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CFHealthHub: Complex intervention to support adherence to treatment in adults with cystic fibrosis: external pilot trial

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Objectives:

Test processes for / feasibility of a full-scale RCT evaluating CFHealthHub (CFHH) a theory-based complex intervention; test the acceptability of CFHH.

Methods:

Design: Non-blinded, pilot, parallel-group RCT (ISRCTN13076797).

Participants: People with CF at two units. Eligible: aged 16+; on UK registry; willing to take inhaled mucolytics and antibiotics via a chipped nebuliser. Those post lung transplant or on the active lung transplant list, unable to give informed consent or using dry powder inhalers are excluded.

Interventions: (1) collection / feedback of adherence data via chipped nebuliser and software platform, with strategies to empower self-management delivered online and in six face-to-face meetings over 5m with trained interventionists (n=32); (2) usual care (n=32).

Primary outcome: Feasibility of RCT defined as: (1) recruitment of >48 participants (75% of target) in four months; (2) valid primary outcome data for >85% of those randomised. Key clinical outcome: number of pulmonary exacerbations in a five-month period (Fuchs criteria).

Randomisation: 1:1 allocation via centralised web-based randomisation system, stratified by centre and days on intravenous antibiotics in previous year

Results:

Between 13/06/16 and 30/09/16, 64 participants were randomised to CFHH (n=31) or control (n=33) mean rate 4 per week. One unexpected serious adverse event was unrelated to CFHH. Retention rates, intervention acceptability and process data will be available by 31/03/2017.

Conclusion:

Recruitment to a full-scale trial is feasible.