PEC Innovation 5 (2024) 100328

Contents lists available at ScienceDirect

PEC Innovation

journal homepage: www.elsevier.com/locate/pecinn

A self-management package for pulmonary fibrosis: A feasibility study

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ARTICLE INFO

Keywords:
Self-management
Patient education
Pulmonary fibrosis
Interstitial lung disease
Feasibility
Acceptability
Randomised controlled trial
Qualitative evaluation

ABSTRACT

Background and objective: There is currently no self-management package designed to meet the needs of people with pulmonary fibrosis (PF). This study evaluated the feasibility and acceptability of a PF-specific self-management package.

Methods: Adults with PF were randomly allocated (1:1) to either receive the self-management package with healthcare professional (HCP) support or standardised PF information. Primary outcomes were feasibility and acceptability of the intervention. Secondary outcomes included health-related quality of life, self-efficacy, breathlessness, daily steps, use of PF-related treatments, and healthcare utilisation. Participants' experiences of using the package were explored using qualitative interviews.

Results: Thirty participants were included. Recruitment rate was 91% and 100% of those recruited were randomised. Eighty-seven percent of participants who received the package read ≥1 module and set a goal. Secondary outcomes were feasible to collect with high assessment completion rates (87%). Most participants reported the package was easy to use and enhanced knowledge, but suggested some improvements, while HCP support was highly valued.

Conclusion: A PF-specific self-management package was feasible to deliver and requires further testing in a trial powered to detect changes in clinical outcomes.

Innovation: This is the first self-management package designed specifically for people with PF, informed by patient experience and expert consensus.

1. Introduction

Pulmonary fibrosis (PF) is a chronic lung disease characterised by irreversible scarring of tissue within the lung interstitium [1]. Common symptoms are breathlessness, cough, and fatigue [2]. Current treatments include antifibrotics (pirfenidone and nintedanib) that slow disease progression [3,4], and other non-pharmacological treatments such as oxygen therapy and pulmonary rehabilitation (PR) that can improve symptom management, exercise capacity, and quality of life [5,6]. Despite potential benefits of these treatments, people with PF frequently report unmet informational needs to cope with the disease [7].

Self-management involves an individual managing physical and psychosocial consequences of a disease [8]. Self-management interventions aim to promote positive health behaviours and improve one's ability in managing a disease [9]. In recent years, people with PF and healthcare professionals (HCPs) have considered self-management as an important part of disease management [10-12]. In chronic obstructive pulmonary disease (COPD), interventions comprising multiple self-management components (e.g., patient education, lifestyle adjustment and psychosocial support) have been shown to improve

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https://doi.org/10.1016/j.pecinn.2024.100328
Received 18 April 2024; Received in revised form 1 July 2024; Accepted 3 August 2024
Available online 5 August 2024
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health-related quality of life (HR-QoL) and reduce hospitalisation [13]. However, there is currently no self-management package designed specifically for people with PF.

We undertook a Delphi study that identified 12 components that people with PF and HCPs considered essential for inclusion in a PF-specific self-management package, and highlighted the importance of individualisation, goal setting and feedback [14]. Based on the findings from the Delphi study, we developed a PF-specific self-management package. The aims of this study were to evaluate the feasibility and acceptability of delivering the PF self-management package, and assess the feasibility of the study protocol to be implemented in a larger clinical trial to examine its impact on clinical outcomes.

2. Methods

This study was a single-site, randomised controlled trial (RCT) with an embedded qualitative evaluation, which was conducted between June 2022 and June 2023. Ethics approval was received from the Alfred Hospital, Melbourne, Australia (project number: 39/22). The study protocol was registered on the Australian New Zealand Clinical Trials Registry (ACTRN 12622000649718, date of registration: 3 May 2022). Informed consent was obtained from all study participants.

2.1. Participants

Participants were recruited from the interstitial lung disease clinic and PR program at a tertiary hospital. Eligibility criteria included adults aged ≥18 years old with a physician confirmed diagnosis of PF; ability to read and understand English or have someone who could explain the study in their preferred language; and ability to provide own consent. Demographic and clinical information was collected.

2.2. Randomisation

Recruited participants were randomly allocated in 1:1 ratio to the intervention group (IG) who received the self-management package with HCP support or the control group (CG) who received standardised information about PF. The randomisation sequence was computer-generated performed by an individual independent of the study. The group allocation was concealed. Randomisation occurred following completion of baseline assessments, with the knowledge of group allocation restricted to researchers who delivered the intervention and the participants while the outcome assessor remained blinded.

2.3. Intervention

The study intervention was access to our PF self-management package with remote support from a HCP over 8 weeks. The package consisted of 12 modules ***(***Table 1***; Supplement 1)***, which was developed by HCPs with expertise in PF and people with PF based on the findings from our previous Delphi study [14]. The developed package was in a digital format to provide easy access to external online resources with embedded hyperlinks that were vetted by the research team. A printed package was also available if requested. Each module included key information about the topic and tips, designed to facilitate self-management including the use of goal setting (e.g., to maintain fitness), symptom tracking, self-reflection (e.g., the challenges experienced) and problem-solving (e.g., finding strategies to manage breathlessness).

Individualised support was provided by HCPs with a clinical background in PF via telephone or *Zoom* (San Jose, California, United States) at week 1, 2, 3, 4, and 8 following randomisation. The purpose of these calls was to facilitate the use of the package such as choosing the appropriate modules, setting health goals, and providing feedback regarding the participant's progress. Outcomes of each session were documented by the HCP.

Participants in the CG were provided a weblink to access standardised information about PF on the Lung Foundation Australia's website [15]. Participants received calls that were general in nature with no health advice, conducted by a researcher without a clinical background, at week 1, 2, 3, 4, and 8 following randomisation.

Participants in both groups also received a printed copy of the 'Life with PF' booklet published by the Lung Foundation Australia [16].

2.4. Outcome measures

Primary outcomes were the feasibility of the clinical trial delivering the PF self-management package and acceptability of the package. A priori criteria were set for these outcomes based on guidance from previous studies [17-19] and investigators' experiences.

Feasibility was defined as: 1) recruitment of ≥25% of people who met the eligibility criteria; 2) randomisation of ≥80% of those who were recruited; and 3) at least 80% of enrolled participants completing both baseline and follow-up assessments.

Acceptability of the PF self-management package was defined as: 1) at least 80% of participants receiving the package accessing at least one module; and 2) at least 30% of participants receiving the package setting one goal.

Secondary outcomes were HR-QoL, self-efficacy, breathlessness, and steps per day measured at baseline and study completion. Health-related quality of life, self-efficacy and breathlessness were measured using four validated patient-reported questionnaires: King's Brief ILD (K-BILD) questionnaire [20], EQ-5D-5L questionnaire including the EuroQol Visual Analogue Scale (EQ-VAS) [21], General Self-efficacy Scale (GSE) [22], and modified Medical Research Council (mMRC) dyspnoea scale [23,24]. A higher score in the K-BILD, EQ-VAS, and GSE questionnaires, and a lower score in the EQ-5D-5L and mMRC scale indicates a better outcome. Steps per day was measured using an ankle-worn activity monitor *StepWatch* (Modus Health, Washington DC, United States). Participants were asked to wear the monitor for seven consecutive days for optimum reliability [25]. More details of these measuring tools are presented in ***Supplement 2.***

Electronic medical records were reviewed to assess uptake or changes to PF-related treatments (e.g., antifibrotic therapy, oxygen

Table 1
Modules included in the PF self-management package.

1. Understanding treatment options for pulmonary fibrosis
2. Managing medications and side effects
3. Understanding and accessing clinical trials
4. Managing shortness of breath
5. Managing fatigue
6. Managing mood
7. Managing co-existing medical conditions
8. Role and importance of pulmonary rehabilitation and regular physical activity
9. Role of oxygen therapy
10. Smoking cessation advice and support
11. Accessing community support
12. How to communicate with others when living with pulmonary fibrosis

therapy), additional healthcare utilisation (e.g., PR programs, allied health services), and all-cause hospitalisation and emergency department (ED) visits, over the study period.

2.5. Qualitative interviews

Semi-structured interviews were conducted with participants allocated to the IG after completing the end-of-study assessments. An interview guide ***(Supplement 3)*** was used to explore participants' experiences of using the self-management package, as well as the barriers and facilitators to using the package and goal setting. Each interview lasted approximately 30–40 min, was audio recorded, and transcribed verbatim by the researcher conducting the interview (JYTL), who was not involved in intervention delivery or patient care. Two investigators (JYTL and GT) analysed the transcripts independently using a thematic approach with the final results confirmed through iterative discussions.

2.6. Sample size

Sample size was estimated to evaluate the primary outcomes of feasibility and acceptability. Based on guidance from previous literature [26-29], it was estimated that 30 participants (15 per group) was adequate to include a representation of disease severity, treatments and experiences, and inform trial feasibility. The study was not powered to detect differences in secondary outcomes.

2.7. Statistical analysis

Data analyses were preformed using SPSS (Chicago, IL, United States). Feasibility and acceptability outcomes are reported as number and percentage. Secondary outcomes were analysed using an intention-to-treat approach. Normality of the data was assessed using Shapiro-Wilk test. Changes from baseline within each group were analysed using paired samples *t*-test for parametric data, and Wilcoxon Signed-Rank test for non-parametric data. Between-group differences were analysed using independent t-test for parametric data, and Mann-Whitney *U* test for non-parametric data. Statistical significance was set at $p < 0.05$. Data have been reported as mean (standard deviation) unless specified.

3. Results

3.1. Participants

Thirty participants completed baseline assessment with 15 randomised to each group ***(***Fig. 1***)***. Characteristics of participants are summarised in Table 2. Idiopathic pulmonary fibrosis, unclassifiable interstitial lung disease, and hypersensitivity pneumonitis were the most common diagnoses. Overall, the average age, gender distribution, PF severity, and number of comorbidities were comparable across both groups. Use of antifibrotics and oxygen therapy at enrolment were both greater in the CG. All cause-hospitalisation and ED visits within the last 12 months prior to study enrolment were greater in the IG compared to the CG.

3.2. Study feasibility

Thirty-three people met the eligibility criteria and 30 (91%) were recruited. Non-participation was related to family bereavement, feeling too overwhelmed with declining health and life events, and refusal to wear the *StepWatch*. All 30 recruited participants completed baseline assessments, however one participant in CG had no *StepWatch* data which we speculated to be due to a device error. All 30 participants were randomised, with one participant withdrawing from the study following randomisation due to a rapid deterioration in health.

Eight (53%) participants completed all five support sessions; six

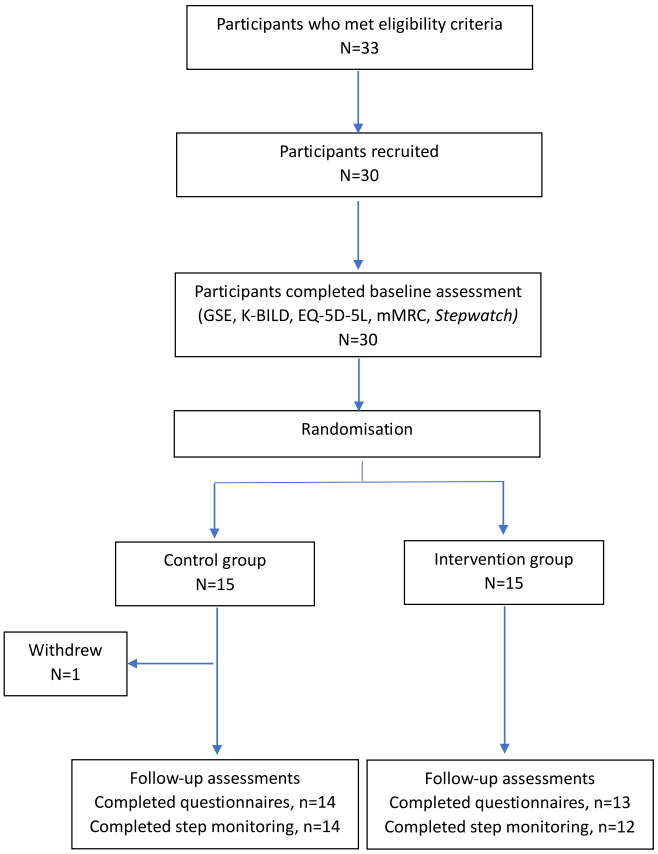

Fig. 1. Consolidated Standards of Reporting Trials (CONSORT) diagram.
GSE: General Self-efficacy Scale; K-BILD: King's Brief Interstitial Lung Disease questionnaire; EQ-5D-5L: EuroQol questionnaire including five dimensions and five levels; mMRC: modified Medical Research Council dyspnoea scale.

(40%) completed four sessions; and one had three sessions. All received the last call at week 8. The reasons for non-completion were mostly due to participants not being contactable. Almost all participants received support via telephone ($n = 14$), one participant preferred *Zoom* and in-person contact during clinic visit as speaking on the phone induced breathlessness. One participant also found telephone calls challenging due to hearing impairment. The average time spent on each call was 17 min (ranged 5–45 min), with total call time for each participant throughout the study being approximately 90 min (range 30–160 min).

Twenty-six (87%) participants completed both questionnaires and step monitoring at study completion. One participant completed only the questionnaires but did not wear the *StepWatch* due to a severe skin rash related to medication side effect. Three participants did not complete either component.

Based on our a priori criteria, the delivery of the self-management package and the study protocol were feasible ***(***Table 3***)***.

3.3. Acceptability of the PF self-management package

Thirteen of the 15 participants in the IG (87%) reported that they used the package. Two participants did not use the package as they were dealing with health issues (one related to PF, the other one related to cancer). The average number of modules selected was three (ranged 1–8), with modules related to PR and managing symptoms being the most common ***(***Table 4***)***. Other topics of the participants' interest were: managing co-existing medication conditions ($n = 5$); managing mood ($n = 4$); understanding treatment options for PF (n = 4); how to communicate with others when living with PF ($n = 2$); understanding and accessing clinical trials ($n = 1$); and accessing community support (n =

Table 2
Participant characteristics at baseline.

	Control group ($n = 15$)	Intervention group ($n = 15$)
Age, *mean years (SD)*	70.6 (10.4)	70.5 (6.0)
Gender, *male*	13 (87)	11 (73)
Diagnosis		
Asbestosis	1 (7)	0 (0)
CPFE	2 (13)	2 (13)
CTD-ILD	0 (0)	3 (20)
Fibrotic NSIP	0 (0)	2 (13)
HP	2 (13)	4 (27)
IPF	5 (33)	3 (20)
Unclassifiable ILD	5 (33)	1 (7)
Years since diagnosis, *median (range)*	1.7 (6 days - 7.3 years)	3.5 (20 days - 10.2 years)
FVC, *% predicted*	69.6 (17.4), *n = 15*	64.3 (20.9), *n = 14*
TLCO, *% predicted*	49.7 (16.9), *n = 15*	59.4 (17.6), *n = 13*
6MWD, *m*	407.9 (100.3), *n = 13*	433.7 (137.3), *n = 13*
BMI, kg/m^2	27.4 (2.9)	27.7 (6.1)
Number of comorbidities, *median (range)*	4 (0–7)	4 (0–8)
Comorbidities		
Anxiety / depression	1 (7)	1 (7)
Asthma	3 (20)	1 (7)
Autoimmune disease	0 (0)	3 (20)
Cancer	2 (13)	3 (20)
Cardiovascular disease	5 (33)	6 (40)
Disorders affecting bone or joints *	5 (33)	6 (40)
Gastroesophageal disease	5 (33)	3 (20)
Hypertension	7 (47)	6 (40)
Metabolic disease	10 (67)	5 (33)
Pulmonary hypertension	1 (13)	3 (20)
Sleep apnoea	3 (20)	4 (27)
Other comorbidities ^	6 (53)	11 (86)
Current antifibrotic therapy, *yes*	9 (60)	4 (27)
Current oxygen therapy, *yes*	7 (46)	4 (27)
Current PR participation, *yes*	4 (27)	3 (20)
Previous PR participation, *yes*	3 (20)	7 (47)
All-cause hospitalisation in last 12 months	4 (27)	8 (53)
All-cause ED visit in last 12 months	1 (7)	6 (40)
K-BILD		
Psychological	54.8 (27.3)	53.0 (14.0)
Breathlessness and activities	35.7 (24.1)	34.4 (16.6)
Chest symptoms	58.2 (25.2)	63.2 (19.4)
Total score	52.5 (18.7)	52.2 (10.9)
EQ-5D-5L, *median (range)*		
Mobility	4 (2–5)	4 (3–5)
Personal care	5 (2–5)	4 (3–5)
Usual activities	4 (2–5)	3 (3–5)
Pain / discomfort	4 (3–5)	4 (2–5)
Anxiety / depression	4 (3–5)	4 (3–5)
EQ-VAS	69 (30–90)	60 (25–83)
GSE	32.7 (5.2)	31.5 (2.8)
mMRC, *median (range)*	2 (0–4)	1 (1–3)
Steps per day	2196 (955), *n = 14*	3205 (1349)

Data are presented as number of participants, *n (%)* unless specified.
SD: standard deviation; CPFE: combined pulmonary fibrosis and emphysema; CTD-ILD: connective tissue disease-related interstitial lung disease; NSIP: non-specific interstitial pneumonia; HP: hypersensitivity pneumonitis; IPF: idiopathic pulmonary fibrosis; FVC: forced vital capacity; TLCO: Transfer capacity of the lung for carbon monoxide; 6MWD: 6-min walk distance; BMI: body mass index; PR: pulmonary rehabilitation; ED: emergency department; K-BILD: King's Brief Interstitial Lung Disease questionnaire; EQ-5D-5L: EuroQol questionnaire including five dimensions and five levels; EQ-VAS: EuroQoL Visual Analogue Scale; GSE: General Self-Efficacy scale; mMRC: modified Medical Research Council dyspnoea scale.

* Disorders affecting bone or joints included osteoporosis, osteoarthritis, gout, back pain, spinal dysfunction or stenosis.

^ Other comorbidities included vertigo, cataract, macular degeneration, epilepsy, peripheral neuropathy, peripheral vascular disease, and renal disease.

Table 3
Feasibility of delivering the self-management package.

A priori criteria	Actual %
Feasibility defined as:	
Recruitment of ≥25% of people who met the eligibility criteria	91% ($n = 30$ of 33)
Randomisation of ≥80% of people who were recruited	100%, with a 3% withdrawal rate ($n = 1$)
At least 80% of enrolled participants completing both baseline and follow-up assessments	100% completed all components of baseline assessments 87% ($n = 26$ of 30) completed all components of follow-up assessments
Additional information regarding intervention delivery	**n (%), N = 15**
Completion of support sessions	
5 sessions	8 (53)
4 sessions	6 (40)
3 sessions	1 (7)
Mode of support session	
Telephone	14 (93)
Zoom/in-person	1 (7)
Time spent on each session, *average (range)*	17 (5–45) min
Time spent on each participant over 8 weeks, *average (range)*	89 (30–160) min

Table 4
Acceptability of the self-management package.

A priori criteria	Actual %
Acceptability defined as:	
At least 80% of participants receiving the self-management package accessing at least one module	87% (n = 13 of 15)
At least 30% of participants receiving the self-management package setting one goal	87% (n = 13 of 15)
Additional information regarding acceptability	**n (%), N = 13**
Number of modules selected by participants, *average (range)*	3 (1–8)
Topics most commonly selected	
Role and importance of pulmonary rehabilitation and regular physical activity	8 (62)
Managing shortness of breath	7 (54)
Managing fatigue	7 (54)
Role of oxygen therapy	6 (46)
Managing medications and side effects	6 (46)
Participants self-reporting progress on attaining a goal	13 (100)
Confidence in managing health at week 8, n = 15	
High	8 (53)
Moderate	5 (33)
Did not rate	2 (13)

1). All participants who used the package set at least one goal ($n = 13$), which included gaining a better understanding of oxygen therapy, maintaining physical activity or fitness, commencing or continuing PR, managing weight, mental wellbeing or symptoms, identifying social support, and making progress on the package. All reported that they had made progress or had achieved their goal at study completion, with the majority reporting moderate-to-high confidence in managing their health. According to our a priori criteria, the PF self-management package was acceptable for use ***(***Table 4***)***.

3.4. Secondary outcomes

At study completion, there was no significant change in HR-QoL, self-efficacy, breathlessness, or steps per day compared to baseline (Table 5).

No deaths or adverse events were reported over the study period. At study completion, all-cause hospitalisation was higher in the IG than CG (36% vs 14%), of which three admissions were PF-related (1 in IG; 2 in CG). More participants in the IG had commenced oxygen therapy compared to control (14% vs 0%). More participants in the IG had commenced PR programs compared to control (47% vs 7%), with 75% ($n = 6$ of 8) being naïve to PR programs. More participants in the IG used additional health services over the study period (e.g., extra general practitioner visits, new appointments with specialists or allied health professionals) compared to control (33% vs 7%) (Table 6).

3.5. Qualitative interviews

Thirteen participants in the IG completed a qualitative interview. Eighty-five percent ($n = 11$) of those who reported using the self-management package found it a positive experience. One participant could not recall using the package and one found the package too overwhelming while dealing with medication side effects and completing a PR program.

3.5.1. Content of the self-management package

Participants found the package easy to navigate and understand, and the information included was deemed trustworthy and encouraging. However, different terminologies used in resources from different countries caused some confusion. One participant found the online resources in some modules excessive and suggested listing the "core resources". About half of the participants spoke about or expressed interest in information on diet, nutrition and managing weight loss that were not included in the package.

Table 6
Healthcare utilisation and changes in treatment over the study period.

	Control group (n = 14) *n (%)*	Intervention group (n = 14) *n (%)*
All-cause hospitalisation	2 (14)	5 (36)
All-cause ED visits	2 (14)	0 (0)
Antifibrotic therapy		
Commenced	2 (14)	3 (21)
Discontinued	1 (7)	0 (0)
Commenced then discontinued	0 (0)	2 (14)
Changed	1 (7)	1 (7)
	- dosage changed	- type changed
Oxygen therapy		
Commenced	0 (0)	2 (14)
Discontinued	1 (7)	0 (0)
Changed	2 (14)	3 (21)
	- flow rate increased	- LTOT to exertion only (n = 2); frequency increased (n = 1)
PR		
Commenced	1 (7)	7 (47)
Completed	1 (7)	1 (7)
Additional health services *	1 (7)	5 (33)

ED: emergency department; LTOT: long-term oxygen therapy; PR: pulmonary rehabilitation.
* Additional services included new appointments with physiotherapist, dietitian, psychologist, continence specialist, skin specialist, ear, nose and throat specialist, and additional general practitioner visits.

Table 5
Changes in secondary outcomes.

Outcome measures	CG		Change within group (n = 14)	IG		Change within group (n = 13)	Difference between groups
	Baseline	Follow-up		Baseline	Follow-up		
K-BILD, *mean (SD)*							
Psychological	55.6 (28.1)	51.2 (23.7)	−4.5 (8.7)	50.4 (10.7)	53.5 (14.4)	3.0 (11.3)	$p = 0.063$
Breathlessness and activities	37.0 (24.4)	39.7 (23.8)	2.7 (7.8)	30.8 (13.9)	34.9 (15.6)	4.1 (10.2)	$p = 0.692$
Chest symptoms	60.1 (25.1)	60.4 (22.3)	0.3 (13.4)	60.3 (17.8)	62.6 (19.3)	2.3 (18.9)	$p = 0.754$
Total score	53.4 (19.2)	52.4 (17.0)	−0.9 (5.5)	49.8 (8.0)	52.1 (9.3)	2.3 (5.9)	$p = 0.163$
EQ-5D-5L, *median (range)*							
Mobility	4 (2–5)	4 (2–5)	0 (−3–2)	4 (3–5)	4 (1–5)	0 (−4–2)	$p = 0.704$
Self-care	5 (2–5)	5 (1–5)	0 (−4–2)	4 (3–5)	5 (1–5)	0 (−4–2)	$p = 0.956$
Usual activities	4 (2–5)	4 (2–5)	0 (−3–2)	3 (3–5)	3 (1–5)	0 (−3–1)	$p = 0.568$
Pain / discomfort	4 (3–5)	4 (1–5)	0 (−4–2)	4 (2–5)	4 (2–5)	0 (−2–2)	$p = 0.271$
Anxiety / depression	4 (3–5)	4 (1–5)	0 (−4–1)	4 (3–5)	4 (1–5)	0 (−4–1)	$p = 0.647$
EQ-VAS	69 (30–90)	74.5 (35–93)	5 (−17–13)	60 (25–83)	70 (40–80)	20 (−34–55)	$p = 0.437$
GSE score, *mean (SD)*	32.9 (5.4)	32.1 (4.7)	−0.7 (3.7)	31.4 (2.9)	30.8 (3.2)	−0.6 (2.4)	$p = 0.935$
mMRC score, *median (range)*	2 (0–4)	2 (0–3)	0 (−2–3)	1 (1–3)	1 (1–3)	0 (−1–1)	$p = 0.284$
Steps per day, *mean (SD)*	2327 (851)	2348 (1166)	N = 13 20 (1073)	3065 (1119)	2952 (1399)	N = 12 −113 (1029)	$p = 0.755$

CG: control group; IG: intervention group; K-BILD: King's Brief Interstitial Lung Disease questionnaire; SD: standard deviation; EQ-5D-5L: EuroQol questionnaire including five dimensions and five levels; EQ-VAS: EuroQoL Visual Analogue Scale; GSE: General Self-efficacy scale; mMRC: modified Medical Research Council dyspnoea scale.
For changes in EQ-5D-5L, EQ-VAS, and mMRC scores: within-group differences between baseline and follow-up were analysed using Wilcoxon Signed-Rank test; between-group differences were compared using Mann Whitney U test.
For changes in K-BILD scores, GSE scores, and steps per day: within-group differences between baseline and follow-up were analysed using paired-sample t-test; between-group differences were compared using independent t-test.

3.5.2. Format and delivery of the self-management package

Most participants preferred a printed package but found a digital version allowed easy access to the online resources. Two required initial assistance from family in using the computer. Many found it useful to have the whole package, but one participant found it overwhelming and preferred to receive only the relevant modules when needed. Three participants suggested that the package would be beneficial if provided around the time of diagnosis.

3.5.3. Support from HCPs was highly valued

Participants highly valued the support provided by HCPs, which helped them monitor their progress, clarify uncertainties, and obtain feedback and encouragement about managing their health. The HCPs delivering the support were described as knowledgeable, empathetic, and encouraging. Some indicated that having contact with the same HCP personalised and enhanced the discussions regarding their progress. One suggested that follow-up emails after each call would help to recall the discussions.

3.5.4. Benefits of using the self-management package

Participants reported an increased understanding of PF, symptoms, treatment options and available support, and feeling more confident in managing the disease. The package prompted participants to ask their HCPs questions related to their care. Almost all reported applying the self-management knowledge learnt from the package. For those who previously had limited knowledge, the package "opened a few doors". For others, the package helped to reinforce previous knowledge, put the information into context (e.g., having an exercise plan), and reassured that they were doing the best they can.

3.5.5. Barriers and facilitators of goal setting

Some participants found it challenging to set a goal. Barriers reported included deteriorating health, and the uncertainties about disease progression and the effects of medications, especially in those who were new to antifibrotic therapy. Many acknowledged that goals must be dynamic, realistic, and achievable according to their health status. It was suggested that having knowledge and confidence in managing the disease may facilitate goal setting, while monitoring progress and receiving feedback (e.g., from HCPs and self-monitoring symptoms, oxygen needs and exercise capacity) helped to adjust their goals.

4. Discussion and conclusion

4.1. Discussion

This study demonstrated that the protocol developed to deliver a PF-specific self-management package was feasible and acceptable. Most participants found the package easy to use and enhanced their knowledge and confidence in self-management. However, some improvements related to the number of online resources provided and description of the terminologies used were suggested. Information related to diet, nutrition and managing weight was indicated as missing in the package. Support from HCPs helped to monitor progress, clarify uncertainties, and provide feedback. Barriers to goal setting included deteriorating health and uncertainties about disease progression and treatment effects. Facilitators included having adequate knowledge and confidence in managing the disease, regular monitoring and feedback. There was no change in HR-QoL, self-efficacy, breathlessness and physical activity level, but more participants in the IG had commenced PR programs and used additional health services over the study period.

Although the protocol used to recruit participants in this study was deemed feasible, several factors may be considered to enhance recruitment. In our study, eligible participants recruited from a single site were generally interested in research and travel was not an issue as site visits were not required. Recruitment of participants on a larger scale or from multiple sites may need to consider participant factors such as their interest in the study, availability, travel distance, and the ability or willingness to complete study requirements such as wearing an activity monitor [26,28-30]. In addition, advocacy from HCPs who provide patient care facilitated the recruitment process in our study. Engaging HCPs who manage potentially suitable participants to actively promote and encourage participation may facilitate recruitment, however providing clear indications regarding inclusion criteria to HCPs involved would also be important [28,31]. The time taken for HCP to deliver the package (on average 90 min over 8 weeks) should also be considered for future implementation.

Several modifications to the self-management package content and its delivery can be considered based on participants' feedback. Whilst the package was generally easy to use and understand, some participants found the amount of content to be excessive, so the number of online resources may need to be reduced, "core" resources identified and modules delivered only when they are selected, rather than all at once. Broader definitions of terminologies may be needed to minimise confusion about the terms used in resources from different countries. Common topics that the participants were interested in were similar to that reported by other studies [7,11]. However, additional components focused on diet, nutrition and managing weight should also be considered in future studies. Furthermore, although our participants were on average 70 years of age, only two reported seeking some assistance to access a digital version of the package. However, it is important to consider internet access and digital literacy as potential barriers to using technology in older participants [32], Nevertheless, the importance of providing a printed package should not be overlooked. Lastly, whilst receiving the whole package was acceptable to most participants, it can be overwhelming to some, highlighting the importance of individualisation when delivering the package [33].

In our study, 93% of participants completed 80% of the planned support calls. A high adherence rate is common in home-based interventions as they address travel barriers [28]. However, some barriers to communicating via telephone calls should be considered such as hearing impairment and breathlessness, as reported by two participants. Other barriers to retaining participants include death, illness, and loss of interest or time [30]. In contrast, findings from our study and other studies found providing feedback on the study progress, building trust and rapport with the participant, and delivering support by the same facilitator can assist with study completion, which may also facilitate adherence to the intervention when used in clinical practice [28,30,31].

This study showed an increase in healthcare utilisation and uptake of PF-related treatments in participants who received the self-management package compared to control, which may be reassuring to HCPs who had concerns about patients being reluctant to reach out for help [12]. In addition, more participants in the IG initiated PR for the first time compared to control, suggesting that the intervention may have the potential to address the issues with low PR uptake [34,35]. Other programs comprised of patient education have shown similar findings related to PR referral and visits to allied health professionals [36,37], however, findings regarding other physician visits are inconsistent [27,37-39]. It is possible that self-management interventions might give rise to increases in healthcare utilisation such as doctor and hospital visits, as patients may be better able to detect important changes in their health status, and more proactive in their management. This may have implications for healthcare resources and costs, which should be explored in future trials. Whilst no significant changes were observed in HR-QoL, self-efficacy, breathlessness and physical activity level, a larger trial is required to further evaluate the impact of the self-management package on such outcomes.

This study is the first to evaluate the feasibility and acceptability of delivering a consensus-based self-management package designed for people with PF. Although the study included only 30 participants, these participants covered a range of PF severity and treatment experiences. However, the participants were from one site only and therefore, generalisation of the results is limited. Whilst the sample size was

sufficient to inform study feasibility and acceptability of the package, it was not powered to assess efficacy of the package, therefore, a larger trial is required to determine its impact on patient outcomes. The patient outcomes assessed in this study were related to the goals of self-management [9], but psychological wellbeing should also be assessed in future studies as people with PF often report unmet needs in managing this aspect. Another limitation is that qualitative interviews were not conducted with participants in the CG and HCPs delivering the intervention. Data collected in these interviews can be helpful in informing study feasibility. Lastly, the HCPs providing support did not receive uniform training to deliver the intervention which can have an impact on the consistency of the support.

4.2. Innovation

Self-management is a novel concept in PF. Prior to the availability of anti-fibrotic medications in the last decade, many patients experienced relentlessly progressive disease and early death, with limited opportunity for self-management and active participation in healthcare. However, with the advent of new pharmacological treatments, the expectations of patients and healthcare professionals have changed, with self-management now identified as a priority [10-12]. Self-management is not new to the respiratory field, being a well-accepted component of best care in obstructive lung conditions such as COPD and asthma, where it improves patient outcomes [13]. A core component of such programs includes early detection and self-management of exacerbations of lung disease; we have previously reported that some healthcare professionals may consider this a risk in PF due to the absence of self-initiated treatments for PF exacerbations, and higher mortality rates than other lung diseases [12]. The current study demonstrates, for the first time, that an individualised, PF-specific self-management package was feasible to deliver, with no adverse events. This opens the possibility of a role for self-management in comprehensive, patient-centred PF care, however further research is required to understand its impact on patient and health system outcomes. Development of a PF-specific self-management approach adds to the range of non-drug interventions that aim to improve wellbeing in this patient group, and complements research investigating the feasibility of PF-specific symptom management and palliative care packages [40 - 43].

4.3. Conclusion

Delivery of a PF-specific self-management package was feasible. The findings provide a basis for a larger trial powered to assess the efficacy of the package and its impact on patient outcomes

Informed consent and participant details

I confirm that informed consent was obtained from all participants and all personal identifiers have been removed or disguised and cannot be identified through the details provided in the article.

Funding

This work is supported by a scholarship provided by the Lung Foundation Australia's Hope Research Fund and Monash Univeristy, and financial support from the Centre for Research Excellence in Pulmonary Fibrosis, funded by the National Health and Medical Research Council.

CRediT authorship contribution statement

Joanna Y.T. Lee: Writing – original draft, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Gabriella Tikellis:** Writing – review & editing, Supervision, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Mariana Hoffman:** Writing – review & editing, Methodology, Formal analysis, Data curation. **Christie R. Mellerick:** Writing – review & editing, Data curation. **Karen Symons:** Writing – review & editing, Data curation. **Janet Bondarenko:** Writing – review & editing, Data curation. **Yet H. Khor:** Writing – review & editing, Data curation. **Ian Glaspole:** Writing – review & editing, Data curation. **Anne E. Holland:** Writing – review & editing, Supervision, Methodology, Investigation, Data curation, Conceptualization.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Yet H. Khor reports a relationship with National Health and Medical Research Council that includes: funding grants. Yet H. Khor reports a relationship with Medical Research Future Fund that includes: funding grants. Yet H. Khor reports a relationship with Air Liquide Healthcare that includes: non-financial support. Yet H. Khor reports a relationship with Lung Foundation Australia that includes: funding grants. Yet H. Khor reports a relationship with Thoracic Society of Australia and New Zealand that includes: funding grants. Yet H. Khor reports a relationship with The Royal Australasian College of Physicians that includes: funding grants. Co-author is a board director (Special Interest Group Convenor) at the Thoracic Society of Australia and New Zealand; a guideline methodologist (Clinical Problems Assembly Program Committee) at the American Thoracic Society; and an associate editor for the European Respiratory Journal, European Respiratory Society - Y.H.K. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgement

The authors would like to thank the patients who generously agreed to participate in this study.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.pecinn.2024.100328.

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