome measures

The secondary outcome measures of the RECEIVER trial are fully detailed within table 2 in chapter two of this thesis and include survival and admission-related metrics.

4.1.2 Data collection: Participant inputted PROs

For the RECEIVER cohort, CAT scores were collected as part of the daily PROs. Additional MRC dyspnoea scores and health-related quality of life measures were collected within the weekly and monthly PRO question sets. PRO data were

visible in the clinician dashboard (figure 15 A + B). Extraction of this longitudinal data allowed analysis of symptom burden and quality of life over time.

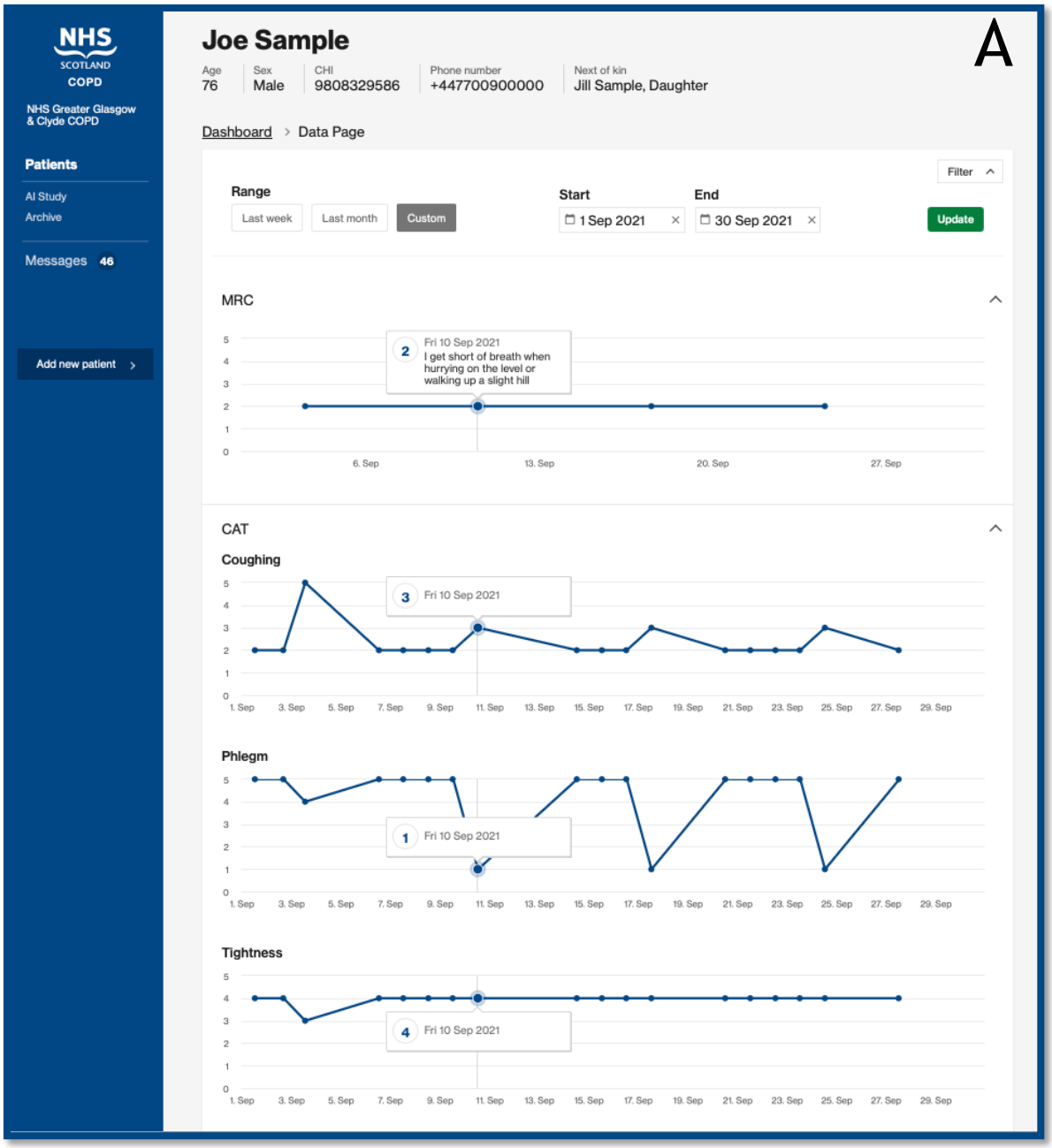


Figure 15 Screenshots showing part of the clinician dashboard display of a participant's patient reported outcome (PRO) responses for A) the weekly MRC dyspnoea score and part of the daily COPD assessment tool (CAT) score, and B) part of the daily and weekly symptom and exacerbation event responses. Synthetic patient data is shown for illustrative purposes only.
Abbreviation: MRC, medical research council.

4.1.3 Data collection: Clinical data

4.1.3.1 Clinical event data

For the RECEIVER cohort, COPD or respiratory-related admission episode data were collated from review of the EHRs, examining the 12 months prior to study enrolment and 12 months post enrolment to the end of the study or date of death if prior to 31st August 2021. A COPD or respiratory-related admission was defined as those where the cause related to either COPD (e.g. COPD exacerbation) or a respiratory-related condition (e.g. community acquired pneumonia). Elective admissions were included if they related to optimisation of COPD management. Where there was uncertainty as to the nature of an admission, consensus was achieved by discussion within the investigator team.

The length of the admission was recorded as occupied bed days (OBD), counted as whole days from date of attendance to discharge. ED attendances of less than 24 hours were therefore counted as one day.

Admission event data were recorded within the clinician dashboard and could be visualised overtime (display shown in figures 16).

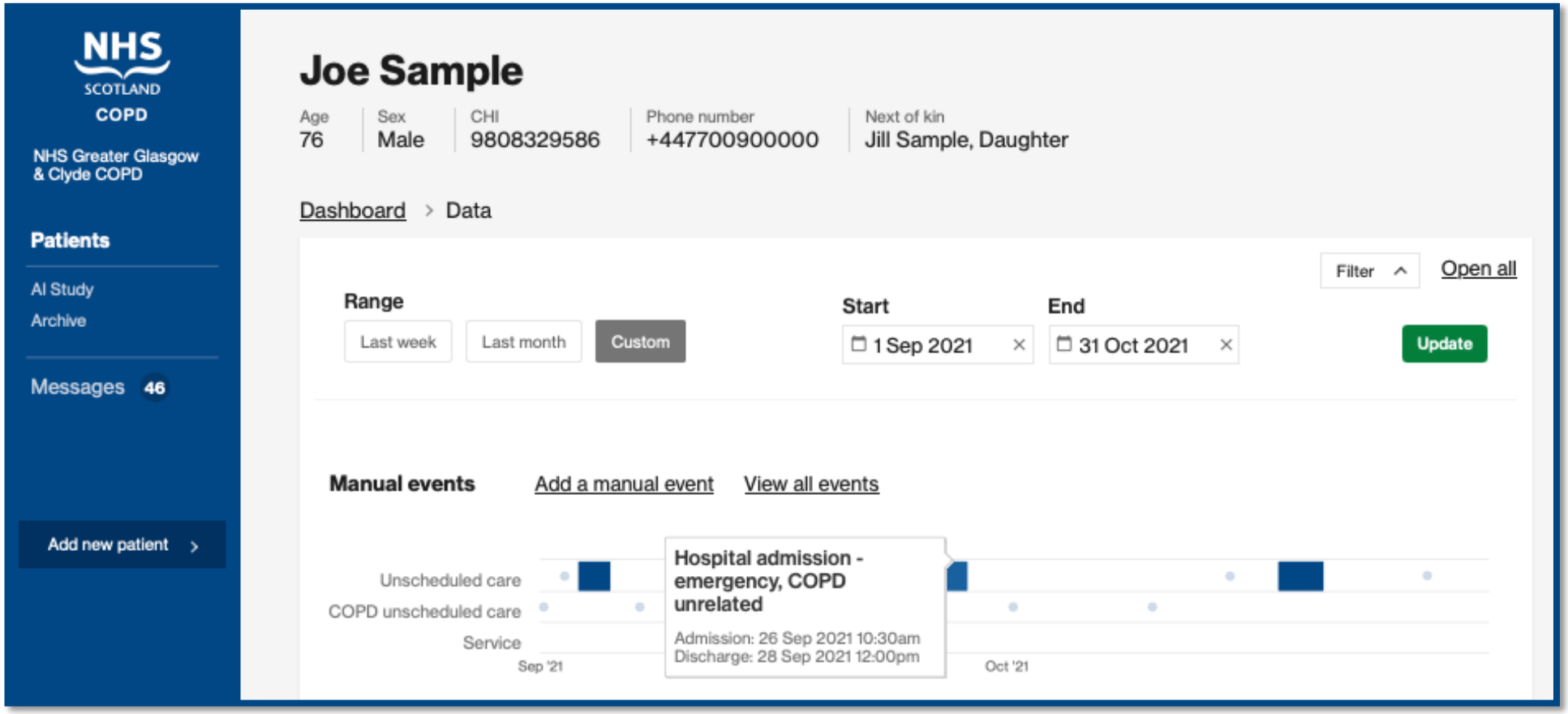


Figure 16 Event data as displayed in clinician dashboard for COPD-related hospital admissions. Synthetic patient data are shown for illustrative purposes only.

4.1.3.2 Community exacerbations

For the RECEIVER cohort, frequency of community exacerbation events were obtained from self-reported answers to a weekly PRO question, which asked participants if they had taken a course of antibiotics and/or steroids for an exacerbation that week. A 'yes' response was designed to be a surrogate marker of a community-managed exacerbation. In addition to the PRO response, community-managed exacerbation events could be manually recorded on the clinician dashboard where participant had reported treatment of an exacerbation by other means (e.g. through app messaging or during clinical contact).

Self-reported and manually entered community-managed exacerbation events were displayed in the clinician dashboard and could be visualised over time (figure 17).

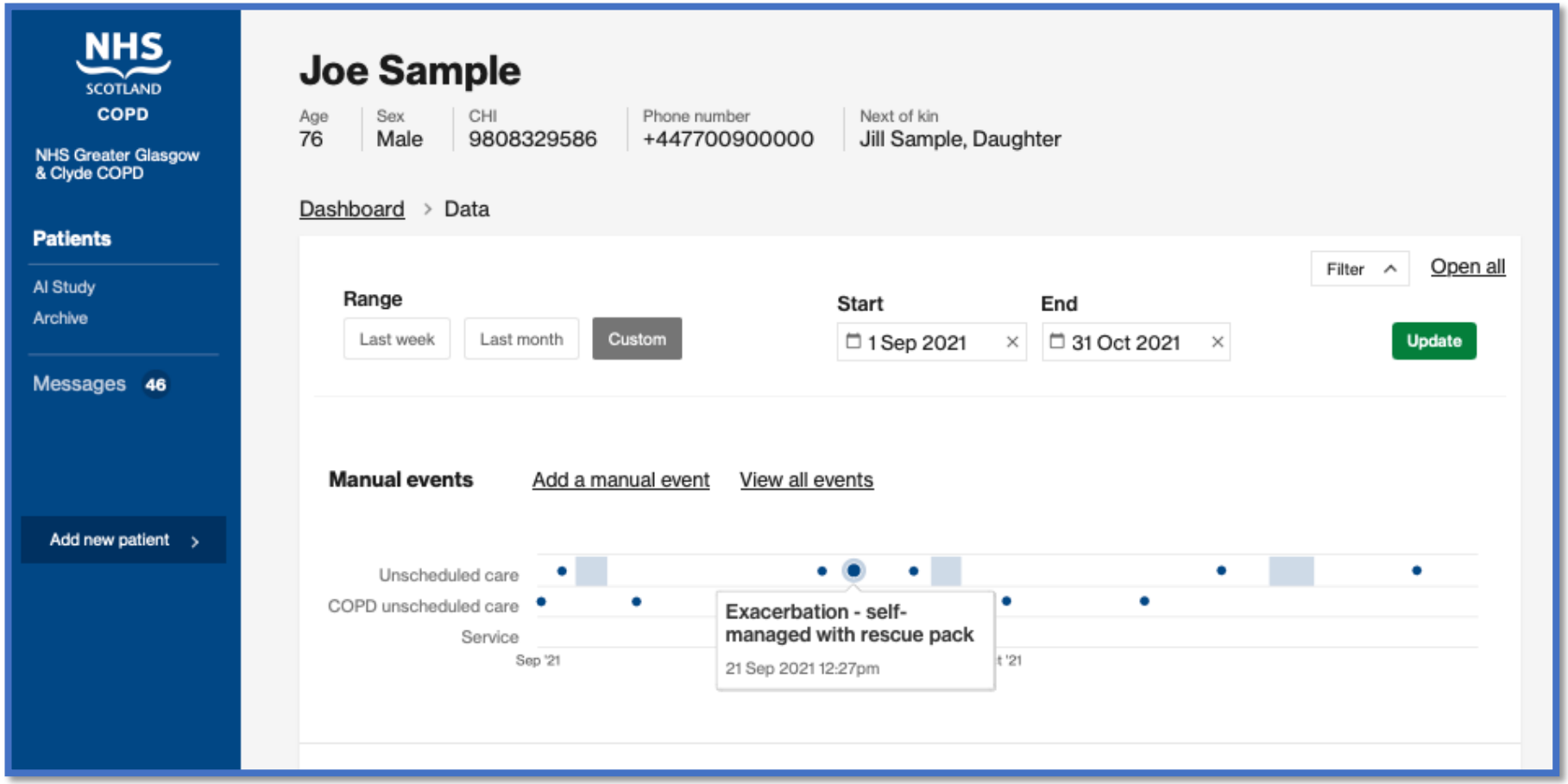


Figure 17 Event data as displayed in clinician dashboard for self-reported community exacerbation, following 'yes' response by participant if they had taken a course of antibiotics and/or steroids for an exacerbation that week. Synthetic patient data are shown for illustrative purposes only.

4.1.4 Data factory outputs from COPD support service database for RECEIVER trial participants

Utilisation of the governance approved de-identified cloud data factory outputs, detailed in chapter 2, allowed collation of PRO responses and event data.

4.1.5 Control cohort creation

Comparison of event data from the RECEIVER cohort was to a contemporary case-matched control cohort. The control cohort was established from a linked and deidentified dataset produced by the WoS SafeHaven, which included demographic, hospital admission with ICD-10 diagnostic codes and mortality data for individual's resident within NHS GG&C with a diagnosis of COPD. Control cohort identification was conducted iteratively by identifying individuals within the SafeHaven NHS GG&C COPD dataset who met the matching criteria for each RECEIVER participant and then selected the top five closest matches by age from the matched group.

Matching criteria =
a) Had a COPD or respiratory related admission in the seven-days up to the onboarding date of the RECEIVER participant
b) alive at the onboarding date of the RECEIVER participant
c) same sex as the RECEIVER participant
d) not already matched to another RECEIVER participant
e) Not a user of the intervention (COPD digital service)

Due to data availability and constraints within the SafeHaven deidentified dataset, additional disease related criteria could not be matched for (e.g. medications, co-morbidities, lung function, smoking status). Each RECEIVER participant was matched to five controls to mitigate any biases resulting from incomplete data for the control cohort.

Alternative time windows for a respiratory-related admission (defined below) of up to 12 months were considered for the control cohort. However, a seven-day window was considered most appropriate to avoid introduction of additional

biases (e.g. seasonal variability of COPD events), and to best align with the evaluation of the 12-month pre-post index event and survival data.

4.1.5.1 Respiratory-related admission events and occupied bed days in the control cohort

A comprehensive list of ICD-10 diagnosis codes was reviewed and sorted into respiratory and non-respiratory related diagnosis. The code descriptions that were included for respiratory-related diagnoses are listed in table 7. Those with respiratory-related diagnoses listed against an admission in the SMR01 (admissions) data within the SafeHaven COPD dataset were counted as a respiratory-related admission. These definitions were then applied to the control cohort to give a comparable admission event and OBD count.

ICD-10 diagnostic code description
'CHRONIC OBSTRUCTIVE PULMONARY DISEASE'
PNEUMONITIS DUE TO FOOD AND VOMIT'
RESPIRATORY FAILURE, UNSPECIFIED; TYPE UNSPECIFIED'
CHRONIC RESPIRATORY FAILURE; TYPE II [HYPERCAPNIC]'
BRONCHOPNEUMONIA, UNSPECIFIED'
DYSPNOEA'
PLEURAL EFFUSION IN CONDITIONS CLASSIFIED ELSEWHERE'
RESPIRATORY FAILURE, UNSPECIFIED; TYPE [HYPERCAPNIC]'
PLEURAL EFFUSION, NOT ELSEWHERE CLASSIFIED'
CHRONIC RESPIRATORY FAILURE'
OTHER BACTERIAL PNEUMONIA'
ABN MICROBIOLOGICAL FINDINGS IN SPECS FROM RESPIRATORY ORGANS AND THORAX'
RESPIRATORY FAILURE, UNSPECIFIED'
PNEUMONIA, UNSPECIFIED'
LOBAR PNEUMONIA, UNSPECIFIED'
COUGH'
PLEURAL PLAQUE WITH PRESENCE OF ASBESTOS'
PLEURAL PLAQUE WITHOUT ASBESTOS'
OTHER DISORDERS OF LUNG'
OTHER SPECIFIED PLEURAL CONDITIONS'
PULMONARY COLLAPSE'
ACQUIRED ABSENCE OF LUNG [PART OF]'
ASPHYXIATION'
RESPIRATORY FAILURE, UNSPECIFIED; TYPE [HYPOXIC]'
TRACHEOSTOMY STATUS'

ACUTE RESPIRATORY FAILURE'
UNSPECIFIED ACUTE LOWER RESPIRATORY INFECTION'
OTHER SPECIFIED SYMPTOMS AND SIGNS INVOLVING THE CIRC AND RESP SYSTEMS'
BACTERIAL PNEUMONIA, UNSPECIFIED', 'PYOTHORAX WITHOUT FISTULA'
DISEASES OF BRONCHUS, NOT ELSEWHERE CLASSIFIED'
PNEUMONIA DUE TO HAEMOPHILUS INFLUENZAE'
ABNORMAL SPUTUM'
OTHER POSTPROCEDURAL RESPIRATORY DISORDERS'
OTHER AND UNSPECIFIED ABNORMALITIES OF BREATHING'
INFLUENZA WITH OTHER RESP MANIFESTATIONS, SEASONAL INFLUENZA VIRUS IDENTIF'
PERSONAL HISTORY OF DISEASES OF THE RESPIRATORY SYSTEM'
PNEUMONIA DUE TO STREPTOCOCCUS PNEUMONIAE'
WHEEZING'
CHEST PAIN ON BREATHING'
HAEMOPTYSIS'
INFLUENZA WITH OTHER MANIFESTATIONS, VIRUS NOT IDENTIFIED'
OTHER SPECIFIED RESPIRATORY DISORDERS'
ACUTE UPPER RESPIRATORY INFECTION, UNSPECIFIED'
T.B. OF LUNG, W/O MENTION OF BACTERIOLOGICAL OR HISTOLOGICAL CONFIRMATION'
DEPENDENCE ON RESPIRATOR'
PLEURISY'
BRONCHITIS, NOT SPECIFIED AS ACUTE OR CHRONIC'

Table 7 List of ICD-10 diagnostic codes used to identify respiratory-related admissions within the SMR01 (admissions) dataset during the creation and data analysis of the matched contemporary control cohort.

4.1.6 Collection of physiological data

For those participants who were setup with a Fitbit Charge 3 device, daily average heart rate, step count and sleep duration were collated and stored in the cloud data factory via the API with the Fitbit app. Similarly, for those participants receiving home NIV therapy with remotely monitored auto Lumis150 devices, daily average NIV usage, mask leak and pressure data were collated and stored.

Exploratory analyses of these data, where available, was conducted to ascertain the utility of using these metrics for clinical event prediction.

4.1.7 Data handling, aggregation and analysis

De-identified clinical details data were obtained through the service data factory output.

Data handling, aggregation and analysis was performed using Microsoft Excel and R version 4.0.5.

Kaplan-Meier survival analysis with log rank test was used to estimate survival to admission, death and admission or death in RECEIVER and control cohorts. Hazard ratios (HRs) and 95% lower/upper confidence intervals were calculated using Cox regression to compare survival between cohorts. Comparison between the number of admissions and OBD in 12 months pre-post study enrolment (RECEIVER cohort) or index admission (control cohort) was undertaken using Wilcoxon signed-rank test. Significance and effect size was determined for each cohort.

Significance was assessed at the 0.05 level.

4.2 Results

4.2.1 Baseline characteristics of RECEIVER trial participants and control cohort

The RECEIVER participant and 5:1 matched control cohort characteristics are shown in table 8. The severity of disease amongst the control cohort is noted from the high admission counts in the year prior to study index, and mirrors the similar metric seen within the RECEIVER cohort.

	RECEIVER	Control
Number of individuals	83	415
Age at baseline, mean (SD), years	64.4 (9.3)	64.6 (9.1)
Sex, % female	63.9	63.9
COPD or respiratory-related admissions in the previous year, mean (SD)	2.46 (2.25)	2.47 (2.92)

Table 8 Condensed baseline characteristics of the RECEIVER trial participants alongside the available data for the matched control cohort compiled from the NHS Greater Glasgow & Clyde SafeHaven COPD dataset.

4.2.2 Annual admissions prior to and following the intervention

COPD or respiratory-related admissions and OBDs were higher in the 12 months prior to the intervention/index date compared to the following year in both the RECEIVER and control cohorts (Figure 18 A + B). However, the effect size of this event reduction was higher in the RECEIVER cohort compared to the control cohort considering both admission and OBD count (table 9). This equates to 0.59 fewer mean admissions and 4.74 fewer mean OBDs in the RECEIVER cohort for the year after study enrolment versus the controls. Separate analysis of admission data that included those who died within the first year of follow up was undertaken to investigate potential compounding effects of individuals dying within the first year of follow up (table 10). The effect size for the RECEIVER participants showed a greater reduction across the admission data regardless of survival status and persisted across both analyses.

An example of the clinical events visualisation showing the number of admissions and length of stay in the year prior to and post intervention enrolment for one of

the study participants as it appeared in the clinician dashboard is displayed in figure 19.

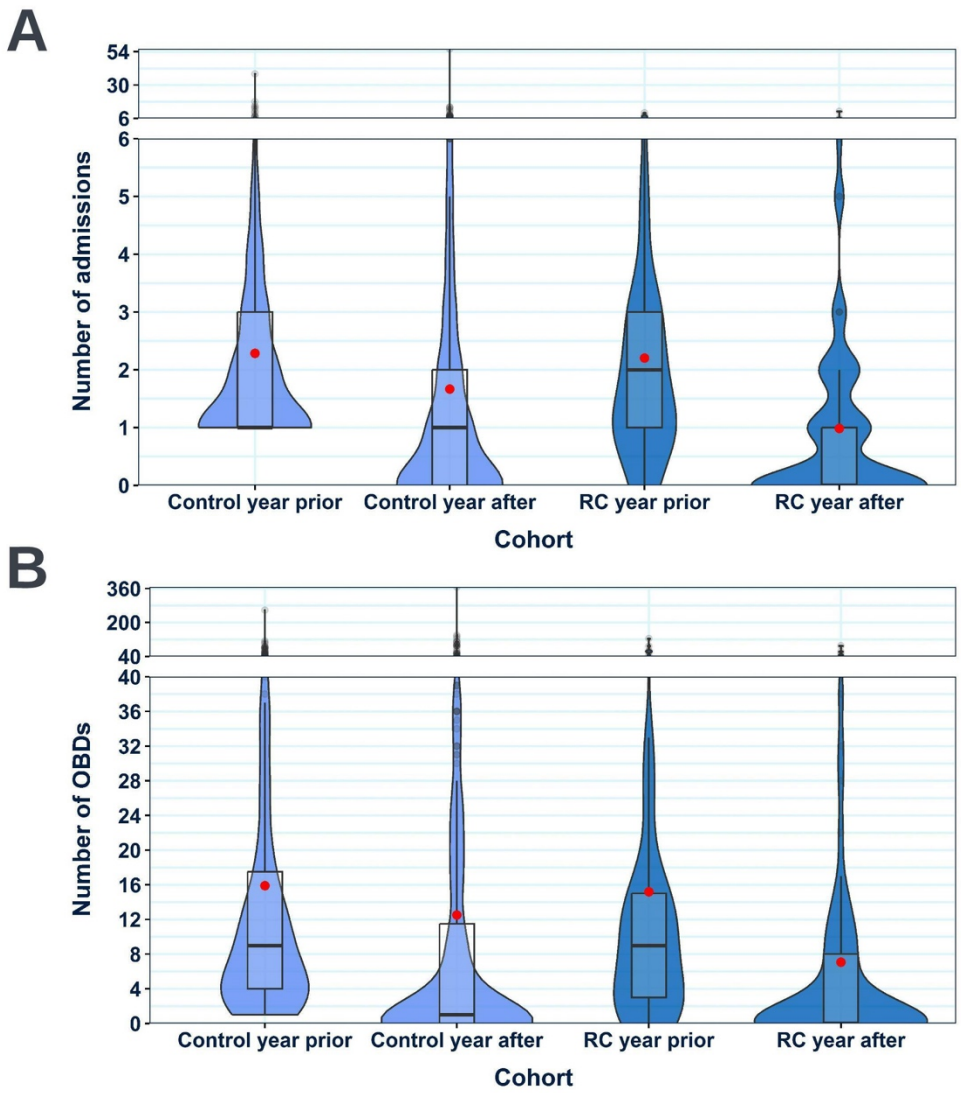


Figure 18 Violin box plots showing the number of A) COPD or respiratory-related admissions, and B) occupied bed days in the 12-months prior to and post index date for the RECEIVER participants and matched control cohort. Data shown is for individuals alive after 12-months post index date. A violin boxplot is selected to allow completed data provision, and a visualisation of data spread across the cohort. For their interpretation: standard boxplots illustrate the variation of values (median and IQR), the relative frequency of individual data points is illustrated by the width of the violin plot at each point on the y-axis, and mean values are shown by red dots.

			Mean			Wilcoxon Signed-Rank Test Effect Size
			Year before	Year After	Change	
Admissions	**RECEIVER**	n=69	2.2	0.99	1.21	0.621*
	Control	n=315	2.29	1.67	0.62	0.423*
Occupied bed days	**RECEIVER**	n=69	15.19	7.07	8.12	0.535*
	Control	n=315	15.9	12.52	3.38	0.314*

*Table 9 Compilation of the admissions data for the RECEIVER and control cohorts for individuals alive after 12-months post index date. Mean COPD or respiratory-related and occupied bed day (OBD) counts for the 12-months pre, and post index date are shown alongside mean change for each group and effect sizes of these changes (Wilcoxon signed-rank test, *p<0.001).*

			Mean			Wilcoxon Signed-Rank Test Effect Size
			Year before	Year After	Change	
Admissions	**RECEIVER**	n=83	2.46	1.17	1.29	0.594*
	Control	n=415	2.47	1.58	0.89	0.498*
Occupied bed days	**RECEIVER**	n=83	19.18	9.95	9.23	0.491*
	Control	n=415	19.18	12.2	6.98	0.368*

*Table 10 Compilation of admissions data for the RECEIVER and control cohorts including individuals who died within the first year of follow up. Mean COPD or respiratory-related and occupied bed day counts for the 12-months pre, and post index date are shown alongside mean change for each group and effect sizes of these changes (Wilcoxon signed-rank test, *p<0.001).*

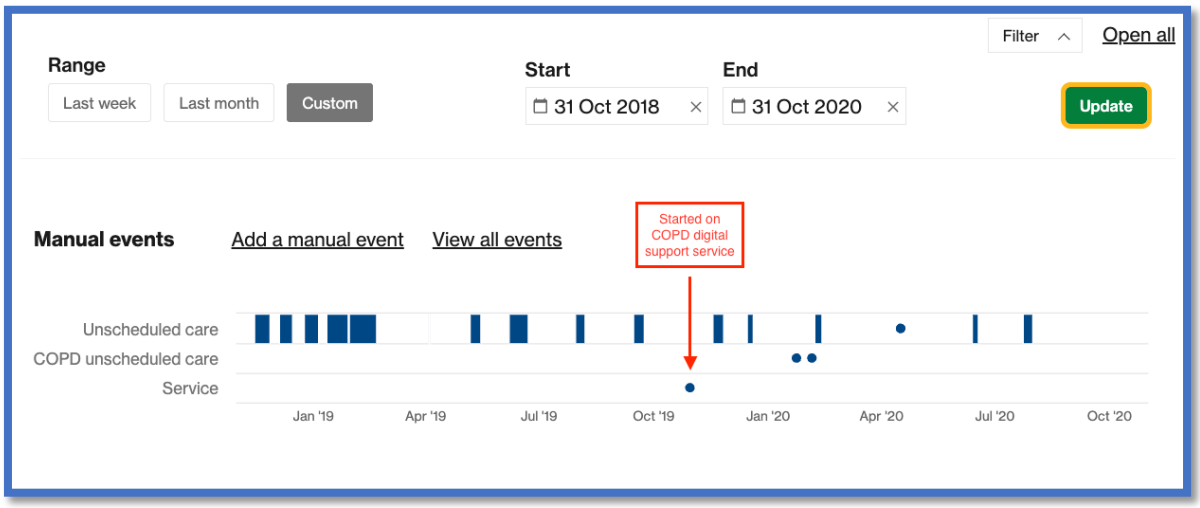


Figure 19 Clinical event visualisation. Example taken from the clinician dashboard for one of the RECEIVER participants showing the number of admissions and length of stay one-year pre and post onboarding to the digital service intervention. The blue vertical bars in 'unscheduled care' lane represents an admission episode, with the width of each dictated by the length of stay (the wider the bar, the longer the admission was). A reduction in number of admissions and in length of stay per admission are seen following enrolment onto the COPD digital support service intervention for this participant.

4.2.3 Survival analysis

Kaplan-Meier survival analysis was undertaken, with a log rank test. Median time to death, or readmission from a COPD or respiratory-related cause was found to be significantly increased at 335 days in the RECEIVER cohort compared to 155 days the control cohort (figure 20). A significant difference in time to event across the follow-up period between cohorts is seen (p = 0.047), with an unadjusted hazard ratio of 0.740 (0.550 – 0.996) (table 11).

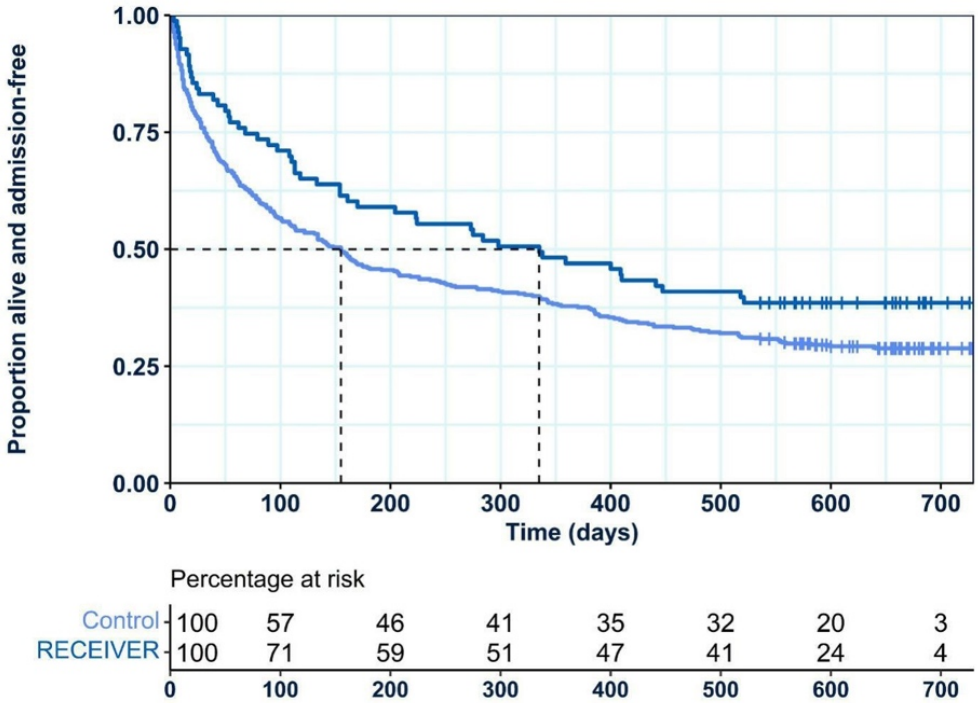


Figure 20 Survival analysis visualisation and percentage at risk table comparing time to death or first COPD or respiratory-related admission from study index between RECEIVER (dark blue line) and control (light blue line) cohorts.

	COPD or respiratory-related admission or death	COPD or respiratory-related admission	Death
RECEIVER (median time to event)	335	400	n/a
Control (median time to event)	155	255	n/a
Unadjusted hazard ratios (RECEIVER vs control)	0.740 (0.550-0.996)	0.827 (0.603-1.135)	0.743 (0.463-1.191)
Log rank test	p = 0.047	p = 0.241	p = 0.215

Table 11 Survival analysis comparison between RECEIVER and matched control cohort. Median time to a) death, b) death, or first COPD or respiratory-related admission, and c) first COPD or respiratory-related admission, are shown. Unadjusted hazard ratios are presented with corresponding 95% confidence intervals, as well as p-values for log rank tests comparing each endpoint between the cohorts

A prolonged time to first COPD or respiratory-related admission was also seen for the RECEIVER cohort when considering this endpoint alone, 400 days vs 255 days (Figure 21), although this difference was not significant between the cohorts (p = 0.241) (table 11).

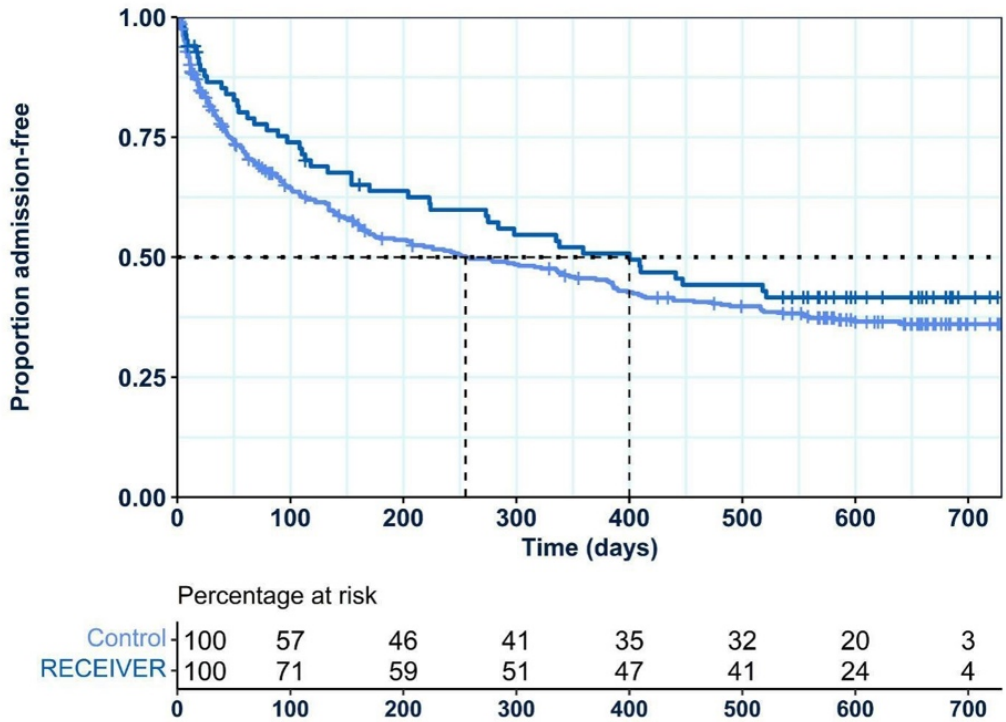


Figure 21 Survival analysis visualisation and percentage at risk table comparing time to first COPD or respiratory-related admission from study index between RECEIVER (dark blue line) and control (light blue line) cohorts.

A reduction in 12-month mortality was seen amongst the RECEIVER cohort compared to the control cohort when examining this endpoint separately (figure 22). 83% of RECEIVER participants were alive at 12 months verses 76% of the control cohort, however the difference in over-all survival between the two cohorts was not statistically significant (p = 0.215) (table 11).

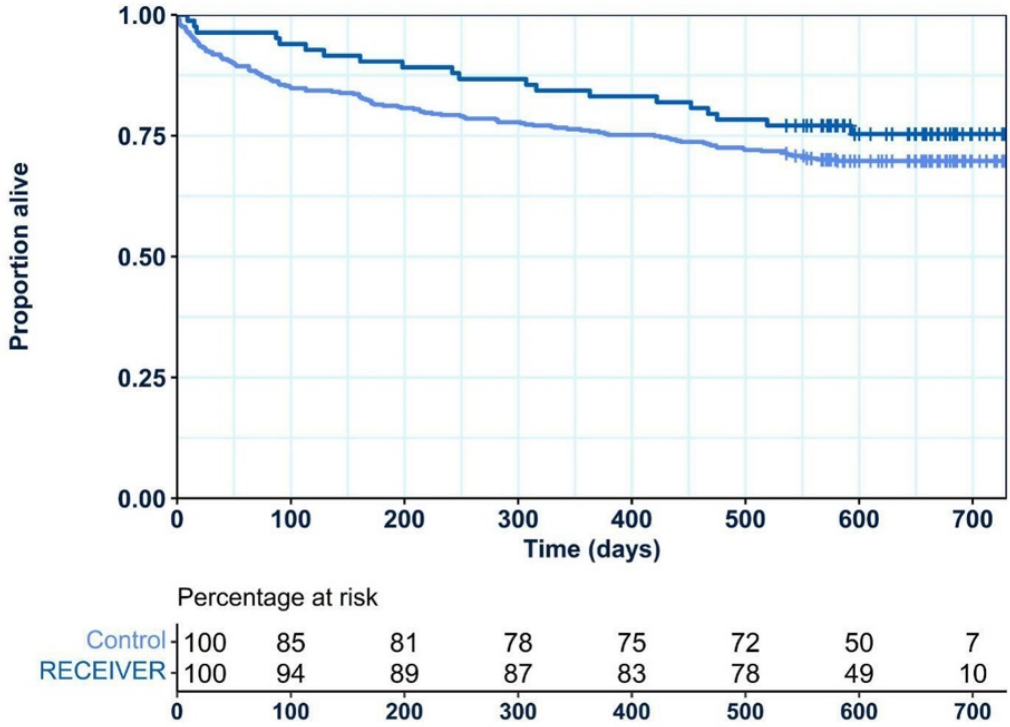


Figure 22 Survival analysis visualisation and percentage at risk table comparing time to death from study index between RECEIVER (dark blue line) and control (light blue line) cohorts.

4.2.4 Community-managed exacerbation event count

To account for sustained symptoms relating to the same exacerbation and for extended courses of treatment for some individuals, further refining criteria was developed and referred to as the 'PRO LOGIC' criteria.

'PRO LOGIC' for defining a new community-managed exacerbation event from a 'yes' response to the weekly PRO question:

- More than 5 weeks since previous 'yes' response: always considered a new community managed exacerbation event.
- More than 2 weeks but less than 5 weeks since the last 'yes' response: only a new community managed exacerbation event if there were two consecutive 'no' responses between the previous 'yes' response and the 'yes' response in question.

A proportion of the self-reported community exacerbation events were manually verified by members of the clinical team using electronic prescribing records to

ascertain if an acute prescription had been issued in the community. Messaging threads were also reviewed as well as notes held within a participants EHR.

Good correlation was seen between 'PRO LOGIC' definition and the clinician-verifiable events (Spearman's rank correlation coefficient = 0.8423), which justified the wider use of 'PRO LOGIC' to count community-managed exacerbation event counts across the full data set.

The PRO-LOGIC algorithm was applied to the whole of the RECEIVER PRO dataset, and the number of reported community-managed exacerbation events were collated. A median of two events per year were seen in the 12-months post-trial enrolment for the RECEIVER cohort (figure 23). A higher number of community-managed exacerbations were noted amongst the sub-group of participants with the highest levels of app utilisation.

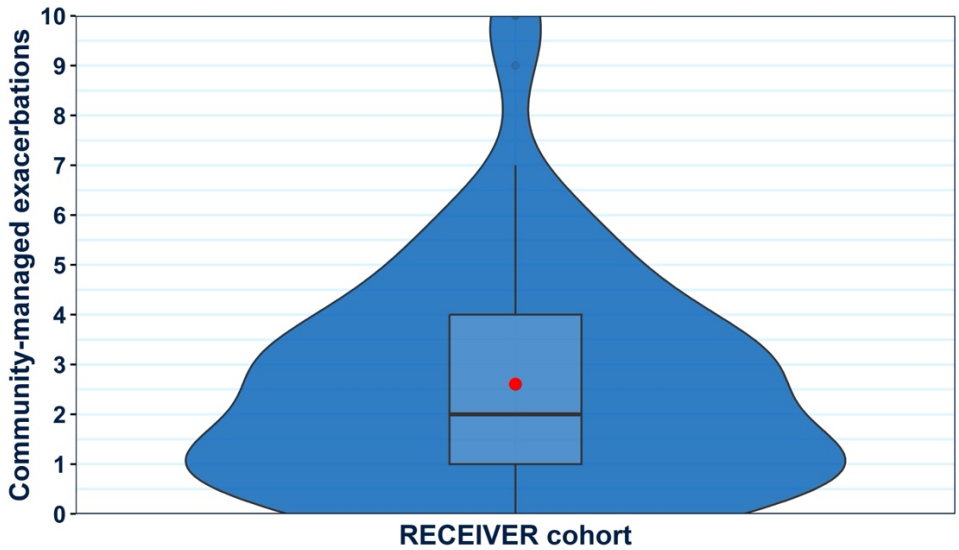
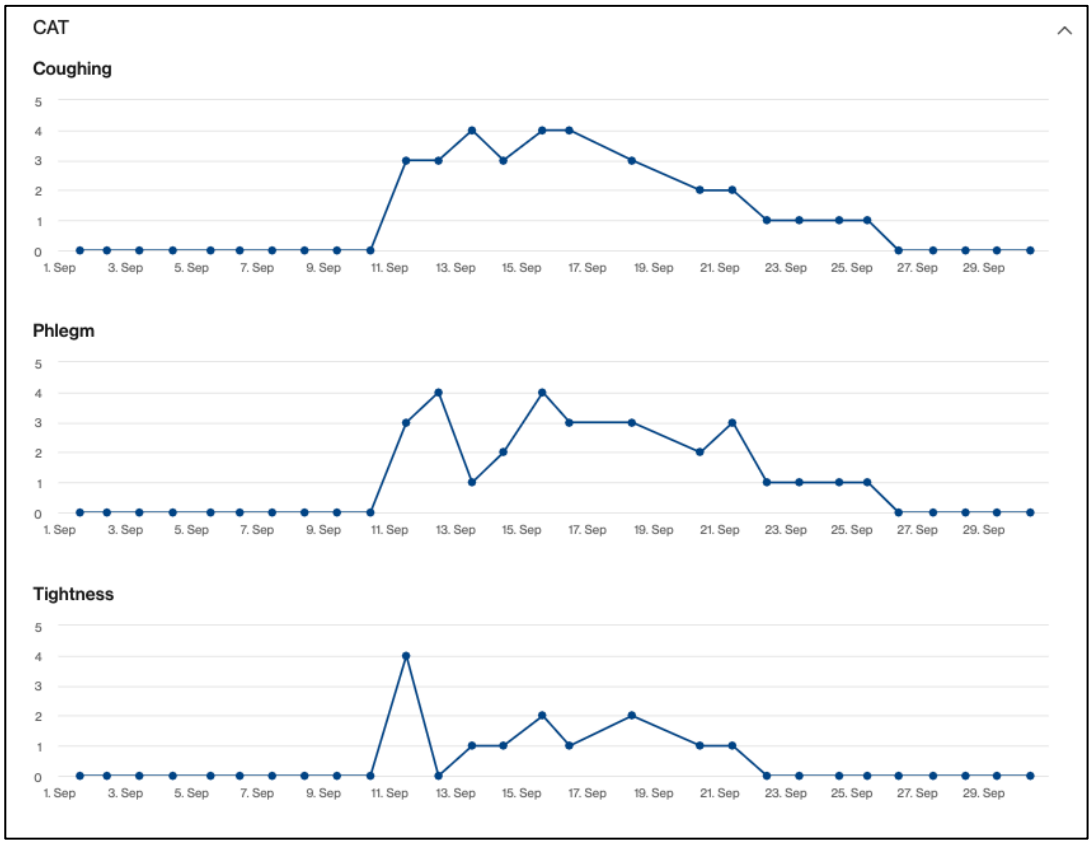


Figure 23 Violin boxplot displaying the median number of community-managed exacerbation events for the RECEIVER cohort as calculated by patient reported outcome (PRO) submission and the PRO-LOGIC algorithm. A violin boxplot is selected to allow completed data provision, and a visualisation of data spread across the cohort. For their interpretation: standard boxplots illustrate the variation of values (median and IQR), the relative frequency of individual data points is illustrated by the width of the violin plot at each point on the y-axis, and mean values are shown by red dots.

4.2.5 Patient reported outcome (PRO) values and changes observed overtime

Changes in CAT score were noted for some individuals around exacerbation and admission events indicating variability at a granular level (figure 24). However, stability in symptom and QoL scores was seen across the duration of follow up when QoL PRO values were collated and compared across four 26-week windows relative to enrolment (figure 25 A + B).



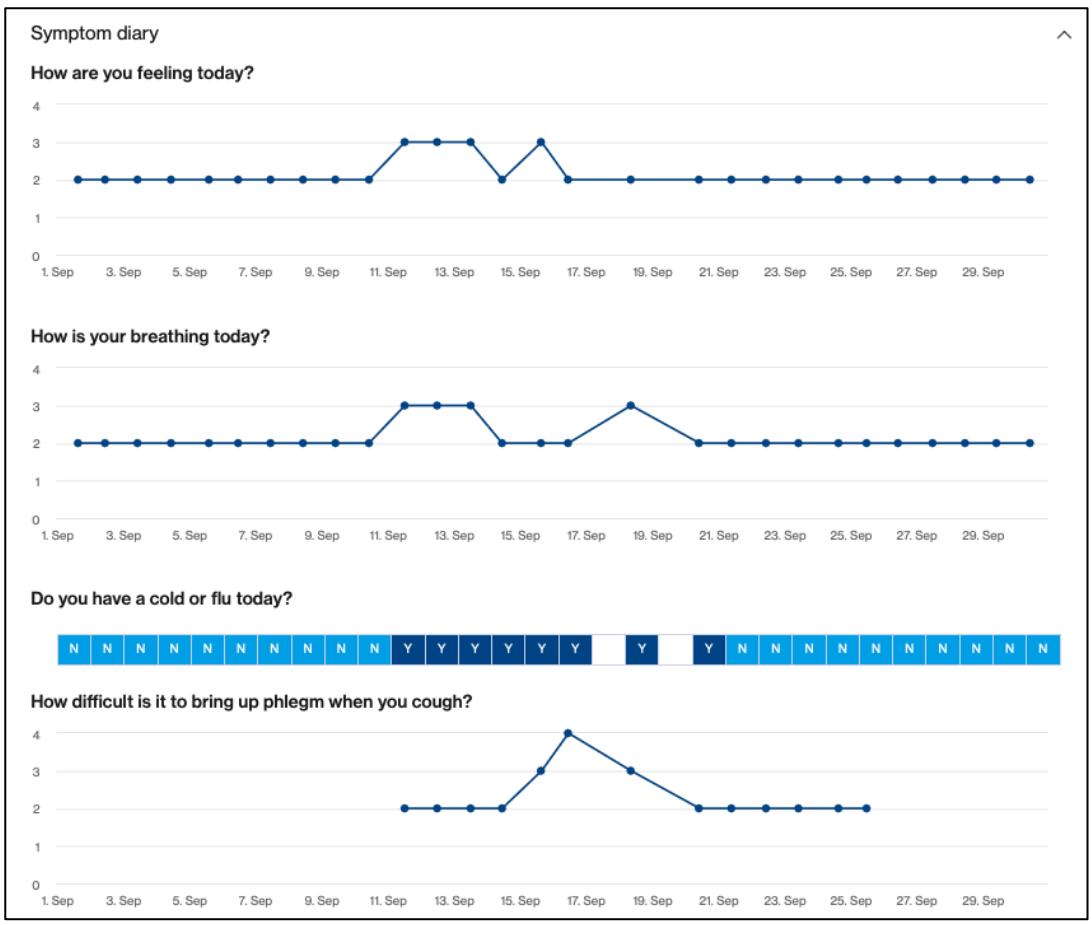


Figure 24 Example of CAT and symptom score variation around time of exacerbation (when answer to the question 'do you have a cold or flu today?' is marked Y). Scores then return to pre-exacerbation values. Abbreviation: CAT, COPD assessment tool

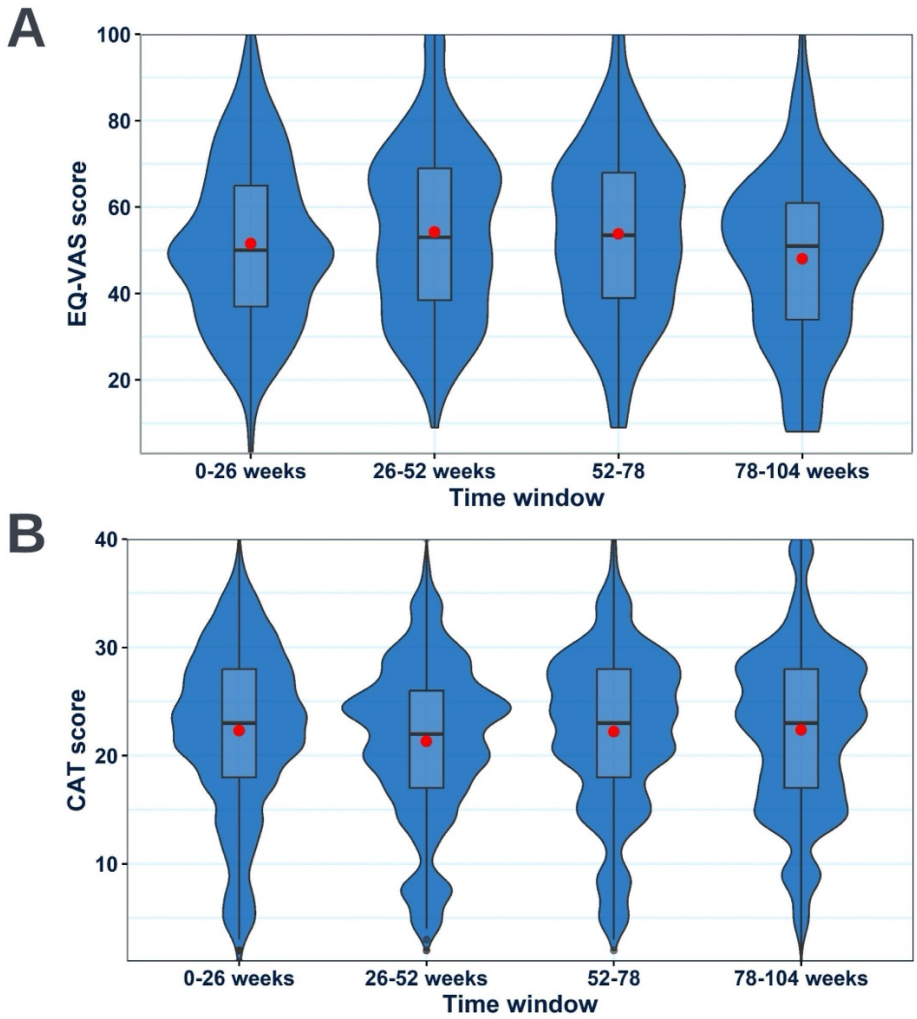


Figure 25 Violin boxplots showing the distribution of A) CAT scores and B) EQ-VAS scores reported by the RECEIVER participants across 26-week windows relative to onboarding. Average of all CAT entries = 22.01, MRC = 3.47, EQ-VAS = 52.44. A violin boxplot is selected to allow completed data provision, and a visualisation of data spread across the cohort. For their interpretation: standard boxplots illustrate the variation of values (median and IQR), the relative frequency of individual data points is illustrated by the width of the violin plot at each point on the y-axis, and mean values are shown by red dots. Abbreviation: CAT, COPD assessment tool. EQ-5D-5L, brief, multi-attribute, generic health status measure

4.2.6 Exploratory analysis of Fitbit and non-invasive ventilation data

Unfortunately, maintenance of the data connection between the Fitbit and NIV devices and the digital service platform was problematic. Exploratory analysis looking at stratification by step count, average heart rate and home NIV therapy parameters identified some trends differentiating patterns with hospital admissions events and/or mortality vs stable patients. However, given the issues with data missingness and research team capacity a decision was made not to proceed further with this analysis within this thesis.

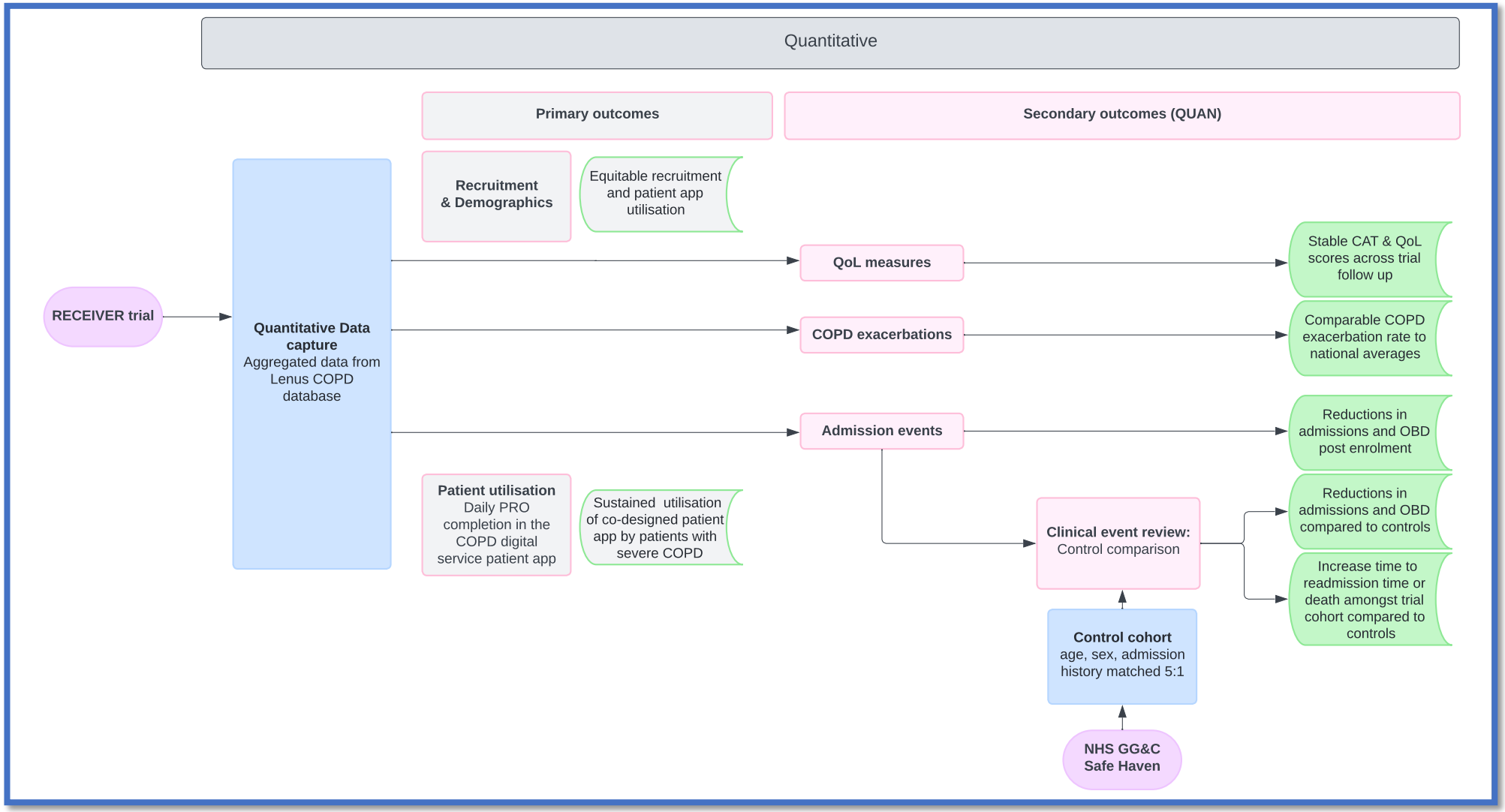


Figure 26 Summary diagram of the secondary outcome analysis and findings from the RECEIVER trial, alongside the primary outcomes
Abbreviations: PRO, patient reported outcome. CAT, COPD assessment tool. QoL, Quality of Life. OBD, occupied bed days. NHS GG&C, NHS Greater Glasgow & Clyde.

4.3 Chapter discussion

An expanded summary diagram of the results of the RECEIVER trial are shown in figure 26, with the secondary outcome findings alongside the primary.

Analysis of secondary clinical outcomes has shown improvements in survival metrics and admission reductions for trial participants when compared to matched controls, with time to readmission or death being significantly increased amongst the RECEIVER cohort. Although reductions in admission number and OBDs at 12 month follow up were seen across both the RECEIVER and control cohort, the effect size within the trial group was substantially larger. These results give reassurance to the safety of the patient app when it is deployed as part of digital enhancement of routine care. Specifically, it gives an important safety signal that participants were not staying at home inappropriately and declining without seeking appropriate care.

The interpretation of clinical outcomes should, however, be measured. The RECEIVER trial was an observational study with risk of multiple biases and also ran during the time of the COVID-19 pandemic where notable changes in healthcare and society were observed. These factors have been partially mitigated by the location and time-period matched control cohort. The reductions in admission events and OBDs that were also seen in the control cohort are in keeping with findings from the COVID-19 pandemic (Alqahtani, Oyelade, *et al.*, 2021; So *et al.*, 2021). This indicates that the control cohort is representative of broader population with severe COPD and is a suitable comparator to establish baseline COVID-19 impact on outcomes in the absence of the COPD digital service intervention. The control cohort was also derived from the same health board as RECEIVER participants. Potential bias from seasonality, location, and COVID-19 pandemic impacts on COPD event rates has also been reduced by matching index date and outcome follow up period to RECEIVER participants. The incomplete information for the control cohort is an important caveat to note. The available data for the control cohort did not include co-morbidity, lung function or smoking status information. This is a necessary compromise when using routine clinical data for controlled analysis in such way. However, accepting these compromises the two cohorts were well matched based on all available date.

Noting the limitations mentioned, the observed clinical improvements are still encouraging at both an individual and population level. Reductions in admissions and occupied bed days could have wider benefits to healthcare systems, such as cost savings from admission avoidance and reduced strain on hospital capacity. Reduced admissions also reduce environmental impact of COPD, with hospital admissions accounting for a considerable proportion of NHS emissions (NHS England, 2020).

The community-managed exacerbations event rate of 2-3 exacerbations per patient per year in the RECEIVER trial cohort post enrolment was comparable to previously published UK population data (Whittaker *et al.*, 2022). This provided reassurance that increased or uncontrolled antibiotic-prednisolone prescribing was not occurring, as a potential adverse consequence of self-management. The 'PRO-LOGIC' algorithm that was used to count community-managed exacerbation events showed good correlation with clinically verified events. However, verification of events required manual access and interpretation of electronic prescription records on an individual basis within 6 months of the event occurring and was not possible for all patient-recorded episodes. Incorporation of prescription data into the analysis of these events could add an additional layer of verification in future evaluations.

Recording of community exacerbation events was also dependant on individual completing PROs on a regular basis. The motivation of participants to complete their PROs and therefore record exacerbation events cannot be established from these data. Are those that are more unwell completing more regularly therefore is there increased capture of community-managed events amongst the cohort who are more unwell in general verses the more stable patients who are comfortable to complete less? Whilst future quantitative research incorporating the pharmacy data held within the EHR could provide additional information about community exacerbation event rates, qualitative research is needed to further explore participants motivation to aid understanding of PRO completion.

In the analysis of the PRO responses for the RECEIVER participants, there was stability in symptom burden and QoL scores across the data collection period. This is encouraging to see considering COPD is a progressive condition and often associated with a steady decline over time. Patient recall of exacerbation

history can vary in accuracy (Quint *et al.*, 2011; Frei *et al.*, 2016; Abrham *et al.*, 2024). Having detailed symptom trends and insights data available can enrich patient-initiated unscheduled contact or during routine clinic review. There is the potential to save the patient-clinician time spent on information gathering and give the clinical team access to a more accurate record of a patient's clinical state and disease story. Variation in PRO values was noted at an individual level for some, around the time of exacerbations. Further analysis of this aspect was out of scope for this thesis but remains an important consideration for future research, particularly involving the incorporation of machine learning and short-term exacerbation risk prediction models.

There were no associations seen between the utilisation patterns (PRO usage quartiles) and demographic factors, disease severity factors, comorbidities, additional therapies or admission rate over follow up (Chapter three, tables 5 and 6). This is similar to findings reported elsewhere (Nouri *et al.*, 2020) and does not point to an obvious subpopulation of people with COPD who should be targeted for selective provision of digital tools. This therefore indicates that it is likely to be more beneficial to keep inclusion/digital service provision as broad as possible until there is a better understanding of participant utilisation and motivation factors.

Overall, secondary endpoint findings are consistent with previous telehealth, remote-monitoring and self-management-based COPD digital services, which have shown improved clinical outcomes (North *et al.*, 2020; van Buul *et al.*, 2021). But contrast findings of studies where improvements were not seen, including conclusions from systematic reviews (McCabe, McCann and Brady, 2017; Rinne, Lindenauer and Au, 2019). Several key components that were different compared to the contrasting studies including; patient-clinician co-design of the intervention to maximise utility, accessibility and usability, verified COPD diagnosis at onboarding, daily prompts to complete PROs, access to asynchronous messaging, individualised medication information (inhaler prescription details and rescue medication if applicable), and use of the service intervention alongside routine clinical care contacts, rather than at prespecified regular data reviews.

There is an anticipation that digital tools have helped support guideline-based care including COPD management, with a positive impact on participant outcomes as a result. The improved trial outcomes are in line with those seen for participants in a previous trial undertaken within NHS GG&C who were successfully taught self-management, supporting this view (Bucknall *et al.*, 2012). But as previously noted, it is recognised that digital interventions are complex, and their impacts are likely to be driven by more than binary causation and interaction. There is therefore a need to explore the patient-perceived benefits of the service to indicate the motivations behind usage and suggest potential behavioural change mechanisms that could be driving these improvements. This could also contribute to the wider understanding of use of the service overall, and may indicate which aspects are of most value, to aid the development, iteration and promotion of future projects.

4.4 Connection to qualitative phase of data collection

The ability to capture qualitative data about the digital support service was included within the protocol and consent for the RECEIVER trial. It was recognised that capturing user perspectives would be an important aspect to include in evaluations of this digital intervention, but scope and timing of these elements were initially fluid. The emerging positive trial results, along with research gaps highlighted in chapter one, sharpened the objectives of this thesis, shaping the timing and focusing the direction of the qualitative approach undertaken. Following the methodology of the explanatory mixed methods study design, as outlined in chapter two, the next chapter will detail how qualitative data were captured to build on the understanding of the initial quantitative results; seeking to explore user participation with the digital service, understand some of the potential reasons behind persisting usage and what benefits users may have perceived. This integration is illustrated in figure 27.

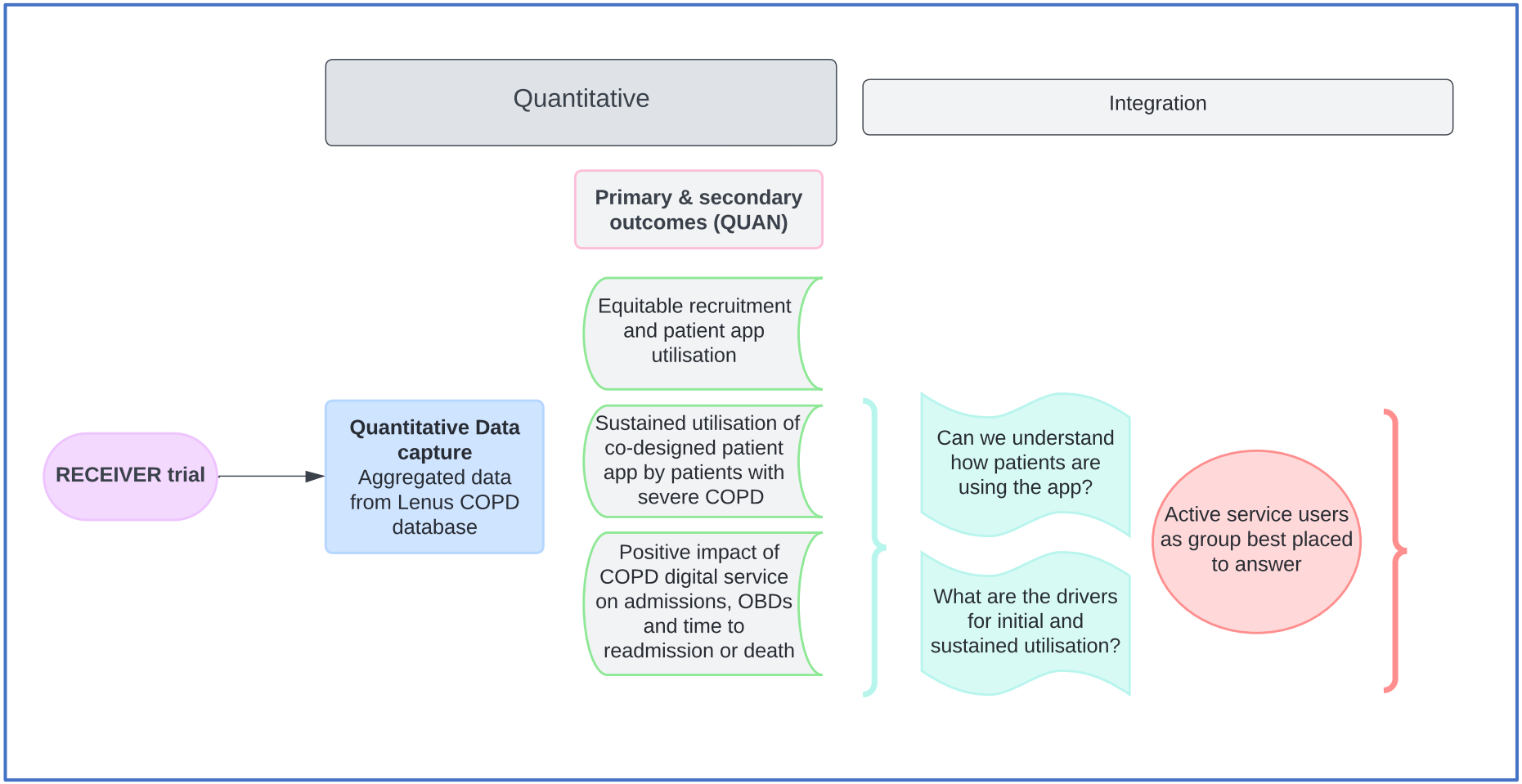


Figure 27 Summary diagram showing primary and secondary outcome findings from the RECEIVER trial and proposed integration with qualitative research methods to gain greater understanding of the quantitative results seen amongst persisting users.
Abbreviation: QUAN, quantitative. OBD, occupied bed days

5 Qualitative analysis

The avoidance of exacerbations and resultant hospitalisations are prioritised by people with COPD (Zhang *et al.*, 2018). There is a strong argument for focusing on research that addresses the aspects most important to those living with a condition, particularly if research agendas set by academics or the pharmaceutical industry do not necessarily reflect the priorities of patients and the health service (Alqahtani, Aquilina, *et al.*, 2021).

The previous chapters have shown persisting usage of the digital support service patient app over time within the RECEIVER trial and indicated a reduction in admission events for participants with access to the support service when compared to matched controls. However, it was not possible to comment on the potential motivations for persisting usage or behaviour change mechanisms that may have contributed to the impacts seen amongst participants through the quantitative work alone. Qualitative data can capture the participant voice, providing a more comprehensive viewpoint and describe aspects that may be missed or not appreciated within quantitative results.

I wanted to understand how the participants were using the app, what had potentially promoted or enabled their use, and why they had continued to use it. Within the wider DYNAMIC project and, more latterly, expedited by the outbreak of COVID-19, the support service provision has been scaled up and expanded, therefore I wanted to explore what lessons could be learnt from those using the service that could also help project growth.

This chapter describes the choice of participants who were felt to be best placed to answer the research questions mentioned above and details the chapter specific methods employed to collect the qualitative data. The results of the qualitative analysis are shown, with details of recruitment and participant demographics, and the candidate themes and associated sub themes that were developed. The chapter concludes with discussion of the strengths and limitations of this phase of my research project.

5.1 Rationale for the participant sampled

The extent of the usage of the COPD app across the duration of the trial was much greater than the primary endpoint that had been initially set. Significant improvement in clinical outcomes were also seen for RECEIVER participants when compared to matched controls.

In discussion with the rest of research team, I could see the persisting usage patterns emerging during the course of the trial and wanted to understand what participant usage was driven by and perceptions of the service from the 'patient user' point of view. Persisting users of the digital service at the point of data censor were therefore chosen to give a broader understanding of their on-going use of the service, and any potential benefits they may have experienced through that use.

5.2 Methods

This section details the methods used to conduct the semi-structured interviews and analysis of the qualitative data that was acquired.

5.2.1 Eligibility

Participants who consented and were enrolled into the RECEIVER trial were eligible to take part in the qualitative component of the study.

5.2.2 Sampling strategy

A purposeful sampling strategy was initially employed, selecting active users from amongst the RECEIVER trial participants. "Active users" were defined as those who had used the app (entered PROs) within a month of study quantitative data censor point (31st Aug 2021). Following the initial purposeful collation of this participant list, the sampling strategy transitioned to become a convenience sample of those that were contactable and agreeable to be interviewed.

5.2.3 Sample size

An initial target of 15 – 20 of the recruited RECEIVER participants was proposed. This is in line with research aiming to identify patterns across data (Braun and Clarke, 2013), whilst working within the time constraints of the research study, seeking to gain a rich set of viewpoints through meaningful engagement with data but not to the point where there is so much data that it prevents this from being achieved (Onwuegbuzie and Leech, 2005).

5.2.4 Recruitment and consent

Participants were approached to take part in the semi-structured interviews by members of the research team. Written consent for qualitative interviews was obtained during the initial RECEIVER trial consent process. The research purpose was reviewed with the participants and verbal repetition of consent was obtained at the time of the interviews, as well as consent for the interview to be recorded and transcribed. The participants did not receive any monetary or other incentive for taking part.

5.2.5 Interview schedule

An interview schedule was created as a topic guide of areas to cover based on results and questions generated from the initial data analysis of the RECEIVER trial in discussion with the wider research team. A reflective review of the data was undertaken following each interview, noting when question areas required additions or editing to better address the research topics. The interview schedule was updated to consolidate and build on the insights that were being generated. Iterations of the interview schedule were discussed with a second member of the research team (DJL – male, ED consultant, experienced qualitative researcher) to gain consensus about proposed changes. The final version of the interview schedule is included in the appendix (3).

5.2.6 Data collection

The semi-structured interviews were conducted by me, a female postdoctoral researcher, who also works as a clinical research fellow (medical doctor) in

sleep, breathing support and respiratory medicine. The interviews were audio-recorded and transcribed by an external company. The transcripts were checked thoroughly against the original audio to ensure accuracy.

In response to the coronavirus pandemic and for participant welfare, the first round of interviews took place over the phone. Following relaxation of the coronavirus restrictions, in-person interviews could be undertaken in the second round of data collection although most participants still requested that interviews took place remotely over the phone. Video calls were unable to be conducted due to limited organisationally approved resources and participant's reluctance to use unfamiliar technology.

Additional demographic and usage data were collated from the digital COPD support service database and used to provide context to the interview data. Field notes and a self-reflective log were also collected after conducting the interviews and during analysis of the data, to capture developing ideas.

Data collection was undertaken across two time periods. The first set of interviews took place between September 2021 – February 2022. The second set of interviews took place between September 2022 – October 2022.

5.2.7 Data analysis

Iterative analysis of the interview transcripts was performed following each round of semi-structured interviews.

5.2.7.1 First analysis period – familiarising, coding and generating initial themes

Initial analysis was undertaken with first set of interview transcripts (nine semi-structured interviews).

At the start of the analysis, I read and re-read each transcript. Having already performed the interviews and checked the transcripts for accuracy against the original recordings, I felt familiar and comfortable with the dataset. I began by highlighting areas of interest within each transcript, with handwritten annotations and short descriptions of what they contained and why I'd found

them interesting. In the initial stages, there were many highlighted areas as I thought everything was 'of interest'. I felt overwhelmed with the amount of information collated, not wanting to discount anything, as well as being unsure whether what I was concentrating on was relevant. I had to take a step back and reorientate myself with the research question and purpose of the interviews to allow myself to refocus. For many of the participants I spoke to, their lives were dominated by their COPD and their experiences of living with the condition were very humbling and I did not want this context to be lost. Although I refocused my attention and concentrated on fewer highlighted areas, I continued to acknowledge the contextual information that may be contained in other parts.

The initial codes were collated from analytically meaningful descriptions and developed through constant comparison within and between transcripts. A sample of the transcripts were reviewed and coded independently by second member of research team (DJL) and the outputs compared. DJL and I discussed the similarities/divergences of generated codes, the development of coding labels and potential themes. The interview schedule was updated ahead of the second round of interviews to reflect areas of interest for further exploration and detail.

5.2.7.2 Second analysis period – further coding and developing of themes

Following the second round of semi-structured interviews, five additional transcripts were analysed alongside the original nine transcripts in the second analysis period.

As with the first set of interviews, each transcript was read and re-read to promote familiarisation with the data. Performing the same process for the second time felt much easier and I was able to see patterns in the data more easily. Areas of interest were again highlighted, and descriptive codes and code labels applied. NVivo was used to collate the coded data to allow comparison across transcripts and creation of candidate themes. NVivo is a computer software program that allows researchers to systematically manage and visualise qualitative data.

5.2.7.3 Reviewing themes

DJL reviewed a further sample of transcripts against the collated codes and the outputs were compared. Candidate theme creation and development were discussed, noting apparent alignment and deviations within the dataset, as well as expanding to review them in terms of the wider research context.

A descriptive analysis of each theme was undertaken to develop the understanding of what each represents and how they contribute to answering the research question.

5.2.7.4 Refining, defining and naming themes

Analysis and candidate themes were then presented to the wider research team for sense check, with expanded discussions to finalise theme refinement. Some of the initial background codes were summarised to give context to the finalised candidate themes.

5.2.8 Information power to determine adequate data collection

The concept of information power was used to guide the number of interviews conducted and determine when an adequate amount of data had been collected. Sufficient information power is dependent on the aim of the study, the sample specificity, the quality of dialogue and the analysis strategy; ergo the more information the sample holds, relevant for the actual study, the lower the number of participants is needed (Malterud, Siersma and Guassora, 2016).

The alternative concept of data saturation was also considered. Data saturation refers to the point in data collection when no additional issues or insights can be drawn from the data, and all relevant conceptual categories have been identified, explored and exhausted (Hennink, Kaiser and Marconi, 2017). Originating from the development of specific Grounded Theory methodologies, this concept is often applied during other analytical approached without explanation of how the concept should be understood (Malterud, Siersma and Guassora, 2016). As I was not using Grounded Theory in the analysis of my

qualitative data, the application of the term data saturation was not appropriate, and I chose to use concept of information power instead.

5.2.9 Technology used

Devices used in the recording of telephone interviews:
- Re-Tell Telephone Recording Connector, part 157
- Phillips Pocket Memo LFH9600 Digital Voice Recorder

Device used for audio recording of in-person interviews:
- Microsoft Teams on iPad Pro

Transcripts were created from anonymised audio files by an external transcribing company (TP Transcriptions Limited).

Collation and coding of transcripts:
- NVivo – version 12.7.0

Audio and transcript files were securely stored within NHS GG&C Microsoft Teams space.

5.3 Semi-structured interview results

19 participants were approached for the semi-structured interviews, 15 participants responded and agreed to take part. 12 of the interviews were conducted over the phone and two were conducted in person in a hospital environment. Interview time totalled 437mins, with an average of 31mins per interview. One participant was unable to complete the semi-structured interview due to issues with communication but still wished to contribute. They therefore provided written answers to a focused number of questions from the interview schedule via the COPD support service messaging facility.

The demographic information and usage patterns of the interviewed participants are shown in table 12. Two thirds of these participants were female. The average age of interview participants at baseline was 63.3.

The average number of admissions across the interview participants in the year prior to the RECEIVER study was 1.6, with an average occupied bed day count of 11.1 days. Post study admission average was 0.6, with an average occupied bed day count of 3.0. At an individual level, only one individual had more admissions post study enrolment than pre, with five people having same number of admissions pre-post, and the remainder having fewer admissions.

All participants were ‘active users’ of the service at the point of data review in September 2021.

Study ID	Gender	Age	SIMD	FEV1% pred	PRO usage type^	Average age	Average FEV1% pred	Average PRO submission/week	Interview type
RC04	F	75	3	38	Regular user	63.3	47.3	5.9	Telephone
RC06	M	60	2	21	Regular user				Telephone
RC10	F	71	2	38	Regular user				Telephone
RC11	M	65	1	36	Very regular user				Telephone
RC17	F	57	3	46	Regular user				Telephone
RC21	F	61	1	75	Intermittent user				Telephone
RC22	M	68	3	49	Very regular user				Telephone
RC38	M	58	2	21	Very regular user				Telephone
RC43	F	77	1	93	Regular user				Telephone
RC45	F	50	1	23	Very regular user				Telephone
RC63	F	51	1	74	Regular user				Telephone
RC84	F	75	2	40	Intermittent user				Telephone
RC79	F	58	1	65	Intermittent user				In person
RC48	F	46	4	25	Very regular user				In person
RC74*	M	78	1	65	Regular user				Written responses

Table 12 Demographics and usage patterns for semi-structured interview participants
** Participant completed focused set of questions via messaging on COPD digital support service because of verbal communication issues precluding telephone interview*
^ Patient reported outcome (PRO) usage type represents quartile stratification of usage based on average PRO submission per week across 1st calendar year of trial; Very regular user = average weekly PRO submission rate 6.42 - 7.0, Regular user = 4.55 - 6.41, Intermittent user = 2.23 - 4.54.
Abbreviations: SIMD, Scottish Index of Multiple Deprivation. FEV1, forced expiratory volume in 1 second.

5.3.1 Background context

> *Situating the sample – description of research participants and their life circumstances to aid judgement of the range of persons and situations to which findings may be relevant. (Elliott, Fischer and Rennie, 1999)*

Initial background information about disease specific experience and day-to-day use and functionality of the COPD app was captured within the semi structured interviews. These descriptions are included to give context to the candidate themes that have been developed and frame the 'real-life' circumstances in which the app was used.

5.3.1.1 COPD symptom experience

Participants described classical features of COPD in their experiences of living with the disease, with variability in frequency of occurrence. Symptoms of breathlessness, along with chronic cough and chest tightness, were commonly mentioned. The majority of participants had experienced an exacerbation of their COPD. Although the actual term exacerbation was not frequently recognised, most participants were able to describe recognising a worsening of the symptoms that they associated with a flare-up of their chest and the need to seek additional treatment. For some participants, their experience of exacerbations was limited, implying a level of relative stability. Participants had a shared experience of being hospitalised because of their COPD. Many recalled the increased severity of their symptoms and emergency nature of their admissions.

5.3.1.2 Impact of COPD

Although there were similarities between the COPD symptom descriptions that were given by participants, the perceived impact of their COPD varied. Some indicated the struggles that their COPD caused, including limitations to their daily activities and acts of self-care. Descriptions had a negative slant, with restrictions to daily activities highlighted. In contrast, other participants indicated areas of restriction but with a more positive spin, describing the ways

in which they had retained independence and adapted to or accommodated symptoms in their lives.

The impact of COPD was commonly described in association with mental health issues. Some participants reported experiences of anxiety and panic attacks, either caused by or exacerbating their COPD.

5.3.1.3 Functionality: Day-to-day use of the app

All of the participants described using the app regularly, primarily to answer their PROs. The app itself was commonly described as easy and simple to use, and the questions quick to complete. The time of answering the daily PROs each day varied between participants. Some described incorporating it into a morning routine, stating it was completed following their morning tasks. Others referred to the daily prompt notification as a trigger for answering the questions, with its occurrence directly influencing the likelihood of the questions being answered.

The daily prompt was a common time-reference, with some participants expressing the need to either complete their questions before the notification arrived or shortly after it did.

Issues with logging into the app or the app not working were described in the instances where less than daily use was reported, as well as not completing for motivation reasons.

In addition to answering the daily PROs, several participants also described regular use of the messaging function and awareness of the information contained in the self-management section.

5.3.1.4 Use of Fitbit

All the participants that took part in the semi-structured interviews had been given a Fitbit wearable device at the start of the trial. The degree to which a participant had continued to use their Fitbit varied. A number had fully incorporated it into their routines and regularly referred to their activities in relation to what the Fitbit device had recorded (steps, heart rate etc.).

Usage for others was much less. Although the Fitbit was worn, there was often confusion as to the reliability or meaning of some of the readings that were being shown, particularly relating to movements they didn't feel they had done. Some of the participant had not continued using their Fitbit beyond the initial stages of the RECEIVER trial.

5.4 Qualitative analysis and theme development

Reflexive thematic analysis of the transcripts from the 15 participants was undertaken and collated using NVivo software, with input from the wider research team. From these analyses, I identified four candidate themes.

- ⇒ **Theme One – *Conditions for success***
  - Subtheme one: *confidence and ability with technology*
  - Subtheme two: *external support*
  - Subtheme three: *app features*
  - Subtheme four: *compliance and buy-in*
- ⇒ **Theme Two – *Adding detail and colour***
  - Subtheme one: *use of PRO language*
  - Subtheme two: *added data (from Fitbit)*
- ⇒ **Theme Three – *Background care***
- ⇒ **Theme Four – *A means to help***

These themes and subthemes serve to give an understanding as to the potential reasons why participants have continued to use the COPD digital support service app and what the benefits they have felt from it. They detail the conditions that appear to have facilitated and supported use of the app (theme one) as well as the potential motivations behind continued service usage (themes two, three and four).

5.4.1 Theme One - Conditions for success

This theme describes the factors which appear to have contributed to on-going use of the app, drawing together a number of subthemes that have created conditions for successful use. These include technology confidence, presence of external support, favourable features of the app itself, and participant motivational factors. Success was viewed as a participant being able to use the intervention (e.g. overcoming tech barriers) and integrating this into part of their routine (i.e. promote behaviour change/gain consistency of answers).

5.4.1.1 Confidence and ability with technology

There was large variation in how participants described their ability and confidence with technology. From limited and uninterested, to strongly capable and a source of assistance to other family members. Most participants accessed the app through their own smart phone or tablet computer. Many participants could describe other activities their phones/tablets were used for that involved the internet, although this list was more extensive for some than others. Participants reported feeling more confident with tasks involving technology that they performed regularly and were more comfortable with tasks that were familiar. For some participants, confidence increased with use over time.

Technology confidence appeared to have a direct impact on the extent to which the app was utilised, or different aspects looked at. Although some were confident to answer the questions, the messaging and self-management features were less commonly explored.

> *I'm a bit of a technophobe doctor, I think I told you that before. The app, I never used it properly…..I dare say if I studied it a bit more I would be able to use it a bit more. (RC22)*

For some, the fear of 'breaking' the app or device they were using was mentioned in relation to using the internet or exploring additional functions of the app. This appeared to be more prevalent amongst those participants with self-acknowledged low levels of tech confidence, where additional support from family members was commonly sought.

> *Do you use the internet on your phone?*
> *RES: No, I have never used it. I just use it for phoning and texting, that's me. I'm hopeless, if I get anything I break it and so I don't bother. [laughs] (RC43)*

> *Like I said, if I go into stuff and I hit the wrong button I think, oh ahh what have I done and knocked it all off again. (RC17)*

5.4.1.2 External support

Gaining support for technical issues from family members was commonly reported, particularly from those in a younger generation to the participant.

Support usually involved family members helping to solve problems with the technology or assisting when trying something new.

> *I was wee bit not very good at the beginning but when S (participants relative) sat with me and took me through it I was ok.*
> (RC04 – on relative helping with using the app)

One participant required daily assistance from a family member to log in to the app although they answered the questions themselves. Several participants cited the research team's instructions at setup as helping them get started using the app. Having a degree of support available, whether practically applied or not, appeared to be of benefit to overall tech use and the initial use of the COPD app.

5.4.1.3 App features

The app was universally described as simple to use. Those who were more cautious of their technical capabilities were more inclined to emphasise the ease with which they were able to use the app. One participant commented that they would not have continued to use the app if it was complicated, as had been the case for apps they had abandoned in the past.

> *I would have been frightened at first, but your app is simple, you know, it's not complicated its quick to go into. I mean you don't need to do a thousand bits to get to your bit, so that's simple enough…. Aye, I wouldn't have done it if it was complicated, I would have been like, 'what? Give up'…. Yes if it was complicated I wouldn't have used it, I'd have, well, I don't think I would have because I've been on some things, looking for things, and I think uch (*frustrated*) you've got to go through this and go through that and I just bin it you know what I mean.* (RC17)

Participants commented about the repetitive nature of the questions being asked. Several described being able to answer their questions '*blindfolded*' and being aware of the questions that were due to appear, including recognising the additional questions asked in the weekly and monthly set. The regularity and repetition of the questions shown on the app appeared to serve to enhance the participants' confidence in their ability to use the app.

Consistent reference was made in relation to the notification that was sent at midday, asking participants to complete their daily questions. The daily prompt represented a positive motivating factor in successful completion of the daily question set each day, with suggestion that it's absence would preclude this.

> *Some days I might forget and do them a bit later in the afternoon. But it comes through at 12 o'clock every day…. Usually within the hour I'll answer you know. (RC22)*

> *Yes, well I usually wait until it goes ping at 12 o'clock. And then I will fill it in, I will answer the questions. (RC38)*

Several participants referred to being in a routine when using the app, with the daily notification and repetitive nature of the questions appearing to be a positive contributing factor to its creation.

> *I have got these questions to answer daily. They go on a sliding scale, you know, and you get a number and it doesn't take you long to finish, to go through, you know. It's not an inconvenience for me, and anyway, you know. I have got myself into a routine/habit of answering the questions and that's it. (RC11)*

> *…now everything just falls into place, it's just a daily routine. (RC06)*

> *Yes, it's a routine that's what I think, just I need to answer my questions. (RC48)*

One participant commented on their lack of routine due to mental health problems contributing to infrequent answering of the PROs, with reflection that they would like to get back into a routine with answering again.

> *I need to get back into the routine because I was on a downer and I stopped it all together because I just couldn't be bothered. (RC79)*

Habit forming from repetition and creation of routine is recognised as a component in behaviour change (Gardner and Rebar, 2019). In their systematic review, Szinay et al (2020) identified the establishment of a routine or regular use of a health mobile app had a positive effect on the intention for ongoing engagement (Szinay *et al.*, 2020).

5.4.1.4 Compliance and 'buy-in'

At their initiation onto the RECEIVER trial, participants were asked to complete their PROs daily for the duration of the study. In answering their PROs on a regular basis, they have complied with these instructions. Willingness to partake in research may also imply a degree of 'buy-in' to the intervention and belief that it would be beneficial. Other aspects of compliance were noted in descriptions of participants other health behaviours including their compliance with inhaled medications (which they have also been asked to take regularly).

> *I will get up, I will take my meds, I have one, two, three, sometimes four, lots of stuff to take. And then I separate the carbocisteine, I have that twice a day, and my Seretide 500 I take that roughly about twelve hours later. (RC06)*

The willingness to comply with instructions is likely to have positively impacted the on-going use of the app but it also appears to have promoted the incorporation of answering the questions into part of a daily routine, further fostering regular use.

> *I am quite happy to provide information that I am asked to do. I mean I fill in, I do the daily report, whatever you call it, with my cup of coffee in the morning, so I know that I have done it.* (RC11)

5.4.1.5 Creating conditions for success

This first theme highlights the various factors that appeared to contribute to the effective and practical use of the app. Key elements such as ease of use, daily reminders, and repetitive questioning foster consistent engagement with the app. Understanding the components that encourage and facilitate sustained use of healthcare apps is crucial for their evolution and future development (Watson and Wilkinson, 2022). Prior research has indicated that ease of use, the necessity for education and support, and participant buy-in (promoting compliance) are significant facilitators of digital healthcare usage (Korpershoek *et al.*, 2018; Alwashmi *et al.*, 2020). These are findings further reinforced by this current analysis.

Moreover, the incorporation of the app into daily routines and habit forming, and the use of prompts and reminders are recognised mechanisms that support behavioural change, which underpins successful self-management (Lin and Wu, 2014; Kwasnicka *et al.*, 2016; Perski *et al.*, 2017; Amagai *et al.*, 2022). Figure 28 illustrates how established theories and mechanisms can be effectively applied to the real-world usage of this app by individuals with COPD, demonstrating how their interplay positively influences that usage.

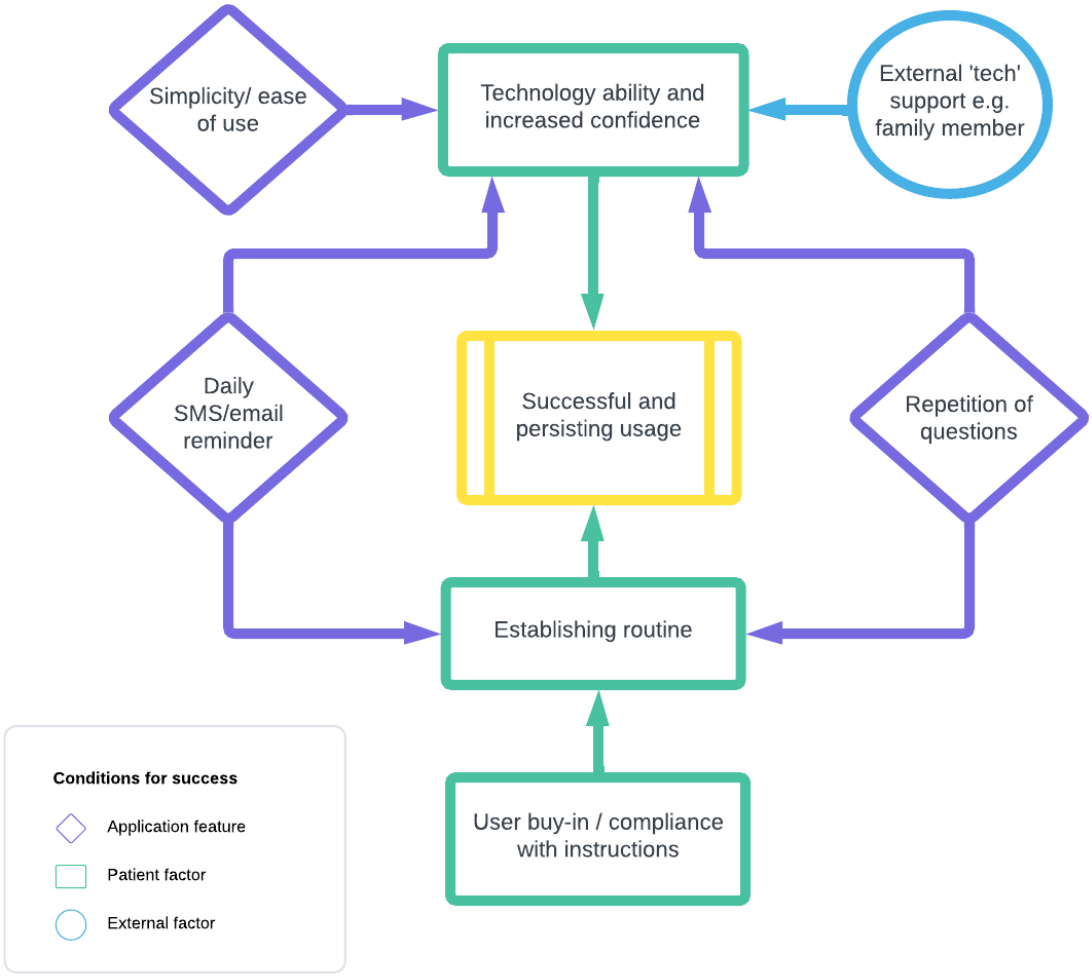


Figure 28 Diagram showing the interconnections between sub themes creating conditions for successful use of the support service patient app. The simplicity of use, along with the repetition of the questions and the daily reminders can be seen to create a favourable environment for those who may be less technically able or confidence, with external support either at setup or ongoing via family members giving further reassurance and confidence to complete. Question repetition and the daily reminder also encourage development of routine, bolstered by the buy-in of participants and willingness to comply with instructions.

5.4.2 Theme Two – Adding detail and colour

The second theme of *adding detail and colour* describes the perceived benefit of self-reflection and added information provided by regular answering daily PROs. Alongside this, the visibility gained through use of PRO language and Fitbit data, and how together they increased disease awareness and supported self-management.

Regular answering of symptom diary questions appeared to lead to establishment of routine and increased confidence in tech ability. The repetitive and structured nature of the questions was also reported to have been assistive for some of the participants in monitoring and keeping track of their own symptoms.

> *I think with the questions, no I have not got any phlegm, I am not wheezy, I am not this or that, so I think you are obviously more aware when you are answering the questions of how you are feeling. (RC06)*

> *Yes, they do help because they actually- You're actually seeing what you're writing down, and if you want to write, well I don't feel like that or I do feel like that- So- It does help. (RC79)*

Most people could recall the process of self-reflection at the point of answering their questions. For some, this moment of reflection supplemented the awareness of their condition that day and gave justification for a change in self-management or activity if changes were noted.

> *And now I am more aware of the symptoms and when to sit down and when to stop and try and control my breathing a wee bit rather than keeping going….Aye, just thinking 'no, I'll get there. I'll get there', you know. (RC17)*

> *Well it will maybe make think, well maybe I should maybe use the nebulizer more today, erm, just wee things like that. (RC10)*

In some cases, the recognition of changes in symptoms were picked up over a longer period of time, influencing reflection on overall health and providing motivation to change.

I think as I have noticed a deterioration, as I've noticed the difficulty I have in breathing, it's made me think that this is, that it's not going to improve it's only going to get worse. And I am not doing anything to combat that, if you know what I mean? I am not getting up off my backside and going for a walk, you know. (RC11)

I am certainly more aware of it, with answering the questions. And I think maybe just listening to the doctors telling me that once you start spitting up stuff and its green and things, I am more aware of the signs of an infection I think… But it's certainly made me far more aware of my general health so it has. (RC38)

The process of answering the questions on a daily basis was not found to be beneficial for all participants. For some, the process felt pointless as there were limited changes to symptoms and did not result in any changes to their own management.

It just feels like I am just constantly press, press, press and it's the same bits I am pressing. There is no change if you know what I mean within twenty-four hours; there is no change really….. No. I take my medication, I take it the same way all the time, there is no difference. (RC21)

AT: Do you find the app useful at all….Is there anything it does help you do? Patient: Well, I'd be lying if I said yes, as I don't really think about it. You know, it's just really some questions it's asking you, there's no feedback from it. (RC84)

Conversely for others, whilst acknowledging limited changes in their symptoms on a day-to-day basis, there was reassurance in noting the stability and perceived advantages on being able to pick up on short-term differences.

As I say it's definitely made me aware everyday, and I can see when an infection is coming or if I've not got any pain, or if my spit starts to turn a different colour, I would check it that day rather then no check it. But if the app was only about once or twice or three times a week, that can change and you've not clicked it.
INT: So actually having the questions every day is a good thing?
RES: Yes, aye, well I think so, yes. (RC17)

Promotion and support of self-management within COPD is seen as a key management strategy to empower patients to enable them to better care for their condition. Increased disease awareness through digital symptom monitoring has previously been shown to aid and promote disease control (Williams *et al.*, 2014; Nissen and Lindhardt, 2017; Lundell *et al.*, 2020).

5.4.2.1 Use of patient reported outcome language

Throughout most of the interviews, participants were able to draw on the language from the daily questions when discussing their condition, both giving numerical quantifications and descriptions of their symptoms. Whether utilised intentionally or subconsciously, the additional vocabulary gave added detail and context to their descriptions.

> *When I've noticed that I was finding, I was becoming, my breathing was becoming more laboured. I increased, I went from maybe two to three, or I have gone from two to three, you know, when I am answering the questions. And I think on a Wednesday, when its, the number of, some extra questions about going to hospital and, I'll give my numbers up on the scale as well, you know. (RC11)*

> *Well some of them, mostly about the phlegm and all that, I think about how is it phlegm wise and coughing wise, the other one's activities. I'm always going- I'm not saying I'm on the go but I keep going, do you know what I mean? And the confidence one is always the same, I'd be all right going out, four…They mostly stay the same apart from the kind of phlegm ones, the chesty ones. (RC48)*

Use of this disease-specific vocabulary appeared to add legitimacy and confidence to the expression of symptomatology that participants report whether internally to themselves or to other healthcare providers. It gave them the language to be able to verbalise and justify their action (e.g. to take additional medication or contact their HCPs) because they had noted a quantifiable change. Through their realist synthesis on the use of patient reported outcome measures (PROMs) across a range of conditions, Greenhalgh et al (2018) reported that patients found that completion of PROMs prompted reflection on their health and go on to develop a deeper understanding of how their condition affects them (Greenhalgh *et al.*, 2018). Akin to this, in their

realist review of implementability of telehealth interventions for self-management support, Vassilev et al (2015) introduced the concept of visibility, with monitoring systems that increase the visibility of symptoms or health problems to self or others having an impact on the uptake of telehealth interventions (Vassilev *et al.*, 2015). They indicated how visibility facilitates and mediates knowledge and motivations, which are inextricably linked to the actual task of self-management.

5.4.2.2 Added data (from Fitbit)

The interaction with the Fitbit wearable featured prominently for some of the participants. Recall of readings alongside daily activities showed how the device had been incorporated into everyday use, with the additional data providing added insight, description, and justification to what the participants were doing.

Detail and data visibility was also gained by those participants that reported Fitbit use, when physiological data was available through their device. Target setting has been commonly shown to motivate individuals to maintain activity levels or even achieve specific goals (Epton, Currie and Armitage, 2017; Shah *et al.*, 2023).This was repeatedly seen amongst the RECEIVER participants who had continued to use their Fitbits alongside the COPD app, despite not being given specific requirements for use of the device or goal setting when they enrolled onto the trial. The motivation to stay active appeared to be driven by a need to achieve their own 'self-defined' step target and was viewed as a positive factor.

> *…that gave me the incentive to get up off my backside and go for these walks, you know, they give me a wee target in my own head and in that way I find it useful. I'll know if I've made the ten thousand steps or not and I can get up and I can go and walk round Victoria Park a couple of times, you know, it is not difficult. Yes but I would say that was there, that sort of gave me a bit of impetus to move, you know. (RC11)*

> *No I look at it on a day-to-day basis just to see how many steps and that I have done. It kind of gave me, like on a bad day, I will think oooft I need to get a wriggle on, do you know what I mean, I have not had enough exercise. (RC17)*

And do you have a target of the steps that you want to go for?
RES: I'd love to do about 10,000.
INT: Ah ha, that's a lot.
RES: But one of the days I did, I think it was about 8,000 and I was over the moon with myself. (RC48)

Additionally, readings were described by some as being used to check against how they were physically feeling; using the additional data as a further sense check of the symptoms they were experiencing, enhancing their insight and giving reassurance or adding justification to their actions from having the data evidence.

Yes, I check it a lot so I do. I always check it at night. But I check it throughout the day as well if I have been doing stuff, like I was emptying my washing machine all day or I take something out in the kitchen, and I was really badly out of breath, my heartbeat went up a bit but it wasn't anything outrageous. I was actually quite pleased with it. (RC38)

The odd time if I feel anxious about something I can feel my heart going like that. And then I'll check, check my Fitbit and then I'll put my wee prong on my finger, and if it's going to high, I just sit down, don't do nothing. (RC79)

Self-generated targets were used by some participants to provide motivation to maintain activity levels, and data values were used to sense check against their other symptoms and justify their actions (e.g. taking time to rest). This aspect has been reported by Wu et al (2019) in their qualitative study exploring how people with COPD would perceive the use of wearable devices in the management of their condition (Wu *et al.*, 2019). Participants expressed interest in having personalised connections to the data provided by wearables, to allow them to make connections between how they are feeling and what their body is doing.

It is important to recognise the value of wearable technology for individuals who are actively engaged and motivated by such tools. Additionally, it appears that the information provided by the third-party Fitbit app may have played a role in driving Fitbit usage. This is particularly noteworthy considering that other than simply wearing the device, the research team did not provide strict guidance or

instructions regarding its use. Meta analysis by Shah et al (2023) of use of wearable technology interventions for people with COPD, reported most benefit seen from multi-component interventions that included wearable devices alongside other facets (Shah *et al.*, 2023).

However, not all interviewed participants chose to use their Fitbit, with technology and connectivity issues preventing meaningful use. This is commonly cited as barrier or de-motivator to ongoing use of technology which collects physiological data, although those that do it in a more passive manner (like Fitbit) tend to have more favourable results (Althobiani *et al.*, 2023).

5.4.3 Theme three – Background care

The theme of *background care* highlights the reassurance and confidence participants felt from the patient app; fuelled not just by the existence of the communication channel but also by a sense of somebody looking after them in the background.

For a large proportion of participants, the patient app and COPD support service represented a caring presence in the background bolstered by the ability to message the clinical team if needed. Having somebody on the '*other side*' of the app was reassuring and helped to boost confidence. There was a person there in the background who they could reach out to if required, providing a '*safety net*'. Even if this participant instigated contact did not frequently occur, just knowing that it could be theoretical used in this way provided moral support.

> *The whole thing in general, it's good to know that I can message you if there's anything - Yes. That's what I like about it….it has kind of help me because at least I know there's somebody there. (RC48)*

> *I feel as though I've got some kind of moral support there in the background, you know? (RC22)*

There were recurrences of reference to *somebody* being there, both in terms of messaging and the app overall, implying reassurance and benefit from a human

aspect to the digital service; a real person being on the other end of it, a familiarity with who was in contact with them.

> *It gives you confidence and it is just nice to know there is somebody at the end of it (RC04)*
>
> *I am really happy with it because I know that there is somebody there that if needs be I can message.(RC06)*
>
> *….it kind of makes me feel as if I am kinda involved and somebody is kind of listening. (RC38)*

The process of seeking (or being able to seek) advice was deemed important to participants, with the messaging cited as a means of doing this easily.

> *Yes it has helped, especially the message and question part as you can get the best advice in the answers. (RC74 – text response)*
>
> *So as I say, just doing it, its good to know you have got it there, do you know what I mean, I can message any time. (RC17)*

One participant also referenced the way in which their family used the messaging facility to contact the clinicians on their behalf, something they felt was particularly important to them.

> *Sometime my daughter will message F (CNS nurse), if there's something she's not sure about, she might message, which I find quite helpful. (RC04)*

There was a sense of reassurance gained through access to the app, with having a 'safety net' in the background and the ability to reach out if needed. The presence of the messaging component gave the means to foster a care relationship between participants and clinicians. This sense of security and reassurance has previously been found in several studies of interventions which included additional means of communication to clinical support. Van Lieshout et al (2020) evaluated the implementation of a remote monitoring programme for COPD and noted the inadvertent development of a care coordinator function of the clinical team through messaging with participants (van Lieshout *et al.*, 2020). As in the RECEIVER trial, this had not been an aspect that they had specifically dictated at the outset of the project, but it had emerged as a

positive and valued asset. For van Lieshout et al, this positive care relationship was felt to have contributed to participant engagement. In their realist review of the implementability of telehealth interventions for self-management support, Vassilev et al (2015) also highlighted relationships with professionals as a factor that could potentially contribute to the success of an intervention (Vassilev *et al.*, 2015).

The presence of *somebody* being there in the background was recurrently mentioned in the context of messaging and the patient app itself, implying importance of human connection. This mirrors findings from studies in both COPD and other long-term conditions. In a secondary meta-analysis of the impact of technology systems and level of support in digital mental health interventions, Sasseville et al (2023) found online messaging to be the most effective technology to improve anxiety and depression outcomes (Sasseville *et al.*, 2023), with interventions partially supported by healthcare professionals being more effective than those that were self-administered. Van Zelst et al (2021) evaluated adherence with an eHealth platform to support people with COPD and found increased usage and engagement in a blended setting, where healthcare professionals interacted with participants based on their symptom reports, compared to adherence with independent use without clinician support (van Zelst *et al.*, 2021).

However, this is not clear cut. There are reports from research participants of reassurance and feeling looked-after noted across a range of studies that varied in the levels of support and monitoring delivered (Brunton, Bower and Sanders, 2015). Within the RECEIVER trial, the messaging function existed for participant to contact the clinical team if they wanted. Instructions were given at time of enrolment that question responses were not actively monitored, the ball was in their court to get in touch if advice was needed but that it was not an emergency service and if they were acutely unwell to use routine channels for medical advice and help. Despite this, participants described a sense of assurance because they felt they were being ‘watched over’. In the study by Williams et al (2014) they described the use of the EDGE COPD app, where participants required to enter daily symptoms that were viewed by research team (to ensure submission) but not specifically acted on (Williams *et al.*, 2014).

Participants were informed at enrolment that would still need to contact usual healthcare providers if they felt unwell. In spite of this, the qualitative interviews with participants still found that they got reassurance from and valued continuity of care through sharing of information but without a specific means to contact. During the Telescot telemonitoring trial (Pinnock *et al.*, 2013), participant symptoms were actively monitored on a daily basis with contact initiated by clinical team if readings outside of predefined parameters or if no data were received. Study participants again noted value from the reassurance of being looked after but the clinical team felt this created a negative dependency on them, and a removal of participant independence through active monitoring (Hanley *et al.*, 2018).

This aspect of reassurance seems to be present across multiple different interventions and levels of contact. Whilst this is a complex factor to decipher, the presence of a human component or communicator could be seen as unifying element. This mirrors the findings of a health foundation commissioned survey in 2023, which explored the publics attitudes towards the use of digital health technologies and data. They found that although the public were in favour of technologies that aimed to support them to look after their health (e.g. self-monitoring devices), those that may be perceived to 'come between' the clinician and patient, such as chatbots, had much less support (Thornton *et al.*, 2023).

5.4.4 Theme four - A means to 'help'

There was a high level of altruism expressed amongst the participants with the majority being enthusiastic about the idea of research and reporting to have joined the trial to 'help'. Several reported previous participation in research. There was a widely held perception of benefit from the information collected via the patient app to the general population of people with COPD, and not just the participants themselves.

> *And if its helping anybody at the end of the day…..I would try any trial, it doesn't bother me…..you never know what you're going to learn and it's a trial, it must do some good. (RC43)*

> *Its not hard and it might help someone helps (sic) further on down the line. (RC22)*

> *Even if it wasn't beneficial to myself and I don't mean to sound like a saint but all these things, they're going to benefit somebody I think in the long run…I'm glad it's happening and onwards and upwards. (RC10)*

Some participants expanded on this, and volunteered suggestions of how they thought the wider NHS/clinicians could also benefit from the information collected in the app.

> *It is probably quite a good idea for you know, for some people, who can get some useful info off it… I think more for the medical professionals to see, if there are getting feedback off of hundreds of people, to see that this happens or that happens, you know over all… Well I think at the end of the day, it will all come together kind of thing and they will check what people are putting in. You know, there might be a certain trend in different ages or something, you know. (RC84)*

This willingness to participate and continue participating, for the sake of others in the future, can be seen as a contributing factor to ongoing engagement and is one of the commonest reasons for participants to take part in traditional clinical trials (McCann, Campbell and Entwistle, 2010; Godskesen *et al.*, 2015; Dufva *et al.*, 2021). Rosenbaum et al (2005) noted independent association between altruism as a reason for participation and adherence in clinical drug trials, showing those expressing altruistic intent towards participating were more likely to adhere to the intervention itself (Rosenbaum *et al.*, 2005). A close-out survey conducted with trial participants from a ventricular dysfunction study by Henzlova et al (1994) showed high proportions of people had enrolled as they wished to contribute to medical science and to help others (Henzlova *et al.*, 1994). It is understandable how altruism may directly affect the initial adherence and compliance to an intervention but just being involved in a clinical trial can have unintended or unrealised consequences. In the same 1994 study, a high number of participants were also found to have adopted positive lifestyle changes despite absence of a specific behaviour change instructions. Additionally, McCann et al (2010) undertook non-participant observation of recruitment consultations and in-depth interviews with people invited to

participate in the UK REFLUX trial. They used term ‘conditional altruism’ to describe that the willingness to help others may influence initial participation in a trial, but that it is unlikely to lead to trial participation in practice unless there is recognition that participation will also benefit them personally (McCann, Campbell and Entwistle, 2010). Although participants signed up to the RECEIVER trial with altruistic motivations, perceived personal benefits gained through use of the service may have influenced their motivation to persevere and continue with it.

5.5 General discussion

This chapter has demonstrated the successful undertaking of semi-structured interviews capturing a range of perspectives and bolstering understanding of the utilisation of COPD support service from point of view of people with COPD.

Through these semi-structured interviews, I have gained an increased comprehension of service fidelity and enablers for ongoing use. Analysis of the interview responses has indicated how the simple nature of the app, along with the repetition of the questions and the daily reminders can be seen to create a favourable environment for those who may be less technically able or confident, with external support either at setup or ongoing via family members giving further confidence. Question repetition and the daily reminder also encourage development of routine, bolstered by the buy-in of participants and willingness to comply with instructions. Additionally, it is important to appreciate that as with any complex interventions, there are likely to be unmeasured and unmeasurable aspects influencing usage. The combination and connection of the external, participant and app features emphasise the need for all aspects of usage to be considered in the development of a digital intervention, as well as the system and service provision it will sit within.

Analysis of the interview data has indicated mechanisms that have enabled usage, but additionally also captured motivations for persisting usage. It has shown how self-monitoring of symptoms plays a role in enhancing disease-state recognition and the ability to detect changes; providing value and visibility, adding detail and colour to participant’s self-perceptions and the ability to use that to rationalise and justify their actions. The Fitbit device was also able to

provide participant users with additional data to further enhance the understanding of how their conditioning affected their day-to-day lives, and motivation to adapt or alter their activities. Self-management knowledge was not formally captured at baseline or follow up in the RECEIVER trial but did appear to be present for most of the interview participants. It was unclear to what extent this knowledge had been learned through the app, or if use of the app built on previous knowledge and gave participants a more structured way to recognise variation in their condition. Inclusion of self-management knowledge metrics in future evaluations of the digital service could help to understand this further.

The use of patient app was seen as providing a connection to respiratory care team, boosting confidence and giving reassurance of being looked-after, with the ability to communicate and reach out if required. There appeared to be comfort gained from *somebody* being there in the background if needed. In my research notes taken at the time of the interviews, I reflected on the familiarity some of the participants had with the clinical team who were looking after their COPD. Some of these clinicians were also involved in the RECEIVER trial, some were adjacent to it. I thought about the influence of this on the reported benefits that had been found from the app and could see that some of reassurance was intertwined with the pre-existing care relationships. Knowing who they were interacting with, and trusting the response added to a sense of security created through use of the service. If thought about from a purely experimental perspective, the pre-existing care relationships would make the accounts highly biased, but they are more reflective of the real-world, where interactions and confidence between patients and clinicians evolve over a number of years, especially when dealing with chronic health conditions. This draws back to element of 'human-ness' required within interactions and suggests that similar reassurance is unlikely to be felt from an automated chatbot-like system. Whilst there may be advantages to digital technologies in supporting and enhancing patient care, there is a need for digital technologies to retain a human, relational dimension (Hardie, Horton and Warburton, 2021).

Finally, the influence of being involved in research was repeatedly apparent. Altruism is a factor that can't be avoided but the data obtained doesn't suggest

that this was the only reasons for participants on-going usage of the patient app and support service. There is likely to have been a proportion of people who continuing to comply solely because of altruistic tendencies but there may also have been those who noted personal benefit in addition to their wish to help others, which motivated ongoing use. Trial participation itself can have unintended or unmeasured benefits. It was likely that altruism played a role in signing up to trial, but it is not possible to quantify the level of influence of altruism on usage in the trial overall. The COPD support service has since been expanded to reach a larger community of individuals with COPD as part of routine clinical care. Evaluations of this scaled up service offers the opportunity to determine whether the patient perceptions identified within the RECEIVER cohort have continued to be relevant beyond the context of the clinical trial.

5.5.1 Contrasting/opposing viewpoints

Although the functionality and ease of utility of the app was universally reported, not all of the interviewed participants perceived similar levels of benefit. This was particularly true of the action of completing daily questions, with the frequency being too often for some and there was no clear usefulness perceived from completing them. For these participants, their persisting usage appears to have been primarily driven by their involvement in the trial and willingness to comply with instructions.

5.5.2 Comparison to wider cohort

The semi-structured interview participants were a subset of the wider RECEIVER cohort. Like the full trial cohort, two thirds of those interviewed were female and were of a similar average age. Additionally, the socioeconomic status of those interviewed mirrored the distribution seen across both the full trial cohort and wider COPD population in NHS GG&C.

All the participants recruited to the wider RECEIVER trial were considered to have high-risk COPD. Accordingly, all interview participants fell within the ‘E’ category of the GOLD COPD severity scoring denoting admission to hospital with a severe exacerbation in the previous 12 months (GOLD, 2024). The majority of participants also fell within the severe or very severe disease classification

based on their percentage predicted FEV1 spirometry value. The average number of admissions in the 12-months prior to enrolment for the interviewed participants was slightly lower than the wider RECEIVER cohort.

Despite having similar medical labels of disease severity, the experience of living with COPD varied immensely between the participants that were interviewed. Even within a well-defined disease group, symptom burden and disease experience were variable so it is understandable how there may be variation in use and outcomes seen from of a complex non-pharmacological intervention.

While the primary aim was to engage with users who had been consistently active, I also aimed to maximise the pool of potential participants that could be potentially approached for the interviews. By implementing criteria that considered usage over the preceding month, I was able to capture a broader range of engagement patterns. This approach ensured that not only those participants who submitted responses every day or week were included. At the time of data review in September 2021, all participants had entered PROs at some point in the preceding month; however, there were considerable variability in the frequency of their weekly PRO submissions, which was evidence in the different PRO usage types.

5.5.3 Limitations of study approach

There were several limitations to the qualitative study approach that was taken. Participation began within the context of a clinical trial therefore it is important to consider the type of people who agreed to take part in the first place. This includes the possibility that they are more likely to be more motivated and activated about their health overall, which may have had an influence over their responses during the semi-structured interviews.

I chose to approach those who had continued to use the digital service. I am aware that they may not have been fully representative of RECEIVER participants as a whole but I wanted to increase the insight and understanding of the patient app usage, therefore participants were selected on basis that would be best placed to provide ‘information rich’ data to analyse (Patton, 2015). I also acknowledge that understanding the reasons for non-usage of the app is an

important aspect to explore. Insights gained from this project could be used to inform future studies that specifically investigate the experiences of individuals who opted not to continue using the service.

Data collection was conducted over two distinct time periods. Initially, a set of interviews were carried out, and the data from these interviews were subsequently collated, transcribed and analysed. After reviewing the findings, it became evident that additional interviews were necessary to gain further insights. While the sampling strategy remained consistent between the two phases, the timing of the interviews may have influenced the willingness of participants to take part in the second round. Specifically, those who agreed to participate during the later phase of interviews may have been individuals who were more motivated overall, given the time that had elapsed since the start of the trial. Conducting data collection and analysis in two stages was a necessary step to ensure richness of the data and increase the overall information power of the qualitative study.

14 semi-structured interviews were conducted, which was marginally lower than the number originally intended to be undertaken. Initially, purposeful sampling was employed to collate potential participants to approach, this then became a convenience sampling due to participant availability. The number of interviews undertaken was ultimately dictated by the ability to recruit participants from a vulnerable population, and the time required to conduct, transcribe and adequately analyse the data. Additionally, a proportion of participants died over the course of the study so were not available for interview follow up. Although I would have valued the opportunity to conduct additional interviews, I felt the data that were collected was of sufficient information power to allow adequate inferences and conclusions to be drawn.

Data collected through interview is subject to social and recall biases that are often unavoidable. The semi-structured interview process was designed not to be leading and to promote openness. As these were one-off interview it was therefore not possible to infer or explore changes in perception other than those based on participant recall.

Interviews were only undertaken with those people who had consented to take part in the main RECEIVER trial and did not include those who had declined participation. Although there may be value in collecting data from the people who did not wish to take part in this specific trial, a wide range of research already exists exploring the motivations, barriers and facilitators of adoptions of digital interventions within COPD and the wider chronic disease environment.

5.5.4 Impact of telephone vs in-person interviews

There is debate as to the advantages of in-person over telephone interview, and differences noted in data gained. In person interactions are thought to influence the development of rapport with participants and allow a more 'natural' encounter (Shuy, 2003). There is believed to be a loss of visual or non-verbal cues during telephone interactions which would otherwise aid communication and convey more subtle layers of meaning (Irvine, 2010). Work by Irvine et al in 2013, found interviewees talked for longer during in person interviews and there were differences noted in behaviour of the interviewer between two modes, with researchers often reflecting on how lack of visual cues affects practice (Irvine, Drew and Sainsbury, 2013). However, Sturges & Hanrahan (2004) conducted interviews views on visitation of jail inmates in California, aimed to collect all data face-to-face but due to difficulties in conducting study proportion of interviews were carried out by telephone. They compared telephone and in person transcript and concluded there were no noticeable differences in responses given (Sturges and Hanrahan, 2004).

During the development of my qualitative methodology, I had planned to undertake in person or face-to-face video interviews, to try to increase the depth and breadth of data collected, whilst appreciating that more data may not necessarily equal better data (Irvine, 2010). However, the majority of the semi-structured interviews were conducted over the telephone. Initially, this was dictated by external pandemic factors and shielding within vulnerable populations but even after restrictions were eased, most of participants were much more comfortable undertaking their interviews over the phone. Whilst it may have been desirable to obtain more in-person interviews, adaptions had to be made when faced with factors outside of researcher control.

5.6 Personal reflection

I have played an integral role in the design and iterative development of the COPD digital support service and web-app as well as the initiation and continuation of the RECEIVER trial. My role as a researcher in this study sat closely alongside my clinical role. This crossover enabled me to develop a rapport with some of the trial participants over time, as both clinical and research interactions have occurred. As a developer and clinician, I could be viewed as an *insider* who possesses *a priori* intimate knowledge of the community and its members (Merton, 1972). There is an argument that objectivity can only be retained as an *outsider*; giving scope to a researcher to stand back and abstract material from the research experience but this implies only one 'reality' to be observed. There is no one 'correct' position, with the insider<>outsider perspective existing on a continuum (Hellawell, 2006). "The perspectives of both outsider and insider reveal "certain truths"… each perspective has its advantages and disadvantages, both intellectual and practical"(Lewis, 1973).

Whilst the relationships and familiarity built during the trial may have influenced the interview data collected, they could also have led interview participants to be more at ease, allowing them to confide accurate and representative responses. Ultimately, my involvement within the development and implementation of this trial allowed me to bring unique insight to this research.

5.7 Chapter conclusion

This chapter has detailed the perceived benefits felt by users of the digital support service and the apparent value gained through PRO entry and care team communication capabilities. It has also demonstrated how features of the app itself have worked alongside participant and external support factors to promote and enhance persisting usage. These findings have built on the positive outcomes seen in the initial stages of the RECEIVER trial and added to the understanding of the usage of the support service. The qualitative findings are summarised in figure 29 alongside the initial quantitative results.

The next chapter will document the expansion of the support service in response to the COVID-19 pandemic and how the evaluations conducted within this scaled-up service compare with the outcomes already presented within this project.

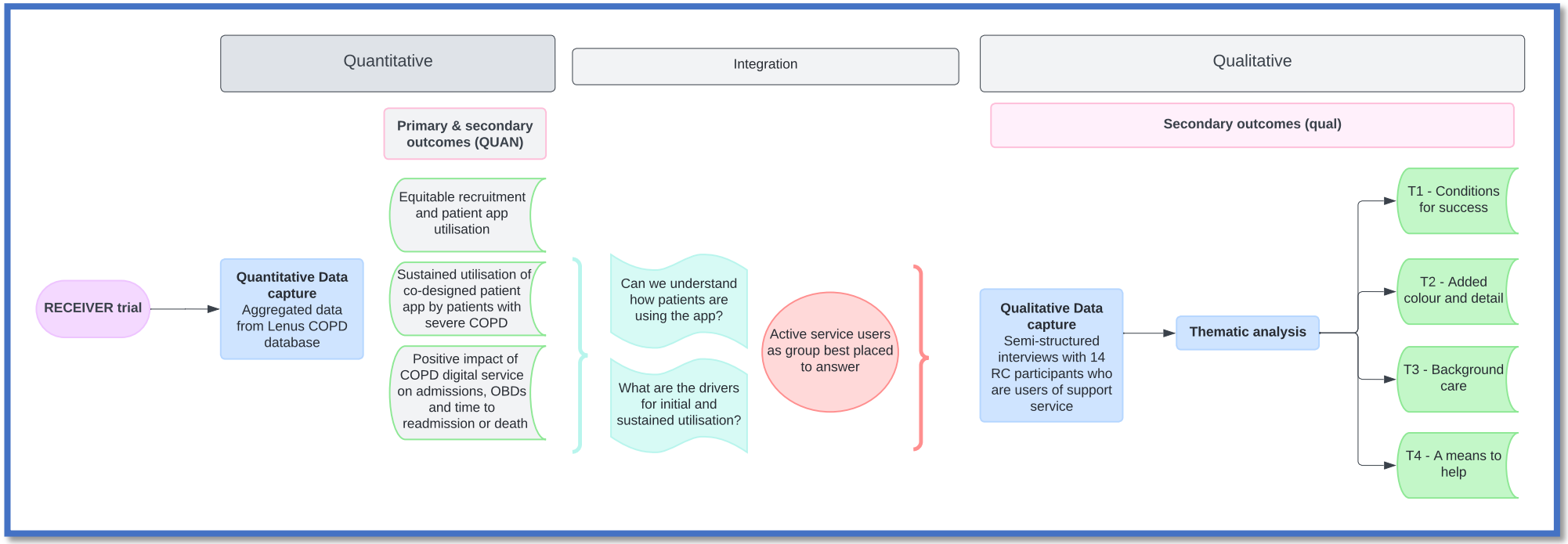


Figure 29 Summary of the qualitative analysis and findings from the semi-structured interviews with users of the support service within the RECEIVER trial, alongside the initial quantitative outcomes and point of mixed methods integration
Abbreviations: QUAN, qualitative. OBD, occupied bed days. Qual, qualitative. RC, RECEIVER

6 Chapter 6 – Wider context and adjacent work

The goal of the DYNAMIC project has always been to explore and optimise the use of digital interventions for people with COPD and expand their usage beyond academic research into real-world clinical care. Building directly on the foundations of the RECEIVER trial and the research within this thesis, and in response to the COVID-19 pandemic, the original DYNAMIC project has evolved; additional work streams have been developed to support and further enhance and optimise COPD care in NHS GG&C. These have included scale-up of the digital support service to the wider COPD population, development of AI-derived risk predictions models and digital transformation of the COPD diagnostic pathway.

This chapter details the scale-up of the digital service and the subsequent service evaluations that have been conducted.

6.1 Scale up of the COPD digital support service

Recruitment to the RECEIVER trial was halted at the announcement of the UK COVID-19 lockdown at the start of 2020. All participants who had previously been enrolled continued within the trial. The last trial participant was recruited on 13th March 2020.

As part of NHS GG&C's COVID-19 emergency response and based on positive interim data from the RECEIVER trial, the patient app and self-management tools were pivoted and adopted for use in routine clinical care within NHS GG&C in May 2020. The digital support service was recognised as a valuable resource to assist in providing admission avoidance, continuity of care, and management support for people with COPD.

I led the rapid co-design and development of the original COPD support website. A web-based system was created, allowing remote setup to the COPD digital support service following vetting for eligibility by respiratory clinicians. The web flow is shown in figure 30 (accessible at https://support.nhscopd.scot/apply). Eligible people were then invited to register and join the digital service remotely via a secure emailed link.

During the initial COVID-19 response, governance approval was granted for the support website sign-up information to be sent via SMS to people with COPD who were or had previously been known to secondary care respiratory teams. This included those who attended pulmonary rehabilitation, had early supported discharge support, or were on long term oxygen therapy registers. Promotion of the service was also undertaken via NHS GG&C social media platforms and local newspapers, with direction to the support website for further information and to register interest.

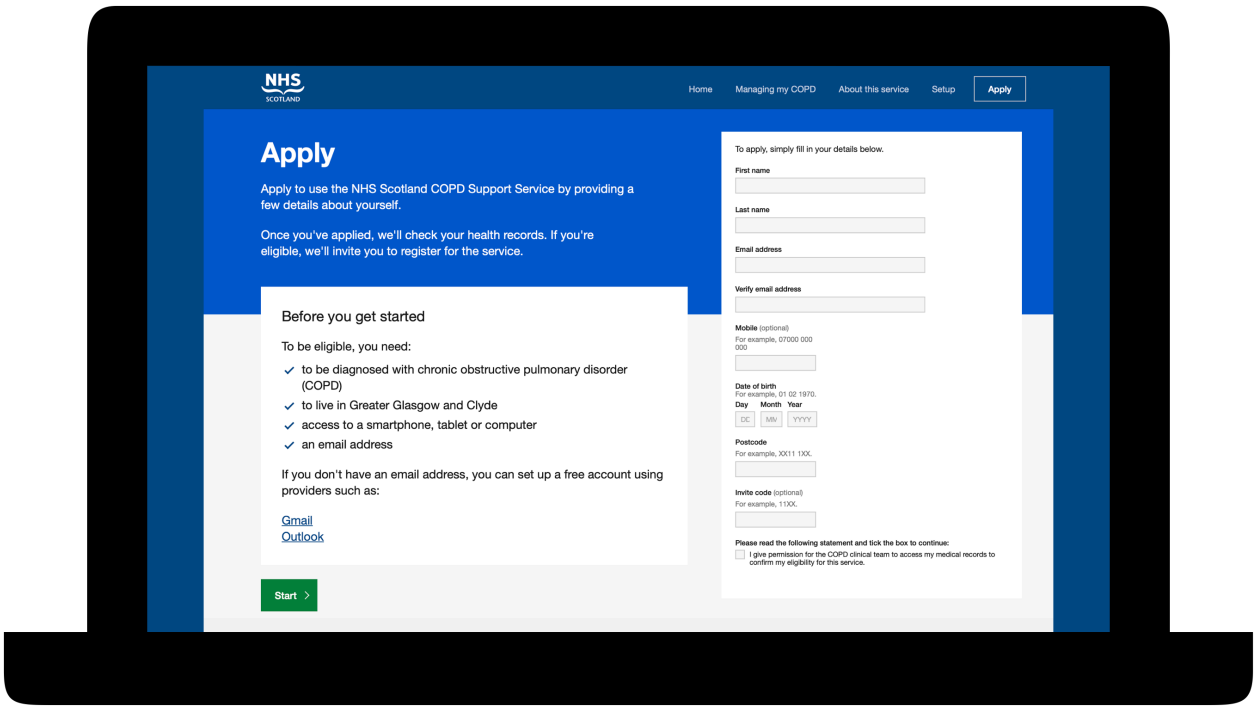


Figure 30 Online application screens accessible through COPD support website. Information provided about eligibility at start of application flow, and details and consent captured via information form to allow clinicians to view electronic health record to confirm eligibility.

Online application and remote sign-up remain the main route of setup to the COPD digital support service and is now available to any person with COPD resident in NHS GG&C. Details about the service are provided at patient reviews in pulmonary rehabilitation, early support discharge, diagnostics and community COPD services, including in primary care. Patient information leaflets have also been created from feedback and learnings gained within the RECEIVER trial, to further promote the service (included in appendix 4).

6.2 Service evaluations

6.2.1 Service usage and clinical outcome evaluation

Using the methodology developed for the RECEIVER trial, retrospective evaluations of the scaled-up service have been performed, including analysis of utilisation rates, patterns of usage, and long-term clinical outcomes.

These data were incorporated into the report produced for the National Institute for Health and Care Excellence (NICE) Early Value Assessment (EVA) Evidence Submission in February 2024 (McNair *et al.*, 2024) and internal documentation supporting the service procurement process.

6.2.2 Qualitative feedback from scale-up patients about the use of the digital support service

Qualitative patient feedback from users of the scaled-up digital service was collected by user experience researchers from StormID/Lenus Health. This feedback process was undertaken as part the patient and public involvement and engagement (PPIE) activities for the subsequent AI-based research project that is utilising AI-derived risk prediction score in the management of COPD (DYNAMIC-AI).

6.2.3 Clinical outcome and utilisation evaluation methods

6.2.3.1 Data collection

Data were collated from all individuals onboarded onto the COPD support service in NHS GG&C between 1st May 2020 (when remote service provision was established) to 31st October 2022, to allow a minimum of 1-year post-onboarding follow up to be undertaken. Data were censored at 2-years post-onboarding, or on 31st October 2023 for people who had been in the service for less than 2 years.

Demographic, clinical summary, hospital admission and mortality data were obtained from electronic health record data and collated in the support service

clinician dashboard, including baseline admission data over the year prior to onboarding to the service. De-identified clinical and PRO data were aggregated from the support service database via cloud data factory and made available as a .csv file for analysis through the NHS Scotland Health Data Exchange.

6.2.3.2 Data Analysis

Service users were split into two different sub-groups based on whether they had a history of a COPD or respiratory-related admission in the year prior to onboarding ('baseline admission' sub-cohort) or not ('no baseline admission' sub-cohort). This cohort stratification was implemented as the baseline COPD severity and risk of adverse events between these cohorts would be different.

Utilisation was measured by the number of PRO responses submitted and was presented as the percentage of service users submitting at least one set of PROs per week.

Mirroring the analysis performed in the RECEIVER trial, time to endpoint survival metrics, and changes in COPD or respiratory-related admissions and OBDs from baseline to the year(s) following onboarding were collated. Analysis of the differences between gender and SIMD quintiles were also evaluated.

Data handling, aggregation and analysis was performed using R version 4.3.1.

6.2.4 Patient feedback methods

Participants were approached to be involved in the user research by the respiratory innovation clinical team. Interviews were conducted over the phone by the lead user researcher at Storm ID. An interview guide was designed to gather background information about the patient and their COPD, and feedback on their use of the digital service. This guide was based on the interview schedule used in the RECEIVER trial qualitative interviews.

The patient responses were collated and presented by the user research team. The full user research report is included in the appendix (5).

6.2.5 Ethics approval

Data protection impact assessments (DPIAs), system security evaluations and data processing agreements are in place for the ongoing use and service evaluations of the COPD digital support service. Data access, processing, aggregation of de-identified data and publication of analyses were prospectively approved by NHS GG&C Caldicott Guardian committee.

6.2.6 Results

6.2.6.1 Cohort Characteristics

The baseline characteristics of the scale-up cohort are shown in table 13. A larger proportion of the cohort were female, with an average age of 67. The majority of people were resident in postcode areas in the most deprived quintile of the SIMD, in line with the burden of COPD in Scotland. A third of the cohort (32.2%) had a COPD or respiratory-related hospital admission in the year prior to joining the service, with an average number of 1.91 admissions and 13.1 OBDs.

Number of individuals, n	354	
Age in years at onboarding, mean (SD)	66.62 (9.21)	
Sex	Females	191 (54.0%)
	Males	163 (46.0%)
SIMD quintiles	1	157 (44.4%)
	2	75 (21.2%)
	3	35 (9.9%)
	4	37 (10.5%)
	5	47 (13.3%)
	Not recorded	3 (0.8%)
Baseline admissions status	Baseline admission sub-cohort	114 (32.2%)
	No baseline admission sub-cohort	240 (67.8%)

Table 13 Baseline characteristics of the scale up cohort onboarded to the COPD digital service between May 2020 and September 2022. SIMD 1 = most deprived areas, SIMD 5 = least deprived areas. Abbreviation: SD, standard deviation. SIMD, Scottish Index of Multiple Deprivation

6.2.6.2 Utilisation evaluations

Utilisation metrics were recorded for the scale-up cohort. The percentage of the scale up cohort completing at least one PRO entry each week over the first year of follow up was 63.2%, and 50.4% for the full period of follow up. Further stratification over the full period of follow up showed an average completion rate of 51.3% for those in the baseline admission cohort and 50.1% for those in the no baseline admission cohort. Figure 31 shows the persisting usage of the COPD patient app across both the baseline admission and no baseline admission sub-cohorts, for the two years of follow up.

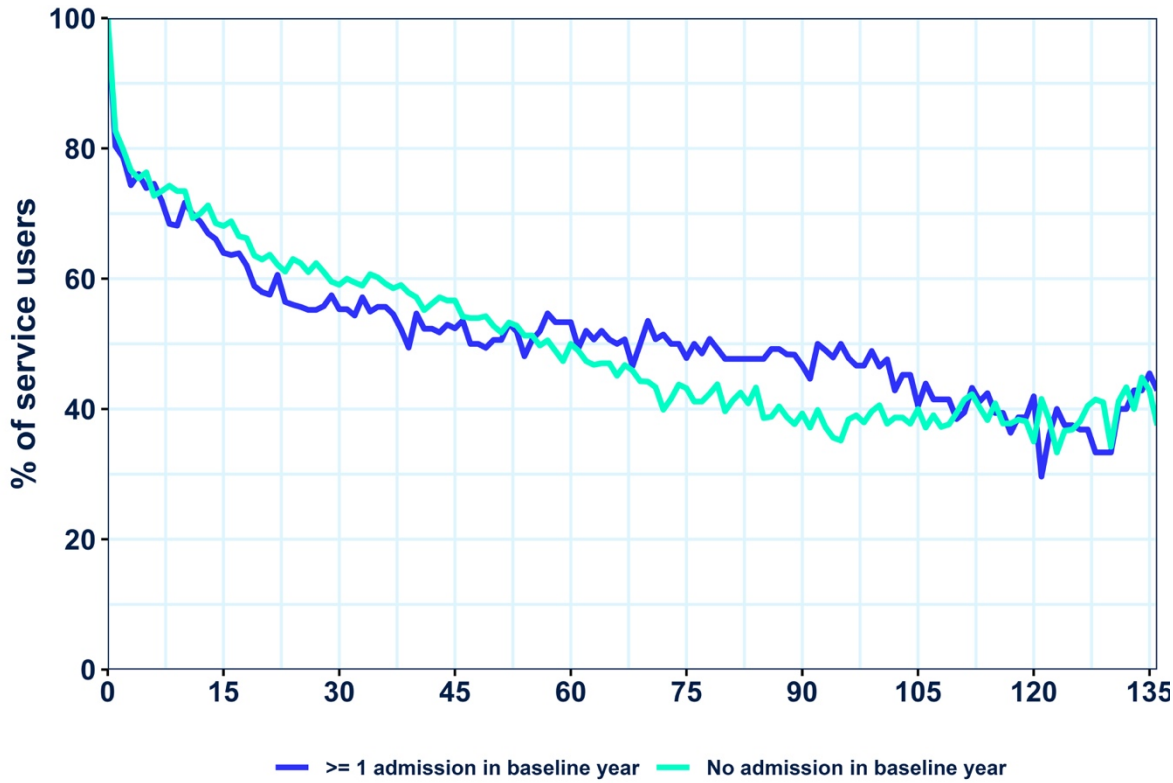


Figure 31 Graph showing the percentage of scale up participants completing at least one set of patient reported outcomes (PRO) per week stratified by admission status. Similar rates of completion are seen across both cohorts.

6.2.6.3 Survival analysis

Figure 32 (A, B + C) shows survival curves for the scale-up cohort, stratified by admission or no-admission in the year prior to joining the service. For all three endpoints (time to COPD or respiratory-related admission, time to death, and time to COPD or respiratory-related admission or death), the time to event was shorter in the sub-cohort of people who had had a respiratory-related hospital admission in the year prior to joining the service. Over the two-year follow up

period, the median time to first COPD or respiratory-related admission and median time to first COPD or respiratory-related admission or death were both reached in the baseline admission sub-cohort (364 days and 325 days). It was not reached in the no baseline admission sub-cohort. Median time to death was not reached for either sub-cohort.

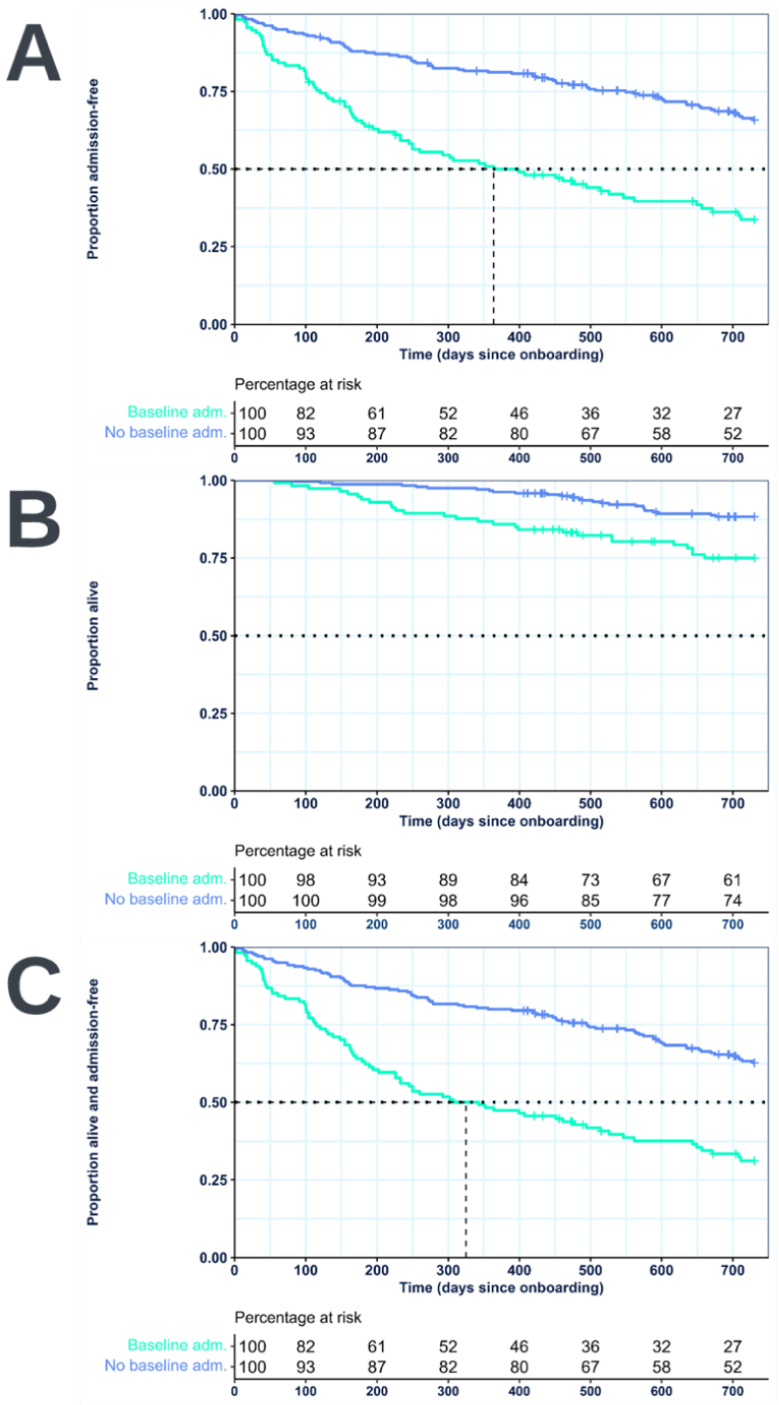


Figure 32 Survival plot visualisations with accompanying percentage at risk tables for patients onboarded to the COPD digital support service from May 2020 - September 2022. Time from onboarding to first COPD or respiratory-related admission (A), survival (B), and survival to first COPD or respiratory-related admission or death (C) are shown. The cohort has been stratified based on occurrence (turquoise line) or absence (blue line) of a COPD or respiratory-related admission in the year prior to onboarding.

6.2.6.4 Respiratory related admission and length of stay

Comparison of the COPD or respiratory-related admissions and OBDs was undertaken for the baseline admission sub-cohort who were alive at the censor date. Table 14 and figure 33 (A + B) show the distribution of admissions and occupied bed day counts per user over the period of 12 months prior to joining the service and 24 months following onboarding to the service. Admission numbers and OBDs are seen to fall in the year following onboarding within this cohort, with a noticeable change visible in the distribution of the pre and post onboarding data.

Higher rates of 12-month admissions post onboarding were seen in the baseline admission sub-cohort, compared to the no baseline admission group (0.49 vs 0.19). 12-month mortality rates were also higher in the baseline admission sub cohort (0.14 vs 0.04). For both cohorts, admission and mortality rates were comparable when stratified by sex.

		Mean (change from previous year)		
	n	Year prior to OB	Year 1 post OB	Year 2 post OB
Admissions	67	1.93	0.88 (-1.05)	0.93 (+0.05)
OBDs	67	12.49	4.81 (-7.68)	8.00 (+3.19)

Table 14 Changes in COPD or respiratory-related admissions and occupied bed days (OBD) for patient onboarded to the digital COPD support service in the baseline admission cohort. The analysis is limited to those who were alive two years after being onboarded onto the service.
Abbreviation: OB, onboarding (to digital service)

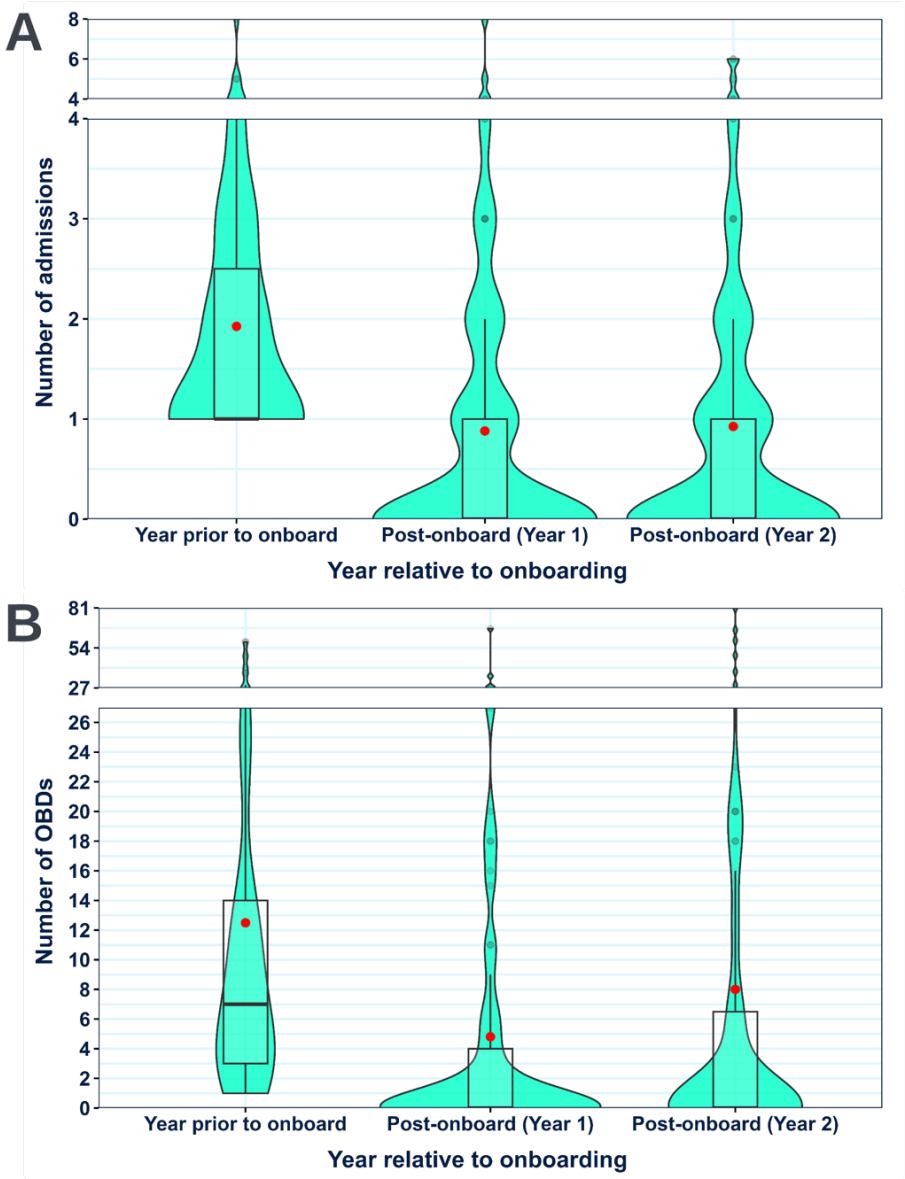


Figure 33 Violin boxplots for the baseline admission sub-cohort, showing the number of COPD or respiratory-related admissions (A), and the occupied bed days (OBD) (B) within the year prior to joining the service, compared with those during the two years following onboarding. Analysis is limited to those who were alive two years after being onboarded onto the service. Violin-box plots are selected to ensure complete data provision, and a visualisation of data spread across the cohort. For their interpretation: standard boxplots illustrate the variation of values (median and IQR), the relative frequency of individual data points is illustrated by the width of the violin plot at each point on the y-axis, and mean values are shown by red dots.

6.2.7 Patient feedback results

10 people, who were all users the COPD digital service within the scale-up cohort, were approached to take part in the user feedback interviews. Seven people agreed and were available to participate. Of the seven participants interviewed, all had been diagnosed with COPD for at least four years, with three participants having been diagnosed over 10 years ago. All reported that their COPD had a significant impact on their day-to-day life.

All of the participants had used the digital support service for 1-2 years and described themselves as 'active users' with all reporting that they completed their PROs almost every day.

Participant were asked to describe how in-control of their condition they felt before and after using the digital service and were asked to provide a score out of 10 to rate their level of perceived control. Across the sample of participants interviewed, there was an anecdotal increase in reported control since starting using the support service. When asked to describe how the control of their condition had changed, participants reported an increased awareness and knowledge of their condition and symptoms from answering PROs. They also reported increased confidence knowing that they can contact the clinical team through the patient app.

A selection of quotes from the interviews are show in figures 34 and 35.

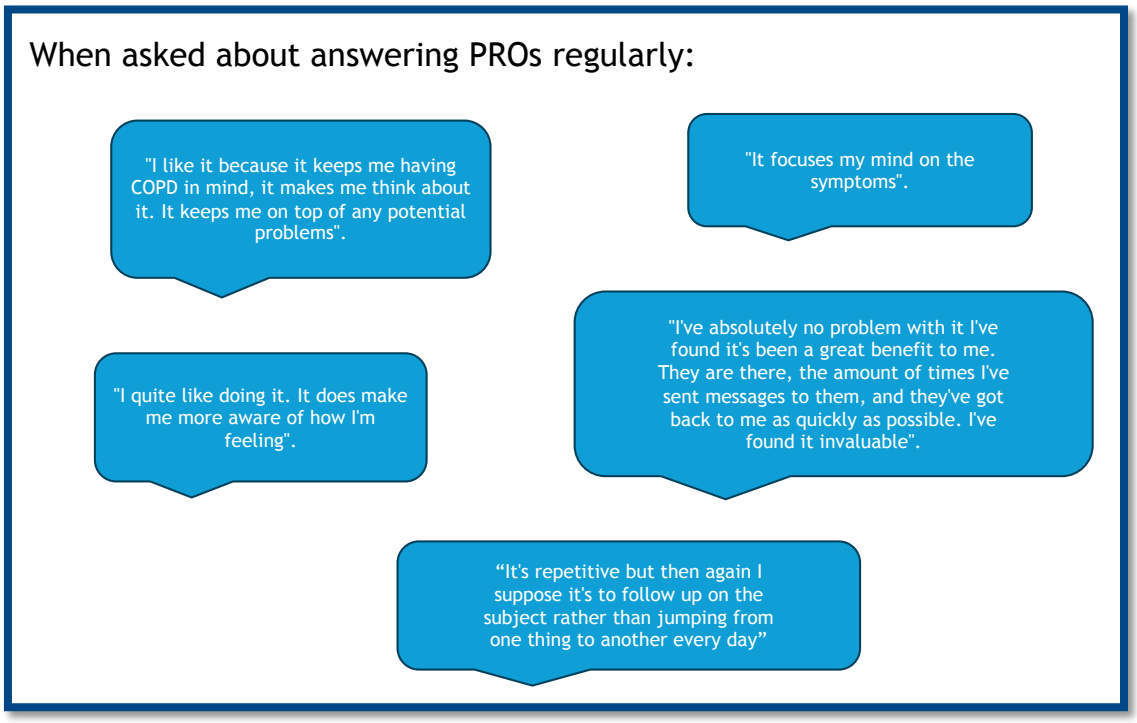


Figure 34 Selection of feedback quotes from user research question asking how participants felt about answering their patient reported outcomes (PRO) regularly.

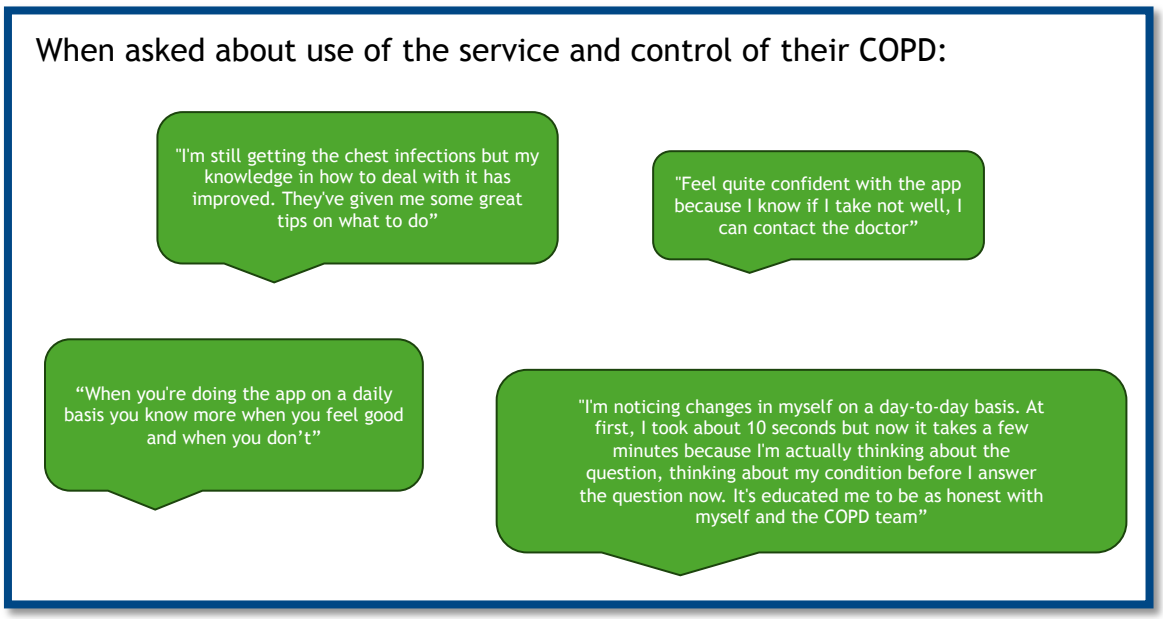


Figure 35 Selection of feedback quotes from user research question asking how participants felt about the use of the digital service and the control of their COPD

6.3 Discussion

This analysis was conducted on a larger cohort compared to the number of participants within the RECEIVER study. Gender proportions and average age was broadly similar. More detailed comparisons including co-morbidity and lung function metrics have not yet been undertaken.

Utilisation averages are also similar within the scale-up cohort compared to the RECEIVER trial, with no variation between sub-cohorts. Persisting utilisation is also seen across the two years of follow up. Initial and 3-month drop off rates were noted amongst a proportion of individuals, which will inform further implementation and evaluation activities as the service evolves and is expanded.

The results seen in the scale-up analysis have replicated the RECEIVER trial results in a substantial cohort of patients, who are representative of the population living with COPD within the West of Scotland. The median time to first admission or death of 325 days within the baseline admission sub-cohort mirrors the results seen in RECEIVER intervention cohort (335 days), and contrasts favourably with the outcomes from the control cohort used within the trial (155 days). Although a direct control cohort was not created for comparison to the scale up cohort, the admission metrics from the scale-up baseline admission sub-cohort do augment the findings from the RECEIVER trial. There were similar reductions in COPD or respiratory-related hospital admissions averaging one per patient per year, with no rebound in admissions and no increase in mortality in the second year.

The sentiments and experiences of the scale-up patient users compare similarly to those given by the RECEIVER participants and can be mapped onto the themes developed within the qualitative aspects of the trial. The participants taking part in the scale-up feedback interviews were persisting users of the service, mirroring the usage types of the RECEIVER interview participants. There were differences in the methods used to collate these feedback data compared to the qualitative methods undertaken within the RECEIVER trial. However, this feedback is likely to be more representative of a real-world cohort of patients, who are using the service out with a research setting. Participation within research has the potential to be subject to the Hawthorne effect, where the

awareness of being studied can have an impact on participant behaviour (McCambridge, Witton and Elbourne, 2014), which is difficult to fully anticipate or completely remove. These findings suggest persistence of the perceived benefits of the service and help to provide validation of the qualitative results from the RECEIVER trial.

The patient feedback, utilisation and admission/survival metrics from these service evaluations bolster the findings from the RECEIVER trial and support the conclusion that access to the COPD digital support service has a positive impact on clinical outcomes for people with COPD.

6.4 Chapter conclusion

The evaluations described in this chapter have provided an overview of the developments to the DYNAMIC portfolio and show how they have built on, complement and strengthen the work that was undertaken within the RECEIVER trial.

The COPD digital service has grown to become a valued and pivotal part of routine COPD care within NHS GG&C. Outside of Glasgow, the digital service is now being used within the community respiratory setting in NHS Lothian and supporting early supportive discharges in NHS Highland (Cooper *et al.*, 2023). Most recently it has been integrated in a virtual ward setting in the Hull University NHS Trust (DYNAMIC-ROSE) with interim evaluations giving early positive indication that results of RECEIVER trial can be replicated in a different population and health system, with reduced subsequent hospital admissions and ED attendances amongst platform users, compared to historical controls (Cushing *et al.*, 2024; McNair, 2024; Turpie, 2024; York Health Economics Consortium, 2024 (included in appendix 6)).

The next chapter will integrate and discuss the results accrued over the whole of my thesis and indicate what this research adds including its contributions to the future direction of the DYNAMIC project.

7 Mixed methods interpretation and thesis discussion

This thesis explored participation utilisation of a novel digital service for people with COPD. An explanatory sequential mixed methods study design was undertaken to explore the usage of the COPD digital support service alongside routine clinical care in NHS GG&C within the RECEIVER clinical trial.

First, quantitative data on service usage and clinical outcomes were collected and analysed. The results showed consistent utilisation of the service, with patients regularly submitting PROs. There were notable reductions in hospital admissions and OBDs following enrolment, along with improvements in time to readmission and survival rates among participants. To better understand the reasons behind the sustained usage of the service by some participants, semi-structured interviews were conducted with a sub-cohort of those who continued to engage with the platform. These interviews revealed key factors that appear to contribute to successful use and highlighted the perceived benefits experienced by participants.

Figure 36 summarises the results and integrations from this explanatory mixed methods study.

This final chapter will detail the interpretation of the integrated data and expand on the insights gained from collating it in this manner. The limitations of the research conducted will be detailed, including the potential impact of the COVID-19 pandemic. This chapter will conclude with a summary of the current research environment in which research from this thesis is situated and the continued evolution of the DYNAMIC scope of work that has been directly influenced by the learnings and outcomes acquired across the course of this research project.

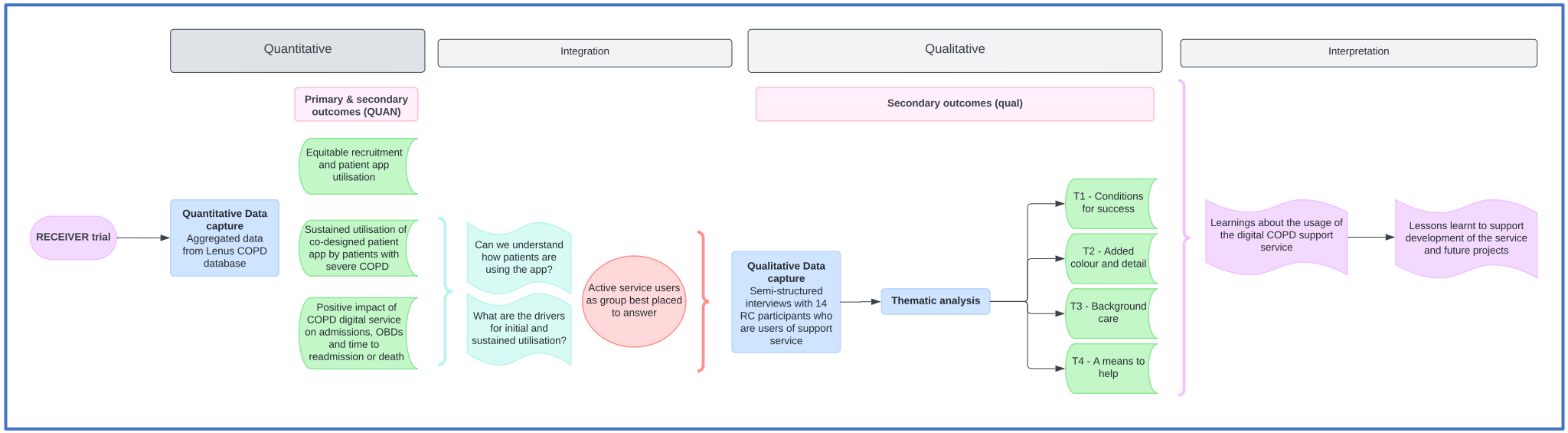


Figure 36 Summary diagram illustrating the quantitative and qualitative results captured within the RECEIVER trial, and indication of knowledge gained through using and combining both research methods.
Abbreviations: QUAN, quantitative. OBD, occupied bed days. Qual, qualitative. RC, RECEIVER.

7.1 Mixed methods interpretation

The research conducted within this thesis has established that using a patient-facing web app to collect daily PRO measures from people with COPD is feasible and allows presentation of these data to clinical teams. This research has shown persisting participant service usage and consistent data entry over an extended time period. Usage of the app has also been shown to occur irrespective of age or socioeconomic status. Variations in patterns of usage were identified by grouping participants based on the frequency of PRO entry per week, adding a different dimension to the usage behaviour. However, comparisons with demographic and clinical event data did not reveal any correlations, which limited the conclusions that could be drawn about determinants of usage. The theme of *conditions for success*, highlighted several factors that appeared to encourage continued usage, beyond what demographic and clinical data could capture. These factors included the confidence gained from the ease of use, the repetition of PRO submissions, daily reminders, and the need for external technology support among some participants. These additional insights suggest strategies and areas for development that could enhance future engagement and ongoing use among similar populations.

Secondary outcomes indicated measurable clinical benefit amongst trial participants when compared to a matched contemporary control cohort across survival and admission metrics. Improved self-management skills and co-management through the support service could have contributed to the clinical improvements seen, but discerning this was not possible from the quantitative data alone. The theme of *added detail and colour* highlighted the perception of enhanced symptoms reflection and recognition through the daily PROs, alongside insights gained from language and personal data visibility (from Fitbit device use), promoting disease state awareness and calls to self-action when required. Within the initial analysis stage of the quantitative research, exploratory evaluation of the utility of using data gained from the Fitbit wearable had been attempted. There were issues with maintaining the data connection between the Fitbit app and the digital service infrastructure, resulting in sporadic and limited availability of data and analysis had not progressed. However, the

favourable perception of participants towards their Fitbit and the added insight they acquired suggests that there may be value in revisiting this line of analysis.

The theme of *background care* showed the reassurance gained from the presence of and access to a respiratory care team, further promoting and enhancing self-confidence in the ability to manage their own condition. Additionally, while exploratory analysis showed that messaging frequency was at a manageable level from a clinical workload perspective, further work is still to be undertaken with participant specific messaging metrics and message content. The background care theme highlights the potential value gained from future analysis of these data.

While the perceived benefits of the app and involvement in the support service could theoretically have led to improved disease control and fewer exacerbations, which might have explained the observed reductions in hospital admissions, this outcome was not reflected in the developed themes. Avoiding hospital was not specifically mentioned as a benefit of using the app by any of the participants and there were no clear patterns in themed responses when comparing admissions within the interview cohort. Exploratory integrative comparisons between interview themes and average QoL metrics also revealed no specific patterns. The participants' perceptions of the app's benefits did not appear to be in sync with the clinical outcomes that were measured. However, the main focus of the interviews with participants was on usage, as the primary outcome measure of the RECEIVER study, including why they had continued to use the service and any perceived benefit from using. Questions about reductions in hospital admissions were not specifically included. It has been shown that avoiding hospital admissions is prioritised by people with COPD (Zhang *et al.*, 2018) and the connection with improved exacerbation management may just not have been made within this sub-cohort of users. Previous research has noted a disconnect between patient priorities and perception of healthcare, and the outcomes measured within clinical trials, with a move towards addressing this gap to include the patient voice (de Silva, 2013; Churruca *et al.*, 2021; Auriemma *et al.*, 2023). Incorporation of additional measures of benefit, such as alternative quality of life assessments, extended patient reported outcome measures or metrics related to disease control should

be important considerations in future evaluations of this digital support service. Doing so would expand the understanding of participants' perspective of the intervention and its overall impact on their health outcomes, particularly for cohorts where hospital-related outcomes may not be applicable, such as individuals with less severe COPD who have not been hospitalised or those with newly diagnosed disease.

Digital interventions are complex by their nature, and we are only just starting to gain an understanding of the mechanisms and motivations behind when and how they are used. Measurements taken within a research environment can further compound this aspect (McCambridge, Witton and Elbourne, 2014). For this service, although perceptions of benefit likely motivated some continued use of the app, altruism was an obvious presence within the interviews. The *means to help* theme denoting the desire to contribute to the trial remained a motivator for continued engagement, even if participants experienced personal benefit from use of the app as well. It has been reported that patients who adhere to treatment, even when a placebo, have better health outcomes than poorly adherent patients (Horwitz and Horwitz, 1993). Encouragingly though, improved clinical outcomes and service perceptions have been seen to persist when evaluations of the service were undertaken out with the clinical trial setting within the extended population of people with COPD in Glasgow, and further afield in NHS Highland and Hull University NHS Trust. Whilst acknowledging that altruism is an important contributing factor to the results seen, the other insights developed within this research help to expand on the reasons for usage and the benefits seen beyond altruism. These findings are further supported by the subsequent evaluations, which provide valuable indications of priorities and directions for future project developments.

Leveraging all of these aspects in future iterations of this project, and others like it, could yield favourable reductions in healthcare utilisation that would be both beneficial for patients and for service resources. By freeing up capacity and resources, care teams will potentially be able to manage a broader range of people proactively, including those with limited digital access, ensuring adequate and equitable care delivery via equivalent non-digital service models.

7.2 Study limitations: overall study approach

There were several limitations to the overall approach taken across this research project.

The RECEIVER study was not a randomised control trial so there are limitations to the conclusions that can be drawn, and direct causal links could not be made. However, the use of a matched control cohort did expand the study utility and provide evidence of its potential impact. Use within a real-world clinical setting also provided valuable insights into how the intervention could function within routine clinical care.

Recruitment to the study focused on a 'high risk' cohort, chosen for its potential to demonstrate significant impact, which raises considerations regarding the generalisability of the findings and presents questions about the impact of use by people with lower disease severity. Evaluations of the digital service amongst a wider range of people with COPD within the scale-up cohort did not show a difference in usage between those with or without previous respiratory-related hospital admissions. However, whilst respiratory related hospital admission history is a surrogate of disease severity, it doesn't encompass the full spectrum of disease characteristics (e.g. lung function, smoking history or comorbidities). Consideration of further evaluations of the use of the service amongst different COPD phenotypes is warranted. This includes the potential to expand the control cohort matching criteria to capture supplementary metrics that would encompass those without previous hospital admissions, as well as exploring the role for further measures of self-management capability and disease control and extending the duration of follow up and intervention cohort size to capture potential benefit on healthcare resource utilisation in a lower risk group. Collectively, this will aid understanding of the service's overall effectiveness across the full spectrum of people with COPD.

Interview participants were selected based on their continued use of the digital intervention and their status as alive at the time of the data collection, which affects the degree of transferability of the results. By the nature of type of data collected, the perspectives captured are unique to each individual. Whilst the views can be grouped by theme and present an overall narrative, it was not

possible to interview every participant to gain their opinion. Participants who had not continued to use the digital service were not approached. The decision to select active users for semi-structured interview follow up was made because this group was deemed most likely provide the most information rich data for analysis and would be best placed to answer the research question. The number of people interviewed was ultimately determined by the availability of participants and the time restraints of the research project.

7.3 Study limitations: The influence of the COVID-19 pandemic on healthcare, COPD and the RECEIVER study

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was first detected in China in December 2019. The novel virus rapidly spread throughout Asia and then worldwide by early 2020. The World Health Organisation (WHO) characterised the outbreak as a pandemic on 11th March 2020 (WHO, 2021). To date, over 760 million cases of COVID-19 have been recorded worldwide since December 2019, with over 6.9 million deaths; these are estimates, the actual number is thought to be much higher (WHO, 2023a).

The UK government instigated national lockdown measures on 23rd March 2020 in response to the rapidly growing global pandemic. To contain the spread of the virus, a 'stay-at-home' order was announced, and restrictions placed on all non-essential travel and activities. Vulnerable people (including those with chronic respiratory health conditions) were advised to shield and minimise in person contact with others.

Healthcare usage has changed because of the COVID-19 pandemic (Soares *et al.*, 2021). During the pandemic, most non-urgent medical care was cancelled to divert resources towards the COVID-19 response. Healthcare utilisation for non-covid conditions was also reduced and healthcare avoidance was noted (Roy *et al.*, 2021; Soares *et al.*, 2021). The long-term impacts of this decreased utilisation on healthcare outcomes have yet to be determined and may take many years to manifest (Roy *et al.*, 2021).

7.3.1 Impact of COVID-19 pandemic on people with COPD

For people with COPD, the concerns regarding the coronavirus pandemic mirrored those of people with other long term health conditions. Alongside the fear of contracting the virus itself, studies also reported the perception people with COPD felt about being 'high-risk' and particularly vulnerable for contracting and dying from the coronavirus, as well as stress and anxiety surrounding denial of care because of their underlying condition (Philip *et al.*, 2020; Swain *et al.*, 2023). Practical issues of frustrations surrounding cancellation and disruption of routine appointments was also reported. People with COPD also expressed feelings of 'being forgotten' in relation to previously regular monitoring and routine review (Madawala *et al.*, 2023).

However, not all of the impacts of the COVID-19 pandemic were negative. For some people with COPD, lockdown restrictions bought unexpected benefits. There were reductions noted in exacerbation-related hospital admissions plausibly explained by reductions in seasonal virus transmission associated with pandemic transmission-prevention precautions and social isolation (Alqahtani, Oyelade, *et al.*, 2021; So *et al.*, 2021). Positive health behaviours were adopted, and medication and management adherence was reportedly maintained and even improved, bolstering self-management and disease control (McAuley *et al.*, 2021; Volpato *et al.*, 2021).

7.3.2 Impact mitigation by healthcare services

To mitigate the impacts of the COVID-19 pandemic and lockdown restrictions on routine chronic disease care and management, many healthcare providers pivoted to a remote management service model. In England, the number of outpatients appointments conducted over the phone rose from 4% in February 2020 to 35% in April 2020 (Health Foundation and Nuffield Trust, 2020). GP appointments carried out via phone or video/online increased from 15% in February 2020 to 48% in April (Health Foundation and Nuffield Trust, 2020). Additionally, there was a rapid surge in development of alternative delivery methods of care, with digital technologies playing a key role (Pinnock *et al.*, 2022).

An uptake in the number of people with COPD using telemedicine in 2020 was seen (Boyce *et al.*, 2021; Wu *et al.*, 2021), with a general positive perception of telehealth and telerehabilitation for those who received that type of remotely managed care (Madawala *et al.*, 2023). Reassurance was reported by patients from contact with medical health professionals remotely, more so than from individuals without such contact (Mousing and Sørensen, 2021).

7.3.3 Impact of the COVID-19 pandemic on conducting the RECEIVER trial

Recruitment to the RECEIVER trial was halted at the announcement of the UK COVID-19 lockdown. All participants who had previously been enrolled continued within the trial. The last participant was recruited on 13th March 2020.

Although lockdown restrictions had eased by the time of recruitment to the first qualitative stage of this project, caution surrounding unnecessary healthcare contact activities with vulnerable population groups (such as the high-risk individuals within the RECEIVER trial) remained. As a result, the first set of qualitative interviews were all conducted over the phone.

Attitudes towards maintaining shielding precautions and minimising external contact were ongoing at the time of the second qualitative stage, and although in person interviews were offered, the majority of participants chose to take part via the telephone.

7.3.4 Potential impact of COVID-19 pandemic on the RECEIVER trial results

Recruitment to the RECEIVER trial had been progressing well up until COVID-19 lockdown so there was a very apparent impact on recruitment numbers when it ceased. Although there was no influence of COVID-19 on the incentive to join the trial, it may have incentivised people to continue with their trial participation. This could have been due to the perceptions of benefit to themselves e.g. access to communication with healthcare team being more readily available, similar to the findings of Mousing and Sørensen (2021) who noted benefit and reassurance from individuals who were able to contact their healthcare providers remotely. Equally, wishing to help others may also have played a role, as was seen in vaccine studies conducted during the pandemic

showed altruistic motivations amongst participants (Marsh *et al.*, 2022; Russo *et al.*, 2022; Thomas *et al.*, 2023).

The COVID-19 pandemic and associated shielding procurations may also have influenced the number of exacerbations and admissions seen within the RECEIVER cohort. The inclusion of the contemporary location and time-period matched control cohort partially mitigated this. The reductions in admission events and OBDs seen in the control cohort mirror the results seen elsewhere during the pandemic (Alqahtani, Oyelade, *et al.*, 2021; So *et al.*, 2021), indicating that the control cohort was a suitable comparator to establish baseline COVID-19 impact on outcomes in the absence of the digital COPD service.

The impacts and influences of COVID-19 on healthcare have been widespread and are likely to be long lasting. It has not been possible to discern the full extent of the impact of the pandemic on the RECEIVER trial results, nor avoid its influence. However, interim findings (prior to March 2020) were showing positive signals with early reduction in hospital admissions (mirroring the results subsequently obtained in the DYNAMIC-ROSE study in Hull), and initial user experience feedback had shown positive reception of the intervention and its usability. Ongoing analysis is necessary to evaluate the COPD digital support service as it continues to be used within the evolving healthcare environment of the post pandemic era.

7.4 Current digital healthcare environment for COPD self-management in the UK

The use of digital technologies to support self-management of COPD have been recognised to have to potential to address the challenges of COPD and the national unmet need in the UK. There are known limitations and uncertainties from previous research and there is a need to expand and build on the existing evidence base, with emphasis on real-world clinical application. Within the UK, early value assessments (EVA) allow collation of initial evidence of such digital technologies to determine if earlier patient and system access in the NHS is appropriate while further evidence is generated (NICE, 2022a).

Since the conception and development of the DYNAMIC project, there has been an expansion in the number of digital technologies available for self-management in COPD, alongside the move towards increased utilisation of digital technology in general since the COVID-19 pandemic. Recent NICE EVA guidance has outlined the current environment of digital technologies supporting of the self-management of COPD in adults in the UK and has recommended several digital interventions for use in the UK during the evidence generating period, including the "LenusCOPD" digital support service developed and used within the DYNAMIC project and RECEIVER trial. Other recommended digital technologies include Active+me REMOTE, Clinitouch, COPDhub, COPDPredict, Luscii, myCOPD, and SPACE for COPD (NICE, 2024b).

All recommended technologies are multicomponent and include at least two of the following features:

- Educations about COPD
- An individualised self-management plan accessible within the technology
- Symptom tracking by the user
- Remote monitoring functionality
- Exercise promotion components
- Ability to communicate with healthcare providers

The EVA has highlighted several evidence gaps that are still to be addressed within the current environment as a whole (NICE, 2024a). These include establishing the impact of digital self-management technologies compared to standard non-digital self-management, tracking long-term clinical improvement in COPD using validated measures, measuring resource use both to healthcare services and implementation costs, and adverse event recording. Additionally, the EVA has recommended capturing effectiveness within different subgroups of people with COPD and outlining where the technologies are used within the care pathway.

The evaluations of the Lenus-based COPD digital support service developed by the DYNAMIC project are ongoing and sit slightly ahead of evidence generation by other digital technologies. Additional external appraisals of the service have been undertaken through a NICE Medtech innovation briefing and a Scottish

government Innovative Medical Technology Overview (Health Improvement Scotland and Scottish Health Technology Group, 2021; NICE, 2022b). The findings from this thesis have addressed a number of the evidence gaps noted within these reviews, as well as forming the basis of the subsequent evaluation work that has been conducted. In conjunction with use of the service across other NHS sites, additional opportunities for evidence generation will include planned expansion of digital service usage across adjacent pulmonary rehabilitation services and incorporation into chronic condition management recovery and transformation initiatives in primary and interface care.

7.5 DYNAMIC project next steps

7.5.1 Utilisation of AI-risk prediction models to support the management of people with COPD – DYNAMIC-AI trial

The next phase of clinical research within the DYNAMIC project builds directly upon the work completed within the RECEIVER study and utilises AI-derived risk prediction scores to support clinical decision making in the management of people with COPD.

The vision of being able to capture data to allow training, validation and implementation of machine learning models leading to actional AI-derived insights sat as a key aim within the original DYNAMIC project. Linked to the RECEIVER trial, a team of data scientist from StormID/LenusHealth worked with myself and other members of the respiratory innovation team at NHS GG&C. This collaboration has resulted in the co-development of a 12-month mortality, 90-day readmission, 180-day admission and 90-day exacerbation risk prediction models to aid clinician decision making (Burns *et al.*, 2021; Fernando *et al.*, 2024). These models are now being evaluated within the 'Digital Innovation with Remote Management and Predictive Modelling to Integrate COPD Care with Artificial Intelligence-based Insights' (DYNAMIC AI) trial. This prospective observational cohort clinical investigation is evaluating the patient acceptability, technical feasibility, safety and utility of providing live risk-prediction model scores to COPD clinicians following an implementation-effectiveness study design and is an MHRA regulated device trial (NCT05914220).

Recruitment to DYNAMIC-AI commenced in April 2023 and concluded in January 2024, with a 12 month follow up period, until January 2025. Eligible participants were those people with COPD resident within NHS Greater Glasgow and Clyde, who were users of the COPD digital support service.

Consent was taken electronically through a co-developed consent flow visible to invited participants in the COPD digital support service patient app. The design aesthetic of the core digital service was maintained through the consent flow to maximise familiarity and bolster recruitment (figure 37). Input via patient and public involvement and engagement (PPIE) was sought to ensure trial concept, content and structure of trial information was suitable and acceptable to the intended patient audience and wider general public.

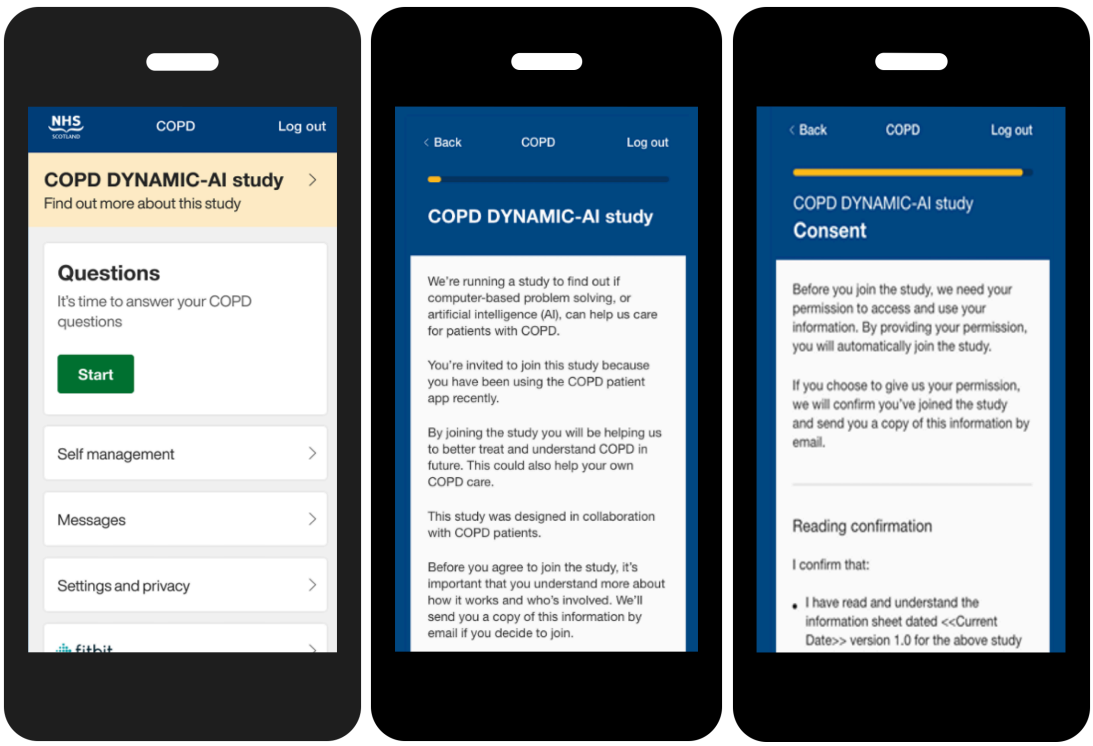


Figure 37 Example of the DYNAMIC-AI clinical investigation electronic consent screens accessible to invited participants through the digital COPD support service.

The primary objectives and outcome measures for the DYNAMIC-AI study are detailed in table 15. Secondary objectives include acquiring detailed acceptability and technical feasibility experience with the 12-month mortality risk prediction model, as well as expansion and development of dataset for training and validation of the other risk prediction models.

Primary objective(s)	To determine the: - acceptability to patients with COPD - technical feasibility and - safety of presenting live AI-based 12-month mortality risk-prediction scores from the COPD AI Insights application to a COPD multi-disciplinary team.
Primary acceptability, feasibility, and safety measures	- evaluation of study acceptability will be inferred from proportion of invited COPD service users who consent to participate in the DYNAMIC-AI study. - evaluation of technical feasibility will be defined as proportion of participants with adequate source data in COPD who have 12-month mortality model-risk scores calculated and presented for multi-disciplinary team (MDT) review in the AI-insights app. - evaluation of safety will be based on occurrence of device-related adverse events and from the prospective evaluations of model risk scores, encompassing clinician actions based on model risk scores and calibration of the predicted events ratio.

Table 15 Primary objectives and primary outcome measures for the DYNAMIC-AI clinical investigation

Interim results following the close of recruitment include successful enrolment of 130 participants, out of the 244 people that were approached. 14 people responded to formally decline participation; the remaining 100 people gave no response to the trial invite. Model inferencing was achieved for 125 of 130 consented participants, with non-accessible electronic healthcare data preventing inference for 5 participants.

Early experience in a live clinical environment suggests considerable potential for reorientation of COPD care, and prospective model performance and clinical experience will continue to be captured during the 12-month follow up phase of the investigation.

7.5.2 Digital transformation of COPD diagnostic service

To support the diagnosis of suspected COPD, a direct access COPD diagnostic service provides outpatient spirometry for patients referred by primary care clinicians in NHS GG&C. Suspension of spirometry services during the COVID-19 pandemic led to a large demand: capacity mismatch and a waiting list backlog of over five thousand patients.

The digital transformation of the COPD diagnostic service to recover and restore COPD diagnostic capacity began in 2023, initiated within the DYNAMIC project. Using the experienced gained from the creation and evaluation of the COPD digital support service and the insights from the RECEIVER trial, new digital tools for clinicians and patient facing resources have been created. Early data from the adoption and service evaluation within the 'POLARIS' project has noted positive clinician user experience, improved clinical workflow efficiency, improved waiting times and increased early uptake of preventative COPD care bundles (unpublished data). In addition to the NHS GG&C development and deployment in the COPD diagnostic pathway, these digital tools are being evolved to support a wider range of cardiorespiratory presentations and pathways, with test adoption at other sites. These pathways and associated structured data will be used to support implantation and evaluation of novel diagnostic tools and provide the basis for further development and deployment of AI-based risk stratification.

The vision is to progress with end-to-end transformation of our COPD and other cardiorespiratory long-term condition pathways. This is based on early accurate diagnosis, risk stratification including personalised decision support, effective delivery of guideline-based interventions with data-driven supervision and integrated co-management.

7.6 Conclusion

This thesis aimed to explore participant utilisation of a novel digital support service for people with COPD. Research objectives have been achieved through a mixed-methods study design, and have established sustained patient utilisation,

patient perceived benefits and positive impact on healthcare utilisation from development and deployment of a digital COPD support service intervention.

The work contained within this thesis is an example of real-world clinical use of a digital service supporting people with COPD to manage their condition. It has detailed the development, methods, and outcome results obtained in the RECEIVER trial evaluating the use of the digital support service. Improvements in clinical outcomes associated with adoption of this service intervention alongside routine clinical care have been demonstrated. The evaluations have shown the role of co-design and iterative development of a technology to meet the needs of the user, and how this can lead to successful and persisting utility.

The results and analyses have given an insight into the practical usage of the digital service intervention by participants. It has highlighted the factors that appeared to support and foster ongoing use of the digital service, including aspects felt to be most favourable and useful to participants, indicating priorities for inclusion in future projects.

Finally, this study has identified additional dimension to the use of this digital service from the participants perspective. There are perceived benefits and potential motivations that underpin persisting usage. Additionally features that may have enhanced patient self-management have been noted. The work in this thesis has drawn together several different utilisation and engagement concepts and shown how they can be applied in a real-world setting.

The co-design, implementation and evidence generation approach that was established within this thesis have fed directly into the evolution of the DYNAMIC programme of work. The outcomes of this research project have contributed to the adoption and evaluation of the service in other organisations, the publication of a supportive NICE early value assessment and to the extension of the digital tools including development, deployment and evaluation of AI-based risk prediction models and transformation of the COPD diagnostic pathway. This research project and its evaluations provide exemplar insights for implementation-effectiveness evaluations of other digital technologies for COPD and other long-term condition co-management.

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Appendices

Appendix 1: RECEIVER COPD Patient-web portal questionnaires, patient reported outcome (PRO) flows

Daily

Symptom diary

1. How are you feeling today?

(1) Better than usual

(2) Normal/usual

(3) Worse than usual

(4) Much worse than usual

2. How is your breathing today?

(1) Better than usual

(2) Normal/usual

(3) Worse than usual

(4) Much worse than usual

3. Do you have a cold or flu today?

• Yes

• No

CAT (score /40) (For each of the following questions, please select the number that best describes you currently.)

4. (0) I never cough

(1)

(2)

(3)

(4)

(5) I cough all the time

5. (0) I have no phlegm (mucus) in my chest at all

(1)

(2)

(3)

(4)

(5) My chest is completely full of phlegm (mucus)

Symptom diary additional questions

How difficult is it to bring up phlegm when you cough?

(1) Not difficult

(2) A little difficult

(3) Quite difficult

(4) Very difficult

What consistency is your phlegm?

(1) Watery

(2) Sticky liquid

(3) Semi-solid

(4) Solid

What colour is your phlegm?

(1) White

(2) Yellow

(3) Green

(4) Dark green

CAT additional questions

6. (0) My chest does not feel tight at all

(1)

(2)

(3)

(4)

(5) My chest feels very tight

7. (0) When I walk up a hill or one flight of stairs I am not breathless

(1)

(2)

(3)

(4)

(5) When I walk up a hill or one flight of stairs I am very breathless

8. (0) I am not limited doing any activities at home

(1)

(2)

(3)

(4)

(5) I am very limited doing activities at home

9. (0) I am confident leaving my home despite my lung condition

(1)

(2)

(3)

(4)

(5) I am not at all confident leaving my home because of my lung condition

10. (0) I sleep soundly

(1)

(2)

(3)

(4)

(5) I don’t sleep soundly because of my lung condition

11. (0) I have lots of energy

(1)

(2)

(3)

(4)

(5) I have no energy at all

Weekly

Symptom diary

1. How are you feeling today?

(1) Better than usual

(2) Normal/usual

(3) Worse than usual

(4) Much worse than usual

2. How is your breathing today?

(1) Better than usual

(2) Normal/usual

(3) Worse than usual

(4) Much worse than usual

3. Do you have a cold or flu today?

• Yes

• No

4. Have you increased your usual breathing treatment this week? (e.g. inhalers, nebulisers, tablets)

• Yes

• No

5. "Have you taken a rescue pack or an acute course of antibiotics or steroids prescribed by a doctor for your COPD this week? *This does not include long-term antibiotics."?*

• Yes

• No

6. Have you visited your GP this week?

• Yes

• No

7. Have you visited your hospital doctor this week?

• Yes

• No

CAT (score /40) (For each of the following questions, please select the number that best describes you currently.)

8. (0) I never cough

(1)

(2)

(3)

(4)

(5) I cough all the time

9. (0) I have no phlegm (mucus) in my chest at all

(1)

(2)

(3)

(4)

(5) My chest is completely full of phlegm (mucus)

Symptom diary additional questions

How difficult is it to bring up phlegm when you cough?

• Not difficult

• A little difficult

• Quite difficult
• Very difficult

What consistency is your phlegm?
• Watery
• Sticky liquid
• Semi-solid
• Solid

What colour is your phlegm?
• White
• Yellow
• Green
• Dark green

CAT additional questions

10. (0) My chest does not feel tight at all
(1)
(2)
(3)
(4)
(5) My chest feels very tight

11. (0) When I walk up a hill or one flight of stairs I am not breathless
(1)
(2)
(3)
(4)
(5) When I walk up a hill or one flight of stairs I am very breathless

12. (0) I am not limited doing any activities at home
(1)
(2)
(3)
(4)
(5) I am very limited doing activities at home

13. (0) I am confident leaving my home despite my lung condition
(1)
(2)

(3)

(4)

(5) I am not at all confident leaving my home because of my lung condition

14. (0) I sleep soundly

(1)

(2)

(3)

(4)

(5) I don't sleep soundly because of my lung condition

15. (0) I have lots of energy

(1)

(2)

(3)

(4)

(5) I have no energy at all

MRC (score /4)

Please tick in the box that applies to you (one box only):

1. I only get breathless with strenuous exercise

2. I get short of breath when hurrying on the level or walking up and slight hill

3. I walk slower than people of the same age on the level because of breathlessness or have to stop for breath when walking at my own pace on the level

4. I stop for breath after walking about 100 yards or after a few minutes on the level

5. I am too breathless to leave the house or I am breathless when dressing

Every 4th week

Symptom diary

16. How are you feeling today?

(1) Better than usual

(2) Normal/usual

(3) Worse than usual

(4) Much worse than usual

17. How is your breathing today?

(1) Better than usual

(2) Normal/usual

(3) Worse than usual
(4) Much worse than usual

18. Do you have a cold or flu today?
• Yes
• No

19. Have you increased your usual breathing treatment this week? (e.g. inhalers, nebulisers, tablets)
• Yes
• No

20. "Have you taken a rescue pack or an acute course of antibiotics or steroids prescribed by a doctor for your COPD this week? *This does not include long-term antibiotics."?*
• Yes
• No

21. Have you visited your GP this week?
• Yes
• No

22. Have you visited your hospital doctor this week?
• Yes
• No

CAT (score /40) (For each of the following questions, please select the number that best describes you currently.)
23. (0) I never cough
(1)
(2)
(3)
(4)
(5) I cough all the time

24. (0) I have no phlegm (mucus) in my chest at all
(1)
(2)
(3)

(4)

(5) My chest is completely full of phlegm (mucus)

Symptom diary additional questions

How difficult is it to bring up phlegm when you cough?

- Not difficult
- A little difficult
- Quite difficult
- Very difficult

What consistency is your phlegm?

- Watery
- Sticky liquid
- Semi-solid
- Solid

What colour is your phlegm?

- White
- Yellow
- Green
- Dark green

CAT additional questions

25. (0) My chest does not feel tight at all

(1)

(2)

(3)

(4)

(5) My chest feels very tight

26. (0) When I walk up a hill or one flight of stairs I am not breathless

(1)

(2)

(3)

(4)

(5) When I walk up a hill or one flight of stairs I am very breathless

27. (0) I am not limited doing any activities at home

(1)

(2)

(3)

(4)

(5) I am very limited doing activities at home

28. (0) I am confident leaving my home despite my lung condition

(1)

(2)

(3)

(4)

(5) I am not at all confident leaving my home because of my lung condition

29. (0) I sleep soundly

(1)

(2)

(3)

(4)

(5) I don't sleep soundly because of my lung condition

30. (0) I have lots of energy

(1)

(2)

(3)

(4)

(5) I have no energy at all

MRC (score /4)

Please tick in the box that applies to you (one box only):

1. I only get breathless with strenuous exercise

2. I get short of breath when hurrying on the level or walking up and slight hill

3. I walk slower than people of the same age on the level because of breathlessness or have to stop for breath when walking at my own pace on the level

4. I stop for breath after walking about 100 yards or after a few minutes on the level

5. I am too breathless to leave the house or I am breathless when dressing

Quality of Life (EQ5D)

Mobility

- I have no problems in walking about
- I have slight problems in walking about
- I have moderate problems in walking about

• I have severe problems in walking about
• I am unable to walk about

Self-care
• I have no problems washing or dressing myself
• I have slight problems washing or dressing myself
• I have moderate problems washing or dressing myself
• I have severe problems washing or dressing myself
• I am unable to wash or dress myself

Usual activities (e.g. work, study, housework, family or leisure activities)
• I have no problems doing my usual activities
• I have slight problems doing my usual activities
• I have moderate problems doing my usual activities
• I have severe problems doing my usual activities
• I am unable to do my usual activities.

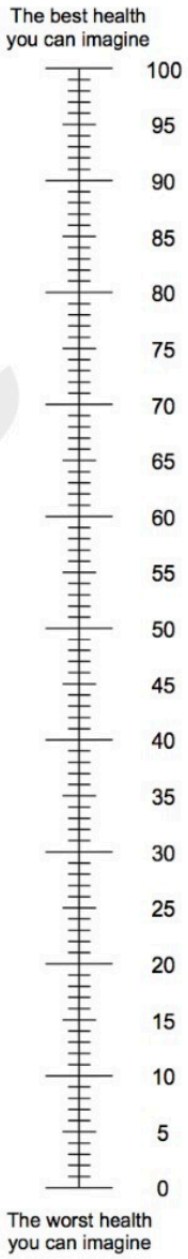
Pain/discomfort
• I have no pain or discomfort
• I have slight pain or discomfort
• I have moderate pain or discomfort• I have severe pain or discomfort
• I have extreme pain or discomfort

Anxiety/depression
• I am not anxious or depressed
• I am slightly anxious or depressed
• I am moderately anxious or depressed
• I am severely anxious or depressed
• I am extremely anxious or depressed

EQ-VAS

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



Sample

Appendix 2. RECEIVER trial patient information sheet

Remote-management of COPD: Evaluating Implementation of Digital Innovations to Enable Routine Care (RECEIVER STUDY)

Participant Information Sheet

We would like to invite you to take part in a research study. Before you decide whether to participate you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information.

Who is conducting the research?

The research team consists of Dr Chris Carlin, Consultant Respiratory Physician, Professor Sandosh Padmanabhan from BHF Glasgow Cardiovascular Research Centre at the University of Glasgow, and the COPD clinical team in NHS Greater Glasgow and Clyde. This study will contribute to post-graduate qualification for Dr Taylor.

What is the purpose of the study?

Chronic obstructive pulmonary disease (COPD) is a common condition. Acute exacerbations of COPD cause increased breathlessness, cough and sputum. These can often result in hospital admission. Studies have shown that the outcome most important to COPD patients is reduction in exacerbations and hospital admissions. Available treatments – including smoking cessation, vaccinations, pulmonary rehabilitation (exercise program) and appropriate inhalers – improve symptoms and reduce exacerbations. It can be challenging for clinicians to explain all about COPD diagnosis. It can be difficult to provide adequate support for these core COPD treatments, and for advanced COPD treatments such as home oxygen therapy or home non-invasive ventilation (NIV). Sometimes it is possible for us to help COPD patients self-manage their condition, and use an action plan for early treatment of exacerbations.

We have devised digital technology innovations – a patient portal and a clinician dashboard presenting your data - to help you and us to better understand your COPD condition, and support

your COPD management. Our overall aim is to reduce COPD exacerbations and hospital admissions. We hope to do this by providing in the web information about COPD diagnosis, support for core and advanced COPD treatments, support for COPD self-management and recording of symptoms and body signals which we think will predict deteriorations in your health. We think that if patient provide this information it will help their nurses and doctors and support better COPD management. This data in should allow us in future to be more proactive with COPD management, rather than waiting to react to any deteriorations in health.

We first need test the usability of our digital technology innovations, and capture evidence of how useful the components of our digital technology seem to be. This will allow design of future clinical trials to further test these innovations. The clinical data that we will acquire from all of our trial participants will also be available to help us and other researchers find new evidence about COPD management and how to improve it.

We hope to recruit at least 400 patients with COPD, identified from our inpatient wards or outpatient clinics at the Queen Elizabeth University Hospital and Glasgow Royal Infirmary.

Why have I been invited?

You have been selected as you are currently under the care of the respiratory team, having either had a recent exacerbation of your COPD, or having high blood carbon dioxide levels because of your COPD. Previous studies have shown that patients with these problems are at the highest-risk of further COPD exacerbations and hospital admissions.

Also, you or an immediate family member has daily access to either a smartphone, or a tablet or computer with broadband internet access.

Do I have to take part?

No. Participation is voluntary. We will describe the study to you and go through this information sheet. You will be asked to sign a consent form to participate. You will be free to withdraw from this study at any point, without giving a reason. This study will not interfere with the standard of care you receive now or in future treatments. If you do wish to withdraw consent, please contact

us as below. If you withdraw your consent to proceed, you will not have any further study procedures performed. Your details would be recorded as not wishing to proceed and that would be included in the end of study analysis.

What does taking part involve?

We will be recruiting patients to the study from July 2019 – June 2020. We'd be following up you and continuing to acquire your data at least until July 2021. If the study showed benefit we'd be planning to continue the digital service long term. If the study and digital service weren't continuing after July 2021 we'd transition your care to our standard COPD clinic follow up.

Once you have agreed to participate in this study, we would help you setup the patient app, and the Fitbit wristband that you would wear continuously throughout the study. If you have high blood carbon dioxide levels we may also be starting you with home NIV equipment.

Participation in the study will involve: -

- Installing (with our help) the NHS GG&C RECEIVER COPD service and Fitbit app on your smartphone, tablet or computer.
- Provision of access to your electronic health records, for inclusion in the RECEIVER COPD clinical platform.
- Recording daily questions throughout the study about your COPD (with some extra questions weekly and monthly), in the COPD portal. These questions take ~1-2 minutes to complete, and we will send you daily reminder notifications.
- Wearing a Fitbit wristband. This requires charging for a 2-hour period once a week, and we will send you reminder notifications to wear and charge the Fitbit.
- Have the data from your home NIV machine (if you require this) connected from the AirView platform to the RECEIVER COPD clinical platform.
- Having access to information about COPD diagnosis and your treatment via the NHS GG&C RECEIVER COPD portal.
- Having access to a self-management action plan for exacerbations of your COPD. The content of this action plan will be agreed with you by the clinical team.

- Having access to a messaging facility with the COPD clinical team. Messages sent through the COPD RECEIVER portal are not suitable for healthcare emergencies, but do allow us to discuss and support your management within normal working hours. The aim of this is to reduce the need for hospital clinic visits, and giving you access to advice to support you with COPD treatment and self-management.

We will acquire standard clinical information about your COPD and general health at your initial and follow up visits, and record this in the clinical platform, alongside all the clinical information that you provide in the COPD RECEIVER portal. We will get additional information about any hospital admissions and any developments with your health from NHS GG&Cs electronic health record. We may ask you to give us some additional feedback on the COPD portal and the RECEIVER service, to help us improve it. We will follow up the outcomes with your health in the 12 months after the completion of the study.

Your standard care will not be compromised by participating in this study, and the study won't require any additional hospital attendances.

What happens to the information?

Your identity and personal information will be confidential to the research and COPD clinical teams. Personal details may be looked at by NHS GG&C R&D team, or regulatory bodies as part of review of study data, to make sure the study is being conducted correctly.

All data will remain confidential and will be stored in electronic records on NHS GG&C IT systems. We will provide a summary output about your COPD, including the RECEIVER study data, to your electronic health record (NHS GG&C clinical portal), so that the information is available to help any other clinicians who are involved in your care.

We will let your GP know that you are taking part in the study, and can also provide the summary information about your COPD to them.

We will analyse the data obtained in the RECEIVER COPD patient and clinical platform, within the clinical platform. We will use a type of analysis called 'machine-learning'. When we combine this with knowledge of how your COPD has progressed in the study, we are able develop risk-predictive models. We hope that these predictive models will allow us to detect potential deteriorations in COPD at an earlier stage. We can't however use these model results until we have adequate data to be sure that these are accurate and reliable for clinical use. If the results of this analysis were positive we would plan to do a further clinical trial to determine how useful these predictive models are.

Once we have completed this study, we will complete study reports to the Research Ethics Committee (who approve and monitor this study), present our results at local, national and international meetings, complete student thesis, and publish our data for other academics and clinicians to use. We will also store all your results in NHS Greater Glasgow and Clyde SafeHaven repository indefinitely – this is identical to current routine electronic health record data. The SafeHaven allows researchers to apply to get this study data anonymised and then accessible – without knowing your personal identity – to use in future for other research purposes.

If you would like to more about the results and reports from the study please contact Dr Carlin (See contact details below).

NHS Greater Glasgow and Clyde is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. NHS Greater Glasgow and Clyde will keep identifiable information about you indefinitely (as part of your electronic health record, and within NHS SafeHaven).

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw

from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.
You can find out more about how we use your information at https://www.nhsggc.org.uk/about-us/professional-support-sites/nhsggc-safe-haven/governance/caldicott-principles-data-protection-act/ and/or by contacting 0141 355 2020.

What are the possible benefits of taking part?

Contributing to this study may provide us with valuable information about how to better manage COPD for you and for other patients in the future. We hope that the information, self-management support and messaging functions of the RECEIVER COPD portal will directly improve your COPD status, and reduce exacerbations and hospitalisations. We can't be certain about this until we have completed the study.

What are the possible disadvantages and risks taking part?

There are no apparent disadvantages to participating in this study. We hope that it is understood that the self-management advice and patient-clinician messaging in the app can't cover for emergency health conditions, or all health problems that you might encounter. You will still need to have access standard NHS health advice and assessment, though we hope this will be reduced, and the quality of your NHS care improved by the data that this study will obtain.

Who has reviewed the study?

This study has been reviewed by the NHS National Research Ethics Service.

Who do I contact if I encounter any problems or have any further questions?

Technical problems with the RECEIVER COPD portal, the Fitbit device or your NIV equipment can be passed on via the portal message system. Alternatively, you can contact the respiratory nurse specialist team, or Dr Carlin, as below.

If you have questions or concerns about this project that you'd wish to discuss with an independent clinician, please contact Dr Gordon MacGregor, Consultant Respiratory Physician Queen Elizabeth University Hospital, telephone: xxxx xxx xxxx

In the event of any complaint arising from the conduct of this study, you can discuss this with the clinical team, or with NHS GG&C complaints department (Phone: xxxx xxx xxxx email: complaints@ggc.scot.nhs.uk, webpage: https://www.nhsggc.org.uk/get-in-touch-get-involved/complaints/

Contacts:

Respiratory Nurse Specialists: Queen Elizabeth University Hospital

Tel – xxxx xxx xxxx

Respiratory Nurse Specialists: Glasgow Royal Infirmary

Tel – xxxx xxx xxxx

Chief Investigator

Dr Chris Carlin

Consultant Physician

Department of Respiratory Medicine

Queen Elizabeth University Hospital

1345 Govan Road

Glasgow G51 4TF

Tel - xxxx xxx xxxx

Thank-you for reading this information sheet

Appendix 3. RECEIVER Qualitative Component – Interview Schedule

Intro - Thank you for agreeing to take part. I am conducting these interviews as part of the evaluations of the RECEIVER trial and my PhD, seeking to understand how people have been using the COPD app and whether it has been useful or not. (Info given at initial contact, prior to interview telephone call. Verbal consent taken that happy to take part in interview and purpose and uses of interviews recapped (as stated in original PIS/consent form). If it's ok with you, I'd like to record this phone call. The purpose of doing this is so I can listen back and check our notes to make sure we've captured your feedback accurately. Access to the recordings will be limited to the research team. If you'd rather not have the session recorded, we can continue without it. I'll start the recording now if that is ok?

Please can you tell me your full name and DOB.
Can you confirm that you understand the purpose of these interviews and that the data we collect may be used as part of scientific and academic publications.
Please confirm that you consent to taking part in this interview and are happy for this conversation to be recorded/transcribed

I am going to ask some questions about you and your COPD, then move on to talk about our app. There are no right or wrong ways to answer the questions, so please be as open and honest as you feel comfortable being. Interview is to learn about your perspective and experience, which is unique to you, so I am going to let you do all the talking. If there is any clinical questions that crop up, I will make a note and we can cover it at the end or schedule another time if appropriate. If at any point you would rather not answer a question or you'd like to end the call, just let me know.

Do you have any questions before we begin?

Interview Questions:

Participant info

1. Can you tell me a little bit about when you were first diagnosed with COPD? What happened?

2. Can you tell me about the symptoms you experience with your COPD?

3. Can you describe the types of treatments – inhalers/nebuliser

4. Have ever needed to take abx/steroids for chest, what was that like? Describe last time had to take them
   – symptoms, how recognised, what did they do to manage?
   (exacerbation/flare up - is that a term you have heard being used before? Where did you hear it?)

5. As part of helping people with COPD, we try to teach them to recognise changes with their COPD and what to do about them, to help take control of their condition – this is often referred to as self-management.
   - Is that something you have heard about before?
   - Can you describe a time when you may have used self-management?
   - How do you feel about being in control/practicing self-management?

6. Who normally looks after your COPD? (If app/resp nurses – who supported before using app?)
   - How often do see them?
   - How do you get in touch with them?
   - In an ideal world, what type of support would you like to have for your COPD? What form would it take? Who should provide it?

7. Have you ever needed to come into hospital because of your COPD? What made you come into hospital? Can you tell me a bit about your experience?

8. In what ways did the COVID-19 pandemic affect you and your COPD?

Technology

1. Can you tell me a bit about what bits of technology/devices you have access to at home? (with internet access)

2. What types of things would you use your devices for (if anything)?

3. How confident do you feel about using smart phone/tablet/laptop in general? Were you always confident/not confident, in what ways do you think it has changed?

4. Do any of your family/friends/carers help you with using your smart phone/tablet/laptop? How have they helped?

5. (apart from COPD app) Do you use any to monitor your health/COPD? (sats prob, Fitbit, BP)
   - how do you interpret readings?
   - what would you do if thought the reading was abnormal?

App utilisation & impact

1. What device(s) do use to access COPD app?

2. Can you talk me through how you use the app? What do you think about when you answer the questions?
   - ease of use
   - how often using, what influences when use
   - any help from family, do discuss answers?
   - why do use it? What has made them keep using it?

3. How do you feel about using the app?
   - how has using the COPD app affected the way you manage your COPD?
   - Have you felt any personal benefit from using the app?
   - Has it helped you manage your COPD; can you explain how it has?
   - Why have you continued to use it?
   - In what ways has the COPD app affected your everyday life?

4. How do you think the clinical team uses the information you enter into the app each day?
   - How do you think the app is helping to look after your COPD?

5. Which other parts of the app have you used? (messaging/self-management advice) How have you used them?
   - (If used messages) Can I ask what you messaged about?
   - how do you feel about being able to message the clinical team in this way?

6. *(if not already covered) Are you still using the Fitbit? Can you tell me about how you use that? (Where do you find info about steps, watch vs Fitbit app?)*

7. Have you experienced any exacerbations since using the app?
   - Is there anything you think you now do differently to manage your exacerbations?

8. Can you tell me about anything you don't find useful with the app?
   - What were the main issues/difficulties you were facing when using the COPD app?

9. If you had to describe the COPD app to a friend/relative and how it works, what would you say? Would you recommend it?

10. What would stop you using the app? How do you feel if you don't fill in your questions?

11. If you could improve the app in any way, what would you do?

Future

There is a huge amount of data that has been collected through the app as well as all the information that is held in electronic health records. We want to see if we can use computer programmes to help look through all that data quickly and find patterns, focus on important information and pick up on changes that us, as humans, might not be able to see so easily because of the sheer amount of data that is involved. When we use computer programmes in that way, it is often referred to as Artificial Intelligence or machine learning.

1. Are those terms that you have heard of before?
2. How would you feel about your healthcare data being used in that way?

Any patterns or changes that the computer programme picked up on would be fed back to the clinical team as additional/supporting information, to help us manage your condition. We would not be letting computer make any decisions on its own. This would be in addition to everything we already do, we want to see whether this extra source of information would be useful in helping to manage your COPD.

3. How would you feel about that being added into how we manage your healthcare/COPD?
4. Is there anything that you would be concerned about? Any aspect that you might want more information about?
   - *how much information would want to know, what sort of information would want to know?*

Other:

1. Is there anything we haven't covered that you would like to mention?

Appendix 4. COPD digital support service patient information leaflets

Service Introduction

NHS Greater Glasgow and Clyde

Chronic Obstructive Pulmonary Disease (COPD) Digital Support Service

Did you know?

Digital tools are available to support the management of your COPD

They help

Give your care team a better picture of your health using data you choose to provide

Join to:

- Track your symptoms from home
- Detect when they worsen
- Message with your care team
- Access your care plan and get support

Visit support.nhscopd.scot/join or email copd.support@ggc.scot.nhs.uk today

Intelligent Disease Management

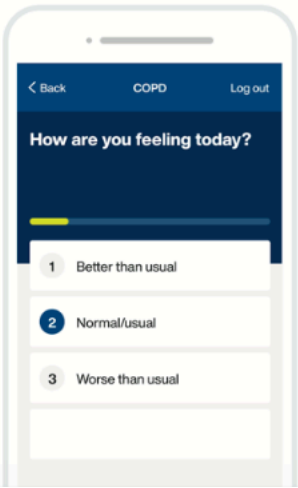
Service Introduction

NHS Greater Glasgow and Clyde

Chronic Obstructive Pulmonary Disease (COPD) Digital Support Service

Five reasons to join

1. It's hard to describe any changes you have felt in your condition
2. You want to better understand and manage changes in your symptoms
3. You want your care team to have better data to support you
4. You want an easy way to contact your care team for advice and support
5. You want access to more information that will help you manage your COPD



Review date: January 2026

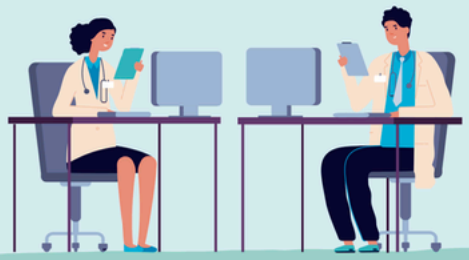
How It Works

NHS Greater Glasgow and Clyde

Chronic Obstructive Pulmonary Disease (COPD) Digital Support Service

Get started

1. You can easily access the service online - There's nothing to download
2. Open the email invitation from your care team and click 'start' then 'register'
3. Your care team securely reviews the data you agree to share to support your health



Visit support.nhscopd.scot/setup/getting-started or email copd.support@ggc.scot.nhs.uk for more information on joining the service

Intelligent Disease Management

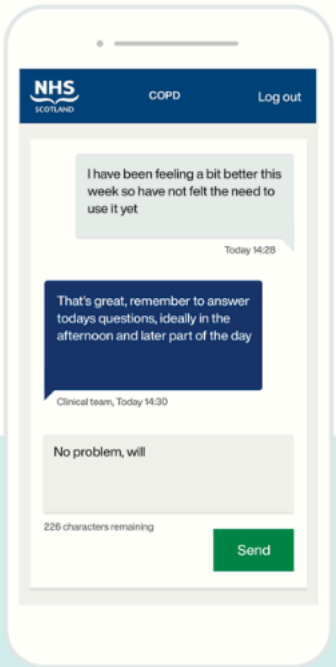
How It Works

NHS Greater Glasgow and Clyde

Chronic Obstructive Pulmonary Disease (COPD) Digital Support Service

Get supported

Answer the question prompts regularly to build a better picture of your health



Use the messaging feature to get advice and help directly from your care team

Easily access your inhaler and rescue medication information

Need help now?

Do not use the service for urgent medical attention.
Go to www.nhsinform.scot, contact your GP or phone NHS 111.
If it's an emergency, phone 999.

Review date: January 2026

Appendix 5. NHSX COPD AI – Patient engagement report

PATIENT ENGAGEMENT REPORT - NHSX COPD AI

Round 1 - Patient Engagement Report

26th November 2021

Prepared by

Rebecca Scott

Lead User Researcher

Overview

During the Discovery phase of the NHSX COPD AI Insights project we conducted a series of user research interviews with COPD patients. Patients who participated in this research were all active users of the digital COPD service in NHS Greater Glasgow & Clyde (GG&C). Patients were recruited for research through the clinical team. We have engaged with 7 patients during this round of research. An additional 3 patients were invited to user interviews but either declined to take part or were unavailable. All interviews with patients were conducted by phone due to the current COVID-19 situation. The purpose of this research was to explore patient sentiment to the use of artificial intelligence (AI) in healthcare, and more specifically to gather feedback on the future use of AI within the COPD service to make predictions about a patient's health. The interview guide was designed to gather background information about the patient first to better understand their experience of having COPD. Additional questions were asked to gather feedback on the digital service, before moving on to questions relating to AI and its potential use in a health care setting.

Findings

Length of condition
Of the patients who were interviewed, all had been diagnosed with COPD at least 4 years ago with 3 participants having been diagnosed over 10 years ago.

Impact of COPD on day-to-day life
All participants reported that having COPD has a significant impact on their day-to-day life, often with basic daily tasks becoming difficult or unmanageable as their condition has progressed.

- "It affects you really living to be honest."
- "It affects every aspect of your life."
- "It affects your mental health too, it's a difficult thing to accept."

Understanding of the term "exacerbation of your COPD"
5/7 patients were familiar with the term "exacerbation". Of those who said they were familiar, all described experiencing "flare ups" of certain symptoms when they have an exacerbation. Some patients reported experiencing exacerbations frequently whilst others reported not having had one for a number of years.

Use of the digital COPD service
All patients who were interviewed have been using the digital COPD service for 1-2 years. All patients who were interviewed can be described as 'active users', with all reporting that they complete their

PROs almost every day, having missed very few days. When asked how they felt about answering questions about their COPD so regularly, all patients reported feeling either neutral or positive.

- “Monotonous. It's fine, I'm perfectly willing to do it if that contributes to the research and monitoring".
- "I like it because it keeps me having COPD in mind, it makes me think about it. It keeps me on top of any potential problems".
- "It focuses my mind on the symptoms".
- "I quite like doing it. It does make me more aware of how I'm feeling".
- "I think it's helpful answering them.".
- "I've absolutely no problem with it I've found it's been a great benefit to me. They are there, the amount of times I've sent messages to them, and they've got back to me as quickly as possible. I've found it invaluable".
- "I just do it now I don't think about it now, I don't have an opinion on that".
- "It's repetitive but then again I suppose it's to follow up on the subject rather than jumping from one thing to another every day".

One patient felt it had provided them with a way to share information with the clinical team despite being unable to attend appointments due to the Covid-19 pandemic:

- "All hospital appointments were being cancelled so how do the hospital know how your breathing is? At least with this I get asked and I can give them the right answers".

Control of condition before and after using the digital COPD service

Patients were asked to describe how in control of their condition they felt before and after using the digital service. Patients were asked to provide a score, with 1 meaning ‘not in control at all’, and 10 meaning ‘completely in control’. Prior to using the COPD digital service all patients reported that their control of their condition was between 4-7 out of 10, with 1 being not in control at all and 10 being totally in control. Since using the COPD digital service all patients reported that their control of their condition was between 5-10 out of 10, with 1 being not in control at all and 10 being totally in control. This shows an anecdotal increase of control across the sample of patients interviewed since onboarding to the digital COPD service. When asked to describe how their control of their condition had changed over that time, patients reported an increased awareness and knowledge of their condition and symptoms. Patients also described having more confidence knowing they can contact the clinical team through the patient app.

- "I'm still getting the chest infections but my knowledge in how to deal with it has improved. They've given me some great tips on what to do.”
- “When you're doing the app on a daily basis you know more when you feel good and when you don’t.”
- "Feel quite confident with the app because I know if I take not well, I can contact the doctor.”
- "I'm noticing changes in myself on a day-to-day basis. At first, I took about 10 seconds but now it takes a few minutes because I'm actually thinking about the question, thinking about my condition before I answer the question now. It's educated me to be as honest with myself and the COPD team.”

Understanding of clinical use of PRO data

When asked to describe what the clinical team do with the information that is submitted through daily PROs patients had varying levels of understanding. Whilst some patients believed their information was anonymous, others felt it might be reviewed by the clinical team on an almost daily basis. One patient acknowledged that there would be too many patients to be looked at everyday and felt it must be “computerised” in some way.

• “Not sure, I presume it's anonymous and the data is anonymised. Idon't think that they report on me."
• "At the beginning I thought it was a way for them to collect information on the condition as a whole.”
• “I really don't know… Comparing notes on how I am on a daily basis?"
• "Links in to Dr A by the COPD Dr so he can look into it and see how I'm doing every day.”
• "Looking at me and seeing how my days vary. I'm assuming they are not just looking at me but looking at a lot of other people so they can build in plans to educate you and improve your breathing.”
• "I don’t have a clue, I really don't know.”

When asked how they felt about the clinical team having access to the information they submit through the patient app, all patients reported that they felt comfortable sharing this information with the clinical team.

• "I quite agree with them having it because it keeps them up to date on any change in anybody's condition".
• "It reassures me that someone on the other end can see if there is a deterioration in my symptoms".
• "I don't mind anyone having my information I feel like they must be using it for some reason to help others. If I can do something to help other people I'm quite happy about it".
• "I think it's alright, totally fine".

One patient felt that although the clinical team have access to a lot of information, it may not be of use if the data is looked at after their condition has already deteriorated:

• "Good in a way, but it might not help you at the time if you're feeling rough. You might need assistance at that time so I don't know how helpful it would be on that day".

Understanding of artificial intelligence and machine learning
5/7 patients were familiar with the term ‘artificial intelligence’ (AI). Of the 5 who were familiar, 3 patients were able to give a description of their understanding of AI:

• "You mean AI? It’s a way of using data to use it in a cumulative way to form an understanding, how you can get a computer to understand something".
• "Computer generated intelligence, computers that think and can analyse and deduce from it".
• "Basically, the nature of humans evolving to the next level with computers. The computers are so smart that they can do things that humans cannot perform at this moment in time".

Only 1 participant was familiar with the term ‘machine learning’ (ML) and was able to give a description of their understanding of ML:

• "I take it it means that it's improving over time?"

Sentiment of two terms
When asked to describe how they felt about the terms ‘artificial intelligence’ and ‘machine learning’, patients provided the following responses:

• "Robots"
• "I'm not worried about it".
• "Obviously whoever controls the data has some control over your life".
• "I think it’s a way we function now and will in the future. Doesn't matter if I like it or not it's

going to happen".
- "It's natural progression, bring it on."
- "It's here to stay, computers are only going to get smarter and smarter".

Sentiment of AI use in health care

Patients were asked how they felt about AI being used to make predictions about their health in the future. All patients responded positively to the idea that health predictions may become part of the COPD service and used to support clinical decision support.

- "Any tool that a doctor can use to make better predictions has got to be a good thing".
- "I'd be quite happy to take part in that".
- "That would be fine, that would be alright".
- "Brilliant I'm all for it. Put me down as the first on the list".
- "I'm 100% behind it. I'd trial that any time".
- "I think it would be a really good idea"
- "If it could recognise that I think it would be a good idea".
- "I don't have a problem with that. If it's going to help then that's all the better".

One patient emphasised the importance of using this information alongside individual patient context. They felt that although they have COPD, they are fitter than the average person of their age and so they wouldn't want their age to be used as a negative factor. They felt they would want to know what factors were used to make predictions and would always want that information to act as supporting information alongside usual clinical care where they have the opportunity to see and speak to the clinical team responsible for their care.

- "I like the idea that they might be able to use AI to make a good diagnosis. I think there is always an element of the actual individual rather than generic information. I don't want to be put into a box and I worry about how much sophistication there is in AI. If that's going to become a major part that would concern me. I like to see the doctor."

Method of consent

Patients were asked "If the clinical team asked to use your information in that way, how would you like to be asked about it?" By phone call, letter or in the patient app were given as examples. Patients all felt comfortable with providing consent though the patient app. One patient suggested that a phone call first might provide them with reassurance, however this seemed to be related to their digital confidence rather than concerns over the study.

- "Possibly on the app I use it every morning so that would be the easiest way"
- "I think through the app would be a really good way to do it"
- "If somebody phoned me first then that would be fine I would do consent in the app that way"

Areas of concern

When asked if there was anything they would be concerned about, patients generally responded positively. There was a consistent theme relating to data privacy:

- "Not really because it's the NHS it's not out there for the public. I suppose there would be safeguards in place so it would only be clinical teams who have access to it."
- "You've explained it all gets kept private and it's all confidential so no."
- "I'd like it to be kept confidential. I don't want my information spread everywhere, only the people that I've agreed for it to be shared with."
- "I don't think so. They'd only be using what they need to use, I don't think they'd be broadcasting it about it would be on a need-to-know basis."

One patient described wanting detailed information on where the data would be shared and what studies it would be used for:

- "Would it be shared elsewhere? I would want to know exactly, and what it would be used for even if it wasn't my name that was on it, what other studies it would be used for"

Sharing of prediction information

Patients were asked what they would expect the clinical team to do if they had access to predications about their health. Patients consistently described the desire for information of that nature to be delivered through a healthcare professional e.g. a hospital consultant or GP.

Patients also emphasised wanting to be "kept in the loop" with information about their health. One patient felt very strongly about the importance of human relationships between patients and health care professionals and emphasised that information should be filtered through a trusted professional.

- "If they said we'll predict you'll die next Thursday I presume they would keep it to themselves. I would like anything to go through my hospital consultant not directly to me. I have a very good relationship with him, I trust him. if you have some input to him as long as he's capable of evaluating it himself then that's ok."
- "Possibly tell my GP or my GP tell me or a message saying go see your GP or something, something along those lines."
- "Get in touch with me and let me know."
- "Pass it on to my doctor."
- "Telling me, I would like to know the outcome initially."
- "Use it to their best advantage."
- "Human voice, we've noticed such and such and we'd like you to see a GP or a respiratory clinic or whatever."

General feedback

During patient interviews, some general feedback was gathered on the wider COPD service:

- "Respiratory clinic made the difference on my day to day stuff, taught me how to manage it."
- "I worry about overloading poor humble brilliant consultants who have a case of umpteen patients"
- "I far prefer telephone appointments. Great thing to come from the pandemic. I struggle to get out my house even to a hospital appointment it takes me 2 hours to recuperate."
- "I think it's good you can do that everyday but I don't know if the GP knows you do that, do they have any feedback on it. There is a link lost where you're not doing that breathing test (with this covid thing). I don't feel that you're linked up with your surgery."
- "I'm finding that a wee bit difficult, if it was something that was done every year I don't know why it's not to be included now." (referring to breathing tests).

Appendix 6. York Health Economics Consortium (2024) *Economic Evaluation of Lenus COPD Support Service*. University of York.

YHEC
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Economic Evaluation of Lenus COPD Support Service

Methods

An early economic model was developed to consider the incremental costs and consequences of using the Lenus COPD Support Service, compared with standard care for people with severe COPD from an NHS perspective. The model used a one-year time horizon and considered both resource use and clinical outcomes.

The costs of the intervention and standard care were estimated from resource use associated with exacerbations and the use of primary and secondary care. This was based on evidence from the NICE NG115 Economic Model Report and unit costs from the National Schedule of NHS Costs. The intervention arm also incurred licensing, training, and implementation costs. These inputs were provided by Lenus Health and the study conducted by Hull University Teaching Hospitals NHS Trust (HUTH).

Clinical outcomes considered in the model consisted of the number of exacerbations with and without a hospital admission, length of hospital stay, and time to readmission. This data was sourced from a combination of 3-month results from the HUTH study and literature evidence.

Quality adjusted life years (QALYs) were calculated using evidence from the NICE NG115 Economic Model Report. This provided an annual utility value for people with COPD and annual disutilities for exacerbations with and without hospital admission. These results were used to determine whether the intervention was cost-effective.

Sensitivity analysis was conducted to assess the impact of any uncertainty in the inputs. Inputs were varied by 15% in the absence of any other suggested feasible variation. A threshold analysis was also conducted to find the minimum cohort size at which the intervention was cost-effective.

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York Health Economics Consortium

UNIVERSITY of York

Results

The model was run using the HUTH study scenario. This consisted of a cohort of 111 patients using the Lenus Health COPD Support Service. The study demonstrated a cohort reduction of 90 exacerbations resulting in a hospital admission compared with the matched control group of patients not using the intervention. Exacerbations without admission increased by 56 in the intervention arm, giving a net reduction of 34 exacerbations. Since these are much less costly than exacerbations resulting in hospital admission this had a substantial impact on the intervention being cost saving compared to standard care. The length of hospital stay per person was also reduced by 1.1 days compared to standard care.

The Lenus intervention was estimated to cost £601,660 per cohort and £5,420 per person. In comparison, current standard of care was estimated to cost £795,498 per cohort and £7,167 per person, resulting in the intervention being cost saving by £193,838 for the cohort and £1,746 per person, within a one-year time horizon.

The cohort using the Lenus intervention gained 3.04 QALYs, or 0.03 QALYs per person. This produced a dominant incremental cost-effectiveness ratio (ICER), meaning that the intervention was both less costly and more effective than current standard care.

Sensitivity analysis showed that the three inputs with the largest impact on cost-saving were rate of exacerbations with hospital admission using standard care, rate of exacerbations with hospital admission using the intervention, and cost of a hospitalised exacerbation. When these parameters were varied by 15%, the intervention was still shown to be cost saving at these values.

The threshold analysis estimated that the intervention becomes cost saving at a cohort size of 31. It also estimated that the net monetary benefit becomes positive at a cohort size of 25.