primary studies - published RCT

Effect of Expiratory Muscle Training on Peak Cough Flow in Children and Adolescents with Cystic Fibrosis: A Randomized Controlled Trial.

Code: PM33421333 **Year:** 2021 **Date:** **Author:** Emirza C

Study design (if review, criteria of inclusion for studies)

Dual-site, two-arm randomised pilot trial.

Participants

Fifty pwCF (â‰¥10 years, forced expiratory volume in 1 s (FEV(1)) â‰¥40% predicted), stable on Elexacaftor/Tezacaftor/Ivacaftor

Interventions

48 patients were randomly assigned (1:1 with minimisation) to daily ExACT (stopping all other airway clearance techniques) or usual care (UC)

Outcome measures

Feasibility was measured by recruitment, retention and adherence against preset progression criteria. Key measures of safety and signals of efficacy included spirometry (FEV(1)), lung clearance index (LCI(2.5)), pulmonary exacerbations, physical activity, treatment burden and quality of life across 28 days. Qualitative interview data and preliminary health economic data were also collected.

Main results

ExACT was safe over 28 days, measured by change in LCI(2.5) (ExACT -0.1 (0.6) vs UC 0.2 (0.8), mean (SD)) and FEV(1) (ExACT +2.1 (6.6) vs UC -0.8 (5.5), % predicted mean (SD)). Relative (ExACT/UC) differences of 0.97 (0.92, 1.02) for LCI(2.5) and absolute differences (ExACT-UC) of 3.2 (-0.6, 6.9) % predicted for FEV(1) suggest potential intervention efficacy. Few adverse events were reported; none serious. Recruitment and retention data suggest progression to a definitive trial, with 48/117 (41% of approached) randomised, 45/48 (92%) completing the study and a 60% overall adherence rate.

Authors' conclusions

Trial showed ExACT to be a safe, acceptable and feasible intervention for pwCF. These data support advancement to a definitive, longer-term, multisite trial evaluating the safety, efficacy and cost-effectiveness of ExACT, following minor refinement.

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See also

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Keywords

exercise; non pharmacological intervention - devices OR physiotherapy; Airway clearance technique; forced expiration technique; Active Cycle of Breathing Technique -ACBT-;