A4933/P144 Patient-reported Monitoring of Symptoms and Spirometry via the patientMpower Platform in Idiopathic Pulmonary Fibrosis

Authors: S Walsh[1], T Cahill[1], C Edwards[2], E Costello[2], J Walsh[1], A-M Russell[3], A O'Regan[1].
[1]Galway University Hospital, Newcastle Road, Galway H91 YR71, Ireland, [2]patientMpower Ltd., The Digital Depot, Thomas Street, Dublin D08 TCV4, Ireland, [3]Royal Brompton Hospital, Sydney Street, London SW3, UK.

patientMpower Pulmonary Fibrosis Care Kit

RATIONALE

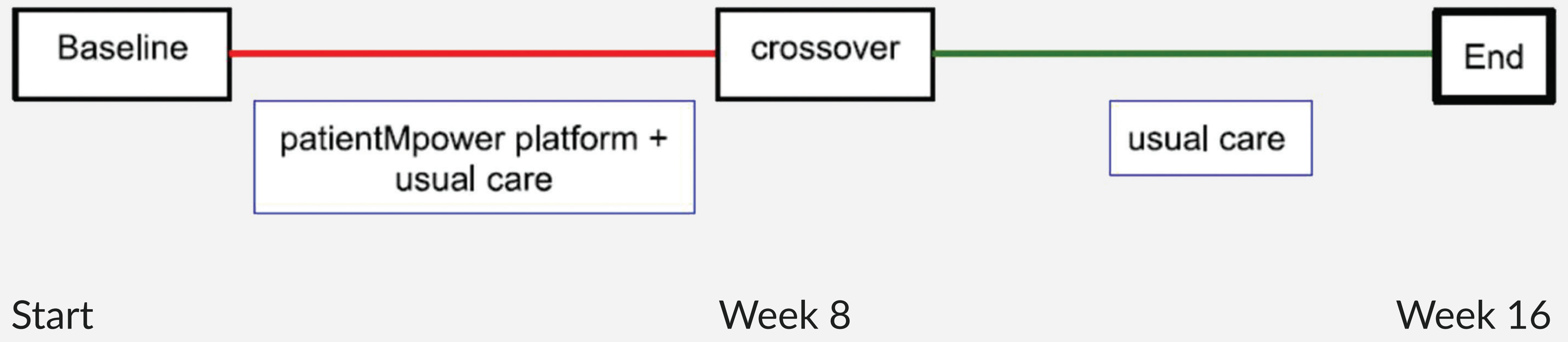
Idiopathic pulmonary fibrosis (IPF) is associated with progressive worsening of pulmonary function [reflected as decline of forced vital capacity (FVC)] with serious limitation of physical activities and quality of life.

The patientMpower (pMp) platform is an electronic health journal developed for IPF. It enables patients to record medication adherence, activity, objective (e.g. FVC) and subjective (e.g. dyspnea) measurements & health outcomes. pMp is downloaded as an app to the patient's mobile phone/device. pMp can connect wirelessly to a spirometer to allow longitudinal collection of patient-measured FVC.

METHODS

Prospective, pilot-scale, open-label, single-centre, usual care-controlled, fixed order crossover observational study (2 x 8 weeks) (www.clinicaltrials.gov NCT 03104322). Planned sample size = 8.

Study Design:



Entry criteria:
Diagnosis of IPF (multidisciplinary team confirmed), age ≥ 40, owns smartphone/tablet, written informed consent, no recent exacerbation/addition of antifibrotic therapy. No changes to usual healthcare.

Recruitment and onboarding: IPF outpatients attending specialist ILD clinic invited to participate. pMp installed & spirometer paired with patients' smartphone/tablet at clinic. Spirobank Smart spirometer (MIR, Rome, Italy; www.spirometry.com) supplied.

Measurements: Patients asked to use pMp daily for ≥ 8 weeks (period 1). FVC (seated: 1/day), dyspnea [modified Medical Research Council (mMRC)], medication adherence, PROM (1/week). Patient (17-point questionnaire) & healthcare professional (6-point questionnaire) opinion sought at week 8. Followed by 8 weeks usual care (period 2). FVC, mMRC, 6-minute walking distance, PROM assessed at clinic at baseline, week 8 & week 16.

Disposition of patients:
Eight patients expressed interest; 7 participated and provided spirometry data. Only 2 (29%) recorded PROM or dyspnea data on pMp. 4 patients (57%) provided opinion on utility and acceptability.

RESULTS

Baseline demographics:

Total patients (n, %)	7 (100%)
Male/female	6/1
Age (years, mean, range)	69 (range 57-79)
Clinic observed FVC (L, mean, range)	2.93 L (range 2.43-3.91)
Clinic observed predicted FVC (%, mean, range)	74% (66-83)
6-minute walking distance (m, mean, range)	508 (200-675)
Clinic observed mMRC [score (number of patients)]	1 (3) 2 (1) 3 (2)
patient-reported FVC1 (L; mean, range)	2.40 L (range 1.51-3.54)
Time from diagnosis (years, mean, range)	2.4 (range 0.5 to 5.5)
Antifibrotic therapy [type (number of patients)]	none (1) pirfenidone (5) nintedanib (1)

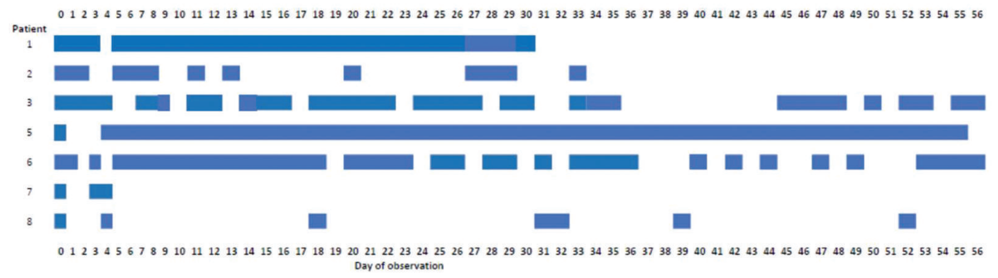
[1]Mean of first seven days. All patients were Caucasian.

Usage of pMp:
pMp used for mean 30 days (range 3-52) during the 56-day pMp observation period.

Home spirometry recorded for mean of 26 days (range 3-52). 4/7 patients recorded spirometry on ≥30 days.

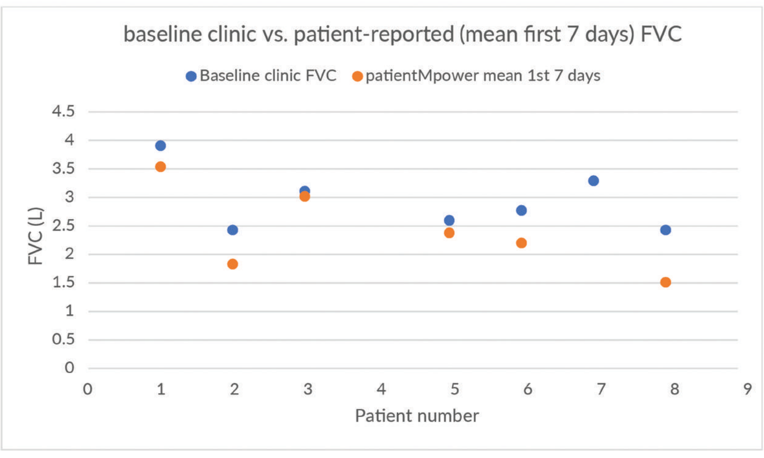
mMRC, medicines adherence or PROM not regularly reported on pMp (despite weekly prompts to record PROM).

Time pattern of spirometry recording per patient (Each cell represents a day on which spirometry was recorded)



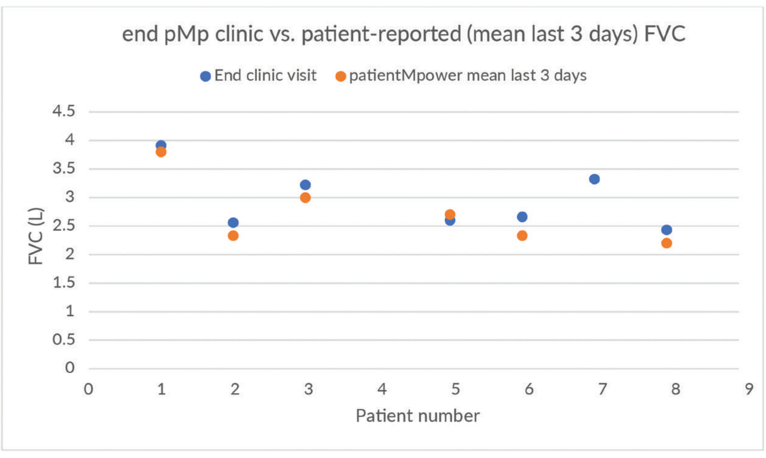
FVC (clinic vs. patient-reported)
Clinic-measured FVC did not decrease significantly over 16 weeks. At baseline, patient-reported FVC was usually lower than clinic FVC but by week 8, there was close agreement between patient-reported and clinic FVC.

Baseline clinic versus patient-reported FVC (per patient):



Insufficient patient-reported FVC data for patient 7

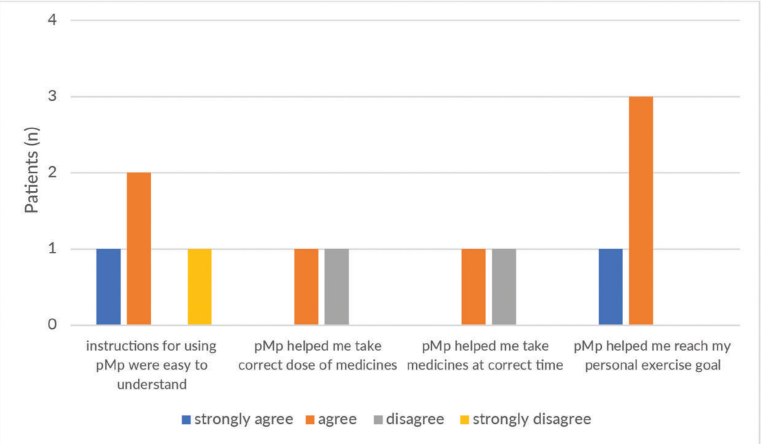
Week 8 clinic versus patient-reported FVC (per patient):

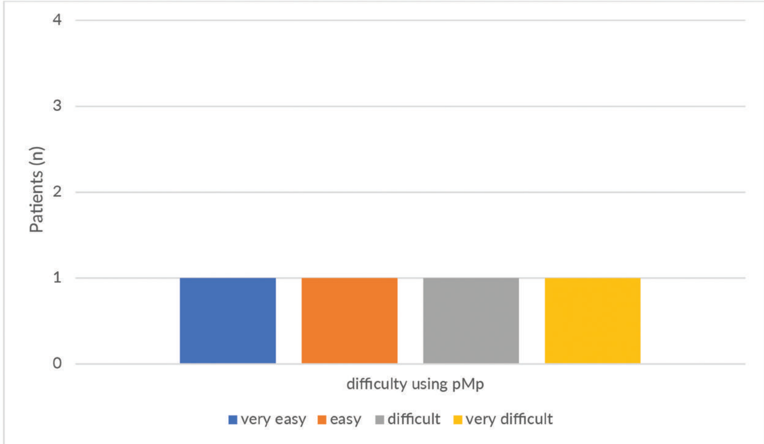


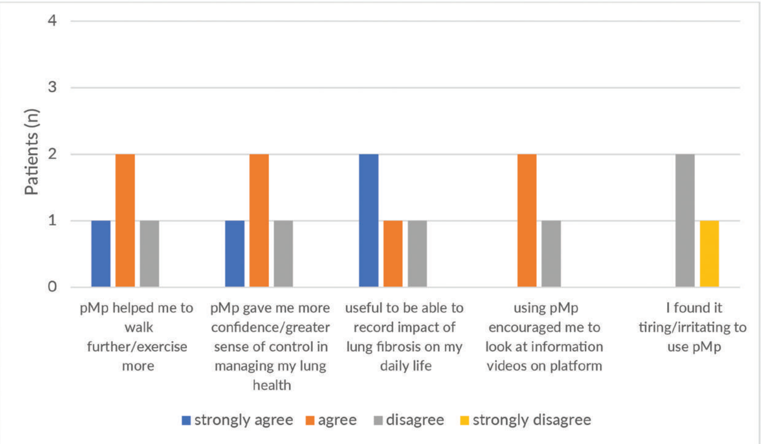
Insufficient patient-reported FVC data for patient 7

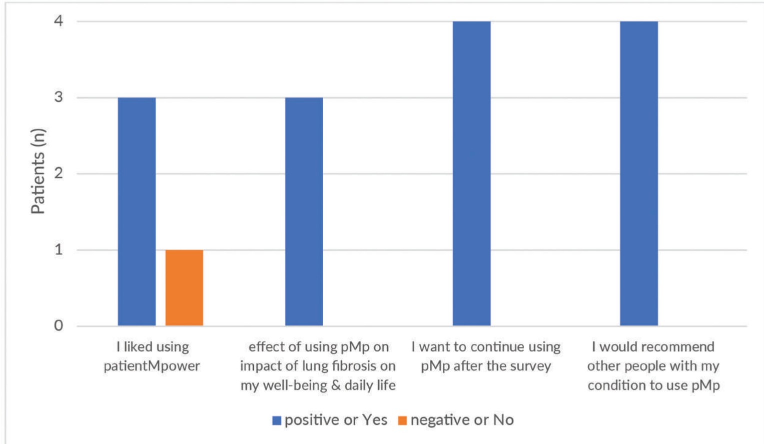
Questionaire responses at week 8
4 patients (57%) provided feedback at median 78 days (range 78-82). Responses were broadly positive (illustrated in four charts below). All wanted to continue using pMp after the study and would recommend it to others. 2/4 respondents reported difficulty in using pMp.

Healthcare professional response only provided for one patient (number 7). Opinion was that pMp was not useful for this patient. Patient stopped using pMp after 5 days and expressed negative opinions.



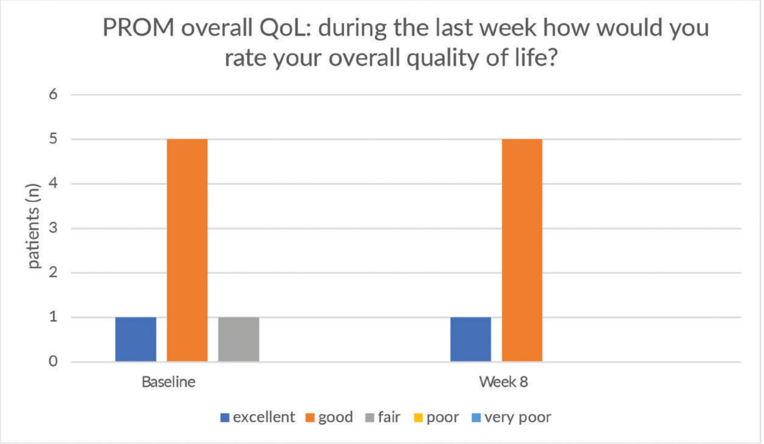




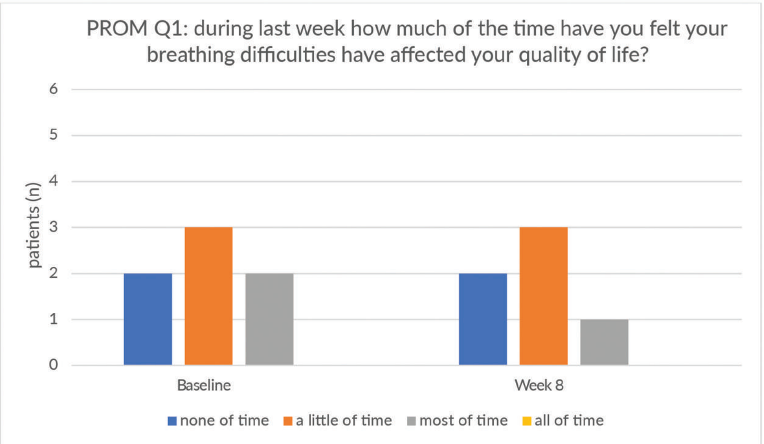


PROM responses (at clinic):
Little change in the overall quality of life scores in this time period. The patient reporting quality of life as "fair" at baseline reported as "good" at week 8.

PROM (clinic-measured) overall quality of life at baseline versus week 8:



PROM (clinic measured) Q1: How have breathing difficulties affected your quality of life?



CONCLUSIONS

Patients with established IPF attending a specialist ILD clinic are willing and able to use an electronic health journal to record data, symptoms and outcomes. Age is not a barrier to this approach.

The patientMpower platform (pMp) is acceptable and feasible to some patients with IPF (at least 4/7 in this study) and all who provided a response wished to continue using pMp after the study and would recommend it to other people with the same lung condition. However, one other patient stopped using pMp after five days and expressed negative opinions.

Patients with IPF appear willing to record home spirometry regularly without prompting which suggests they are interested in monitoring their lung function. There was close agreement between home spirometry and clinic observed FVC values by week 8.

The relevance to patients of recording medicines adherence and symptom scores (e.g. dyspnea, PROM) on pMp is less clear. Consideration should be given to additional use of prompts to improve frequency of recording these measures and broaden the information collected.

This small study suggests that the patientMpower platform is feasible and acceptable to some patients with IPF to use as an electronic health journal to record home spirometry over an 8-week observation period as part of outpatient care at a specialist ILD clinic. This approach may provide a mechanism for early identification of exacerbations or accelerated decline in lung function which may be important in future management plans.

We would like to thank all of the patients who took part in this study.

Commercial support & relevant financial interests:
Study funded by patientMpower Ltd. and Health Service Executive of Ireland Quality Innovation Corridor (grant ICT17-018). C Edwards & E Costello are employees and shareholders of patientMpower Ltd.