A pulmonary rehabilitation shared decision-making intervention for patients living with COPD: PReSent: protocol for a feasibility study

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Shareable abstract (@ERSpublications)
This protocol describes the development and evaluation of a pulmonary rehabilitation shared decision-making intervention, including a patient decision aid and decision coaching workshop, for patients living with COPD, and their health professional https://bit.ly/3gkTZM8

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Abstract

Background Despite the variety of pulmonary rehabilitation programmes for patients living with COPD, uptake remains low. To improve this, it is recommended that health professionals engage patients in informed decisions about pulmonary rehabilitation. Shared decision-making (SDM) facilitates informed and value-based decision-making between patients and health professionals. This protocol describes the development and evaluation of a complex SDM intervention for patients living with COPD, who are referred for pulmonary rehabilitation, and their pulmonary rehabilitation health professional.

Methods and analysis We are developing a complex SDM intervention involving a patient decision aid (PtDA) and a decision coaching workshop. Prior to patient recruitment, pulmonary rehabilitation health professionals will attend the workshop. Upon referral to pulmonary rehabilitation, patients will receive the PtDA to support their decision-making prior to and during their pulmonary rehabilitation assessment with a health professional. The intervention will be evaluated in a one-arm exploratory study to investigate its feasibility and acceptability for patients and health professionals, with an integrated fidelity assessment. The primary outcome is recruitment feasibility, data collection feasibility and intervention fidelity. Secondary outcomes include routine pulmonary rehabilitation data, decisional conflict, patient activation, intervention attendance/attrition and patient and pulmonary rehabilitation health professional experience of the intervention. Quantitative outcomes will be evaluated using the most appropriate statistical test, dependent on the sample distribution. Qualitative outcomes will be evaluated using reflexive thematic analysis. Fidelity will be assessed using the Observer OPTION 5 scale.

Conclusion This intervention will provide structure for an informed and values-based decision-making consultation between a patient with COPD and a pulmonary rehabilitation health professional with the potential for optimising pulmonary rehabilitation decision-making.

Introduction

People living with COPD experience chronic respiratory symptoms including breathlessness, cough, wheeze and excess sputum. These are punctuated by periods of acute exacerbation whereby respiratory symptoms worsen and they may require medication or hospitalisation [1].

To manage the symptoms of COPD holistically, individuals are invited to attend pulmonary rehabilitation. Pulmonary rehabilitation is a complex intervention of personalised and progressive exercise training

alongside disease management education. The programme is evidence-based and known to improve breathlessness, exercise capacity, psychological wellbeing and self-efficacy [2]. It seeks to desensitise people to the experience of breathlessness, thereby supporting the implementation of positive self-management skills [3].

Traditionally, pulmonary rehabilitation is delivered in a group setting with direct supervision from health professionals; however, to support individual needs and enhance uptake, a variety of home-based pulmonary rehabilitation models have been developed, evaluated and implemented into routine patient care, for example, a standardised COPD self-management manual (SPACE for COPD) which includes telephone support from health professionals [4], and a comparable programme delivered online [5]. The four-stage manual, co-produced by patients and health professionals [6], has shown to improve individuals' COPD symptoms and exercise tolerance above usual care, and when compared to traditional pulmonary rehabilitation has proved noninferior for improvements in quality of life [7, 8]. Similarly, the online programme has shown potential for increasing disease knowledge and pulmonary rehabilitation completion for a subset of digitally literate patients [9].

While the onset of the coronavirus disease 2019 pandemic has enhanced the need and appetite for home-based pulmonary rehabilitation, uptake to these programmes remains low. In 2019, referral, uptake and completion rates were below target [10]. The commonly cited barriers to pulmonary rehabilitation engagement include organisational constraints (*e.g.* the location of pulmonary rehabilitation venues, session times [11]), people's beliefs (*e.g.* low self-worth, anticipated negative interactions with health professionals [12]) and people's socioeconomic status (*e.g.* cost of attending pulmonary rehabilitation, digital literacy [13]). It appears that people's perceptions of COPD and self-management are key to their help-seeking behaviour and engagement in recommended treatments (*e.g.* pulmonary rehabilitation [14]). Therefore, it is suggested that health professionals should seek to engage people in informed decisions about their enrolment into pulmonary rehabilitation [11, 15].

A process that facilitates individuals' engagement in healthcare decisions is shared decision-making (SDM). SDM involves individuals and health professionals working together to make a decision. It is different from usual care communication as it requires a discussion to share individuals' and health professionals' perspectives on the health problem, healthcare options, preferences, value of one option over another and agreement and planning on which option is best for the individual. It therefore enables people to make an informed and values-based choice [16].

To support SDM between health professionals and individuals, resources called "patient decision aids" (PtDAs) are often utilised in a healthcare consultation. PtDAs provide evidence-based information about a medical condition and the available healthcare options (*e.g.* the risks and benefits to each). They draw on evidence from decision science on how and what information to present to help reduce individuals' cognitive load and information bias [17]. The adoption of PtDA across multiple healthcare settings has increased the frequency of SDM and patient-centred decisions, particularly by increasing individuals' knowledge, enhancing awareness of risk, reducing any feelings of internal conflict and reducing feelings of passivity [18–23].

While PtDA have shown to support people with COPD to make decisions about mechanical ventilation [24, 25], there are currently no PtDAs to support pulmonary rehabilitation decision-making. These studies observed improvements in individuals' knowledge of treatment options, reduced decisional conflict and enabled individuals to make value-based decisions. However, the authors acknowledged the need for decision coaching skills in the integration of these resources in practice. The provision of training to facilitate health professionals' decision coaching in addition to a PtDA is believed to be a robust SDM intervention [26].

To support people's decision-making for pulmonary rehabilitation, we are developing a PtDA which will be provided to individuals with COPD upon their referral to pulmonary rehabilitation. This is to be utilised prior to and during a SDM consultation with a pulmonary rehabilitation health professional who is trained in decision coaching. We hypothesise that this intervention will be feasible and acceptable for people living with COPD and pulmonary rehabilitation health professionals.

This protocol describes the development and feasibility evaluation of the first pulmonary rehabilitation PtDA for patients living with COPD. It follows the Standard Protocol Items: Recommendations for Interventional Study (SPIRIT) guidance [27] (supplementary material).

Objectives

The primary objective is to develop a complex PtDA intervention facilitating pulmonary rehabilitation decision-making with the aim to evaluate its feasibility and acceptability to patients and health professionals.

Development has been informed by the PtDA development logic model [28], the International Patient Decision Aid Standards (IPDAS) [29], the Ottawa Decision Support Framework [30] and guidance on embedding complex interventions into health settings [31]. Figure 1 illustrates the adapted PtDA logic model utilised.

The specific objectives are as follows.

1) To conduct a needs assessment to explore the decisional needs of patients considering a referral to pulmonary rehabilitation. This includes exploratory qualitative interviews with patients and health professionals and a computerised Implicit Association Test with health professionals [32] (design steps 1 and 2).
2) To conduct a systematic review to determine the effective format and distribution of SDM interventions within the target population (design step 3).

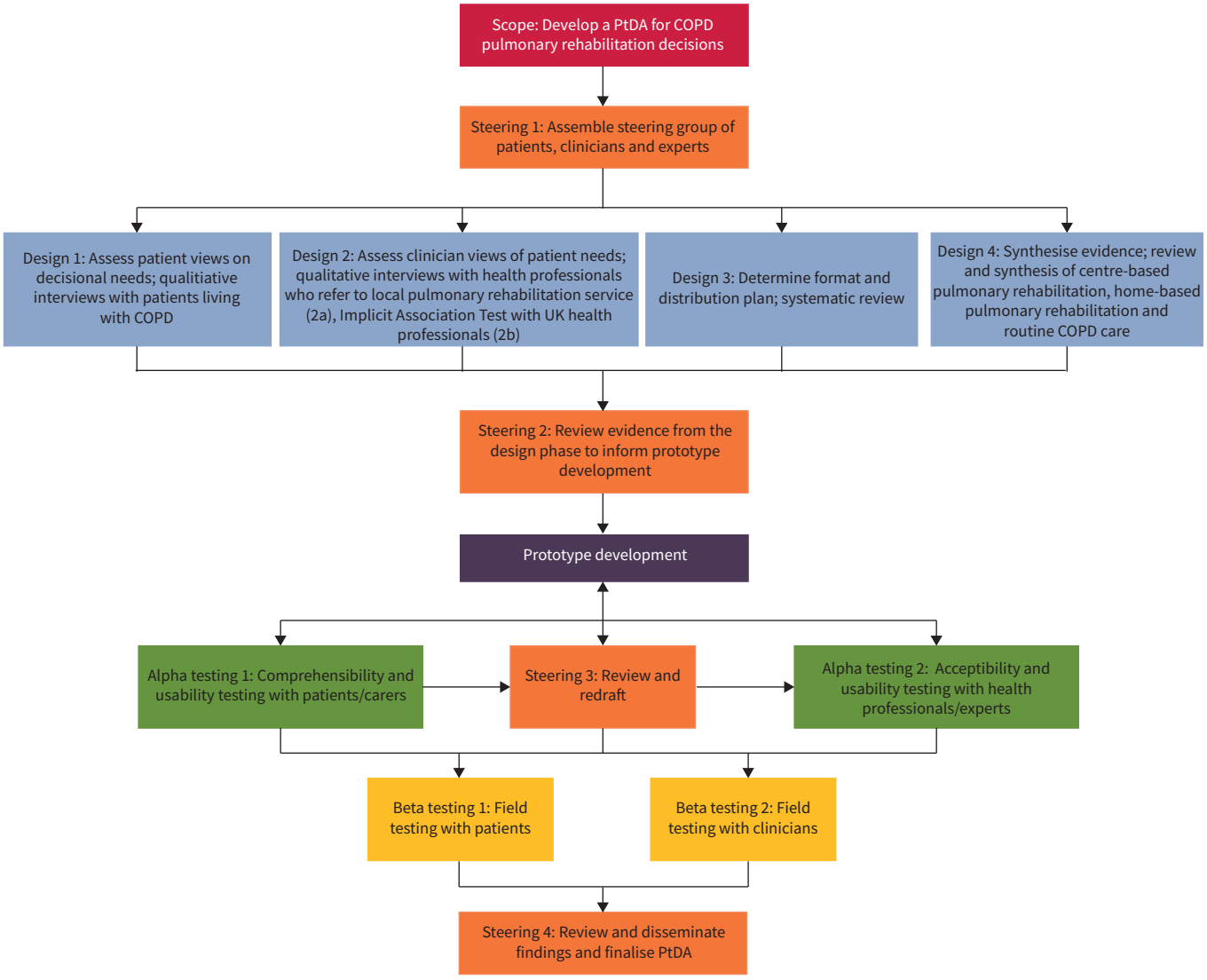

FIGURE 1 The adapted patient decision aid (PtDA) logic model utilised in the protocol.

3) To collate systematic evidence for the pulmonary rehabilitation programme options and usual COPD care (design step 4).
4) To develop the prototype PtDA (informed by design steps 1–4).
5) To conduct alpha-testing of the prototype with patients, carers and health professionals to explore its usability, comprehensibility and acceptability (alpha-testing 1 and 2) and to redraft the prototype, as needed.
6) To conduct a feasibility study to explore:
   - the intervention's feasibility (*i.e.* recruitment capability, feasibility of data collection processes and outcome measures, acceptability and suitability of intervention and research procedures, evaluation of resources and ability to manage and implement the research and intervention, preliminary evaluation of intervention effect) (beta-testing 1 and 2);
   - the intervention's acceptability (*i.e.* patients' and health professionals' satisfaction, intention to continue use, perceived appropriateness and fit with organisational culture) of the SDM intervention (beta-testing 1 and 2).

Study design

This is a one-arm exploratory study to investigate the feasibility and acceptability of a pulmonary rehabilitation SDM intervention for patients living with COPD and pulmonary rehabilitation health professionals, with an integrated fidelity assessment.

The study design and implementation is co-produced with a dedicated steering group consisting of patients, carers, health professionals, and pulmonary rehabilitation and SDM experts.

Methods

Development and evaluation of a pulmonary rehabilitation SDM intervention

Design steps 1 and 2a: qualitative interviews

Qualitative research methods will be utilised to capture a rich and nuanced understanding of the factors influencing patients' decision-making for pulmonary rehabilitation pertinent to our service (*i.e.* the barriers, facilitators and potential improvements which can support patients' decision-making). Semi-structured, one-to-one interviews with patients and health professionals will be conducted and analysed in accordance with the Enhanced Critical Incident Technique protocol [33]. These steps will provide information on the conscious and verbalised factors influencing patients' pulmonary rehabilitation decision-making.

Design step 2b: Implicit Association Test

An adapted, computerised version of the Implicit Association Test (IAT) [32] will be utilised to measure the presence of unconscious bias among health professionals. It will be delivered remotely to participants using the PsyToolkit online platform (www.psytoolkit.org/c/3.3.2/survey?s=ZhpDN) [34, 35].

The IAT will ask participants to categorise words presented on the screen as quickly as possible. They will categorise COPD patient health behaviours (*e.g.* smoking or exercising) with an attribute (*e.g.* pleasant or unpleasant) in a series of block trials, interspersed with training blocks so participants can practice the categorisation process. For example, in block one, participants will be asked to categorise words associated with smoking with pleasant words and words associated with exercising with unpleasant words. In block two, the word associations are then reversed. After each answer a happy or sad face appears, to feed-back whether the answer was correct or not. The block order is randomly assigned to ensure training effects are minimised. The test uses participants' reaction times as a measure of the strength of association between the concepts; the shorter the time to categorise the words, the stronger the association. Concepts which are implicitly associated should be easier and quicker to categorise.

Design step 3: systematic review

A systematic review will be conducted to collate data on how a PtDA should be developed, what it should include, how it should look, how it should be delivered and how it should be evaluated. The protocol for this systematic review is reported elsewhere (PROSPERO ID: CRD42020169897).

Design step 4: synthesis of evidence

The outcome data to insert onto the PtDA will be decided by the dedicated steering group. A review and synthesis of evidence will be conducted for centre-based pulmonary rehabilitation with health professional, home-based pulmonary rehabilitation with telephone support (*e.g.* SPACE for COPD), home-based pulmonary rehabilitation with online support (online SPACE for COPD) and routine COPD care.

Alpha testing 1: patient/carer user testing

Informed by the design phases, a prototype PtDA will be created. This will be tested and reviewed by a local patient and public involvement group, comprised of patients and carers. Specific questions regarding its comprehensibility (*e.g.* How do they understand the content, flow and interactive prompts? Could we make it easier to understand?) and usability (*e.g.* How do they interact with the content, flow and interactive prompts? Could we make it easier to use?) will be posed. The observations will be collated and shared with the steering committee to discuss and inform amendments.

Alpha testing 2: health professional/expert user testing

The prototype PtDA will be individually tested by all members of the dedicated steering group. In addition, it will be tested and reviewed by independent pulmonary rehabilitation specialists. Specific questions will be posed regarding it acceptability (*e.g.* How do they perceive the content, flow and interactive prompts? What would make it more acceptable?) and usability (*e.g.* How do they interact with the content, flow and interactive prompts? Could we make it easier for them to use?). The observations will be compared with those from alpha testing 1 and shared with the steering committee to further discuss and inform amends.

Beta testing 1 and 2: feasibility study

The feasibility and acceptability of the newly developed PtDA will be evaluated in a one-arm exploratory study. The study will capture quantitative, qualitative and process data to inform the need for a full-scale randomised controlled trial.

Participants, interventions and outcomes

Setting

The recruitment site is a university hospital with a dedicated pulmonary rehabilitation and research service based in Leicestershire, UK.

Eligibility criteria

Eligible patient participants will be those with a confirmed diagnosis of COPD (Global Obstructive Lung Disease (GOLD) criteria) [1] and eligible for a referral to pulmonary rehabilitation. Those with a primary diagnosis of another respiratory condition will be excluded.

The health professional participant eligibility criteria for design step 2a and 2b will be those who refer patients living with COPD to pulmonary rehabilitation. For the exploratory qualitative interviews (design 2a), eligible health professionals will be those who refer to pulmonary rehabilitation services within Leicestershire. For the IAT (design 2b), eligible health professionals are those who refer to services across the UK. The health professional participant eligibility criteria for the feasibility study (beta testing 2) are those directly involved in the provision of pulmonary rehabilitation at the Leicestershire service. A full list of inclusion and exclusion criteria is provided in tables 1–4.

Due to the low interventional load and safety of the intervention, the withdrawal of participants is not anticipated; however, participants will be informed of their right to withdraw during consent procedures.

TABLE 1 Eligibility criteria for patient participants

Inclusion criteria	Exclusion criteria
Willing and able to give informed consent for participation in the research	Unable to provide valid informed consent
Male or female, age ⩾40 years	Age <40 years
A confirmed diagnosis of COPD, post-bronchodilator FEV_1/FVC ratio <70%	Primary diagnosis is another chronic respiratory condition
Eligible for attendance at a UHL pulmonary rehabilitation assessment	Ineligible for attendance at a UHL pulmonary rehabilitation assessment (*e.g.* significant comorbidity which limits exercise training)
Able to communicate in written and spoken English[#]	Unable to understand written English[#]

FEV_1: forced expiratory volume in 1 s; FVC: forced vital capacity; UHL: University Hospitals of Leicester NHS Trust. [#]: the research information and shared decision-making intervention is currently only available in English.

TABLE 2 Eligibility criteria for health professionals recruited to exploratory qualitative interviews (design step 2a)

Inclusion criteria	Exclusion criteria
A participant who is willing and able to give informed consent for participation in the research	A participant who is unable to provide valid informed consent
A health professional who actively refers patients with COPD to Leicestershire pulmonary rehabilitation services (>1 year experience in doing so, to ensure that they are familiar with the current pathway)	<1 year experience of referring COPD patients to pulmonary rehabilitation
Male or female, age ⩾18 years	Age <18 years

Intervention

Training health professionals for decision coaching

The SDM intervention is delivered on a one-to-one basis with pulmonary rehabilitation specialists, who are specifically trained to deliver SDM. They will be termed "SDM facilitators".

The training consists of a bespoke 2-h educational workshop specifically relevant to SDM in pulmonary rehabilitation. The workshop involves developing individuals' understanding, appetite and acceptance of SDM using a combination of lecture and practical methods (*e.g.* role play with feedback). The curriculum is informed by Stacey *et al.*'s [18] decision coaching framework, and guidance on teaching SDM and communication skills to health professionals [36–39]. These recommended the use of practical teaching methods with feedback, the importance of distinguishing between patient-centred care and SDM, providing relevant scenarios for trainees to reflect upon, introducing how to use a PtDA and a post-knowledge test.

The objective of the workshop is to provide knowledge and skills practice to enable pulmonary rehabilitation specialists to coach patients' pulmonary rehabilitation decision-making, using a PtDA. The learning outcomes are as follows:

1) To understand the PReSent study and the role of the SDM facilitator.
2) To understand how people make informed decisions.
3) To understand the uniqueness of SDM and how to deliver it using skills and tools.
4) To understand the three-talk model of SDM.
5) To be able to structure a SDM pulmonary rehabilitation assessment appointment using a PtDA.
6) To practice a pulmonary rehabilitation SDM consultation using a PtDA and receive feedback to consolidate knowledge and skills.
7) To consolidate knowledge in a quiz.

The session plan is provided in table 5. Upon completion of the training, attendees are provided with a certificate.

Patient decision aid

The PtDA was developed using Coulter *et al.*'s [28] systematic development process for PtDAs, Ottawa's Patient Decision Aid Development eTraining (https://decisionaid.ohri.ca/eTraining/), the IPDAS checklist [29] and guidance on the development of complex interventions in healthcare [31]. It was co-produced with a dedicated steering group which included patients, pulmonary rehabilitation specialists and experts in pulmonary rehabilitation and SDM.

TABLE 3 Eligibility criteria for health professionals recruited to the Implicit Association Test (IAT) (design step 2b)

Inclusion criteria	Exclusion criteria
Willing and able to provide informed consent for participation in the research	Unable to provide valid informed consent
A UK health professional	Health professionals practising outside of the UK
A health professional who has the capability to refer patients with COPD to pulmonary rehabilitation services	A health professional who does not refer patients with COPD to pulmonary rehabilitation services
Male or female, age ⩾18 years	Age <18 years
Able to communicate in written and spoken English[#]	Unable to understand written English[#]

[#]: the IAT is currently only available in English.

TABLE 4 Eligibility criteria for health professional participants recruited to beta testing 2

Inclusion criteria	Exclusion criteria
A participant who is willing and able to give informed consent for participation in the research	A participant who is unable to provide valid informed consent
A health professional directly involved in the provision of pulmonary rehabilitation (*e.g.* a pulmonary rehabilitation specialist)	A health professional not directly involved in the provision of pulmonary rehabilitation
Male or female, age ⩾18 years	Age <18 years

The PtDA is an informational booklet which explicitly describes the decision posed to the individual, provides a description of COPD, outlines the available options to for patients (*i.e.* centre-based pulmonary rehabilitation with health professionals, home-based pulmonary rehabilitation with telephone support from health professionals, home-based pulmonary rehabilitation with online support from health professionals, routine COPD care), and provides the advantages, disadvantages and consequences of each option with numerical probabilities. Throughout the PtDA, interactive sections are included to engage patients with the content, guide them through the decision-making process, guide them through communication with a health professional and those close to them (*e.g.* relative, carer) and encourage them to attribute personal meaning and preferences to each option, thus supporting informed and value-based decision-making.

The PtDA is provided to patients following their referral to pulmonary rehabilitation. Participants will be advised how to use it and asked to bring it with them when they attend their routine pulmonary rehabilitation assessment appointment. In addition to their routine appointment, patients will engage in a SDM consultation with a SDM facilitator. This will include a collaborative review of the PtDA to enable a choice to be made about which programme the participant would like to enrol onto. Participants will then begin their chosen pulmonary rehabilitation programme.

TABLE 5 Decision coaching workshop session plan

	Content	Time	Aids
Learning activity			
Introductions	Introduce research study Introduce role of facilitator Complete consent forms	10 min	PowerPoint, study consent forms
How do people make informed and evidence-based decisions?	What is an informed decision? (example to illustrate) How do we make informed decisions? (MIND-IT model) Multiple experts and their roles	10 min	PowerPoint presentation
Tools to facilitate shared decision-making	What would help you to have a shared decision-making discussion with patients? Patient decision aid (and evidence)	10 min	PowerPoint presentation
How will a shared decision-making discussion be different to patient-centred discussions?	Patient-centred care Shared decision-making Address barriers through discussion	10 min	PowerPoint presentation
Shared decision-making in practice	The process of shared decision-making (three-talk model). Provide video example of each stage, including preparation for decision-making and ask for feedback	20 min	Video, PowerPoint presentation
A pulmonary rehabilitation shared decision-making consultation	Develop a communication aid to support shared decision-making consultation using a patient decision aid Role play exercise with PPI member (group into threes) Feedback to individual groups Reflection	40 min	PowerPoint presentation
Consolidation quiz		10 min	Paper/electronic form (*e.g.* Google Forms)
Post-session			
Provide webinar materials and certificate of completion			PowerPoint, videos (embedded in PowerPoint) Certificates

MIND-IT: Making Informed Decisions Individually and Together; PPI: patient and public involvement.

With permission from each patient, the SDM consultation will be digitally recorded on an encrypted voice recorder. The lead author and a co-author will independently analyse each recording for adherence to SDM principles using the Observer OPTION 5 scale [40].

Since this is a feasibility study, there are no alternative interventions. All patient participants will receive the PtDA and all health professional participants will receive the decision coaching training.

Outcomes

Design steps 1 and 2a: qualitative interviews

The primary outcome will be a synthesis of the barriers, facilitators and possible improvements which can be made to support patients' pulmonary rehabilitation decision-making.

Design step 2b: Implicit Association Test

The primary outcome will be response latency, which is an indication of the presence or absence of implicit bias.

Design step 4: synthesis of evidence

The primary outcome will be the finalised dataset to be entered onto the PtDA.

Alpha testing 1: patient/carer user testing

The primary outcomes will be the comprehensibility and usability of the PtDA.

Alpha testing 2: health professional user testing

The primary outcome will be the acceptability and usability of the PtDA.

Beta testing 1 and 2: feasibility study

The primary outcome measures will be feasibility of recruitment (*i.e.* recruitment to time and target), feasibility of data collection/outcome measures (*i.e.* data completeness), and intervention fidelity.

The secondary outcome measures will be a change in decisional conflict (using the Decisional Conflict Scale [41]), patient activation (using the Patient Activation Measure [42]), SDM intervention attendance and attrition, patient attitudes/experience of receiving the SDM intervention and SDM facilitator attitudes/experience of delivering the SDM intervention. In addition, the following routine pulmonary rehabilitation outcome measures will be collected: uptake and completion of pulmonary rehabilitation (including programme selection and any crossover from one programme to another), COPD Assessment Test [43], Bristol COPD Knowledge Questionnaire [44], Chronic Respiratory Questionnaire [45], Hospital Anxiety and Depression Scale [46], COPD Patient-Reported Experience Measure 9 [47], Medical Research Council dyspnoea scale [48], incremental shuttle walk test [49] and endurance shuttle walk test [50].

All outcome measures will be collected at baseline and post-pulmonary rehabilitation completion, apart from those relevant only to post-intervention/pulmonary rehabilitation completion (*e.g.* feasibility measures, intervention fidelity, SDM intervention attendance and attrition, patient attitudes/experience of receiving the SDM intervention, SDM facilitator attitudes/experience of delivering the SDM intervention, uptake and completion of pulmonary rehabilitation).

Recruitment and study procedures

The following section contains information relevant only to the steps involving participant recruitment (design steps 1, 2a and 2b; beta testing 1 and 2). All participants will provide written informed consent *via* online, telephone or face-to-face methods prior to study activities. Participants in the beta testing phase will have the option to consent to additional study procedures which will be documented on the consent form (*e.g.* interviews/focus groups). Data will be collected on adverse and serious adverse events in line with the ethics committee's and study sponsor's requirements. The confidentiality of participant data will abide by the Data Protection Act (2018).

Design steps 1 and 2a: qualitative interviews

Participants will be recruited using the proportionate allocation method of stratified sampling to ensure participants are representative of the Leicestershire pulmonary rehabilitation service. For patients, our sampling will consider referral setting (*e.g.* inpatient, outpatient, general practice) and residence (*e.g.* inner-city, urban). For health professionals, our sampling will consider referral setting (*e.g.* primary care, secondary care) and site location (*e.g.* inner-city, urban). Participants will be approached using an

invitation letter. For those who express interest, the researcher will contact them to arrange a suitable date and time for the interview. The researcher will obtain informed consent and then undertake a semi-structured interview either in person or *via* telephone (as per participants' preference). Each interview will be digitally recorded on an encrypted voice recorder. The audio recordings will be transferred securely to a third-party transcription service. The transcripts will be returned and securely stored on the sponsor's encrypted server for analysis. This data will only be accessible to delegated researchers.

Design step 2b: Implicit Association Test

Health professional participants will be approached using social media adverts and dissemination *via* professional groups. Participants who express interest will be invited to conduct an online screening assessment, and if eligible, complete an electronic consent form prior to completion of the computerised IAT. All study procedures will be completed in one ∼30-min online session. Data will be downloaded from the PsyToolkit test portal [34, 35] and stored on the sponsor's encrypted server for analysis.

Beta testing 1 and 2: feasibility study

An outline of the research visits for all participants (SDM facilitators and patients) recruited to the feasibility study is outlined in table 6.

Patient participants will be screened by the pulmonary rehabilitation team to assess their eligibility. Those eligible will be sent an invitation letter detailing the study procedures. For those who express interest, the researcher will invite them to attend a screening and consent visit. The researcher will obtain informed consent and then administer baseline outcome measures through supervised, self-report questionnaires. The participants will be provided with a PtDA. Participants will then attend their routine pulmonary rehabilitation assessment appointment, in which a SDM consultation will occur. With patient participants' permission, the session will be digitally recorded on an encrypted voice recorder and transferred to the sponsor's secure server for analysis.

Following completion or drop-out of pulmonary rehabilitation, participants will repeat the supervised, self-report outcome measures and will be invited to attend an optional focus group to discuss their experiences of the study. Supervised, self-report data will be collected on paper questionnaires and single entered onto a secure database on the sponsor's server. A 10% accuracy check will be conducted to ensure validity of the data. The focus groups will be digitally recorded on an encrypted voice recorder. The audio recordings will be securely sent to a third-party transcription service and returned and stored on the sponsor's secure server for analysis. This will only be accessible to delegated researchers.

Health professionals who work within the pulmonary rehabilitation department at the research site will be approached and invited to undertake the decision coaching training. A detailed information sheet will be provided to them and those who express interest will be contacted to arrange an appropriate date and time to consent to the study. The researcher will obtain informed consent and then provide the decision coaching workshop. Following completion, health professionals will receive a certificate to recognise their new skills. They will then begin to deliver the SDM intervention individually with patient participants consented to the study.

Sample size

Design steps 1 and 2a: qualitative interviews

A sample size of 15 participants (*i.e.* six to seven patients and eight to nine health professionals) was selected, congruent with expert opinion on a minimum data set for qualitative research [52–54]. However, a pragmatic approach will be taken, meaning if new data and concepts are still emerging once the target sample size is met, data collection will continue until data saturation is met. A reflexive log [55] will be maintained prior to and throughout data collection to ensure data transparency.

Design step 2b: Implicit Association Test

This sample size calculation was determined using the online platform Raosoft (www.raosoft.com/samplesize.html), which is suitable for the calculation of sample sizes for surveys. The calculation is based on the following assumptions: the margin of error accepted (5%), the confidence level needed (95%), the population size (number of staff who actively refer to University Hospitals of Leicester pulmonary rehabilitation services, n=128), the response distribution (50%). The calculated sample size is 97 participants.

TABLE 6 Research visits for all participants recruited to the feasibility study

	Procedure	Purpose
1 month prior to visit 1	Recruit and provide decision coaching training to SDM facilitators	To provide health professionals with the knowledge and skills to conduct a SDM consultation with patients, using a PtDA
1–2 weeks before visit 1 (upon referral to pulmonary rehabilitation)	Invitation letter, patient information sheet and reply slip sent to participant Telephone/face-to-face consultation to assess eligibility criteria and arrange research visit	To inform participants of the research procedures To confirm participants' understanding and willingness to participate
Visit 1 (up to 1 week before pulmonary rehabilitation assessment appointment; to be completed face-to-face/telephone depending on COVID-19 restrictions)	Explanation of the purpose of the research and what the participant will be expected to do Sign informed consent form if participant meets the inclusion/exclusion criteria and agrees to participate To collect the following baseline outcome measures: Decisional Conflict Scale Patient Activation Measure Provide PtDA	To ensure participant understanding To obtain consent To obtain a baseline measure for each participant. This will be used to assess the feasibility of delivering the outcome measures and provide data for the preliminary evaluation of the intervention effect To allow the participant an opportunity to engage with the PtDA prior to their pulmonary rehabilitation assessment
Visit 2 (pulmonary rehabilitation assessment; to be completed face-to-face/telephone depending on COVID-19 restrictions)	Collection of routine pulmonary rehabilitation outcome measures: COPD Assessment Test Bristol COPD Knowledge Questionnaire Chronic Respiratory Questionnaire Hospital Anxiety and Depression Scale COPD PREM 9 MRC dyspnoea scale Incremental shuttle walking test Endurance shuttle walking test Administer SDM intervention	To obtain a baseline measure for each participant and provide data for the preliminary evaluation of the intervention effect To elicit a SDM consultation
Visit 3a (pre-pulmonary rehabilitation discharge assessment; to be completed face-to-face/telephone, depending on COVID-19 restrictions)	To collect the following post-intervention outcome measures: Decisional Conflict Scale Patient Activation Measure Intervention attendance and attrition	To obtain a post-intervention measure for each patient. This will be used to assess the feasibility of delivering the outcome measures and provide data for the preliminary evaluation of the intervention effect
Visit 3b (pulmonary rehabilitation discharge; to be completed face-to-face/telephone, depending on COVID-19 restrictions)	Collection of routine pulmonary rehabilitation outcome measures: Uptake and adherence of pulmonary rehabilitation COPD Assessment Test Bristol COPD Knowledge Questionnaire Chronic Respiratory Questionnaire Hospital Anxiety and Depression Scale COPD PREM 9 MRC dyspnoea scale Incremental shuttle walk test Endurance shuttle walk test Patient satisfaction with pulmonary rehabilitation	To obtain a post-intervention measure for each participant and provide data for the preliminary evaluation of the intervention effect
Visit 4 (optional; to be completed face-to-face/telephone/teleconferencing depending on COVID-19 restrictions)	Patient focus group and health professional interviews	To explore the acceptability of the intervention

COVID-19: coronavirus disease 2019; SDM: shared decision-making; PtDA: patient decision aid; PREM: patient-reported experience measure; MRC: Medical Research Council.

Beta testing 1 and 2: feasibility study

A total of 10 SDM facilitators will be recruited from the pulmonary rehabilitation team to deliver the SDM intervention and 30 patient participants will be recruited to engage in the intervention. The chosen sample size is sufficient for the assessment of feasibility [51] and will enable us to estimate a standard deviation, using ⩾80% upper one-sided confidence limit for our primary outcomes and to calculate the sample size needed for a full scale randomised controlled trial (should the results indicate this is warranted).

At the end of the study, ∼15 participants (10 patients, five SDM facilitators) will engage in a focus group (one or two groups) or an interview (up to five interviews). As described earlier, the proposed sample size for the qualitative data collection is congruent with expert opinion [52–54], a pragmatic approach will be utilised to meet data saturation, and a reflexive log will provide data transparency [55].

Data analysis

All statistical analysis will be performed using IBM SPSS (version 26) software. Qualitative analysis will be performed using QSR International NVivo (version 12) software.

Design steps 1 and 2a: qualitative interviews

The qualitative interview data will be analysed using an inductive approach alongside the enhanced critical incident technique (ECIT) [33]. This method identifies items, known as critical incidents, which make a significant positive (helping), negative (hindering) or future recommendation (wish-list) contribution to the topic of interest. For example, and as previously highlighted, patients often cite a lack of transport options as a hindrance to their acceptance of pulmonary rehabilitation. Here the hindering critical incident would be "a lack of transport options".

The first author will extract the helping, hindering and wish-list critical incidents from the first transcript and group them thematically into categories. The remaining transcripts will be analysed and critical incidents will be placed into existing categories, or if incongruent, new categories will be developed. The analysis will continue iteratively until categories became specific and robust. The ECIT's credibility checks will be closely adhered to. These include independent analysis by two additional researchers, the verification of categories and quotes with participants, and the verification and saturation of categories with academic experts.

Design step 2b: Implicit Association Test

Analyses will be by the per-protocol method (*i.e.* participant data will be analysed if an outcome is available). The primary outcome is the response latency of the IAT. The strength of the association between concepts will be measured by the standardised mean difference score of the congruent word pairings and the incongruent word pairings. This will be analysed using a paired t-test with a 95% confidence interval.

Beta testing 1 and 2: feasibility study

Recruitment capability will be assessed by calculating the participation rate and will be presented as percentage proportions. Data collection processes and acceptability of outcome measures will be assessed by reviewing data completeness. This will be calculated and presented as percentage proportions. The change between baseline and post-intervention measures will be compared using paired t-tests for parametric data and the Wilcoxon signed rank-test for nonparametric or categorical data. As this is a feasibility study, there will be no inferential statistics. Uptake and adherence of pulmonary rehabilitation will be calculated and presented as percentage proportions.

Qualitative data from the focus groups and interviews will be analysed independently and then collaboratively between two authors using the reflexive thematic analysis technique [56]. This is a six-step process involving data familiarisation, code generation, searching for themes, reviewing themes, defining themes and producing the written findings.

Monitoring

Data monitoring and auditing

The research will be conducted in accordance with the current approved protocol (version 7.0; 9 November 2021), good clinical practice, relevant regulations and sponsor standard operating procedures. To ensure that it meets these requirements, the sponsor has permission to monitor and audit the study data.

Ethics and dissemination

Research ethics approval

This research was given ethical approval by South Leicester Research Ethics Committee, reference 21/EM/0084.

Access to data

Researchers who are granted access to the study database will have access to the dataset.

Dissemination policy

Upon completion of this research, the findings will be disseminated in line with the host site's dissemination policy. A final trial report will be prepared and sent to the research ethics committee within 12 months of the end of the research. The findings will be submitted for international publication and presentation at national and international conferences. Participants will be invited to a dissemination event where the results of the research are presented to them.

Provenance: Submitted article, peer reviewed.

Author contributions: This research was conceived by A.C. Barradell with supervision from S.J. Singh, L. Houchen-Wolloff, N. Robertson and H.L. Bekker. All authors contributed to this manuscript. A.C. Barradell will take overall responsibility for the conduct of this research, including study design, conduct, data analysis and interpretation, manuscript writing and dissemination of results.

This study is registered at www.clinicaltrials.gov with identifier number NCT04990180. Researchers who are granted access to the study database will have access to the dataset. Informed consent and PtDA materials are available upon request.

Conflict of interests: A.C. Barradell reports receiving support for the present manuscript from NIHR ARC East Midlands, and Centre for Exercise and Rehabilitation Science. The remaining authors have nothing to disclose.

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