The University Of Sheffield.

CFHealthHub
ACtiF

# CFHealthHub RCT

Development and evaluation of an intervention to support Adherence to treatment in adults with CF

# PWCF and exacerbations due to poor adherence

- £30 million is spent annually on inhaled therapy but average adherence only 36%
- PWCF who collect <50% of their medication cost the healthcare system significantly more than PWCF who collect more than 80%
- We have designed an intervention to help adult PWCF see how much treatment they use
- Dose-counting nebulisers (eTrack) will be used to collect data and display it in CFHealthHub (CFHH)
- Modules within CFHH which teach PWCF how to build successful treatment habits
- We will conduct this Pilot Feasibility study to determine whether a larger scale RCT is possible

# Design

Mixed-methods study comprising of:

- Quantitative component: parallel group, open labelled, external RCT;
- Qualitative component: analysis of audio-recorded consultations and interviews.

# SITES

29 centres participating in England, Ireland, Scotland and

Wales

566 participants to be recruited across all 20 sites

Local targets between 20 and 35 participants

# Significant Milestones

- ✓ REC approval granted 2nd March 2017
- ✓ HRA approval granted 3rd April 2017
- ✓ mNCA under review by each local R&D team
- ✓ Local governance checks underway
- ✓ Interventionists formally appointed (n=27)

# Aims

The main aims of the study are to determine:

- The efficacy of CFHealthHub – does it offer any additional benefit over usual care to patients with CF?
- test the fidelity and acceptibility of the intervention via a process evaluation – do patients and clinicians deem the intervention acceptable and how was it delivered in real life?

# Objectives
## Clinical Outcomes

## Primary clinical outcome

- The number of pulmonary exacerbations in 12 month month post-baseline follow-up
- Treatment with IV antibiotics together with ONE of the following:

- 1. change in sputum;
- 2. new or increased hemoptysis;
- 3. increased cough;
- 4. increased dyspnea;
- 5. malaise, fatigue, or lethargy;
- 6. temperature above 38 °C;
- 7. anorexia or weight loss;
- 8. sinus pain or tenderness;
- 9. change in sinus discharge.
- 10. change in physical examination of the chest, derived from notes by site staff.
- 11. decrease in pulmonary function by 10 percent or more from a previously recorded value, derived from notes by site staff; or,
- 12. radiographic changes indicative of pulmonary infection, derived from notes by site staff.

# Objectives
## 4. Clinical Outcomes

**Secondary outcomes** Participant reported outcome measures (participant booklet)

1. EQ5D5L
2. **P**atient **A**ctivation **M**easure -13
3. **C**onfusion, **H**ubbub **A**nd **O**rder **S**cale -6
4. **S**elf-**R**eported **B**ehavioural **A**utomaticity **I**ndex
5. **C**ystic **F**ibrosis **Q**uestionnaire-**R**evised
6. **P**atient **H**ealth **Q**uestionnaire depression scale -8
7. **M**edication **A**dherence **D**ata -3
8. **G**eneral **A**nxiety **D**isorder -7
9. **C**apability **O**pportunity **M**otivation –**B**eliefs about **M**edicines **Q**uestionnaire

Subjective medical adherence question

# Objectives
## 4. Clinical Outcomes

**Secondary outcomes**

1. Other clinical measures

- BMI
- FEV1/FVC

2. Adherence data to evaluate adherence to prescribed medication

3. Resource use form – Health Economic

# Design

Individually randomised to

1. **Usual Care (control)**
2. **CFHH (intervention)**
   - Participants viewing adherence charts in CFHH
   - Face to face sessions with the interventionists and ability to use CFHH alone
   - Setting of goals and targets within CFHH
   - **Study participation from consent till 30/6/19**

# Eligibility criteria

## Inclusion criteria

1. Diagnosed with CF and with data within the CF registry
2. Aged 16 years and above
3. Taking inhaled mucolytics or antibiotics via a chipped nebuliser (e.g. eTrack) or able and willing to take via eTrack

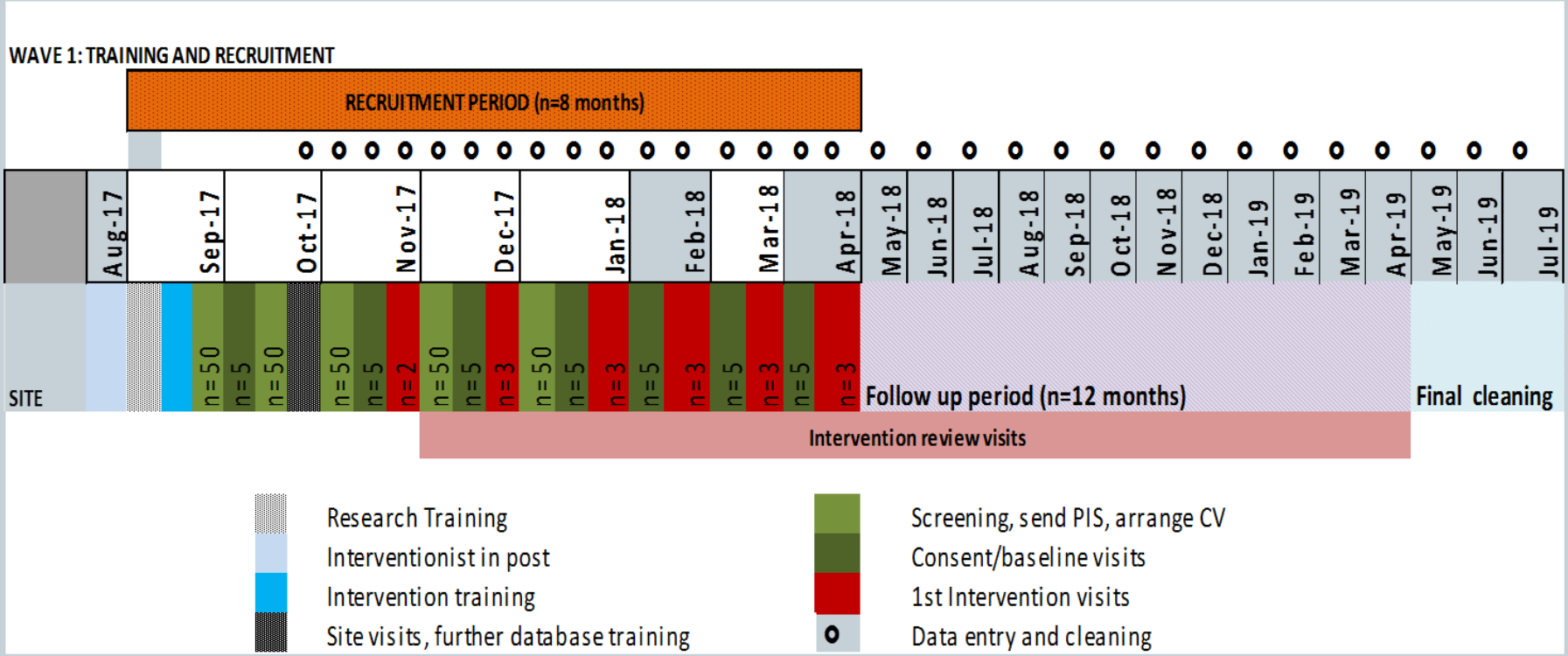
# Eligibility criteria

## Exclusion Criteria

1. Post-lung transplant
2. People on the active lung transplant list
3. Patients receiving palliative care
4. Lacking in capacity to give informed consent
5. Using dry powder devices to take antibiotics or mucolytics

# Recruitment starts

Recruitment starts in waves: September, October, November



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