primary studies - published RCT

Supporting medication adherence for adults with cystic fibrosis: a randomised feasibility study.

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

Pilot, open-label, parallel-group RCT

Participants

People with cystic fibrosis (PWCF) at two Cystic Fibrosis (CF) units. Eligible: aged 16 or older; on the CF registry. Ineligible: post-lung transplant or on the active list; unable to consent; using dry powder inhalers.

Interventions

Central randomisation on a 1:1 allocation to: (1) intervention, linking nebuliser use with data recording and transfer capability to a software platform, and behavioural strategies to support self-management delivered by trained interventionists (n = 32); or, (2) control, typically face-to-face meetings every 3 months with CF team (n = 32).

Outcome measures

RCT feasibility defined as: recruitment of >/= 48 participants (75% of target) in four months (pilot primary outcome); valid exacerbation data available for >/= 85% of those randomised (future RCT primary outcome); change in % medication adherence; FEV1 percent predicted (key secondaries in future RCT); and perceptions of trial procedures, in semi-structured interviews with intervention (n = 14) and control (n = 5) participants, interventionists (n = 3) and CF team members (n = 5).

Main results

The pilot trial recruited to target, randomising 33 to intervention and 31 to control in the four-month period, June-September 2016. At study completion (30th April 2017), 60 (94%; Intervention = 32, Control =28) participants contributed good quality exacerbation data (intervention: 35 exacerbations; control: 25 exacerbation). The mean change in adherence and baseline-adjusted FEV1 percent predicted were higher in the intervention arm by 10% (95% CI: -5.2 to 25.2) and 5% (95% CI -2 to 12%) respectively. Five serious adverse events occurred, none related to the intervention. The mean change in adherence was 10% (95% CI: -5.2 to 25.2), greater in the intervention arm. Interventionists delivered insufficient numbers of review sessions due to concentration on participant recruitment. This left interventionists insufficient time for key intervention procedures. A total of 10 key changes that were made to RCT procedures are summarised.

Authors' conclusions

With improved research processes and lower monthly participant recruitment targets, a full-scale trial is feasible.

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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;