BMJ Open Respiratory Research

Feasibility of home initiation of an airway clearance device (SIMEOX) by telecare in people with non-cystic fibrosis bronchiectasis: a pilot study

Rebecca Hamidfar,[1] Marlene Murris-Espin,[2] Marie Mahot,[3] Raphael Abouly,[3] Hughes Gauchez,[4] Sophie Jacques,[5] Eloise Joffray,[3] Nathalie Arnol,[3] Laurent Morin ,[6] Sylvie Leroy,[7] Jean-Christian Borel [3]

To cite: Hamidfar R, Murris-Espin M, Mahot M, *et al*. Feasibility of home initiation of an airway clearance device (SIMEOX) by telecare in people with non-cystic fibrosis bronchiectasis: a pilot study. *BMJ Open Respir Res* 2023;**10**:e001722. doi:10.1136/bmjresp-2023-001722

Received 21 March 2023
Accepted 20 July 2023

[1]Service de Pneumologie-CRCM adulte Hôpital Michallon, Grenoble Alpes University Hospital, Grenoble, France
[2]Service de Pneumologie-CRCM adulte Hôpital Larrey, CHU Toulouse, Toulouse, France
[3]R&D, ICADOM-AGIR à dom, Meylan, France
[4]Cabinet de Kinésithérapie, Marcq-en-Barœul, France
[5]Cabinet de Kinésithérapie, Rennes, France
[6]Physio-Assist, Montpellier, France
[7]Service de Pneumologie-CRCM adulte Hôpital Pasteur, CHU Nice, Nice, France

Correspondence to
Dr Jean-Christian Borel; j.borel@agiradom.com

ABSTRACT

Background Mucociliary clearance is a cornerstone of the management of people with non-cystic fibrosis bronchiectasis (NCFB). SIMEOX, an innovative device, could facilitate autonomous airway clearance, but its use requires specific training. We hypothesised that telecare would be an effective means to train people with NCFB in the handling of device and to monitor and promote device adherence.

Objectives (1) To evaluate frequency of use of the SIMEOX for 10 weeks after telecare training. (2) To assess user satisfaction and clinical efficacy of the SIMEOX+telecare.

Methods Multicentre, prospective, pilot study in adults with NCFB. A SIMEOX was provided to each participant at inclusion. Physiotherapists performed telecare sessions the first 2 weeks (3–5 sessions) for device training and every 10 days to reinforce motivation and provide technical support.

Results 22 individuals were included, 21 analysed (38% male; mean±SD age 53±18 years; Bronchiectasis Severity Index 6.6±3.5). Fourteen participants (66.7%; 95% CI 43.1% to 84.5%) performed ≥3 SIMEOX sessions/week (self-reported adherence, primary outcome). Median (Q1; Q3) number of self-reported sessions/week for the whole group was 3.7 (1.8; 5.7). Adherence including web registration was 80.9%. At week 12, participant satisfaction rating was 9.0 (7.9; 10.0) on a 10-point visual analogue scale; respiratory function did not change but quality of life improved (COPD Assessment Test score −4.7, 95% CI −7.7 to −1.6, p=0.023; St Georges Respiratory Questionnaire −5.8, 95% CI −10.8 to −0.9, p=0.005).

Conclusion Adherence to and satisfaction with the SIMEOX airway clearance device supported by telecare were high in people with NCFB. The clinical efficacy needs to be confirmed in a randomised controlled trial.

Trial registration number NCT04742270.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Being taught the airway clearance techniques and how to use the equipment at home is one of the most important needs reported by the individuals with non-cystic fibrosis bronchiectasis.

WHAT THIS STUDY ADDS

⇒ The initiation of an innovative airway clearance device and provision of support both exclusively by telecare was feasible and resulted in high adherence with high user satisfaction.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This strategy could be clinically effective and efficient in medicoeconomic terms. The effects should be confirmed by a randomised controlled trial.

INTRODUCTION

Non-cystic fibrosis bronchiectasis (NCFB) is a chronic pulmonary disease with multiple aetiologies. It is characterised by irreversibly and abnormally dilated airways and chronic respiratory symptoms (persistent cough and excessive sputum production). The dilation causes mucus retention and leads to infections and chronic bronchial inflammation.[1] Treatment is multimodal and non-specific, involving anti-inflammatory agents, airway clearance techniques (ACTs) and inhaled antibiotics. Respiratory physiotherapy is essential to facilitate mucociliary clearance, and daily or multiple daily airway clearance sessions are recommended for individuals with a productive cough.[2] These airway clearance sessions, performed with a physiotherapist or autonomously, are a very substantial burden, which limits compliance. Fewer than 60% of individuals with NCFB are reported to use ACTs and about 50% of those who use these techniques do not continue beyond 1 year.[3] Moreover, access to physiotherapy is not always easy because of geographical and time constraints, and the lack of availability of professionals. Yet, '*Having access to physiotherapy and being taught the techniques and how*

to use the equipment at home' is one of the most important needs reported by the individuals concerned.[4]

Telehealth is a relevant means to improve access to care and the quality of care. In the field of chronic respiratory diseases, a number of recent clinical trials on telerehabilitation, mainly in people with COPD, showed that remote care can effectively improve clinical outcomes.[5 6] Furthermore, the COVID-19 pandemic has considerably accelerated the adoption of telecare. The clinical trial conducted by Alghamdi *et al* on airway clearance in people with COPD is illustrative of this context since the investigators had to teach the use of an ACT (Oscillatory PEP) by videoconference whereas the original plan was to perform face-to-face training.[7] This successful experience, imposed by the pandemic context, suggests that telecare may be a feasible solution to train individuals and facilitate access to a professional for any ACTs. However, it is important to bear in mind that the drop-out rate from telehealth clinical trials can be as high as 63% in the intervention arms (compared with 37% in the control arms) and that technical difficulties and complex systems are the two main causes of drop-out.[8]

SIMEOX (Physio-Assist, Aix-en-Provence, France) is an innovative medical device (CE medical approved) for bronchial drainage based on the rheological properties of mucus. Briefly, SIMEOX consists of a mouthpiece connected to the device via a tube and bacterial/viral filter. During relaxed exhalation, the device generates a succession of intermittent negative pressure pulses at a frequency of 12 Hz that disseminate in the bronchial tree. This pneumatic vibratory stimulus liquefies and mobilises lung secretions from the most distal parts of the lung towards the upper airways where they are expectorated naturally. The effectiveness of this medical device has mainly been evaluated in the short term and in healthcare facilities with the assistance of a physiotherapist during sessions.[9 10] A recent clinical trial conducted over a period of 1 month in young people with cystic fibrosis showed that the use of SIMEOX at home was feasible. In that study, participants were trained to use the device during hospitalisation for a few days.[11]

We hypothesised that telecare provided by a physiotherapist would enable individuals to be trained remotely in the use of SIMEOX and would promote self-use. The primary objective of this pilot study was to evaluate the rate of SIMEOX adherence at home, after training by telecare, in individuals with NCFB requiring ACT. Secondary objectives were to assess user satisfaction with, and clinical efficacy of, the SIMEOX+telecare combination.

METHODS

Study design

This prospective, uncontrolled, interventional pilot study was conducted in three different medical facilities (tertiary university hospitals).

Patient involvement

Patients were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

Participants

Adults with a diagnosis of NCFB confirmed by high-resolution CT were eligible if they were (1) in a stable condition, defined as at least 4 weeks from the end of an exacerbation, (2) had estimated bronchorrhoea >10 mL/day and (3) had limited access to a physiotherapist (<3 sessions/week of airway clearance with a physiotherapist). The non-inclusion criteria were pneumothorax or severe haemoptysis (more than 30 mL per 24 hours) within 6 weeks of inclusion. Written informed consent was obtained from all participants.

Setting

Participants made two visits (initial and final), 12 weeks apart, to the investigating site (pulmonology unit). During the initial visit, each participant was provided with a SIMEOX device and the necessary consumables (filters, tubes and mouthpieces) for the duration of the study. During the first 2 weeks, 3–5 videoconference sessions were performed between the participant (at home) and a respiratory physiotherapist who was an expert on the device, to teach the participant how to use the SIMEOX. The first session was dedicated to (1) teaching how the SIMEOX works and (2) teaching deep exhalation and feeling the exhalation through the mouthpiece while sitting in a comfortable position. The physiotherapist guided the participant completely in the use of the device (when to trigger the device and when to stop it). There are no parameters to be set on the SIMEOX. The patient simply varies the power (25%–100%) of the device during the session in order to adapt the amplitude of the intermittent negative pressure so that it is in the right range of effective pressure that does not generate any upper airways obstruction (feedback by green Ligh-Emitting Diodes).

During the second session, the physiotherapist guided the participant verbally through a few cycles to encourage the synchronisation of the exhalation with the device signal, and then the participant performed cycles on their own.

During the third session, the participant performed the whole session independently and the physiotherapist provided correction if necessary. The participant learnt to change body positions. The last two sessions (4–5) were only performed if the participant still had difficulty using the device. After this training period, which was spread over a maximum period of 2 weeks, participants were advised to perform as many sessions as possible (once to several times a day, several days a week to everyday). One session consisted of 20–40 respiratory cycles (exhalations) and lasted approximately 15–20 min. A telecare session was scheduled every 10 days with the physiotherapist to reinforce motivation and provide technical

assistance. There were no supervised SIMEOX sessions after the training phase. Prior to the telecare sessions, the physiotherapist checked the participant's use data on the SIMEOX web application and prepared the discussion issues to review with the patient according to the data results. This telemonitoring application securely collects data from the SIMEOX built in software, such as number of sessions performed, duration of sessions, number of breathing cycles and number of sessions performed, by means of a digital tablet connected to the device via Bluetooth. To note: if the participant did not use the digital tablet, the data could not be collected on the web application.

Variables collected

1. Demographic data (age, sex, body mass index, medical history, socio-professional category and marital status) were collected by the physician in charge in each centre.
2. Respiratory function tests were performed at baseline and at week 12 according to the American Thoracic Society (ATS)/European Respiratory Society (ERS standards.[12]
3. Quality of life (QOL) was assessed using four standard questionnaires: the St Georges Respiratory Questionnaire (SGRQ),[13] the Leicester Cough Questionnaire (LCQ),[14] the COPD Assessment Test questionnaire (CAT)[15] and the QOL-Bronchiectasis (QOL-B).[16]
4. Adherence to the SIMEOX device was both self-reported by the participant in a diary (used to calculate the primary outcome) and recorded on the SIMEOX web application.
5. General behaviour of participants towards their treatments was assessed using the Beliefs about Medicines Questionnaires (BMQ).[17]
6. Clinical events and adverse events: pulmonary exacerbations, defined according to consensus criteria, were collected by medical teams.[18] Adverse events associated with the use of the SIMEOX were also collected.
7. Overall participant satisfaction was measured at week 12 on a Visual Analogue Scale (0–10).

Outcomes

Primary outcome

The primary outcome was the percentage of participants who performed on average ≥3 sessions/week between day 15 (end of the training period) and week 12 (self-reported adherence by the participant in a diary).

Secondary feasibility outcomes

1. Comparison of self-reported adherence (number of sessions/week) with adherence reported automatically on the 'SIMEOX web application' between day 15 and week 12.
2. Change in use of the SIMEOX between day 15 and week 12.
3. Feasibility of respiratory telecare (every 10 days).
4. Factors associated with insufficient (self-reported) adherence to the SIMEOX device.
5. Participant satisfaction with the SIMEOX+telecare.

Secondary clinical outcomes

1. Effect of SIMEOX+telecare combination on symptoms, QOL and respiratory function (see Variables collected section above).
2. Side effects associated with the use of the SIMEOX.

Sample size

In this pilot study, the sample size to be included was estimated at 22 participants to ensure at least 20 complete observations. This estimate was based on the investigators' ability to include individuals over a 6-month period and was consistent with the number of people included in the interventional arm of the trial by Muñoz *et al*.[19]

Statistical analysis

Data were analysed using SAS software V.9.4 (SAS Institute). Continuous variables were expressed as mean±SD or median (Q1; Q3) according to their distribution (Shapiro-Wilk test); categorical variables were reported as absolute numbers and percentages. All the analyses specified below were performed with no replacement of missing data.

Primary endpoint: adherence was described by the number and percentage of participants who performed on average ≥3 sessions/week between day 15 and week 12 (self-reported adherence by the participant in a diary). The 95% CI was estimated using the Wilson procedure with correction for continuity.[20] Secondary endpoints: paired t-tests or Wilcoxon signed rank test (according to the distribution) were used to compare variables between baseline and week 12 (respiratory function and QOL questionnaires) or to compare self-reported adherence with adherence reported on the SIMEOX web application. The factors associated with poor adherence to SIMEOX (<3 sessions/week self-reported) were analysed by comparing variables between adherent and non-adherent participants with the t-test (or the Mann-Whitney U test) for continuous variables and the χ^2 test (or the Fisher's exact test) for categorial variables.

RESULTS

Study sample

Between April and December 2021, 22 individuals with NCFB were included. One participant was later excluded, because of the diagnosis changed (cystic fibrosis). No participants discontinued the study. The main characteristics of the 21 participants who completed the study are reported in table 1.

Primary outcome

In total, 14/21 (66.7%; 95% CI (43.1% to 84.5%)) participants performed ≥3 self-reported sessions/week of

Table 1 Participant characteristics at baseline (n=21)

	Missing data (n (%)	Median (Q1; Q3) or mean±SD or no (%)
Demographic		
Age (years)	0 (0)	53±18
Sex (males)	0 (0)	8 (38.1)
BMI (kg/m²)	0 (0)	21.4±3.2
Living with a partner (yes)	1 (4.8)	16 (76)
Smoking status	1 (4.8)	
Current smoker		0 (0)
Passive smokers		1 (5.0)
Never smoked		11 (55.0)
Ex-smoker		8 (40.0)
Comorbidities		
Asthma	0 (0)	5 (23.8)
COPD	0 (0)	2 (9.5)
Chronic rhinosinusitis	1 (4.8)	11 (55.0)
Aetiology of bronchiectasis	3 (14.3)	
Idiopathic		6 (33.3)
Primary ciliary dyskinesia		3 (16.7)
Childhood Infections		3 (16.7)
COPD		3 (16.7)
ABPA		3 (16.7)
Chronic colonisation		
Pseudomonas aeruginosa (yes)	1 (4.8)	10 (50)
Other germs (yes)	0 (0)	10 (47.6)
Exacerbations		
Exacerbation in the past 1 year	0 (0)	1 (0; 3)
Hospitalisation for exacerbation in the past year	0 (0)	0 (0)
Hospitalisation for exacerbation in the past 2 year	0 (0)	6 (28.6)
Spirometry		
FEV1 (% pred value)	0 (0)	75.3±21.5
FVC (% pred value)	0 (0)	87.6±18.7
FEV1/FVC (%)	0 (0)	66.4±14.7
Treatments (respiratory)		
Inhaled corticosteroid therapy	0 (0)	11 (52.4)
Inhaled bronchodilator therapy	0 (0)	20 (95.2)
Inhaled antibiotic therapy	0 (0)	4 (19.0)
Mucolytics	0 (0)	3 (14.3)
Symptoms and quality of life		
BSI score	2 (9.6)	6.6±3.5
CAT score	1 (4.8)	18.3±8.2
SGRQ total score	1 (4.8)	36.8±18.9
mMRC scale	1 (4.8)	1 (1; 1)
LCQ	3 (14.3)	15.7±3.4

Data are median (Q1; Q3) or mean±SD; number (%) for categorial data.
. ABPA, Allergic BronchoPulmonary Aspergillosis; BMI, body mass index; BSI, Bronchiectasis Severity Index; CAT, COPD Assessment Test; COPD, Chronic Obstructive Pulmonary Disease ; FEV1, forced expiratory volume in 1 s; FVC, forced vital capacity; LCQ, Leicester Cough Questionnaire; mMRC, modified Medical Mesearch Council; % pred val, percentage of predicted value; SGRQ, Saint Georges Respiratory Questionnaire.

SIMEOX between the day 15 (end of training phase) and week 12 (end of study).

Secondary feasibility outcomes

Figure 1 shows the stability of the number of SIMEOX self-reported sessions/week between the end of the training period (day 15) and the end of the study (12 weeks) (representing a 10-week period). Self-reported adherence did not differ from use recorded by the SIMEOX web application, respectively median (Q1; Q3) 3.7 (1.8; 5.7) vs 4.7 (1.7; 5.7) sessions/week (p=0.36), and these variables were strongly correlated (r=0.73; p<0.001). Considering the total number of sessions reported either on the web application or self-reported (without duplication), 17/21 (80.9%) participants performed ≥3 sessions/week regularly during the 10 weeks of follow-up. Although telecare sessions with the physiotherapist were scheduled every 10 days according to the protocol, the mean actual time between telecare sessions was 14±6 days. We did not identify any variables (demographic, marital status, socioprofessional category, smoking status, bronchiectasis aetiology, lung function, mMRC, history of exacerbation, BSI score, bacterial colonisation or daily sputum amount) associated with non-adherence to SIMEOX (<3/week). There was no correlation between SIMEOX adherence and BMQ score (general treatment adherence assessment). However, there was a significant correlation between the number of autonomous SIMEOX sessions/week and the total number of telecare sessions (after training period) performed with the respiratory physiotherapist (Pearson coefficient r=0.45, p=0.043) (figure 2). Finally, overall satisfaction of SIMEOX+telecare was rated at 9.0 (7.9; 10.0) points on a 10-point Visual Analogue Scale.

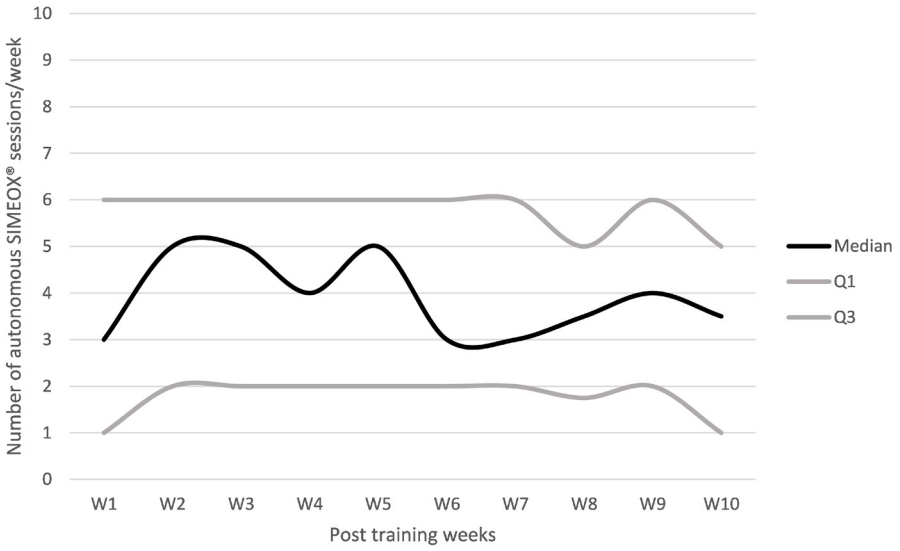

Figure 1 Time course of the number of autonomous SIMEOX sessions/week after the training period (10-week period). Median, Q1, first quartile; Q3, third quartile.

Secondary clinical outcomes

There was no significant change in spirometry outcomes between baseline and study endpoint (table 2). In contrast, the CAT score and the SGRQ total score improved significantly beyond minimal clinically significant differences (MCID); the scores for the vitality and treatment burden domains of the QOL-B questionnaire also improved significantly. The total score of the LCQ also tended to improve. Table 3 shows the changes in the scores of the different domains of the questionnaires.

Finally, with regard to the safety of using the SIMEOX autonomously at home, 10 non-serious side effects were reported as probably attributable to the use of the device in 8 participants (4 traces of blood in the sputum in 4 participant of which only 1 led to the device being suspended for 48 hours; 5 events of pain during sputum

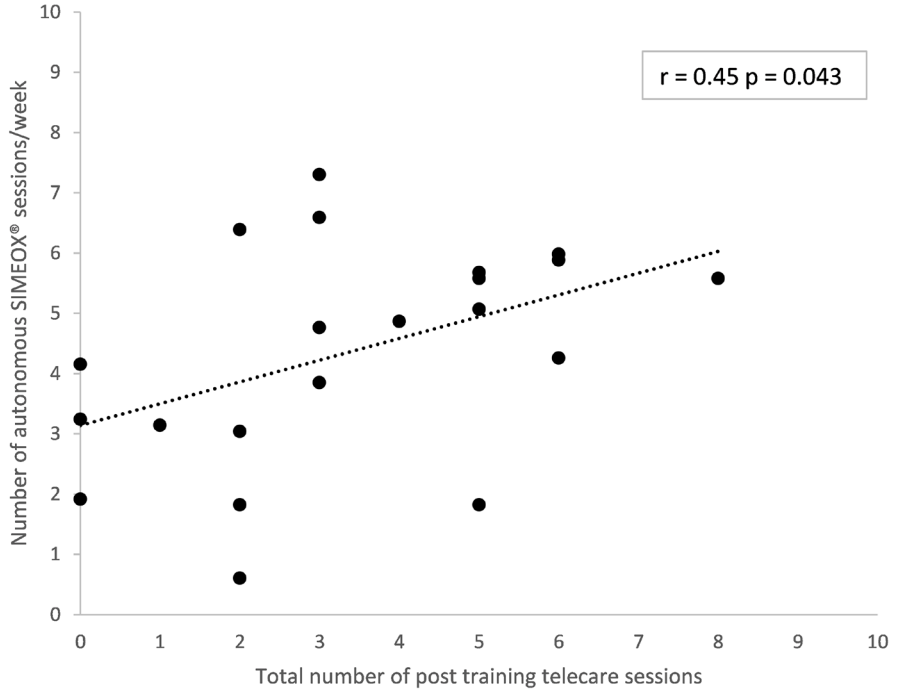

Figure 2 Correlation between the number of autonomous SIMEOX sessions per week and the total number of post-training telecare sessions (10-week period).

Table 2 Changes in spirometry variables between baseline and week 12

	Missing n (%)	Baseline	Endpoint (12 weeks)	Δ (12 weeks–baseline) mean (95% CI)	P value
FEV_1 (L)	0 (0)	2.4±0.8	2.3±0.8	0.0 (–0.1 to 0.1)	0.86
% pred value		75.3±21.5	75.7±22.0	0.4 (–2.8 to 3.7)	0.78
FVC (L)	0 (0)	3.4±1.0	3.4±1.0	0.0 (–0.1 to 0.1)	0.70
% pred value		87.6±18.7	87.1±19.2	–0.5 (–3.5 to 2.5)	0.75
FEV1/FVC (%)	0 (0)	66.4±14.7	67.1±14.6	0.8 (–3.4 to 4.9)	0.40
FEF 25–75 (L/s)	0 (0)	1.7±1.2	1.7±1.1	0.0 (–0.1 to 0.1)	0.61
% pred value		56.1±30.9	58.6±32.4	2.5 (–2.4 to 7.4)	0.59

FEF, forced expiratory flow; FEV1, forced expiratory volume in 1s; FVC, forced vital capacity; % pred value, percentage of predicted value.

expectoration (for 3 participants; no temporary suspension of the device), 1 worsening of gastro-oesophageal reflux (no suspension) in patient with GERD. Most of these side effects were temporary (1–2 weeks) and resolved without any treatment. In total, 4/22 (19.1%) participants were hospitalised during the study for pulmonary exacerbation; the median time to first exacerbation was 53 (18; 79) days. These events were not related to the intervention but one participant suspended the use of SIMEOX for 10 days during the exacerbation. The patient was hospitalised and was unable to use the device during this period (device remained at home).

DISCUSSION

This pilot study showed that the initiation of an innovative airway clearance device and provision of support both exclusively by telecare for 12 weeks was feasible, safe and resulted in high, continued adherence with high user satisfaction, as hypothesised. Adherence was associated

Table 3 Changes in quality of life variable scores between baseline and week 12

	Missing n (%)	Baseline	Endpoint (12 weeks)	Δ (12 weeks–baseline) mean (95% CI)	P value
QOL-B questionnaire					
Respiratory symptoms	5 (23.8)	24.1±3.8	25.0±4.6	0.9 (–1.5 to 3.2)	0.44
Physical functioning	1 (4.8)	16.5 (11.3; 19.8)	17.5 (13.0; 20.0)	0.0 (–1.0 to 1.0)	0.85
Vitality	2 (9.5)	8.1±2.2	8.9±1.9	0.8 (0.2 to 1.5)	0.019
Role functioning	1 (4.8)	15.4±3.4	15.9±3.7	0.5 (–0.6 to 1.6)	0.35
Health perceptions	5 (23.8)	9.5±3.1	10.3±3.0	0.8 (–0.1 to 1.6)	0.08
Emotional functioning	1 (4.8)	13.5±2.4	14.0±2.4	0.5 (–0.4 to 1.4)	0.28
Social functioning	7 (33.3)	11.4±2.2	12.4±1.8	0.9 (–0.1 to 1.9)	0.07
Treatment burden	3 (14.3)	8.1±0.9	9.0±1.2	0.9 (0.1 to 1.8)	0.040
St georges respiratory questionnaire					
Total score	1 (4.8)	36.8±18.9	30.9±20.9	–5.8 (–10.8 to -0.9)	0.023
Symptoms	2 (9.5)	50.7±16.9	44.2±21.3	–6.5 (–16.9 to 3.8)	0.20
Activity	4 (19.0)	49.7±24.1	44.2±24.5	–5.4 (–11.8 to 0.9)	0.09
Impact	2 (9.5)	30.7±17.7	24.8±19.1	–5.9 (–11.9 to 0.0)	0.05
Leicester Cough Questionnaire					
Total score	6 (28.6)	15.5±3.7	16.9±3.0	1.4 (–0.3 to 3.2)	0.10
Physical score	4 (19.0)	4.9±1.2	5.4±1.2	0.55 (–0.04 to 1.15)	0.06
Psychological score	3 (14.3)	4.9±1.4	5.4±1.0	0.58 (–0.03 to 1.18)	0.06
Social score	1 (4.8)	5.6±1.2	6.1±0.8	0.5 (–0.1 to 1.1)	0.08
CAT questionnaire	3 (14.3)	18.8±7.6	14.2±7.6	–4.7 (–7.7 to –1.6)	0.005

Data are mean±SD or median (Q1; Q3).
CAT, COPD Assessment Test; QOL-B, Quality of Life-Bronchiectasis.

with the number of telecare sessions performed with the respiratory physiotherapist. Furthermore, participant QOL improved significantly from baseline to study end.

The SIMEOX device is a bit complex to handle in contrast with devices such as Oscillatory-PEP; it is rather similar to a mechanical in-exsufflator or intrapulmonary percussive device.[21] The use of SIMEOX requires understanding of the functioning of the device (starting of the device, tube and interface connection and mechanism of action of the intrabronchial signal on airway secretions). Furthermore, several adaptations of the power setting are necessary to allow complete exhalation without obstructing the mouthpiece by tongue suction. To our knowledge, there are no similar reports of remote implementation of this type of respiratory device. In the field of non-invasive ventilation, two studies have shown that direct home initiation with specialised nurses adapting the settings remotely provided equivalent results to an inpatient setting; however, in those studies, the first session was done face to face with the nurse at home.[22 23]

Beyond the training phase (arbitrarily defined as the first 2 weeks after inclusion in the study), two-thirds of the participants performed ≥3 sessions/week continuously according to self-reported adherence in the diaries, and the median use for the whole group was almost 5 sessions/week considering the use recorded on the SIMEOX web application. Objective user adherence to ACTs has been little reported in previous studies.[7 19 24] This is why we wanted to compare the self-reported adherence to automatically recorded adherence on the web application. The advantage of an objective measure of adherence recorded online is that it allows the physiotherapist to perform telemonitoring and to better target the content of the telecare sessions.

The correlation between the number of telecare sessions performed and the number of SIMEOX sessions per week suggests that the physiotherapists adapted the frequency of telecare sessions if they perceived a lack of participant autonomy or difficulty handling the device, as well as the participant's wish to be followed up more regularly; this may have improved adherence for some participants. In contrast, we did not identify any criteria associated with non-adherence, and it seems that the general behaviour of participants towards their treatments did not predict the rates of SIMEOX adherence. This result should be interpreted with caution given the limited sample size. Recurrent exacerbations, hospitalisations or chronic colonisation with *Pseudomonas aeruginosa* could be factors associated with the use of ACTs.[3]

This study found improvements in CAT score, the SGRQ total score and some domains of the QOL-B questionnaire that were greater than the reported MCID for these outcome measures.[25] Of particular interest is that the combined SIMEOX+telecare strategy appeared to reduce participant burden. Of course, in the absence of a control group, these improvements should be interpreted with caution, but all participants were stable at inclusion, suggesting that a real improvement occurred over the study period. Furthermore, these results are consistent with the improvements found in patients with NCFB by Murray *et al* in a study of comparable duration and size,[26] and longer-term improvements found by Muñoz *et al*.[19] However, similarly to our results, those studies found no change in lung function.[19 26]

Several limitations to this pilot study need to be highlighted: first, it was not controlled, either regarding the ACT (SIMEOX vs another device/method) or the use of telecare (telecare vs face-to-face sessions). However, our overall objective was to test the feasibility of initiating and monitoring this innovative device completely by telecare before considering a large, randomised controlled trial. Second, the duration of the study was limited (3 months), which may have induced a 'honeymoon effect' among participants discovering an innovative technique; however, weekly adherence remained relatively stable throughout the duration of the study. Thirdly, although the participants were all naive to SIMEOX, as well as other instrumental techniques such as high frequency chest wall oscillation and high frequency intrapulmonary percussion (IPV), they were not necessarily naive to other ACTs, such as the active breathing cycle technique, autogenous drainage, or slow exhalation with the glottis open in the lateral position. However, we did not document their adherence prior to the study (number of weekly drainage sessions performed independently); we only included individuals who had limited access to physiotherapy sessions (<3/week). Previous adherence to ACT may be a key factor regarding feasibility and outcomes. Finally, the cost of the device is currently an obstacle to its widespread use. The demonstration of its efficacy by randomised trials will allow the generalisation of reimbursement by health insurance companies, which is the only way to facilitate the dissemination of a health innovation.

Conclusion

Adherence to and satisfaction with the SIMEOX implemented by telecare over 12 weeks was high in people with NCFB. This strategy could be clinically effective and efficient in medicoeconomic terms. The effects should be confirmed by a randomised controlled trial.

Acknowledgements Johanna ROBERTSON, Physiotherapist, PhD for language editing.

Contributors Conceptualisation: RH, J-CB, LM and SL. Methodology: J-CB and LM Investigation: RH, MM-E, MM, RA, HG, SL and EJ. Funding acquisition: LM. Project administration: EJ. Formal analysis: NA. Reporting of the study: all. J-CB had full access to all study data and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Funding This study was funded by Physio-Assist.

Competing interests J-CB, EJ, MM-E, RA and NA are salaried by the group AGIR à dom-ICADOM (French Homecare provider and CRO); LM is salaried by Physio-Assist. SJ, Hugues Gauchez, R Hamidfar have received personal fees from Physio-assist.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval The study was approved by an ethics committee (CPP Est IV, ID-RCB 2020-A02387-32) in accordance with the declaration of Helsinki and current French legislation. It was registered on ClinicalTrials.Gov (# NCT04742270).

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available on reasonable request. All the anonymised individual participant data collected during the trial are available on reasonable request (no end date).

ORCID iDs
Laurent Morin http://orcid.org/0000-0002-7406-4838
Jean-Christian Borel http://orcid.org/0000-0003-4140-6210

REFERENCES

1 O'Donnell AE. Bronchiectasis. *Chest* 2008;134:815–23.
2 Polverino E, Goeminne PC, McDonnell MJ, *et al*. European respiratory society guidelines for the management of adult Bronchiectasis. *Eur Respir J* 2017;50:1700629.
3 Basavaraj A, Choate R, Addrizzo-Harris D, *et al*. Airway clearance techniques in Bronchiectasis: analysis from the United States Bronchiectasis and non-TB mycobacteria research Registry. *Chest* 2020;158:1376–84.
4 Chang AB, Boyd J, Bell L, *et al*. Clinical and research priorities for children and young people with Bronchiectasis: an international roadmap. *ERJ Open Res* 2021;7:00122-2021.
5 Cox NS, McDonald CF, Mahal A, *et al*. Telerehabilitation for chronic respiratory disease: a randomised controlled equivalence trial. *Thorax* 2022;77:643–51.
6 Vasilopoulou M, Papaioannou AI, Kaltsakas G, *et al*. Home-based maintenance TELE-rehabilitation reduces the risk for acute exacerbations of COPD, Hospitalisations and emergency Department visits. *Eur Respir J* 2017;49:1602129.
7 Alghamdi SM, Alsulayyim AS, Alasmari AM, *et al*. Oscillatory positive Expiratory pressure therapy in COPD (O-COPD): a randomised controlled trial. *Thorax* 2023;78:136–43.
8 Alghamdi SM, Rajah AMA, Aldabayan YS, *et al*. Chronic obstructive pulmonary disease patients' acceptance in E-health clinical trials. *Int J Environ Res Public Health* 2021;18:5230.
9 Schmidt H, Toth M, Kappler-Schorn C, *et al*. Short-term effects of a novel bronchial drainage device: A pilot cohort study in subjects with cystic fibrosis. *Health Sci Rep* 2022;5:e812.
10 Walicka-Serzysko K, Postek M, Jeneralska N, *et al*. The effects of the addition of a new airway clearance device to chest Physiotherapy in children with cystic fibrosis pulmonary exacerbations. *J Mother Child* 2021;24:16–24.
11 Sands D, Walicka-Serzysko K, Milczewska J, *et al*. Efficacy of the Simeox airway clearance technology in the Homecare treatment of children with clinically stable cystic fibrosis: A randomized controlled trial. *Children (Basel)* 2023;10:204.
12 Wanger J, Clausen JL, Coates A, *et al*. Standardisation of the measurement of lung volumes. *Eur Respir J* 2005;26:511–22.
13 Jones PW, Quirk FH, Baveystock CM, *et al*. A self-complete measure of health status for chronic airflow limitation. The St. George's respiratory questionnaire. *Am Rev Respir Dis* 1992;145:1321–7.
14 Murray MP, Turnbull K, MacQuarrie S, *et al*. Validation of the Leicester cough questionnaire in non-cystic fibrosis Bronchiectasis. *European Respiratory Journal* 2009;34:125–31.
15 Finch S, Laska IF, Abo-Leyah H, *et al*. Validation of the COPD assessment test (CAT) as an outcome measure in Bronchiectasis. *Chest* 2020;157:815–23.
16 Quittner AL, O'Donnell AE, Salathe MA, *et al*. Quality of life questionnaire-Bronchiectasis: final Psychometric analyses and determination of minimal important difference scores. *Thorax* 2015;70:12–20.
17 McCullough AR, Tunney MM, Stuart Elborn J, *et al*. Predictors of adherence to treatment in Bronchiectasis. *Respir Med* 2015;109:838–45.
18 Hill AT, Haworth CS, Aliberti S, *et al*. Pulmonary exacerbation in adults with Bronchiectasis: a consensus definition for clinical research. *Eur Respir J* 2017;49:1700051.
19 Muñoz G, de Gracia J, Buxó M, *et al*. Long-term benefits of airway clearance in Bronchiectasis: a randomised placebo-controlled trial. *Eur Respir J* 2018;51:1701926.
20 Wilson EB. Probable inference, the law of succession, and statistical inference. *Journal of the American Statistical Association* 1927;22:209–12.
21 Belli S, Prince I, Savio G, *et al*. Airway clearance techniques: the right choice for the right patient. *Front Med (Lausanne)* 2021;8:544826.
22 Duiverman ML, Vonk JM, Bladder G, *et al*. Home initiation of chronic non-invasive ventilation in COPD patients with chronic Hypercapnic respiratory failure: a randomised controlled trial. *Thorax* 2020;75:244–52.
23 van den Biggelaar RJM, Hazenberg A, Cobben NAM, *et al*. A randomized trial of initiation of chronic noninvasive mechanical ventilation at home vs in-hospital in patients with neuromuscular disease and Thoracic cage disorder: the Dutch homerun trial. *Chest* 2020;158:2493–501.
24 Thompson CS, Harrison S, Ashley J, *et al*. Randomised crossover study of the flutter device and the active cycle of breathing technique in non-cystic fibrosis Bronchiectasis. *Thorax* 2002;57:446–8.
25 McLeese RH, Spinou A, Alfahl Z, *et al*. Psychometrics of health-related quality of life questionnaires in Bronchiectasis: a systematic review and meta-analysis. *Eur Respir J* 2021;58:2100025.
26 Murray MP, Pentland JL, Hill AT. A randomised crossover trial of chest Physiotherapy in non-cystic fibrosis Bronchiectasis. *Eur Respir J* 2009;34:1086–92.