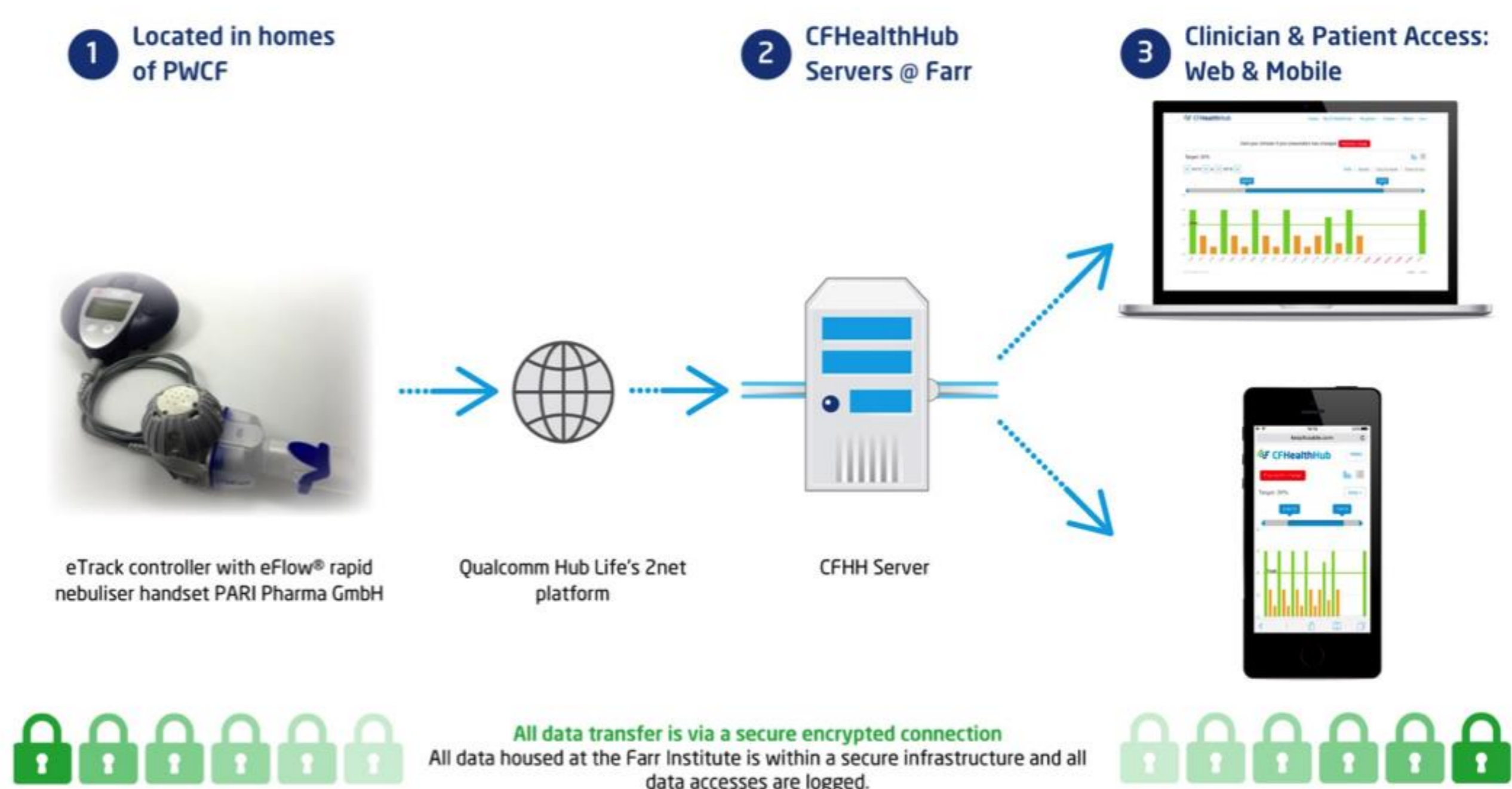


D. Hind<sup>1</sup>, J. Ainsworth<sup>2</sup>, M.A. Arden<sup>3</sup>, H Cantrill<sup>1</sup>, S. Drabble<sup>4</sup>, M. Hutchings<sup>5</sup>, S.M. Keating<sup>1</sup>, C. Maguire<sup>1</sup>, A. O'Cathain<sup>4</sup>, A. Scott<sup>1</sup>, P. Whelan<sup>2</sup>, M. Wildman<sup>5</sup> for the CFHealthHub group.

<sup>1</sup>University of Sheffield, Sheffield Clinical Trials Research Unit, Sheffield, United Kingdom, <sup>2</sup>University of Manchester, Health e-Research Centre, Manchester, United Kingdom, <sup>3</sup>Sheffield Hallam University, Sheffield, United Kingdom, <sup>4</sup>University of Sheffield, School of Health and Related Research (SchARR), Sheffield, United Kingdom, <sup>5</sup>Sheffield Teaching Hospitals NHS Foundation Trust, Sheffield, United Kingdom.

## Co-defining technical requirements for the digital platform

CFHealthHub



### Objectives:

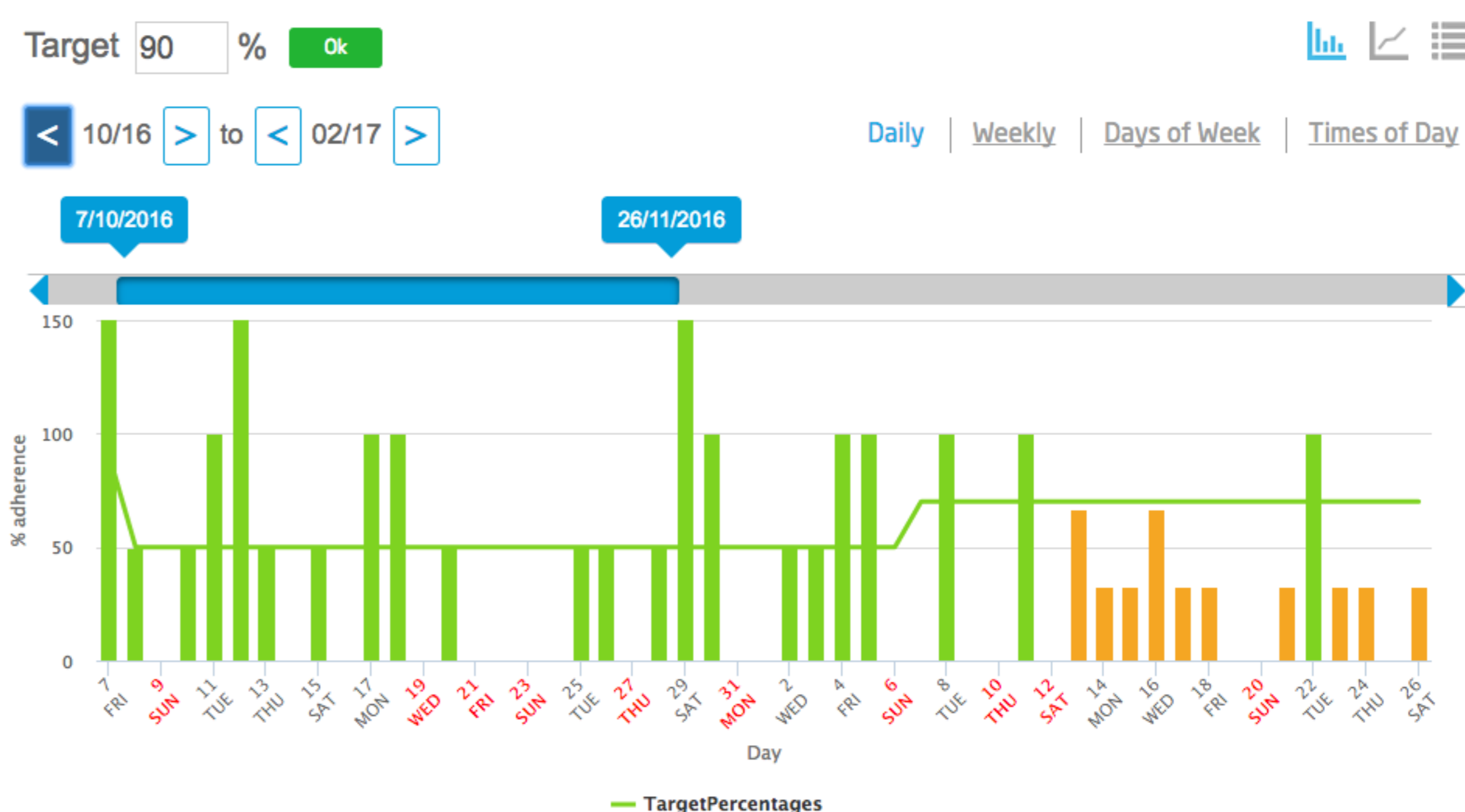
- Co-define technical requirements for a digital platform, including: a website and mobile apps, that can be widely deployed to support adherence to nebuliser treatment in people with CF.
- Test the feasibility of using eTrack/Qualcomm hub technology to provide objective nebuliser adherence data
- Collect participant feedback to co-develop the digital platform and an associated behaviour change intervention through rapid cycle development.
- Test processes for / feasibility of a full-scale RCT and the acceptability of the intervention.

### Methods:

- A co-production of care approach, combined with agile software methodologies (using user-driven iterative prototyping) to identify the requirements for CFHealthHub
  - New versions of digital platform released every 6 weeks over an 18-month period.
  - 30 People With CF (PWCF) and 10 clinicians provided feedback across 12 versions of the platform.
  - Technical scoping of the CF medical device marketplace and analysis of requirements for widespread deployment of CFHealthHub across UK CF centres.
- Intervention development / feasibility study
  - Semi-structured interviews with PWCF (n=5) who used a beta version of the CFHH website for one month.
  - Semi-structured interviews (n=18) and 'thinkaloud' sessions (n=6) with 22 PWCF on the acceptability of the CFHH content and interactions with the physiotherapist
  - Semi-structured interviews (n=25 with intervention and control patients, interventionists and MDT members about acceptability of the intervention and trial.
- Parallel-group pilot, RCT (ISRCTN13076797).
  - Participants: PWCF 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.

CFHealthHub

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### Results:

Technical scoping showed that a digital platform needed to support inputs from multiple (potentially commercially-competing) medical devices. Technical analysis of existing systems highlighted that compliance with emergent interoperability standards was needed to integrate a digital platform into routine care. The CFHH digital platform and intervention visits were acceptable to patients. Issues related to the appearance and content of the website, problems with data transfer, resulted in changes.

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. The intervention was acceptable to patients and interventionists. Patients found the graphical feedback useful. Improvements around the talking heads videos, technical issues and patient engagement are being implemented for the RCT. Retention rates, intervention acceptability and process data will be available after Pilot study data analysis.

### Conclusions:

- We have developed a complex intervention to support medication adherence in PWCF.
- It includes data displays and a website.
- The complex intervention is useable by, acceptable to, and appropriate for PWCF.
- Co-production of care and agile software methodologies were key to meeting the requirements of PWCF and clinicians.
- The software is flexible, compliant with standards, and works on multiple devices and systems.
- Participant recruitment to a full-scale trial is feasible.

