primary studies - published RCT

Self-management intervention to reduce pulmonary exacerbations by supporting treatment adherence in adults with cystic fibrosis: a randomised controlled trial.

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

Randomized controlled trial

Participants

Adults with CF (aged â‰¥16 years; 19 UK centres)

Interventions

A multi-component (complex) self-management intervention to support adherence would reduce exacerbation rates over 12 months. Patients were randomised to the intervention (data-logging nebulisers, a digital platform and behavioural change sessions with trained clinical interventionists) or usual care (data-logging nebulisers).

Outcome measures

Pulmonary exacerbations (primary outcome), objectively measured adherence, body mass index (BMI), lung function (FEV(1)) and Cystic Fibrosis Questionnaire-Revised (CFQ-R). Analyses were by intent to treat over 12 months.

Main results

Among intervention (n=304) and usual care (n=303) participants (51% female, median age 31 years), 88% completed 12-month follow-up. Mean exacerbation rate was 1.63/year with intervention and 1.77/year with usual care (adjusted ratio 0.96; 95% CI 0.83 to 1.12; p=0.64). Adjusted mean differences (95%â€‰CI) were in favour of the intervention versus usual care for objectively measured adherence (9.5% (8.6% to 10.4%)) and BMI (0.3 (0.1 to 0.6) kg/m(2)), with no difference for %FEV(1) (1.4 (-0.2 to 3.0)). Seven CFQ-R subscales showed no between-group difference, but treatment burden reduced for the intervention (3.9 (1.2 to 6.7) points). No intervention-related serious adverse events occurred.

Authors' conclusions

While pulmonary exacerbations and FEV(1) did not show statistically significant differences, the intervention achieved higher objectively measured adherence versus usual care. The adherence difference might be inadequate to influence exacerbations, though higher BMI and lower perceived CF treatment burden were observed.

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See also

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Keywords

Self-Management; Organization; non pharmacological intervention - psyco-soc-edu-org; Inhalation OR nebulised; nebuliser; Behavioural interventions;