IRAS ID:	249148
Name of REC:	London – Surrey Research Ethics Committee
REC reference number:	18/LO/1939
Date of favourable ethical opinion:	18/12/2018

Self-management and support programme for COPD (EDGE2)

Chronic obstructive pulmonary disease (COPD) is a long-term lung condition that makes breathing increasingly difficult. It affects around 3 million people in the UK and many millions worldwide. There is currently no cure, so treatment focuses on managing symptoms, preventing flare-ups, and supporting people to live as well as possible with the condition.

People with COPD are often admitted to hospital when their symptoms suddenly worsen. Around one in four people are readmitted to hospital within three months of a previous admission. This places a heavy burden on patients, carers, and NHS services. Supporting people to manage their condition at home and identifying early signs that someone's health is getting worse, could help reduce emergency admissions and improve care.

Digital technologies, such as tablet computers and wearable devices, offer new ways for people with COPD to monitor their symptoms at home and share information with their clinical team. This could reduce the need for frequent home visits and allow healthcare professionals to respond more quickly when someone needs help.

The EDGE2 study built on earlier work (the EDGE and SEND studies) to explore whether it is practical and acceptable for patients with COPD when admitted to, or shortly after discharge from, hospital to use a tablet-based digital system for COPD monitoring while they are in hospital and after they return home. The system allowed patients to record information about their symptoms and health and aimed to link this information with routine data already collected in hospital. Bringing these data together could, in future, help clinicians better understand changes in a patient's condition and support the development of tools to predict when someone might need hospital care.

The main aim of EDGE2 was to find out whether this approach was feasible and acceptable to patients and clinicians. The study also explored whether patients were willing and able to use different types of monitoring, including tablet computers and wearable devices, and whether physical function assessments could be carried out in hospital and on return to home. The study intended to follow participants for up to twelve months. A nested longitudinal qualitative study was conducted with 15 participants using semi-structured entry interviews: six completing interim interviews and 13 completing exit interviews. The study explored participants' experiences of using the EDGE2 system alongside their lived experience of COPD, and how both changed over time.

A total of 41 people were recruited to the study, and 26 completed one year follow-up. One participant withdrew after consent but before baseline data collection. Two participants died during the period of follow up with the cause of death unrelated to participation in the study. Recruitment took place through Oxford University Hospitals NHS Trust and later Oxford Health NHS Trust. The study was significantly affected by the COVID-19 pandemic, which led to

changes in recruitment and follow-up, including the need for contactless procedures and the inability to carry out face-to-face follow-up visits.

Participants consistently described the significant negative impact of the COVID-19 pandemic on their physical and mental health. This included reduced daily self-care, deterioration in mental health, fear and loneliness. Participants commonly lived with multiple long-term conditions, reported limited practical or day-to-day support, and expressed a desire to remain independent while also being supported. They described concerns about the impact of their condition on others and the speed of their physical deterioration.

The EDGE2 system was described as simple to use, with graphical visualisations supporting understanding of changes over time. Participants noted limitations in the system, including a desire to monitor additional symptoms such as lung function and mood. They described behavioural and emotional impacts associated with system use, including increased physical movement, feelings of being cared for and reassured despite awareness of the system's automated nature, and increased confidence in meeting physical goals. Some participants used the system to reassure others and developed greater awareness by reviewing their data in charts or graphics.

The study found that many people who might benefit most from remote monitoring were recruited at a time when they were very unwell and had limited energy. As a result, taking part in research procedures was challenging for some participants. Use of additional monitoring devices, such as wrist-worn physical activity monitors, was low. However, most participants used the tablet computers, and respiratory nurses reported that the system was valuable for supporting remote management of patients.

The study successfully demonstrated that hospital data could be obtained. However, the primary outcome, linkage of data has not yet been achieved. Resources to allow this linkage are currently being sought. Further analysis of these data, including exploring whether they can help predict changes in health, will be carried out.

Overall, EDGE2 showed that digital self-management support has potential value for people with COPD, particularly when used to support care after discharge from hospital. The findings suggest that future work in this area may be more effective if carried out as service evaluations, allowing a stronger focus on patient safety, clinical benefit, and what makes the greatest difference to people living with COPD.

Additional information

This study commenced in-patients at the Oxford University Hospitals NHS Trust (OUH) from May 2019. Recruitment was paused in March 2020 due to COVID-19. The study recommenced recruitment in the community from newly discharged hospital patients under the care of Oxford Health NHS Trust (OH) in 2021. The method of recruitment was updated to reflect the need for a contactless approach. The last participant was recruited in December 2021.

The mean (SD) age of participants was 68 (7.8) years, 22 (53.7%) were male, 6 (15%) were smokers. Breathlessness was described as somewhat severe by 22 (55%) and 20 (50%) described their health as fair, poor or very poor. At one month 30 (73.2%) of participants could be followed up by telephone or face to face, at 12 months 14 (31%) of participants could be

followed up. At one month, 21 (53.7%) of participants were using a wrist-worn physical activity monitor, this fell to 9 (22%) at 6 months.

Funding – Engineering and Physical Sciences Research Council and NIHR Oxford Biomedical Research Centre.