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A qualitative needs assessment of people with cystic fibrosis and research coordinators to inform future clinical trials incorporating home spirometry as an endpoint

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Background: Home spirometry holds promise as a primary endpoint for clinical trials. Qualitative needs assessments describing the practices and perspectives of people with cystic fibrosis (PwCF), caregivers of PwCF, and research coordinators (RCs) regarding home spirometry can inform strategies for incorporating home spirometry into clinical trials.
Methods: We conducted a series of focus groups that engaged PwCF, caregivers, or RCs (separately), led by an experienced facilitator and conducted via videoconference. PwCF aged 14 and older and caregivers with experience performing home spirometry were recruited through the Cystic Fibrosis Foundation (CFF) Community Voice. RCs with experience coaching home spirometry were recruited through the CFF Therapeutics Development Network from sites participating in the PROMISE study. Participants provided informed consent and completed an online survey before the focus group to describe their demographic characteristics and home spirometry devices. Focus groups elicited current experiences and barriers to and facilitators of home spirometry across six target areas, followed by discussion and prioritization. Target areas for PwCF and caregivers included research incentives, burden of procedures, reminders, remote coaching, training, and spirometry results. Target areas for RCs included participant and RC training, remote coaching, monitoring progress, participant engagement, and institution-specific issues. Qualitative analyses followed the deductive approach of template analysis [1]. Common themes identified in each session were reviewed in all PwCF or RC sessions to identify areas of consensus, which were used to formulate recommendations for future clinical trials.
Results: From September to November 2021, 27 PwCF and six caregivers stratified according to age and role (teens, adults aged 18–39, adults aged ≥40, caregivers) participated in seven sessions, and 24 RCs participated in five sessions. Groups identified barriers to and facilitators of use of home spirometry. Although most PwCF and caregivers found home spirometry convenient, many experienced technical barriers, reported a learning curve to home measurement, and expressed uncertainty about the quality and reliability of measurements. Major barriers that RCs identified involved tailoring participant training to individual needs, scheduling remote coaching, and performing effective coaching remotely. Participants offered age-specific recommendations in key domains: training materials and procedures (for PwCF and RCs), remote coaching, monitoring progress, maintaining engagement, and other areas, including differences in the conduct and interpretation of research versus clinical and home versus office spirometry.
Conclusions: Recommendations from this qualitative needs assessment of PwCF, caregivers, and RCs regarding home spirometry in the research setting have been incorporated into the design of OUTREACH, a CFF-funded, multicenter, prospective study of the accuracy, variability, feasibility, and acceptability of home spirometry as a clinical trial endpoint. Our results can also help inform the design of future remote clinical trials.
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Reference

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Chest computed tomography assessment to monitor cystic fibrosis structural lung disease progression in bronchiectasis during late childhood and adolescence

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Background: Cystic fibrosis (CF) lung disease is characterized by progressive bronchiectasis and airway wall thickening (AWT) starting in early childhood. Using the Perth-Rotterdam Annotated Grid Morphometric Analysis for CF (PRAGMA-CF), the follow-up of the Australasian Cystic Fibrosis Bronchoalveolar Lavage (ACFBAL) study (CF-FAB study) showed that the extent of lung disease in young children with CF (CwCF) was an important risk factor for progressive structural lung disease in adolescence [1]. Recently, a fully automated method was developed and validated to measure airway and artery (AA) dimensions for sensitive detection of bronchiectasis and AWT. The aim of our study was to monitor progression of bronchiectasis and AWT over late childhood into adolescence in a longitudinal follow-up study (CF-FAB) of the ACFBAL cohort using the AA method and PRAGMA-CF.
Methods: CF-FAB enrolled CwCF who completed the ACFBAL study in Australia and New Zealand. Computed tomography (CT) scans were obtained at two time points approximately 18 months apart. CT scans were analyzed using manual PRAGMA-CF and the automated AA method (LungQ-AA, v2.1.0, Thirona, the Netherlands). PRAGMA-CF computes the volume fraction of the following structural lung components on the inspiratory CT scan: % bronchiectasis, mucus plugging (%MP), %AWT, and atelectasis (%Atelec). The composite score %Disease (%Dis) is defined as the sum of % bronchiectasis, %MP, and %AWT. LungQ-AA automatically segments the bronchial tree and identifies segmental (G_0) and distal ($G_{1\text{-}13}$) airway generation. For each identified airway, the following dimensions are quantified: diameters of airway outer edge (A_{out}), airway lumen wall (A_{lumen}), artery (A) and airway wall thickness (A_{wt}), and AA-ratios: A_{out}/A, A_{lumen}/A, and A_{wt}/A. Bronchiectasis was defined as A_{out}/A greater than 1.1 or A_{lumen}/A greater than 0.8 and AWT as A_{wt}/A greater than 0.3. Mixed-effects models were used for analysis.
Results: One hundred twenty CwCF with a mean baseline age of 12.8 ± 1.6 were enrolled, and 115 baseline and 110 follow-up CT scans were obtained with a mean interval of 26 months. Coded CT scans were manually scored in random order using PRAGMA-CF. %Dis increased by 0.44% per year ($p = 0.03$) and % bronchiectasis increased by 0.38% per year ($p = 0.01$), respectively. No significant progression was observed for %AWT ($p = 0.98$). One hundred eighty-five CT scans from 100 CwCF could be analyzed using LungQ-AA (39 excluded because slice thickness was greater than 1.5 mm and 1 for reason unknown). On baseline CT scans (n = 96), 30,792 AA pairs and on follow-up CT scans (n = 89) 32,024 AA pairs were detected from G_1 to G_{13} and analyzed; significant progressions were found in A_{out}/A and