BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-020750
Article Type:	Protocol
Date Submitted by the Author:	22-Nov-2017
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Keywords:	Pulmonary rehabilitation, Inclusive design, Patient-centred design, Care journey, Patients’ capability, COPD

STUDY PROTOCOL

Improving uptake and attendance for pulmonary rehabilitation: an Inclusive Design/ mixed-methods study protocol

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Keywords: Pulmonary rehabilitation, Inclusive Design, Patient-centred design, Care journey, Patients' capability, COPD

Word count (abstract) / limit: 297/300 words

Word count (text)/limit: 3638/5500 words without figures and tables

ABSTRACT

Introduction:

1.2 million people in the UK have Chronic Obstructive Pulmonary Disease (COPD) that causes breathlessness, difficulty with daily activities, infections and hospitalisation. Pulmonary rehabilitation (PR), a programme of supervised exercise and education, is recommended for patients with COPD. However, only 1 in 10 of those who need it receive PR and there are no proven solutions to increase the number of people attending PR. The UK National COPD Audit Programme concluded that the COPD treatment might not be accessible to people with disabilities. This paper applies an Inclusive Design approach to PR services to understand people's needs and maximise the number of patients accessing PR. It aims to improve COPD care journeys by identifying barriers, in relation to patients' capabilities, that can affect their access to PR.

Methods and analysis:

The protocol includes four steps. Step 1 will involve interviews with healthcare professionals and patients with COPD to gather insight into their experiences within the COPD care journeys. A hierarchical task analysis will be used to map care journeys. Step 2 will estimate the service exclusion: the demand of every task will be rated by pre-defined scales and the proportion of the population excluded from the service will be estimated by an exclusion calculator. Step 3 will identify the challenges of PR service. Framework analysis will be used to guide data analysis. Step 4 will generate an approach to improve the care journey and validate the feasibility of this approach through further interviews and focus groups with healthcare professionals and patients.

Ethics and Dissemination:

The Cambridge Central Research Ethics Committee approved the study protocol (17/EE/0136). Study results will be disseminated through peer-reviewed journals, conferences and the British Lung Foundation networks. They will also contribute to a Research for Patient Benefit project on improving uptake of PR.

ARTICLE SUMMARY

Strengths and limitations of this study:

- This is the first study using the Inclusive Design approach, to reduce exclusion and improve the accessibility of pulmonary rehabilitation services.
- Mapping the care journey will ensure that representative healthcare professionals and patients are included to generate a systematic representation of the real care processes.
- Although this study makes pulmonary rehabilitation its focus, the protocol could be modified for application to other healthcare services, particularly for other long-term conditions.
- This paper considers physical and cognitive exclusion, other types of exclusion, for instance social or psychological, are not included in the analysis.
- The exclusion data is based on the general population rather than specific medical conditions. However, it is the only holistic source of data about people’s capabilities in the UK.

INTRODUCTION

Underutilisation of pulmonary rehabilitation

Chronic obstructive pulmonary disease (COPD) is a progressive lung disease in which people experience breathlessness, exercise incapacity and are vulnerable to exacerbations, frequently requiring hospitalisation. According to the World Health Organisation estimates, 65 million people have moderate to severe COPD. Globally, it is estimated about three million deaths were caused by the disease in 2015 (that is, 5% of all deaths globally in that year). Approximately 1.2 million people live with COPD[2] in the UK and a large proportion of them are older people. This condition costs the UK National Health Service (NHS), a publicly funded national healthcare system for England, £800 million per year, mostly relating to hospital admissions.[3] The UK National Institute for Health and Care Excellence (NICE) recommends that pulmonary rehabilitation (PR), providing supervised exercise and education, can be offered to patients functionally disabled by COPD.[4] PR improves symptoms, exercise capacity and quality of life[5] and leads to fewer repeat exacerbations requiring admission or hospital attendance.[6 7] It plays an important role in fostering self-management skills.[8]

The National COPD Audit Programme[9] estimated the prevalence of COPD patients eligible for PR in England and Wales in 2013/14 was 446,000; however, despite evidence-based guidelines[9 10] there were only 68,000 referrals (15% of normative need) during that period and of those only 69% attended an initial assessment (10% of normative need).[9] The audit highlighted the need to improve referral and uptake rates. It recommended that PR referral pathways, healthcare professional training, information for patients and referrers and barriers to patient access should be reviewed. The audit also demonstrated that the availability of COPD treatment for the full range of severity of disability is not inclusive.[12]

The evidence gap

Several studies have been carried out to identify barriers that prevent access to pulmonary rehabilitation.[13–21] Most of these barriers have been identified as emanating from system characteristics and patients' and clinicians' beliefs and attitudes, rather than from patients' personal characteristics. For example, referral to PR can be influenced by a difficult referral process and the lack of knowledge about PR; while uptake can be affected by the quality of the healthcare professional's conversation with patients about PR, and patients' beliefs about PR. There is little understanding of how patients' personal capabilities (including mobility, dexterity, reach and stretch, vision, hearing, thinking and communication) relate to their ability to access PR and affect implementation of the care service. People's personal capability to access a healthcare service is a prerequisite for them to use it, so it is very important to consider patients' capabilities in order to improve access to PR services. Insight into the capability demand (i.e., the demands that the care pathway makes on people's capability) within the COPD care pathway would help care providers to better understand the needs of patients and to support their engagement in PR. Little research has yet focused on people's capability-related needs while accessing COPD care within the community.

Study aim

The aim of the study is to improve access to PR services. An Inclusive Design approach will be used to estimate the system demands on patients with COPD and evaluate PR services' exclusion. It will identify the ways in which the care pathway excludes patients and the ways in which the care pathway design can be modified to provide inclusive access to PR for as many eligible patients as possible.

The research question is: how can Inclusive Design be used to improve patients' experience of accessing pulmonary rehabilitation within the community?

Concept of Inclusive Design

Inclusive Design can be defined as: i) "the design of mainstream products and/or services that are accessible to, and usable by, people with the widest range of abilities within the widest range of situations without the need for special adaptation or design",[22] and ii) ensuring that the demand made on an individual in a given environment does not exceed their capability to respond. In this study, Inclusive Design refers to the latter definition.

The Inclusive Design approach is a rigorous user-centred approach, where the fundamental premise is that accessible and usable products or services can only be developed or implemented by first knowing the intended users.[23] By understanding the user's capability-demand in healthcare context, it would be easier to understand their capability-related needs for care and enhance the implementation of the healthcare services.

People's capabilities

Capabilities in this context refer to people's abilities to access health services. There are mainly two factors that cause a change in people's capability: one is an age-related change in capability and the other is a change in condition-related capability. Regarding patients with COPD, a large proportion are older people[2] and the condition of COPD as well as the ageing process may cause fatigue, which affects abilities such as mobility and communication. For example, patients with COPD may not be able to walk for long distances as their condition may make them feel breathless.

Care pathway/ journey

'Care pathway' or 'care journey' are both terms used to describe the process of healthcare service delivery.

Care pathways are more generic and described from an organisational perspective. A pathway may take the form of an integrated management plan that provides a sequence and timing of actions necessary to achieve a standard care process and optimal efficiency for clinicians.[24] For example, the main stages in the NHS primary care pathway of COPD rehabilitation are shown in figure 1.

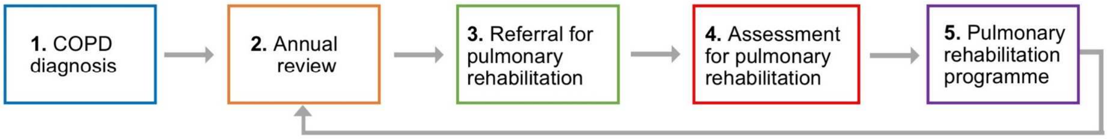

Figure 1 The main stages in the NHS primary care pathway of COPD rehabilitation

A patient's care journey refers to the process that he or she goes through in order to receive the care. As shown in figure 2, we define the care journey as a series of tasks, for example, the first stage in figure 1, i.e., COPD diagnosis can be further broken down into four tasks: i) make an appointment with General Practitioner (GP); ii) go to the GP practice; iii) have a GP consultation; vi) obtain diagnosis. The detailed care journeys that patients experience in accessing the PR service will be more easily identified in the context of a deeper understanding of COPD services.

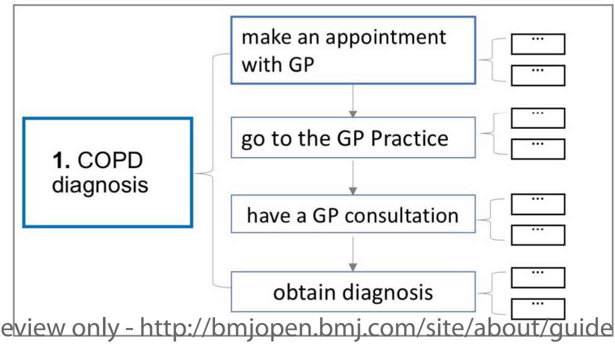

Figure 2 Care journeys consist of specific tasks

The connection between Inclusive Design and patient access to PR

Any service makes demands on patients, and patients have to have sufficient capabilities in order to respond to these demands and access the service (figure 3). If the demands of accessing the PR service exceed the capabilities of the patients then exclusion or difficulty in using the service will arise. Taking the task “go to the GP practice” as an example, if the home of a patient with COPD is relatively far from the GP surgery and the patient’s mobility is limited, then he or she may not be able to get to the GP practice. In this case, this patient is excluded from the PR service as he or she cannot even see the doctor. With better understanding of the tasks in the patients’ care journey, we are able to estimate the service’s system demands on patients’ capabilities and analyse the extent of system inclusion.

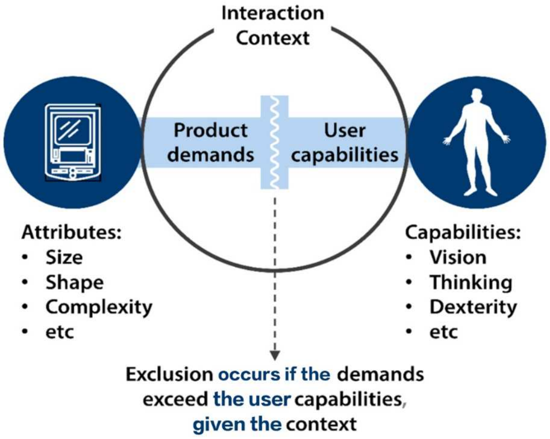

Figure 3 Interaction Context-Demand and Capabilities. (Persad et al. 2007)
The example is of a physical product but this applies equally to services.
Reproduced from www.inclusivedesigntoolkit.com with permission.

METHODS AND ANALYSIS

Study procedures

As illustrated in figure 4, the research is divided into four steps: semi-structured interviews will be used in Step 1 (Mapping pathway); Step 2 (Estimate exclusion) and Step 3 (Identify challenges) are mainly data analysis; and interviews and focus groups will be used in Step 4 (Propose recommendation).

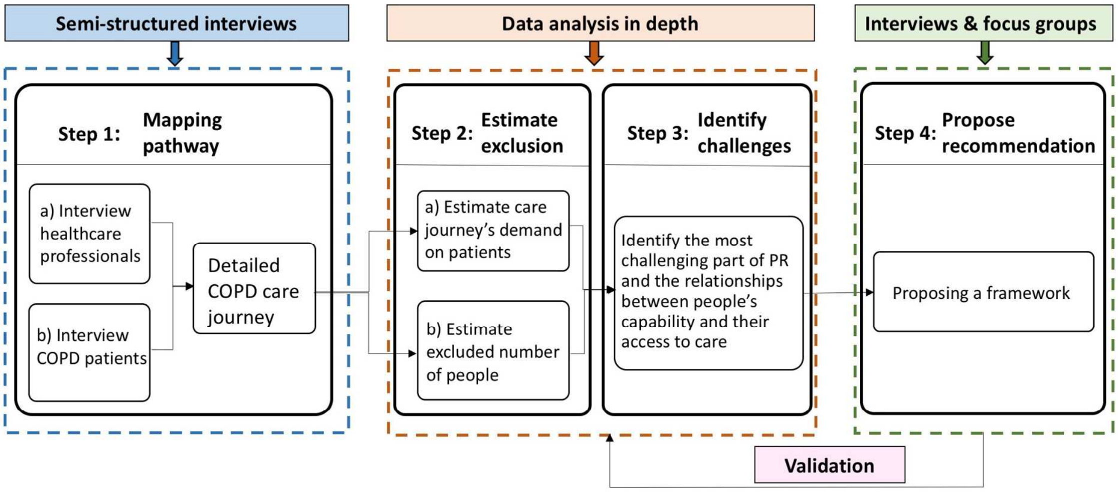

Figure 4 Study design

Step 1: Mapping pathway

a) Interviews with healthcare professionals:

We will conduct interviews with healthcare professionals (including GPs, practice nurses, and physiotherapists) who refer patients to PR, as well as PR service managers and healthcare commissioners (see section *sampling and recruitment* for details).

The interviews with healthcare professionals will gather insight into their experiences and perception of the COPD care pathway. The detailed primary care clinicians' pathways for PR will be identified based on the interview data. This understanding of the care pathway from the clinicians' perspective will be used to help map patients' care journeys.

b) Interviews with patients:

Three categories of patients with COPD will be interviewed: patients who have accepted a PR offer, patients who declined a PR offer and patients who have never been referred to PR (see section *sampling and recruitment* for details).

The interviews with patients with COPD will capture the detailed COPD care journey from patients' perspectives, gather insight into patients' experiences of PR and their care needs, and assess the capabilities of patients with COPD.

Data analysis: i) Transcriptions and field notes will be managed and analysed using NVivo software. ii) The detailed care journeys that patients go through to receive COPD treatment and the detailed care pathway that healthcare professionals engage in delivering COPD treatment will be summarised and represented as a hierarchical task analysis[25] (figure 5). For example, the stage 1 *COPD diagnosis* in figure 1 can be further broken down into the following steps: make an appointment with GP, go to the GP Practice, have a GP consultation, and obtain diagnosis (figure 2). Making an appointment with a GP can be done by telephone, computer, could be booked by dropping in or booked by others. Making an appointment by telephone can be further broken down into the following steps: make a telephone call, request an appointment, agree on details and mark in diary. iii) The compatibilities and the conflicts of the care pathway from healthcare professionals' and the care journey from patients' perspective will also be investigated.

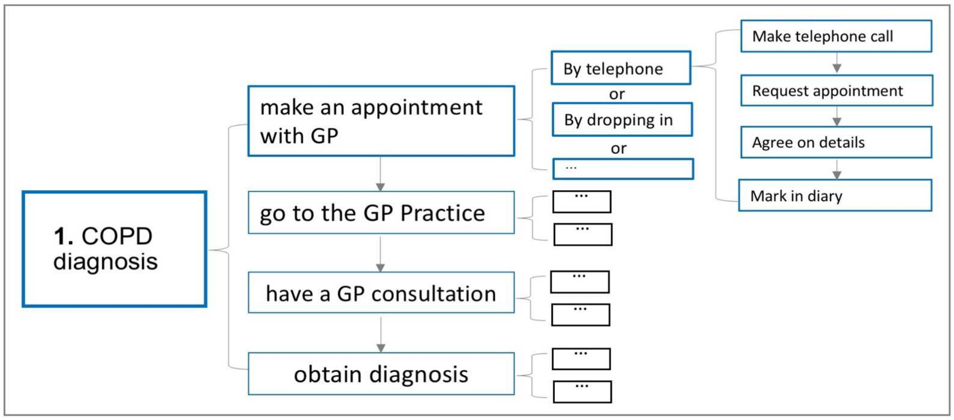

Figure 5 Example for care journey represented in a hierarchal task analysis

Output: A map of the patients' care journey will be defined. This will be used in Step 2 to estimate the reasons and levels of exclusion.

Step 2: Estimate exclusion

a) Estimate how demanding the COPD care journey is for patients

Tasks will be analysed to determine the demands of the COPD care journey on patients. Specifically, the demand of every task will be rated by pre-defined scales. These scales were constructed based on the questions in the Disability Follow-up to the Family Resources Survey, which was originally performed to help plan welfare support for disabled people.[26] Subsequently, this data has been used to assess numerous products and services.[26–28] Examples of assessing hearing, reach and speech comprehension demand scales are shown in figure 6. Higher demand on peoples' capabilities causes higher scale ratings, and the symbol ">" off scale means it is excessive for a mainstream service.

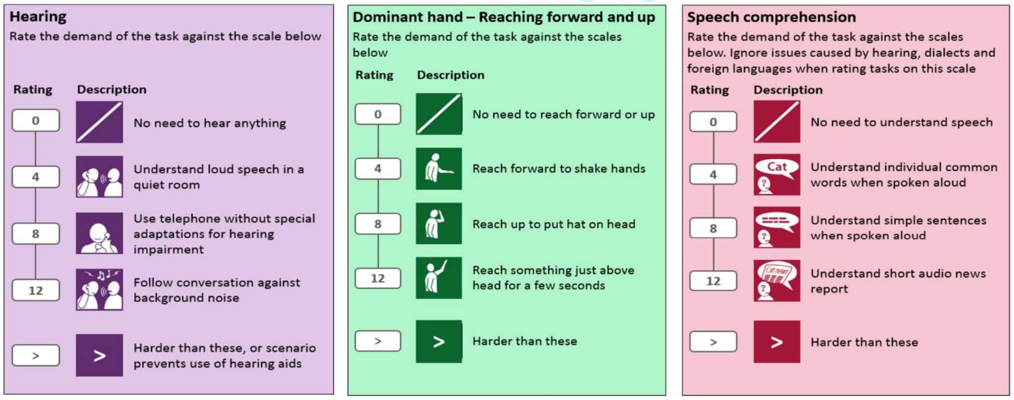

Figure 6 The standard of measuring hearing (left), reaching forward and up (middle) and speech comprehension (right)

With the pre-defined scales, the demand on every task will be assessed. For example, the task, to make a telephone call, places demands on patients' sensory capabilities (to hear clearly throughout the call and see the number buttons), motor capabilities (to hold the phone and press the number buttons), and cognitive capabilities (to remember/know the telephone number to call and communicate with the receptionist). The demand of this task on patients' hearing capability is close to the scale 8, i.e., use telephone without special adaptations for hearing impairment, so the hearing demand is rated scale 8. The level of the tasks' description is matched against the details of pre-defined scales.

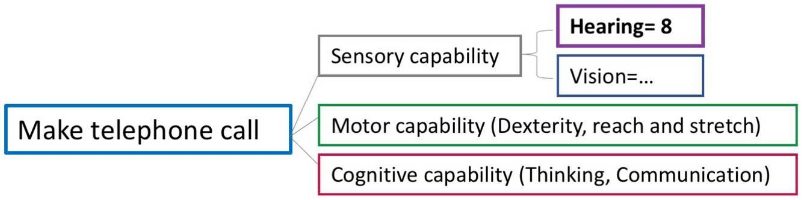

Figure 7 Demand on capability of making a phone call

b) Estimate the number of people excluded from PR on the basis of their capabilities

The "Exclusion Calculator" produced by the University of Cambridge Engineering Design Centre represents a large database of British users with a range of disabilities and quantified information regarding the use of a product according to their disability.[29] The original population data is from the Disability Follow-up to the Family Resources Survey[26] which estimates the proportion of the British population who are unable to use a service because of the demands that it places on the users' capabilities. A version of this calculator is freely available on the Inclusive Design Toolkit website.[29]

The "Exclusion Calculator" will be used to estimate the number of people excluded from accessing PR by inputting the estimated demands of each task along COPD care journeys.

Output: An augmented patient care journey map with the type and levels of exclusion will be estimated. This exclusion data will evidence the connection between people's capabilities and their ability to access PR in Step 3.

Step 3: Identify challenges

Understand the most challenging part of PR and analyse the relationship between people's capabilities and their access to PR services. The interviews, rated demand and the excluded number of people will provide clues to identify the most challenging issues linked to PR and develop an initial approach. It will also help to analyse the relationships between people's capabilities and the possibilities of their accessing PR.

Data analysis: Framework analysis[30] will be used to structure the data analysis (including interview transcript and exclusion data). First, initial categories/ themes will be identified and put in the coding matrix; then, the relationship among the different coded data will be analysed; finally, the core categories to propose the initial approach will be established.

Output: An initial approach that helps identify patients' needs will be proposed, which aims to understand barriers, especially those barriers caused by not taking into account patients' capabilities when they access PR. The initial approach will be validated in Step 4.

STEP 4: Propose recommendation

Propose and validate an approach that can help better understand people's capability demand within the process of PR.

i) Further interviews of healthcare professionals (GPs, practice nurses, or physiotherapists) will be conducted to check the feasibility of the approach. Potential participants (new or existing interviewees) will be invited to participate by email or via a phone call.

ii) Two focus groups will be organised that include healthcare professionals and patients with COPD to check the feasibility of the improvements.

iii) The approach to improve the PR service will be further refined based on the data of interviews and focus groups.

Data analysis: The interview and focus group data will be transcribed and coded in an inductive coding structure to help refine the approach.

Output: The result of the focus group, together with the data analysis from the interview, will help better understand the barriers that prevent patients with COPD from accessing PR. A validated approach that contains the improvements will be available to and inform the implementation of PR service.

Study setting

Interviews with healthcare professionals will take place at their place of work or other NHS premises by arrangement.

Interviews with patients will take place on community premises where pulmonary rehabilitation classes are conducted, where Breathe Easy group meetings are held or at a location of choice (i.e., the Engineering Department of University of Cambridge or their home with someone accompanying the researcher).

Sampling and recruitment

Eligibility Criteria

- Healthcare professionals who can refer to PR programmes, physiotherapists who provide PR, PR service managers, and the CCG strategy managers in Cambridgeshire and Peterborough.
- People resident in the East of England, aged 18 or over, with a diagnosis of COPD, and stable disease, eligible for PR as defined by the guideline recommendations and able to read/write in English.

Size of sample

Warren (2002) suggested that the minimum number of interviews needs to be between twenty and thirty for an interview-based qualitative study to be published.[31] Mason (2010) reported that the interview number range was 1 to 95 (with a mean of 31 and a median of 28) for interview-based qualitative studies in doctoral theses.[32] Adler also advised the best number of people for a qualitative research is between a dozen and 60, with 30 being the mean.[33] The size of sample in this study will be consistent with these recommendations and the details are shown in table 1. To enhance validity, the sample size may be adjusted by the need to reach data saturation.

Table 1 The size of sample

Category	Healthcare professionals	Patients with COPD	Total
Mapping pathway: Semi-structured interview	6 healthcare professionals (including GPs, practice nurses, or physiotherapists) and 1-2 service managers and 1-2 commissioners. (face-to-face or by telephone)	10-15 patients with COPD including those accepted an PR offer, declined an PR offer, and never referred if possible. (face-to-face or by telephone)	18-25
Validation: Further Interviews	face-to-face interview 2-4 healthcare professionals and email 5-10 healthcare professionals to seek comments.	Not applicable	2-4 interviews 5-10 emails
Validation: Focus groups	1 physiotherapist × 2 groups who attend the Breathe Easy Support group	8-10 patients × 2 groups who attend the Breathe Easy Support group	10-24 (focus groups)

Sampling technique

Snowball sampling refers to enough data are being gathered to be useful for research as the sample builds up. This sampling strategy will be used to gather data in Cambridgeshire and Peterborough. Sampling will be informed by the interview results to represent a range of care pathways/journeys and their experiences along the care pathways/journeys. A stakeholder map will be used to help identify a representative sample and gather adequate data. The researcher will seek advice from the interviewees to ensure all the key stakeholders are covered. If any role within the stakeholder map is missing or affects the data analysis, the researcher will try to find appropriate interviewees. The detailed plan is shown in table 2 and table 3 (where *n* refers to the number of people):

Table 2 Recruitment plan for healthcare professionals

Healthcare professionals' role	Understanding of PR pathway
GPs/ Practice nurses (n=6)	Familiar with the process of diagnosis, annual review, and referral
Physiotherapists (n=4-6)	Familiar with the process of referral, assessment for PR, PR programme, and annual review
PR service manager (n=1-2)	Familiar with the whole PR pathway process and having connections with other professionals
Commissioners& manager (n=1-2)	Familiar with the process of designing the COPD care pathway

Table 3 Recruitment plan for patients

	PR programme	Age group	Capability
People with COPD	Accepted PR offer (n=6-8) Declined PR offer (n=2-4) Never referred (n=2-3)	16-49 50-64 65-74 (n≥5) 75+ (n≥2)	Hearing, Vision, Mobility, Dexterity, Reach and Stretch, Communication, Thinking. Ensure a full range of capability loss is covered by the samples

Sampling identification

Access methods have been discussed with Clinical Research Network (CRN) Eastern.

Healthcare professionals (HCPs) will be identified by:

i. working with CRN Eastern locality managers to access HCPs;
ii. accessing HCPs through visiting or emailing GP Practices;
iii. accessing PR providers through East of England (EoE) PR network.

In terms of identifying patients with COPD:

i. people who have accepted a PR offer will be identified through PR provider registers.
ii. people who declined a PR offer may be challenging to engage. HCPs and PR providers will be asked to identify people they know and we will work with the British Lung Foundation to engage this group, e.g., through telephone interviews/ home visits, or interviews while people are visiting their practice for an annual review.
iii. people who have never been referred to PR will be identified through COPD registers in participating GP practices. One GP practice is in the city centre, while the other is in a rural area.

Research bias

The literature review, interviews and focus group will be used to gain multiple perspectives on the understanding of healthcare professionals' and patients' experiences. The research has been carefully designed and has been reviewed by experts to ensure it informs us of the current challenges that patients experience when accessing PR. Specifically, the research protocol has been reviewed by the Research Advisory Committee (RAC) of Cambridge University Hospitals and advice has been received from the members of the Patient and Public Involvement (PPI) panel, Cambridge University Hospital (NHS Foundation Trust). Five patients with COPD have contributed to research questions, aim, participant sheets, interview schedule, consent forms and the plain English summary. Several discussions have been held with three physiotherapists who provided clinicians' perspectives on the research questions, aim, participant sheets, interview schedule and consent forms for healthcare professionals. The lay summary and interview materials (participant information sheets) have been reviewed by nine members of the PPI panel, Cambridge University Hospitals. They have confirmed the language used is understandable and have provided useful comments to refine the research.

ETHICS AND DISSEMINATION

Assessment and management of risk

Participants may be vulnerable due to age/frailty. In order to manage this risk, they will be identified via GP practices or PR services to whom they are known and who can ensure participants are aware of their diagnosis of COPD prior to approaching them. Sources of support will be identified to whom participants can be directed.

If there is a concern about a person's health or safety we may contact their GP; however, as this would mean breaking confidentiality it would only be done if the person were clearly at risk. When making appointments for patients to attend research activities, researchers will ensure that the time and location are acceptable to the participant.

It is recognised that interviews may involve discussion of sensitive topics regarding the patients' health, lifestyle or quality of life. To address this:

- All study materials, including interview questions, have been developed in collaboration with a patient and public involvement group to ensure topics are addressed in a sensitive way.
- Participants will be directed to sources of support and information.

Data protection and patient confidentiality

The Patient Information Sheet will detail the data to be collected and how it will be stored.

The study will comply with the Data Protection Act, which requires data to be anonymised as soon as it is practical to do so. The study staff will ensure that participants' anonymity is maintained. Staff taking consent will ask patients only for personal data that confirms their eligibility for the study and at no point will study staff have access to patients' medical records.

On entering the study, participants will be assigned an ID. Participant names will only be identifiable on a cross-referenced list of IDs and names, which will be stored in a locked filing cabinet on Trust premises. When recordings of interviews or focus groups are transcribed, only the ID will be used as an identifier.

Data collected will be entered onto secure computers in the Engineering Design Centre (EDC) at the University of Cambridge and will only be accessible to the study team. Paper documents will be stored in a locked cupboard in the EDC and will only be accessible to the study team.

All electronic files will be password protected and access restricted to the study team. Participants will be identified only by a participant ID number on any electronic database. The name and any other identifying details will not be included in any study data electronic file. Data sharing and storage will meet the requirements of the National Institutes of Health Research. Data will be securely stored in the University of Cambridge Research Repository.

Ethical approval

This research has been ethically reviewed and approved by Cambridge Central Research Ethics Committee. The study' REC reference number is 17/EE/0136. It has two work packages: work package 1 which uses an Inclusive Design approach is presented above; work package 2 is to develop a toolkit to increase referral to and uptake of Pulmonary Rehabilitation (PR) in primary care.

Dissemination

We will work closely with the British Lung Foundation (BLF), who have a track record of disseminating innovation through patient networks, publications, online information, service development and HCP engagement. Two academic papers will be published in peer-reviewed journals compliant with policy on open access on: i) capabilities of patients with COPD, ii) comparison of COPD care pathways between HCPs and patients with COPD. Presentations will be given at regional, national and international academic and professional conferences, e.g. East Anglian Thoracic Society, British Thoracic Society and European Respiratory Society. The output will also comprise a part of a doctoral thesis by the lead author. The study started in June 2017 and will continue until February 2018.

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Acknowledgements

The authors would like to acknowledge Dr Jonathan Fuld, Lucy Bennett at Cambridge University Hospitals NHS Foundation Trust for their help and support in developing research; The authors would like to thank the Patient and Public Involvement (PPI) panel of Cambridge University Hospital, Nicola Cavaleri and Denise Chappell from the Language Unit who help review and refine the protocol. The Exclusion Calculator was produced by the Cambridge Engineering Design Centre, as part of the ID-3 Inclusive Design Consortium run by the Centre for Business Innovation, will be used in this research.

Contributors

YL initiated the protocol. TD and PJC provide supervision for research and reviewed as well as finalised the protocol. FE drafted the background, ethics and dissemination and reviewed the protocol.

Funding statement

The research is part funded by Collaboration for Leadership in Applied Health Research & Care (CLAHRC) East of England and Buchanan Fund of Downing College. China Scholarship Council provides funding for the researcher's PhD study.

Competing interests

The authors declare that they have no competing interests.

Provenance and peer review

Not commissioned; peer reviewed by the Research Advisory Committee (RAC) of Cambridge University Hospitals

Data sharing statement

The Inclusive Design methods and tools are available from our website: http://www.inclusivedesigntoolkit.com

Open access

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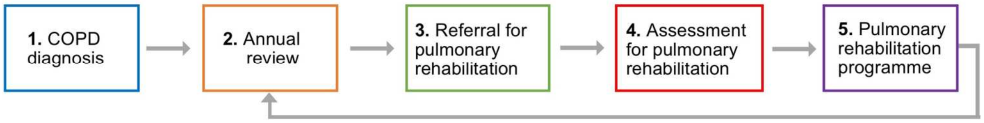

Figure 1 The main stages in the NHS primary care pathway of COPD rehabilitation

199x26mm (300 x 300 DPI)

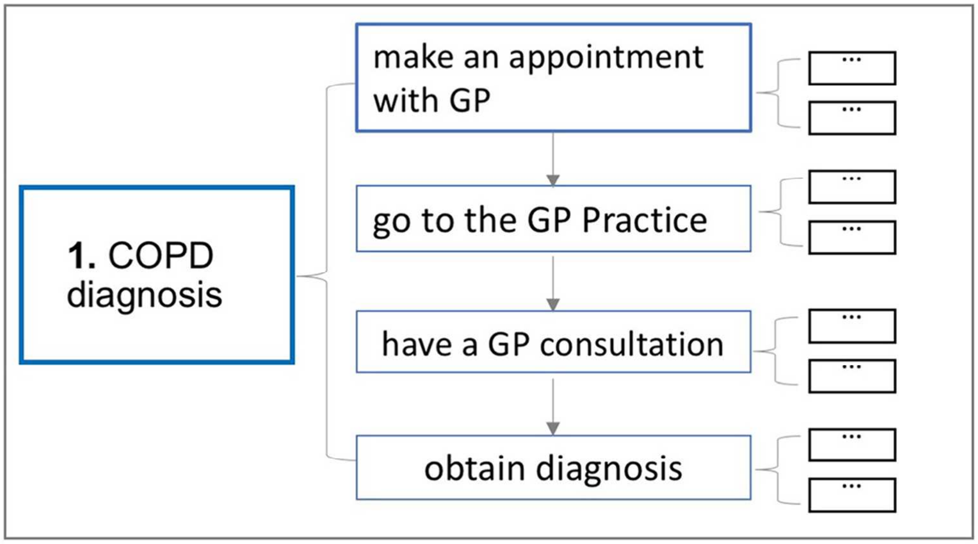

Figure 2 Care journeys consist of specific tasks

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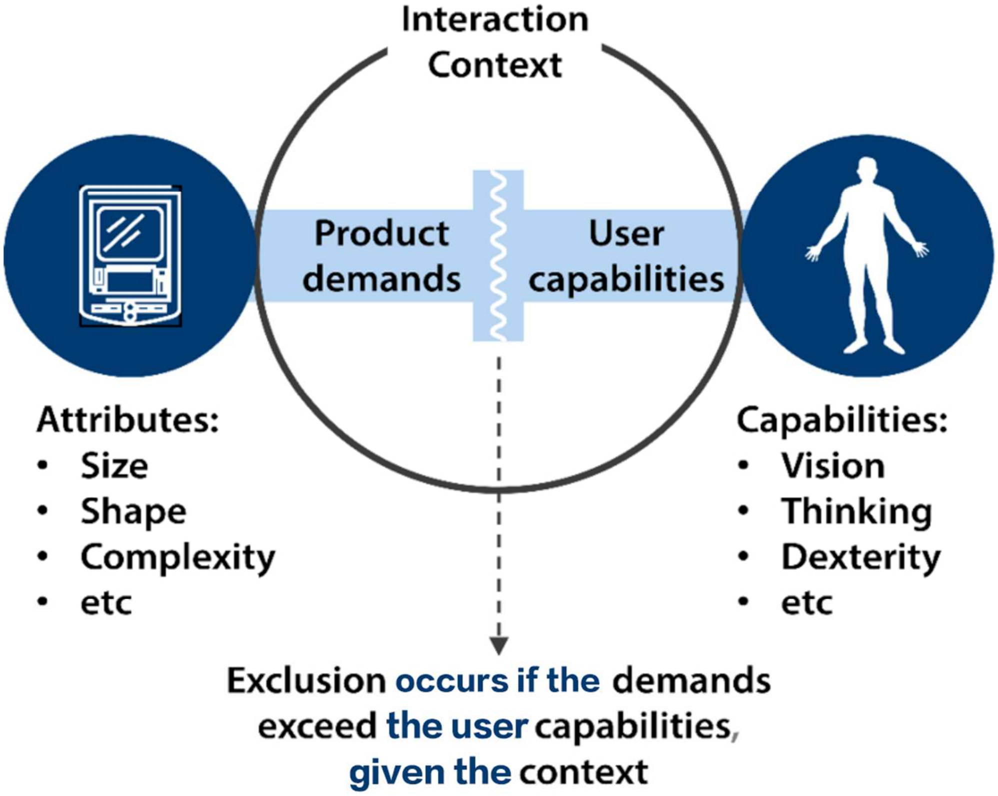

Figure 3 Interaction Context-Demand and Capabilities. (Persad et al. 2007)
The example is of a physical product but this applies equally to services.
Reproduced from www.inclusivedesigntoolkit.com with permission.

100x81mm (300 x 300 DPI)

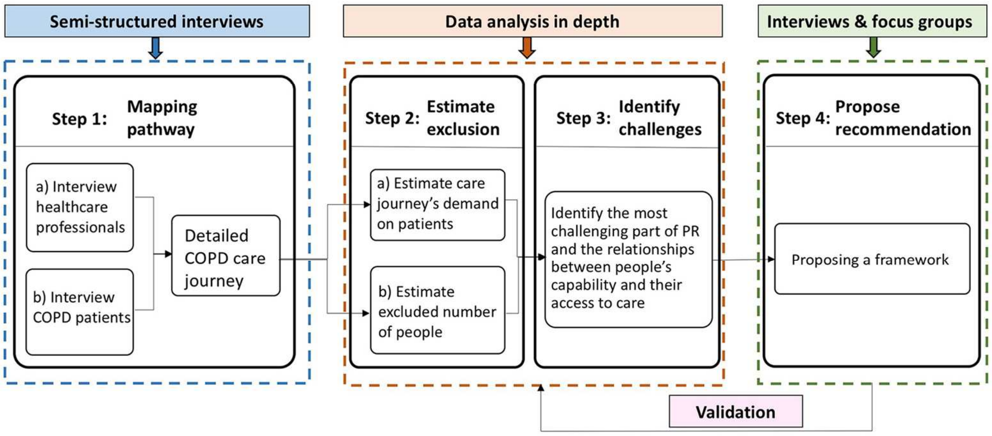

Figure 4 Study design

150x66mm (300 x 300 DPI)

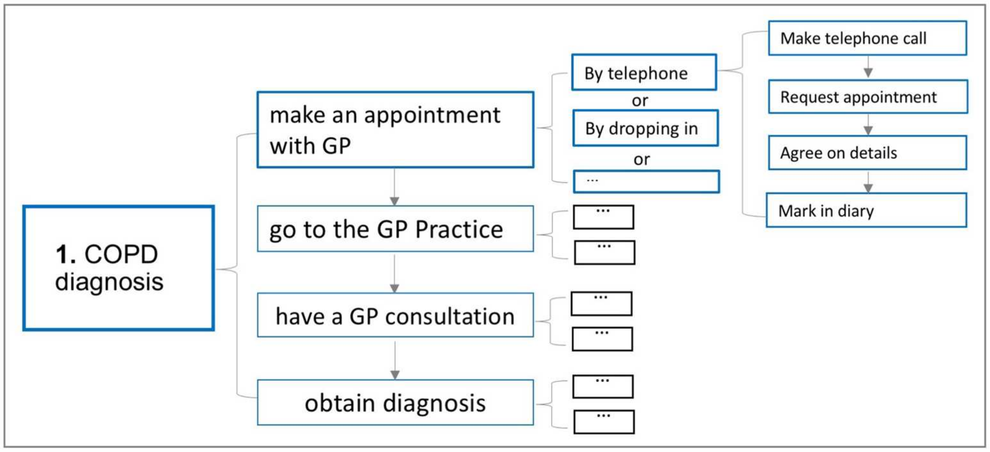

Figure 5 Example for care journey represented in a hierarchal task analysis

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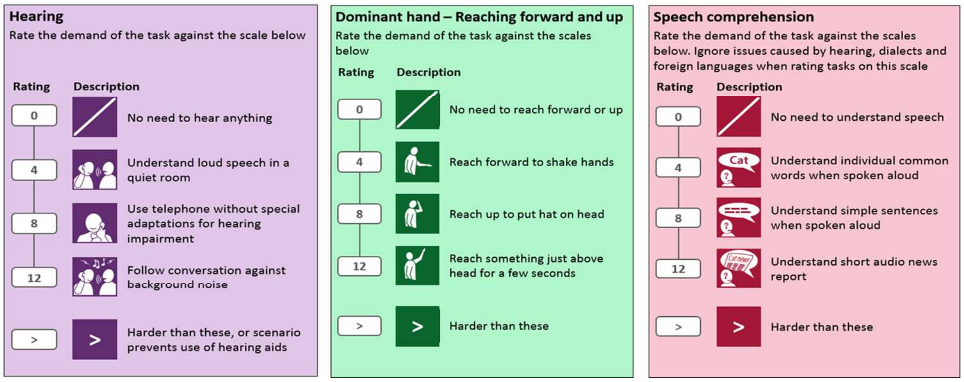

Hearing

Rate the demand of the task against the scale below

Rating	Description
0	No need to hear anything
4	Understand loud speech in a quiet room
8	Use telephone without special adaptations for hearing impairment
12	Follow conversation against background noise
>	Harder than these, or scenario prevents use of hearing aids

Dominant hand – Reaching forward and up

Rate the demand of the task against the scales below

Rating	Description
0	No need to reach forward or up
4	Reach forward to shake hands
8	Reach up to put hat on head
12	Reach something just above head for a few seconds
>	Harder than these

Speech comprehension

Rate the demand of the task against the scales below. Ignore issues caused by hearing, dialects and foreign languages when rating tasks on this scale

Rating	Description
0	No need to understand speech
4	Understand individual common words when spoken aloud
8	Understand simple sentences when spoken aloud
12	Understand short audio news report
>	Harder than these

igure 6 The standard of measuring hearing (left), reaching forward and up (middle) and speech comprehension (right)

150x56mm (300 x 300 DPI)

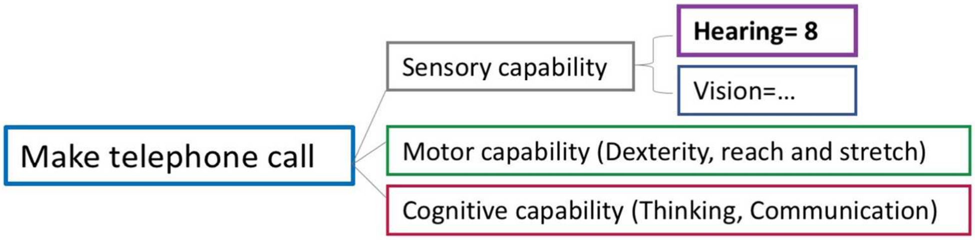

Figure 7 Demand on capability of making a phone call

180x44mm (300 x 300 DPI)

Checklist

No	Item	Description	Page
1	Planned or ongoing studies	Manuscripts that report work already carried out will not be considered as protocols. The dates of the study must be included in the manuscript and cover letter.	13
2	Protocols for studies that will require ethical approval	Protocols for studies that will require ethical approval, such as trials, are unlikely to be considered without having received that approval.	13
3	Title	This should include the specific study type, e.g. Randomised controlled trial.	1
4	Abstract	This should be structured with the following sections. Introduction; methods and analysis; ethics and dissemination.	2
		Registration details should be included as a final section, if appropriate.	Not applicable
5	Strengths and limitations of this study	A section, placed after the abstract, consisting of the heading 'Strengths and limitations of this study', and containing up to five short bullet points, no longer than one sentence each, that relate specifically to the methods.	3
6	Introduction	Explain the rationale for the study and what evidence gap it may fill. Appropriate previous literature should be referenced, including relevant systematic reviews.	4-6
7	Methods and analysis	Provide a full description of the study design, including the following:	6-12
		i. how the sample will be selected;	10
		ii. interventions to be measured;	Not applicable
		iii. the sample size calculation (drawing on previous literature) with an estimate of how many participants will be needed for the primary outcome to be statistically, clinically and/or politically significant;	10-11
		iv. what outcomes will be measured and how;	7-10
		v. a data analysis plan.	7-10
8	Ethics and dissemination	Ethical and safety considerations and any dissemination plan (publications, data deposition and curation) should be covered here.	12-13
9	Full references		14
10	Authors' contributions	State how each author was involved in writing the protocol.	13
11	Funding statement	Preferably worded as follows. Either: 'this work was supported by [name of funder] grant number [xxx]' or 'this research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors'.	13
12	Competing interests statement		13

BMJ Open

Understanding influences on the uptake of pulmonary rehabilitation in the East of England: an Inclusive Design / mixed-methods study protocol

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-020750.R1
Article Type:	Protocol
Date Submitted by the Author:	08-Feb-2018
Complete List of Authors:	Liu, Yuanyuan; University of Cambridge Department of Engineering, Engineering Design Centre Dickerson, Terry; University of Cambridge Department of Engineering, Engineering Design Centre Early, Frances; Cambridge University Hospitals NHS Foundation Trust, Centre for Self Management Support Fuld, Jonathan; Cambridge University Hospitals NHS Foundation Trust, Centre for Self Management Support Clarkson, John; University of Cambridge Department of Engineering, Engineering Design Centre
Primary Subject Heading:	Research methods
Secondary Subject Heading:	Health services research, Qualitative research
Keywords:	Pulmonary rehabilitation, Inclusive design, Patient-centred design, Care journey, Patients’ capability, COPD

STUDY PROTOCOL

Understanding influences on the uptake of pulmonary rehabilitation in the East of England: an Inclusive Design / mixed-methods study protocol

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Keywords: Pulmonary rehabilitation, Inclusive Design, Patient-centred design, Care journey, Patients' capability, COPD

Word count (abstract) / limit: 295/300 words
Word count (text)/limit: 4781/5500 words without figures and tables

ABSTRACT

Introduction:

1.2 million people in the UK have Chronic Obstructive Pulmonary Disease (COPD) that causes breathlessness, difficulty with daily activities, infections and hospitalisation. Pulmonary rehabilitation (PR), a programme of supervised exercise and education, is recommended for patients with COPD. However, only 1 in 10 of those who need it receive PR. Also, the UK National COPD Audit Programme concluded that the COPD treatment might not be accessible to people with disabilities. This paper applies an Inclusive Design approach to community-based PR service provisions. It aims to inform improvements to the PR service by identifying barriers to the uptake of PR in the COPD care journey in relation to patients' capabilities that can affect their access to PR.

Methods and analysis:

The protocol includes four steps. Step 1 will involve interviews with healthcare professionals and patients to gather insight into their experiences and produce a hierarchical task analysis of the COPD care journeys. Step 2 will estimate the service exclusion: the demand of every task on patients' capabilities will be rated by pre-defined scales and the proportion of the population excluded from the service will be estimated by an exclusion calculator. Step 3 will identify the challenges of the PR service; a framework analysis will guide the data analysis of the interviews and care journey. Step 4 will propose recommendations to help patients manage their COPD care informed by the challenges identified in step 3 and refine recommendations through interviews and focus groups.

Ethics and Dissemination:

The Cambridge Central Research Ethics Committee gave the study protocol a positive ethical opinion (17/EE/0136). Study results will be disseminated through peer-reviewed journals, conferences and the British Lung Foundation networks. They will also be fed into a Research for Patient Benefit project on increasing the referral and uptake of PR.

ARTICLE SUMMARY

Strengths and limitations of this study:

- This protocol uses a novel Inclusive Design method and tools to identify and quantify health service exclusion and make recommendations for improving the accessibility of community-based pulmonary rehabilitation (PR) services.
- Representative healthcare professionals and patients were involved in all aspects of the protocol development to ensure a systematic representation of the real care processes and identification of real issues.
- While there are many factors which influence the uptake of PR, this study focuses on patients' individual capabilities in relation to accessing the service.
- Although PR forms the basis of this protocol, the focus could be modified for application to other healthcare services, particularly for community-based treatments of other long-term conditions.
- The Inclusive Design methods and tools consider physical and cognitive exclusion, while other types of exclusion, for instance social or psychological, are not included in the analysis.

INTRODUCTION

Underutilisation of pulmonary rehabilitation (PR)

Chronic obstructive pulmonary disease (COPD) is a progressive lung disease in which people experience breathlessness, exercise incapacity and vulnerability to exacerbations, frequently requiring hospitalisation. According to the World Health Organisation estimates, 65 million people have moderate to severe COPD.[1] Globally, it is estimated that about three million deaths were caused by the disease in 2015 (that is, 5% of all deaths globally in that year). Approximately 1.2 million people live with COPD[2] in the UK and a large proportion of them are older people. This condition costs the UK National Health Service (NHS), a publicly funded national healthcare system, £800 million per year, mostly relating to hospital admissions.[3] The UK National Institute for Health and Care Excellence (NICE) recommends that PR, providing supervised exercise and education, can be offered to patients functionally disabled by COPD.[4] PR improves symptoms, exercise capacity and quality of life[5] and leads to fewer repeating exacerbations requiring admission or hospital attendance.[6 7] It plays an important role in fostering self-management skills.[8]

The National COPD Audit Programme[9] estimated that the number of COPD patients eligible for PR in England and Wales in 2013/14 was 446,000; however, despite evidence-based guidelines,[10 11] there were only 68,000 referrals (15% of normative need) during that period and only 69% of those attended an initial assessment (10% of normative need).[9] Referral and attendance figures in the East of England are not available but we have no reason to believe that the local figures are significantly different from the national figures. The audit highlighted the need to improve referral and uptake rates. It recommended that PR referral pathways, healthcare professional training, information for patients and referrers and barriers to patient access should be reviewed. The audit also demonstrated that the availability of COPD treatment for the full range of severity of disability is not inclusive.[12]

The evidence gap

Several studies have been carried out to identify barriers that prevent access to PR.[13–21] Most of these barriers have been identified as relating to the context or environment, people's knowledge, and patients' and clinicians' beliefs.[22] For example, referral to PR can be influenced by a difficult referral process and a lack of knowledge about PR; while uptake can be affected by the lack of transport and geographic distance to a program, as well as the quality of the healthcare professional's conversation with patients about PR. There is little understanding of how patients' own physical and cognitive capabilities (including mobility, dexterity, reach and stretch, vision, hearing, thinking and communication) relate to their ability to access PR and affect implementation of the care service. People's personal capability to access a healthcare service is a prerequisite for them to use it. Moreover, patients with COPD are likely to have limited mobility. Hence, it is very important to consider patients' capabilities in order to improve access to PR services. Insight into the capability demand within the COPD care pathway (i.e., the demands that the care pathway makes on people's capability) would help care providers to better understand the needs of patients and to support their engagement in PR. Therefore, this research will focus on understanding people's capability-related needs while accessing PR within the community.

Study aim

The aim of the study is to provide recommendations for how primary care PR services in the East of England could improve and increase patients' access to PR services. An Inclusive Design approach will be used to estimate the system demands on patients with COPD and evaluate PR services' exclusion, identifying ways in which the care pathway excludes patients and ways in which the care pathway design can be modified to provide inclusive access to PR for as many eligible patients as possible.

The research question is: how can Inclusive Design be used to improve patients' access to PR services within the community?

METHODS AND ANALYSIS

Overview of methods

Three central concepts will be characterised, namely, a) Inclusive Design; b) people's capabilities; and c) the care pathway/journey. In addition, the link between Inclusive Design and patients' access to PR will be considered.

a) Inclusive Design

Inclusive Design can be defined as: i) "the design of mainstream products and/or services that are accessible to, and usable by, people with the widest range of abilities within the widest range of situations without the need for special adaptation or design",[23] and ii) ensuring that the demand made on an individual in a given environment does not exceed their capability to respond.[24] In this study, Inclusive Design refers to the latter definition.

The Inclusive Design approach is a rigorous user-centred approach, where the fundamental premise is that accessible and usable products or services can only be developed or implemented by first knowing the intended users.[25] By understanding the user's capability-demand in a healthcare context, it is easier to understand their capability-related needs for care and enhance the implementation of the healthcare services.

b) People's capabilities

Capabilities in this context refer to people's abilities to access health services. There are mainly two factors that cause a change in people's capability: one is an age-related change in capability and the other is a change in condition-related capability. Regarding patients with COPD, a large proportion are older people[2] and the condition of COPD, as well as the ageing process, may significantly impact their capability. People with COPD may be more frail, weaker and have reduced exercise and activity levels.[26] Moreover, they may be burdened by high levels of anxiety and depression as well as recognised cognitive impairment, particularly at the time of exacerbation.[27] Many patients have significant differences in their functioning compared to peers. While some of these manifestations relate solely to the presence of COPD, multi-morbidity is common and clearly could further impact on patients' capabilities.

c) Care pathway/journey

'Care pathway' or 'care journey' are both terms used to describe the process of healthcare service delivery. Care pathways are more generic and described from an organisational perspective. A pathway may take the form of an integrated management plan that provides a sequence and timing of actions necessary to achieve a standard care process and optimal efficiency for clinicians.[28] For example, the main stages in the NHS primary care pathway of COPD rehabilitation are shown in figure 1.

A patient's care journey refers to the process that he or she goes through in order to receive the care. As shown in figure 2, we define the care journey as a series of tasks. For example, the first stage in figure 1, i.e., COPD diagnosis, can be further broken down into four tasks: i) make an appointment with a General Practitioner (GP); ii) go to the GP practice; iii) have a GP consultation; vi) obtain a diagnosis. The detailed care journeys that patients experience in accessing the PR service would be more easily identified in the context of a deeper understanding of COPD services.

The connection between Inclusive Design and patients' access to PR

Any service makes demands on patients, and patients have to have sufficient capabilities in order to respond to these demands and access the service (figure 3).[29] If the demands of accessing the PR service exceed the capabilities of the patients then exclusion or difficulty in using the service will arise. Taking the task "go to the GP practice" as an example, if the home of a patient with COPD is relatively far from the GP surgery and the patient's mobility is limited, then he or she may not be able to get to the GP practice. In this case, this patient is excluded from the PR service as he or she cannot even see the doctor. With a better understanding of the tasks in the patient care journey, we are able to estimate the service's system demands on patients' capabilities and analyse the extent of system inclusion.

Study procedures

As illustrated in figure 4, the research is divided into four steps: semi-structured interviews will be used in Step 1 (Mapping pathway); Step 2 (Estimate exclusion) and Step 3 (Identify challenges) are mainly data analysis; and interviews and focus groups will be used in Step 4 (Propose recommendation).

Step 1: Mapping pathway

a) Interviews with healthcare professionals (HCPs):

We will conduct interviews with HCPs (including GPs, practice nurses, and physiotherapists) who refer patients to PR, as well as PR service managers and healthcare commissioners (see section *sampling and recruitment* for details).

The interviews with HCPs will gather insight into their experiences and perception of the COPD care pathway. The main stage of the NHS primary care pathway (see figure 1) will be presented to HCPs and the detailed primary care clinicians' pathways for PR will be identified based on the interview data. This understanding of the care pathway from the clinicians' perspective will be used to help map patients' care journeys. Specifically, we will focus on the pathway from diagnosis to PR programme attendance, while recognising the number of possible different routes to PR referral. Patients' ability to do exercises and take part in PR once they have accessed the service is not the focus of this research. The questions are shown in Supplementary Appendix 1.

b) Interviews with patients:

Three categories of patients with COPD will be interviewed: patients who have accepted a PR offer, patients who have declined a PR offer and patients who have never been referred to PR (see section *sampling and recruitment* for details).

The interviews with patients with COPD will capture the detailed COPD care journey from patients' perspectives, gather insight into patients' experiences of PR and their care needs, and assess the capabilities of patients with COPD. The questions are shown in Supplementary Appendices 2 and 3.

Data analysis: i) Transcriptions and field notes will be managed and analysed using NVivo software. ii) The detailed care journeys that patients go through to receive COPD treatment and the detailed care pathway that HCPs engage in when delivering COPD treatment will be summarised and represented as a hierarchical task analysis[30] (figure 5). For example, the stage 1 *COPD diagnosis* in figure 1 could be further broken down into the following steps: make an appointment with a GP, go to the GP Practice, have a GP consultation, and obtain diagnosis (figure 2). Making an appointment with a GP can be done by telephone or computer, could be booked by dropping in or could be booked by others. Making an appointment by telephone can be further broken down into the following steps: make a telephone call, request an appointment, agree on details and mark in diary. iii) The similarities and differences between the care pathway from the HCPs' perspectives and the care journey from the patients' perspectives will also be explored.

Output: A map of the patients' care journey will be defined. This will be used in Step 2 to estimate the reasons and levels of exclusion.

Step 2: Estimate exclusion

a) Estimate how demanding the COPD care journey is for patients

Tasks will be analysed to determine the demands of the COPD care journey on patients. Specifically, the demand of every task will be rated by pre-defined scales. These scales were constructed based on the questions in the Disability Follow-up to the Family Resources Survey, which was originally performed to help plan welfare support for disabled people.[31] The survey of more than 7000 people included many with respiratory conditions including COPD. Subsequently, these data have been used to assess numerous products and services.[31–33] Examples of assessing hearing, reach and speech comprehension demand scales are shown in figure 6. Higher demand on peoples' capabilities causes higher scale ratings, and the symbol "$>$" off scale means it is excessive for a mainstream service.

With the pre-defined scales, the demand on every task will be assessed. For example, the task 'to make a telephone call' places demands on patients' sensory capabilities (to hear clearly throughout the call and see the number buttons), motor capabilities (to hold the phone and press the number buttons), and cognitive capabilities (to remember/know the telephone number to call and communicate with the receptionist). The demand of this task on patients' hearing capability is close to the scale 8, i.e., use telephone without special adaptations for hearing impairment, so the hearing demand is rated scale 8 (figure 7). The level of the tasks' description is matched against the details of pre-defined scales.

b) Estimate the number of people excluded from PR on the basis of their capabilities

The "Exclusion Calculator" (an Inclusive Design tool) produced by the University of Cambridge Engineering Design Centre uses a large database of British users with a range of disabilities to estimate the proportion of the British population (Great Britain) that is unable to use a product or service because of the demands that it places on the users' capability.[34] A version of this calculator is freely available on the Inclusive Design Toolkit website.[34] By inputting the estimated demands of each task along the COPD care journey, the "Exclusion Calculator" can estimate the number of people within general population excluded from accessing PR (in every task and on the whole care journey). Figure 8 shows an example of measuring the hearing exclusion for the task 'make a telephone call'.

The original population data (sample size n=7618) is from the Disability Follow-up to the Family Resources Survey[31]. Among these participants, there were nearly 1000 participants who self-reported that they have a respiratory issue and it is likely that a significant number of these people could benefit from PR. Although the exclusion numbers from the calculator are based on the general population (rather than those with COPD), we can still obtain insights about challenges raised by the COPD care journeys from the exclusion levels predicted. For some tasks, the calculator will overestimate the level of exclusion but still give useful insights as a loss in capability may not be due to COPD. Nonetheless, changes in the demand of PR on the patients with COPD will be reflected by changes in exploration from the whole population.

Output: The patient care journey map, enhanced by the types and levels of exclusion, will be used to evidence the relationship between people's capabilities and their ability to access PR in Step 3.

Step 3: Identify challenges

Understand the most challenging part of PR and analyse the relationship between people's capabilities and their access to PR services. The interviews, rated demand and the excluded number of people will provide clues to identify the most challenging issues linked to PR and develop initial recommendations. It will also help to analyse the relationships between people's capabilities and their potential to access PR.

Data analysis: An inductive Framework Analysis[35] will be used to structure the data analysis (including interview transcript and exclusion data). First, initial categories/themes will be identified and put in the coding matrix; then, the relationship among the different coded data will be analysed. Finally, the core categories to propose the initial recommendations will be established.

Output: The initial recommendations that helps identify patients' needs will be proposed, which contains a set of questions that prompts patients to consider their potential needs along their COPD care journey, in particular those needs that are caused by reduced capabilities when trying to access PR. The initial recommendations will be refined in Step 4.

STEP 4: Propose recommendation(s)

Propose and refine recommendations that aims to help patients understand their needs and manage their COPD care. These recommendations could be used as an interactive tool between HCPs and patients to help HCPs to better understand patients' needs, especially the capability demand within the process of PR.

i) Further interviews with HCPs (including GPs, practice nurses, or physiotherapists) will be conducted to obtain the views of HCPs on the proposed recommendations. Potential participants (new or existing interviewees) will be invited to participate by email or via a phone call.

ii) Two focus groups will be organised that include both patients with COPD and HCPs to obtain the views of patients and HCPs on the proposed recommendations.

iii) The recommendations will be further refined based on the data from the interviews and focus groups.

Data analysis: The interview and focus group data will be transcribed and coded in an inductive coding structure to help refine the recommendations.

Output: The data analysis from the interviews and focus groups, will help to better understand the needs of COPD patients accessing PR. The refined recommendations that contains the key points of the COPD care journey will be available to inform the delivery of the PR service.

Study setting

Interviews with HCPs will take place at their place of work or other NHS premises by arrangement.

Interviews with patients will take place on community premises where PR classes are conducted, where Breathe Easy group meetings are held or at a location of choice (i.e., the Engineering Department of University of Cambridge or their home with someone accompanying the researcher or in a coffee shop). Interviews that are conducted in a PR setting will be on a one-to-one basis to minimise any bias or any external influence. Overall the researchers will need to be pragmatic about the timing, location and other environmental factors; however, the analysts will formally reflect on the influence of contextual factors on the interpretation of the results.

Sampling and recruitment

Sampling sites

Sampling will be carried out in a single region, the East of England in the UK, that covers both urban and rural areas. The sites available to the researchers will be limited; however, sites in both urban and rural setting will be included to encourage a broad selection of professionals and patients to enrol in the study.

Eligibility Criteria

- HCPs who can refer to PR programmes from their primary care annual review, physiotherapists who provide PR, PR service managers, and the CCG strategy managers in Cambridgeshire and Peterborough.
- People resident in the East of England, aged 18 or over, with a diagnosis of COPD, free from exacerbation or hospitalisation within the preceding four weeks, eligible for PR as defined by the guideline recommendations and able to read/write in English.

Size of sample

Warren (2002) suggested that the minimum number of interviews needs to be between twenty and thirty for an interview-based qualitative study to be published.[36] Mason reported that the interview number range was 1 to 95 (with a mean of 31 and a median of 28) for interview-based qualitative studies in doctoral theses.[37] Adler also advised the best number of people for a qualitative research is between a dozen and 60, with 30 being the mean.[38] The size of sample in this study will be consistent with these recommendations and the details are shown in table 1. However, the sizes of the sub-groups may be substantially smaller than the guidance discussed above. Hence, to enhance the validity of the results, where practicable, the sub-group sample size may be adjusted to reach data saturation. This approach complements the sampling techniques as described below.

Table 1 The size of sample

Category	Healthcare professionals (HCPs)	Patients with COPD	Total
Mapping pathway: Semi-structured interview	6 HCPs (including GPs, practice nurses, or physiotherapists) and 1-2 service managers and 1-2 commissioners. (face-to-face or by telephone)	11-17 patients with COPD including those accepted an PR offer, declined an PR offer, and never referred. (face-to-face or by telephone)	18-25
Validation: Interviews	face-to-face interview 2-4 HCPs and email 5-10 HCPs to seek comments.	Not applicable	2-4 interviews 5-10 emails
Validation: Focus groups	1 physiotherapist × 2 groups who attend the Breathe Easy Support group	8-10 patients × 2 groups who attend the Breathe Easy Support group	10-24 (focus groups)

Sampling technique

Data saturation refers to a process of data collection whereby no substantial new insight data are generated. This sampling strategy will be used to gather data in Cambridgeshire and Peterborough. Sampling will be informed by the interview results to represent a range of care pathways/journeys and their experiences along the care pathways/journeys. A stakeholder map will be used to help identify a representative sample and gather adequate data. The researcher will seek advice from the interviewees to ensure all the key stakeholders are covered. If any role within the stakeholder map is missing or affects the data analysis, the researcher will try to find appropriate interviewees. The detailed plan is shown in table 2 and table 3 (where *n* refers to the number of people):

Table 2 Recruitment plan for healthcare professionals

Healthcare professionals' role	Understanding of PR pathway
GPs/ Practice nurses (n=6)	Familiar with the process of diagnosis, annual review, and referral
Physiotherapists (n=4-6)	Familiar with the process of referral, assessment for PR, PR programme, and annual review
PR service manager (n=1-2)	Familiar with the whole PR pathway process and having connections with other professionals
Commissioners & manager (n=1-2)	Familiar with the process of designing or supporting the COPD care pathway

Table 3 Recruitment plan for patients

	PR programme	Age group	Capability
People with COPD	Accepted PR offer (n=5-7) Declined PR offer (n=3-5) Never referred (n=3-5)	16-49 50-64 65-74 (n≥5) 75+ (n≥2)	Hearing, Vision, Mobility, Dexterity, Reach and Stretch, Communication, Thinking. Ensure a full range of capability loss is covered by the samples

Sampling identification

Access methods have been discussed with Clinical Research Network (CRN) Eastern.

HCPs will be identified by:

i. working with CRN Eastern locality managers to access HCPs;
ii. accessing HCPs through visiting or emailing GP Practices;
iii. accessing PR providers through East of England (EoE) PR network.

In terms of identifying patients with COPD:

i. people who have accepted a PR offer will be identified through PR provider registers.
ii. people who declined a PR offer may be challenging to engage. HCPs and PR providers will be asked to identify people they know and we will work with the British Lung Foundation to engage this group, e.g., through telephone interviews/ home visits, or interviews while people are visiting their practice for an annual review.
iii. people who have never been referred to PR will be identified through COPD registers in participating GP practices. We will sample one GP practice in a city centre and another in a rural area.

Research bias

The interviews and focus groups will be used to gain multiple perspectives on the understanding of HCPs' and patients' experiences. The research has been carefully designed and has been reviewed by experts to ensure it will inform us of the current challenges that patients experience when accessing PR. Specifically, the research protocol has been reviewed by the Research Advisory Committee (RAC) of Cambridge University Hospitals and advice has been received from the members of the Patient and Public Involvement (PPI) panel, Cambridge University Hospital (NHS Foundation Trust). Five patients with COPD have contributed to the research questions, aim, participant sheets, interview schedule, consent forms and the plain English summary. Several discussions have been held with three physiotherapists who provided clinicians' perspectives on the research questions, aim, participant sheets, interview schedule and consent forms for HCPs. The lay summary and interview materials (participant information sheets) have been reviewed by nine members of the PPI panel, Cambridge University Hospitals. They have confirmed the language used is understandable and have provided useful comments to refine the research.

To reduce the risk of bias during data analysis the work will be supervised by a senior researcher. A second researcher will independently analyse the data at each stage of the analysis. The primary and secondary analysts will compare results and resolve any discrepancies. Should any discrepancies not be resolved, the supervising senior researcher shall adjudicate.

DISCUSSION

In this protocol, we describe a novel approach to service improvement which takes a structured and rigorous stance towards analysing barriers to PR referral and uptake. An Inclusive Design approach has been widely used to understand customer diversity and respond to this diversity with informed design decisions.[39] The Inclusive Design methods used in this study have been adapted from their original context (measuring the exclusion of consumer products) and applied to care journey analysis. Specifically, one of the Inclusive Design tools, exclusion calculator estimates the proportion of the British population who would be unable to use a product or service because of the demands that it places on the users' capabilities. The tool has been widely used in measuring the exclusion of consumer products. For healthcare setting, similar to products setting, it is also important to understand use's capability and demand, so that healthcare service can be better developed and benefit more people, i.e. more inclusive. A strength of the approach is that it has both qualitative and quantitative perspectives that give not only insight into how and where changes can be made but also what impact the changes might have on the uptake of PR. As the exclusion calculator data is sampled based on general British population rather than people with COPD, the exclusion levels may be overestimated, but it can still give clues and insights about the needs of people with COPD. How using general population data affects the results will be subtle, depending on the specific tasks where the greatest exclusion occurs and the capabilities needed to perform those tasks. The analysist will need to apply some care in interpreting the details of the exclusion results.

We focus on the primary care journey for people with COPD. We recognise that referrals for PR stem from a multiplicity of sources (e.g. at exacerbation, by community specialist teams, through secondary care). However, the learning applied to one specific route, e.g. from an annual review, is likely to identify at least some of the capability issues arising in other routes. This protocol is part of a first study into the application of Inclusive Design to healthcare processes. The authors have published one research that explores the role of Inclusive Design in improving people's access to back pain treatment.[40] The protocol can be adapted and applied to other PR pathways and indeed pathways for other conditions.

In this study, we enquire about people's self-reported capabilities, rather than test them in practice to determine capabilities. This methodology of seeking self-reported capabilities is validated[41] and more feasible than extensive field testing.

The protocol focuses on physical and cognitive factors that contribute to preventing people from accessing PR services. We recognise that factors such as mental health, social exclusion and other factors may also affect the uptake of PR. Hence this protocol is only a partial answer to identifying PR service exclusions. However as previously stated, it is a prerequisite for accessing a healthcare service in which the service demands made do not exceed the capability of patients.

ETHICS AND DISSEMINATION

Assessment and management of risk

Participants may be vulnerable due to age/frailty. In order to manage this risk, they will be identified via GP practices or PR services to whom they are known and who can ensure participants are aware of their diagnosis of COPD prior to the researcher approaching them. Sources of support will be identified to whom participants can be directed.

If there is a concern about a person's health or safety the researcher may contact the relevant GP; however, as this would mean breaking confidentiality it would only be done if the person were clearly at risk. When making appointments for patients to attend research activities, researchers will ensure that the time and location are acceptable to the participant.

It is recognised that interviews may involve discussion of sensitive topics regarding the patients' health, lifestyle or quality of life. To address this:

- All study materials, including interview questions, have been developed in collaboration with a patient and public involvement group to ensure topics are addressed in a sensitive way.
- Participants will be directed to sources of support and information.

Data protection and patient confidentiality

The Patient Information Sheet will detail the data to be collected and how it will be stored.

The study will comply with the Data Protection Act, which requires data to be anonymised as soon as it is practical to do so. The study staff will ensure that participants' anonymity is maintained. Staff seeking consent will ask patients only for personal data that confirms their eligibility for the study and at no point will study staff have access to patients' medical records.

On entering the study, participants will be assigned an ID. Participant names will only be identifiable on a cross-referenced list of IDs and names, which will be stored in a locked filing cabinet on Trust premises. When recordings of interviews or focus groups are transcribed, only the ID will be used as an identifier.

Data collected will be entered onto secure computers in the Engineering Design Centre (EDC) at the University of Cambridge and will only be accessible to the study team. Paper documents will be stored in a locked cupboard in the EDC and will only be accessible to the study team.

All electronic files will be password protected and access restricted to the study team. Participants will be identified only by a participant ID number on any electronic database. The name and any other identifying details will not be included in any study data electronic file. Data sharing and storage will meet the requirements of the National Institutes of Health Research. Data will be securely stored in the University of Cambridge Research Repository.

Ethical approval

This research has been ethically reviewed and approved by Cambridge Central Research Ethics Committee. The study' REC reference number is 17/EE/0136. It has two work packages: work package 1 which uses an Inclusive Design approach is presented above; work package 2 is to develop a toolkit to increase referral to and uptake of PR in primary care.

Dissemination

We will work closely with the British Lung Foundation (BLF), who have a track record of disseminating innovation through patient networks, publications, online information, service development and HCP engagement. Two academic papers will be published in peer-reviewed journals compliant with policy on open access on: i) capabilities of patients with COPD, ii) comparison of COPD care pathways between HCPs and patients with COPD. Presentations will be given at regional, national and international academic and professional conferences, e.g. East Anglian Thoracic Society, British Thoracic Society and European

Respiratory Society. The output will also comprise a part of a doctoral thesis by the lead author. The study started in June 2017 and will continue until February 2018.

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Acknowledgements

The authors would like to acknowledge Lucy Bennett at Cambridge University Hospitals NHS Foundation Trust for her help and support in developing the research; The authors would like to thank the Patient and Public Involvement (PPI) panel of Cambridge University Hospital, Nicola Cavaleri and Denise Chappell from the Language Unit who helped review and refine the protocol. The Exclusion Calculator was produced by the Cambridge Engineering Design Centre, as part of the ID-3 Inclusive Design Consortium run by the Centre for Business Innovation which will be used in this research.

Contributors

YL initiated the protocol. TD and PJC provided supervision for the research and reviewed as well as finalised the protocol. FE drafted the background, ethics and dissemination and reviewed the protocol. JF was involved in the design of the protocol, clinical guidance for delivery of the study and revision of the manuscript.

Funding statement

The research is part funded by the NIHR Collaboration for Leadership in Applied Health Research & Care (CLAHRC) East of England and Buchanan Fund of Downing College. The China Scholarship Council provided funding for the researcher's PhD study. The views expressed are those of the authors and not necessarily those of the NHS, NIHR or Department of Health and Social Care.

Competing interests

The authors declare that they have no competing interests.

Provenance and peer review

Not commissioned; peer reviewed by the Research Advisory Committee (RAC) of Cambridge University Hospitals

Data sharing statement

The Inclusive Design methods and tools are available from our website: http://www.inclusivedesigntoolkit.com

Open access

Our manuscript describes a study protocol. As such, we cannot elaborate on additional unpublished data (yet). This is an Open Access article distributed in accordance with the Creative Commons Attribution Non-Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work noncommercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. See: http:// creativecommons.org/licenses/by-nc/4.0/

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FIGURE LEGENDS

Figure 1 The main stages in the NHS primary care pathway of COPD rehabilitation
The main stages in the NHS primary care pathway of COPD rehabilitation are: 1) COPD diagnosis, 2) annual review, 3) referral for pulmonary rehabilitation, 4) assessment for pulmonary rehabilitation, and 5) pulmonary rehabilitation programme.

Figure 2 Care journeys consist of specific tasks
The first stage of the NHS primary care pathway of COPD rehabilitation, COPD diagnosis, can be further broken down into four tasks: i) make an appointment with a General Practitioner (GP); ii) go to the GP practice; iii) have a GP consultation; vi) obtain a diagnosis.

Figure 3 Interaction Context-Demand and Capabilities. (Persad et al. 2007)
The example is of a physical product but this applies equally to services.
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Figure 4 Study design

Figure 5 Example for care journey represented in a hierarchal task analysis, not all tasks and sub tasks are shown for clarity.

Figure 6 The standard of measuring hearing (left), reaching forward and up (middle) and speech comprehension (right)
Examples of assessing hearing, reach and speech comprehension demand scales are shown.

Figure 7 Demand on capability of making a phone call

Figure 8 Calculating exclusion (i.e., the hearing exclusion for the task ‘make a telephone call’)

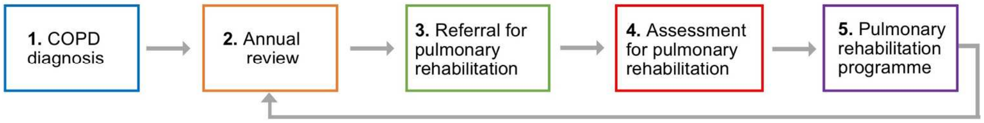

Figure 1 The main stages in the NHS primary care pathway of COPD rehabilitation

199x26mm (300 x 300 DPI)

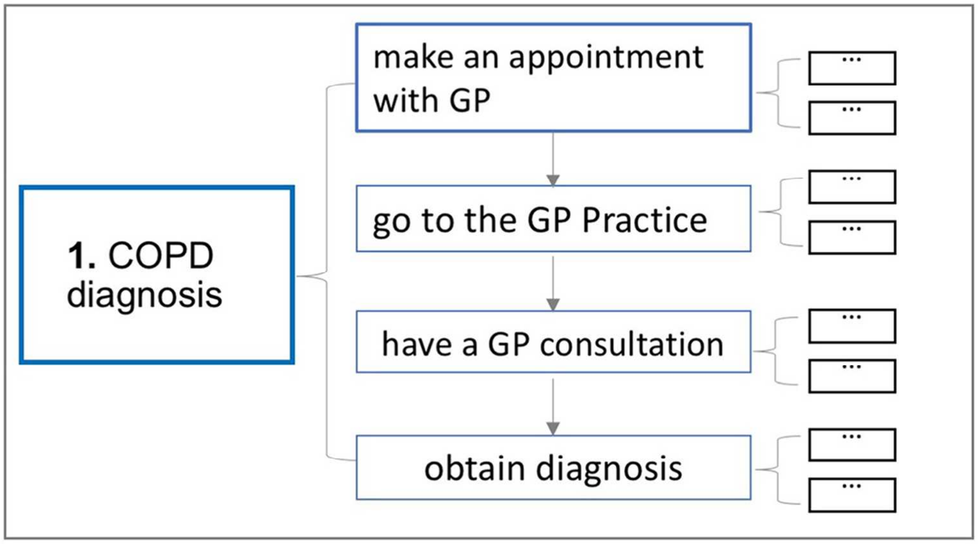

Figure 2 Care journeys consist of specific tasks

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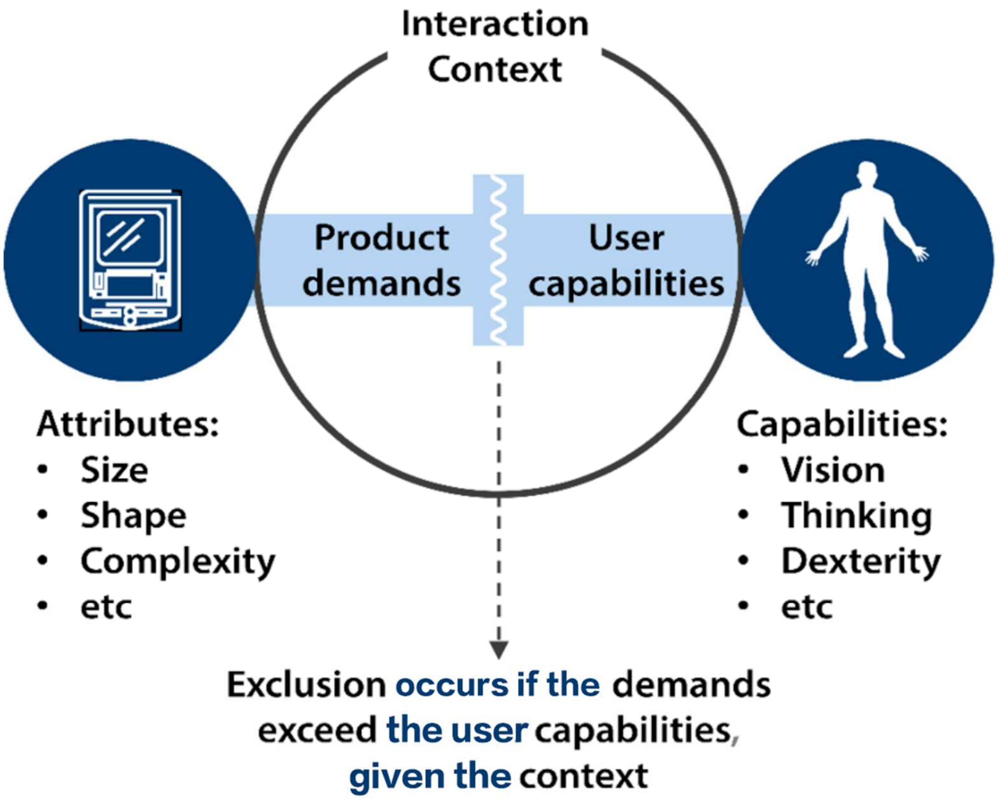

Figure 3 Interaction Context-Demand and Capabilities. (Persad et al. 2007)
The example is of a physical product but this applies equally to services.
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100x81mm (300 x 300 DPI)

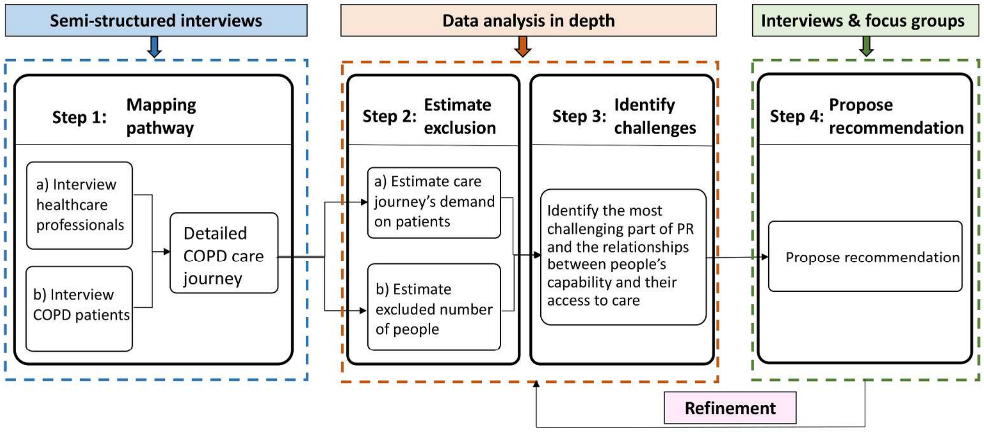

Figure 4 Study design‼ ┼

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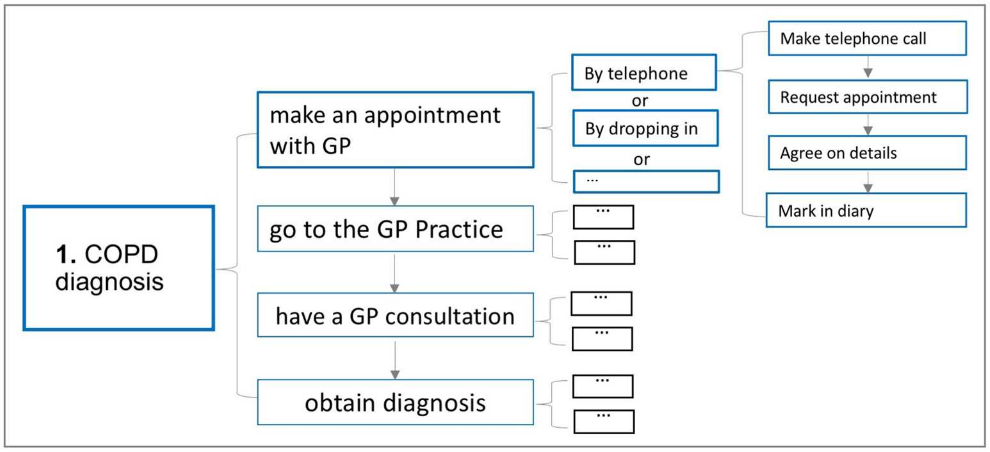


Figure 5 Example for care journey represented in a hierarchal task analysis, not all tasks and sub tasks are shown for clarity.

150x69mm (300 x 300 DPI)

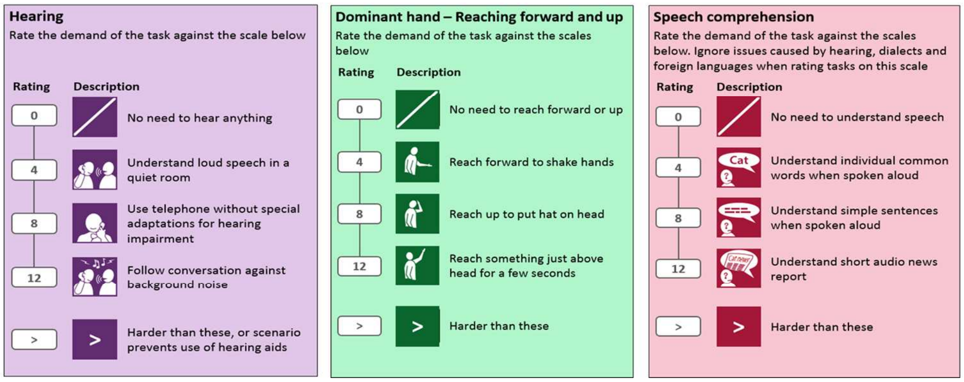


Figure 6 The standard of measuring hearing (left), reaching forward and up (middle) and speech comprehension (right)‼ ┼

150x56mm (300 x 300 DPI)

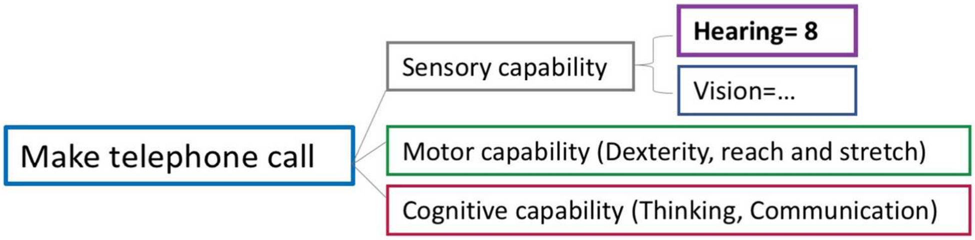


Figure 7 Demand on capability of making a phone call

180x44mm (300 x 300 DPI)

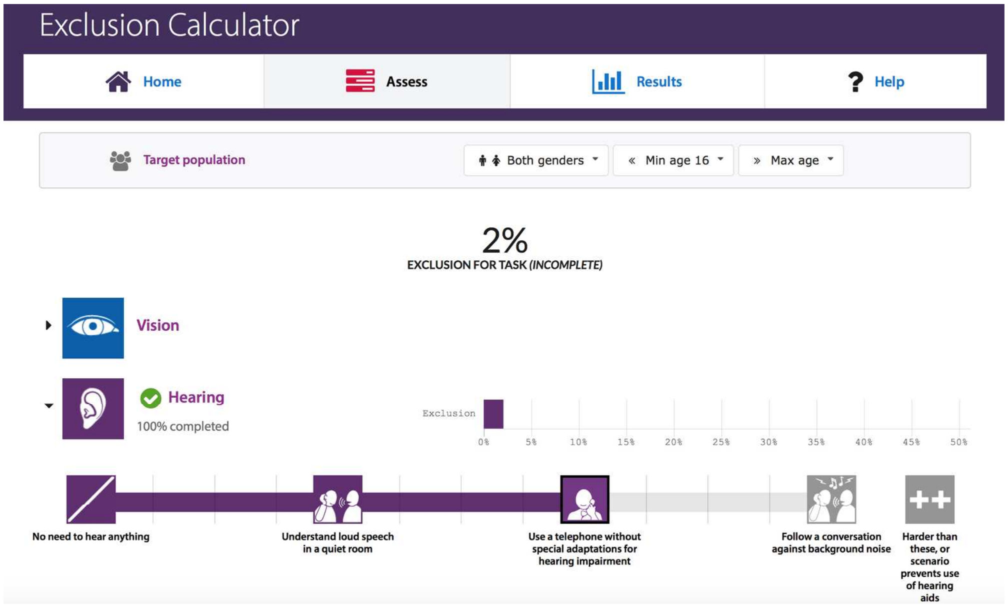


Figure 8 Calculating exclusion (i.e., the hearing exclusion for the task 'make a telephone call')

209x126mm (300 x 300 DPI)

Appendix 1: Questions for semi-structured interview with HCPs

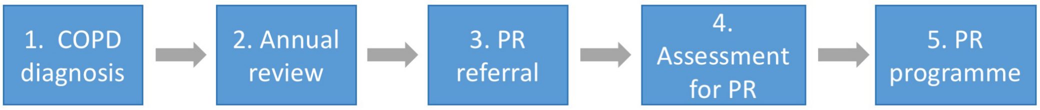
Icebreaker

- Are you happy to start?
- How long have you been working here?
- Could you brief introduce your team? e.g., how many people in your team, what kind of services you offer to patients.

The purpose of this interview is to understand your perceptions and experiences of providing COPD care.

- **COPD journey/ Pathway**
- Have you ever used the phrase "care pathway" or "care journey" during your working? Which one (pathway or journey) do you use more frequently?
  A care journey refers to the process that patients go through in order to receive care, for example. When patients would like to see their GP, they will have to book an appointment, go the GP surgery and probably waiting a while and then do the consulting with GP. This whole process we call it care journey.

- Looking at the picture, do you agree with this primary care pulmonary rehabilitation pathway? Is there any difference in the pathway you have known?
  Probes: Can you describe a more detailed care pathway of PR? I am interested in all the professionals that are involved, i.e., what they do for the people with COPD and the information they need.



- What is your main role along the primary care pulmonary rehabilitation (PR) pathway?
  Probes: what other professionals do you have to work with? Can you describe what they do for you?
- What information do you expect to receive from other professionals you work with?
  What information will you pass to the next stage's healthcare professionals?
  Probes: Could you tell me more about------?

- Does the COPD patient have some knowledge about the PR pathway? / Do they know where they can get support?
  Probes: Could you tell me more about------?

- Can you recall the last time you talked with a new patient with COPD? Can you describe what you did for him or her? Perhaps it may be useful to think of how things happened along the care pathway. How did you feel at that moment?
  Probes: Could you tell me more about------?

- **Perception and experience of Pulmonary rehabilitation service:**
- From your perspective, what is the purpose of pulmonary rehabilitation?
  Probes: Can you tell me more about------?

- Can you recall a person with COPD who was reluctant to take up PR? What factors do you think affected his/ her uptake and attendance?
  What factors do you think may affect people's uptake and attendance of the PR pathway?
  Probes: Which (three) factors do you think are most important?

- Do you know someone who declined PR because they think the course does not provide what they need?
  Probes: Could you tell me more about------?

- How do you know whether or not a patient who took up the PR programme or quit at a later stage?
  Probes: How do you communicate with your patients? What information do you expect your patients to tell you? What information do you convey to the patients?
- Does PR always work? Can it be further improved?
  Probes: Could you tell me more about------?

- **The relationship between capabilities and accessibility**
- Do you think there are any connections between people's personal capabilities (physical and cognitive abilities) and their uptake and attendance of PR?

- What affect those people cannot access pulmonary rehabilitation (any stage of the pathway)?

- Do people give up PR because they think their capabilities are not sufficient to manage the PR programme?
  Probes: Can you tell me more about------?

Appendix 2: Questions for semi-structured interview with patients

- **COPD journey of people with COPD:**
  - Have you ever heard someone mentioned care journey or pathway to you?
  - Can you share your COPD care journey, from how you diagnose to the pulmonary rehab?
  - Looking at the picture, do you agree with this primary care pulmonary rehabilitation pathway? Can you possibly help me identify your care journey? Is there any difference in the pathway you have experienced?

  - From your perspective, which part of the care journey do you think is most challenging? And which part would be relatively easier for you?
    Probes: Could you possibly tell me more about your needs along the journey?

- **Needs of people with COPD**
  - Have you ever been referred to pulmonary rehabilitation?
  - For people who have not been referred to PR:
    Have you ever heard about pulmonary rehab?
  - For people declined an PR offer:
    I know you was referred to pulmonary rehab but declined, I wonder why you declined your PR offer?

  For people accept an PR offer:
  - Can you recall your experience when you had just been referred to pulmonary rehabilitation? Is this your first time to do pulmonary rehabilitation or not? If not, are there any differences between the 1st and 2nd time?
    Probes: What was your feeling at that time? Can you tell me more about------?
  - Can you remember the first time you talked with your physiotherapist in the rehab centre? Can you remember what they told you?
    Probes: How you communicate with your physiotherapist/GP/practice nurse/doctor?
  - How do you feel about pulmonary rehabilitation? Do you think it is helpful?
    Probes: Could you tell me more about------?
  - In your experience of accessing pulmonary rehabilitation, which things do you think do you think good? And what things do you think could be better?
    Probes: What about------ is it that made it so bad? Why do you think ----- is bad?
  - Are there things that you think would have improved your pulmonary rehabilitation experience?
    Probes: Could you tell me more about------?

- **The relationship between capabilities and accessibility**
  - Here we are going to do a capability measure test. There will be about 6 sets of questions.
    The details questions can be seen in Appendix 3: Questions for measuring people's capability.
  - How long have you been diagnosed with COPD? Have there been any significant changes in your life since your diagnosis?
  - Do you think your capabilities (i.e., how well your vision, hearing, mobility, reach and stretch, dexterity, thinking and communication) will affect your access to pulmonary rehabilitation or not?

- Have there been any changes in your capabilities (vision, hearing, mobility, reach and stretch, dexterity, thinking and communication) since you were diagnosed? Do these changes affect your pulmonary rehabilitation especially the uptake and attendance process?

- **Personal information**
- Would you mind me asking you some personal information?
- What is your occupation?
- Please select your Age group

  Under 16
  16-19
  30-44
  45-59
  60-74
  Over 75
  Do not wish to disclose

Appendix 3: Questions for measuring people's capability

Here we are going to do a capability measure test. There will be about 6 sets of questions.

1. VISION

- Do you use glasses?
- Can you see well enough to read a newspaper headline (with your glasses)?
- Can you see well enough to read a large print book (with your glasses)?
- Can you see well enough to read the ordinary newspaper print (with your glasses)?
- Can you see well enough to read GP's letter or medication instruction (with your glasses)?
- Has your vision affected your access to (get to) COPD care treatment or not?

2. HEARING

- Can you understand loud speech in a quiet room?
- Can you use the telephone without special adaptations for hearing impairment?
- Do you have great difficulty following a conversation if there is background noise – for example, a T.V., radio or children playing?
- Can you see hear your GP or physiotherapists' words clearly?
- Has your hearing affected your access to (get to) COPD care treatment or not?

3. THINKING

- Can you concentrate on a short TV ad without getting distracted?
- Can you concentrate enough to make toast without getting distracted?
- Can you concentrate enough to run a bath without getting distracted?
- Can you think clearly, or do your thoughts tend to be muddled or slow?

THINKING - Memory

- Can you remember your name?
- Can you remember your best friend's name?
- Can you remember names of people in your family or friends whom you see regularly?

THINKING - Literacy

- Can you read and understand individual common words, e.g. cat, house?
- Can you read and understand a sentence, i.e., in a tabloid newspaper?
- Can you read and understand a short newspaper article, i.e., in a tabloid newspaper?

THINKING - Speaking comprehension

- Can you understand individual common words when spoken aloud?
- Can you understand simple sentences when spoken aloud?
- Can you understand short audio news report?

THINKING - speaking

- Can you speak common words clearly enough that others can understand?
- Can you ask a simple question clearly enough that others understand it?
- Can you speak clearly enough that others understand you in typical everyday conversations?
- Do you have any difficulty to answer questions and talk with your GP or physiotherapists?
- Has your thinking and communication affected your access to (get to) COPD care treatment or not?

4. DEXTERITY

- Can you turn a tap or the control knob of a cooker?
- Can you pick up a small object, like a safety pin from a table-top using your fingers
- Can you use a pen or pencil to write without difficulty?

DEXTERITY - Lifting strength

- Can you pick up and hold a mug of coffee or tea by the handle?
- Can you pick up and carry a bottle of wine or a glass bottle of milk without condensation?
- Can you pick up and carry four pints of milk or a 2.5kg bag of potatoes?
- Has your dexterity affected your access to (get to) COPD care treatment or not?

5. REACH AND STRETCH - reach forward and up

- Can you reach forward to shake hands with your friends?
- Can you reach up to put a hat on head?
- Can you reach something just above head for a few seconds?

REACH AND STRETCH - reach down

- Can you reach down to knee level with one arm, supporting yourself with other arm if needed?
- Can you reach down to the floor level with one arm, supporting yourself with the other arm if needed?
- Can you get down to floor level to use dustpan& brush, supporting yourself on the way if needed?
- Has your reach and stretch affected your access to (get to) COPD care treatment or not?

6. MOBILITY

- What is the furthest you can walk on your own without stopping and without severe discomfort?

☐ I am able to walk only a few steps.
☐ I am able to walk 50m without help and without stopping, with aids if needed.
☐ I am able to walk 175m without help and without stopping, with aids if needed.
☐ I am able to walk 350m without help and without stopping, with aids if needed.
☐ Not sure

- What is the longest stairs you can climb on your own without stopping and without severe discomfort?

☐ I am able to climb 12 stairs without help and without using a handrail.
☐ I am able to climb 12 stairs without help, using a handrail if necessary.
☐ I am able to climb one step without help.
☐ I always require assistance.
☐ Not sure.

- Which one is more match your Standing and balancing ability?

☐ I am able to stand momentarily, without holding on to anything
☐ I am able to stand for a minute, without holding on to anything.
☐ I am able to stand for 10 minutes, without holding on to anything
☐ Not sure.

- Has your mobility affected your access to (get to) COPD care treatment or not?

Checklist

No	Item	Description	Page
1	Planned or ongoing studies	Manuscripts that report work already carried out will not be considered as protocols. The dates of the study must be included in the manuscript and cover letter.	12-13
2	Protocols for studies that will require ethical approval	Protocols for studies that will require ethical approval, such as trials, are unlikely to be considered without having received that approval.	12
3	Title	This should include the specific study type, e.g. Randomised controlled trial.	1
4	Abstract	This should be structured with the following sections. Introduction; methods and analysis; ethics and dissemination.	2
		Registration details should be included as a final section, if appropriate.	Not applicable
5	Strengths and limitations of this study	A section, placed after the abstract, consisting of the heading 'Strengths and limitations of this study', and containing up to five short bullet points, no longer than one sentence each, that relate specifically to the methods.	3
6	Introduction	Explain the rationale for the study and what evidence gap it may fill. Appropriate previous literature should be referenced, including relevant systematic reviews.	4-5
7	Methods and analysis	Provide a full description of the study design, including the following:	5-11
		i. how the sample will be selected;	9-10
		ii. interventions to be measured;	Not applicable
		iii. the sample size calculation (drawing on previous literature) with an estimate of how many participants will be needed for the primary outcome to be statistically, clinically and/or politically significant;	9
		iv. what outcomes will be measured and how;	6-8
		v. a data analysis plan.	6-8
8	Ethics and dissemination	Ethical and safety considerations and any dissemination plan (publications, data deposition and curation) should be covered here.	11-13
9	Full references		13-14
10	Authors' contributions	State how each author was involved in writing the protocol.	13
11	Funding statement	Preferably worded as follows. Either: 'this work was supported by [name of funder] grant number [xxx]' or 'this research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors'.	13
12	Competing interests statement		13

BMJ Open

Understanding influences on the uptake of pulmonary rehabilitation in the East of England: an Inclusive Design / mixed-methods study protocol

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-020750.R2
Article Type:	Protocol
Date Submitted by the Author:	09-Mar-2018
Complete List of Authors:	Liu, Yuanyuan; University of Cambridge Department of Engineering, Engineering Design Centre Dickerson, Terry; University of Cambridge Department of Engineering, Engineering Design Centre Early, Frances; Cambridge University Hospitals NHS Foundation Trust, Centre for Self Management Support Fuld, Jonathan; Cambridge University Hospitals NHS Foundation Trust, Centre for Self Management Support Clarkson, John; University of Cambridge Department of Engineering, Engineering Design Centre
Primary Subject Heading:	Research methods
Secondary Subject Heading:	Health services research, Qualitative research
Keywords:	Pulmonary rehabilitation, Inclusive design, Patient-centred design, Care journey, Patients’ capability, COPD

STUDY PROTOCOL

Understanding influences on the uptake of pulmonary rehabilitation in the East of England: an Inclusive Design / mixed-methods study protocol

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Keywords: Pulmonary rehabilitation, Inclusive Design, Patient-centred design, Care journey, Patients' capability, COPD

Word count (abstract) / limit: 295/300 words
Word count (text)/limit: 4832/5500 words without figures and tables

ABSTRACT

Introduction:

1.2 million people in the UK have Chronic Obstructive Pulmonary Disease (COPD) that causes breathlessness, difficulty with daily activities, infections and hospitalisation. Pulmonary rehabilitation (PR), a programme of supervised exercise and education, is recommended for patients with COPD. However, only 1 in 10 of those who need it receive PR. Also, the UK National COPD Audit Programme concluded that the COPD treatment might not be accessible to people with disabilities. This paper applies an Inclusive Design approach to community-based PR service provisions. It aims to inform improvements to the PR service by identifying barriers to the uptake of PR in the COPD care journey in relation to patients' capabilities that can affect their access to PR.

Methods and analysis:

The protocol includes four steps. Step 1 will involve interviews with healthcare professionals and patients to gather insight into their experiences and produce a hierarchical task analysis of the COPD care journeys. Step 2 will estimate the service exclusion: the demand of every task on patients' capabilities will be rated by pre-defined scales and the proportion of the population excluded from the service will be estimated by an exclusion calculator. Step 3 will identify the challenges of the PR service; a framework analysis will guide the data analysis of the interviews and care journey. Step 4 will propose recommendations to help patients manage their COPD care informed by the challenges identified in step 3 and refine recommendations through interviews and focus groups.

Ethics and Dissemination:

The Cambridge Central Research Ethics Committee gave the study protocol a positive ethical opinion (17/EE/0136). Study results will be disseminated through peer-reviewed journals, conferences and the British Lung Foundation networks. They will also be fed into a Research for Patient Benefit project on increasing the referral and uptake of PR.

ARTICLE SUMMARY

Strengths and limitations of this study:

- This protocol uses a novel Inclusive Design method and tools to identify and quantify health service exclusion and make recommendations for improving the accessibility of community-based pulmonary rehabilitation (PR) services.
- Representative healthcare professionals and patients were involved in all aspects of the protocol development to ensure a systematic representation of the real care processes and identification of real issues.
- While there are many factors which influence the uptake of PR, this study focuses on patients' individual capabilities in relation to accessing the service.
- Although PR forms the basis of this protocol, the focus could be modified for application to other healthcare services, particularly for community-based treatments of other long-term conditions.
- The Inclusive Design methods and tools consider physical and cognitive exclusion, while other types of exclusion, for instance social or psychological, are not included in the analysis.

INTRODUCTION

Underutilisation of pulmonary rehabilitation (PR)

Chronic obstructive pulmonary disease (COPD) is a progressive lung disease in which people experience breathlessness, exercise incapacity and vulnerability to exacerbations, frequently requiring hospitalisation. According to the World Health Organisation estimates, 65 million people have moderate to severe COPD.[1] Globally, it is estimated that about three million deaths were caused by the disease in 2015 (that is, 5% of all deaths globally in that year). Approximately 1.2 million people live with COPD[2] in the UK and a large proportion of them are older people. This condition costs the UK National Health Service (NHS), a publicly funded national healthcare system, £800 million per year, mostly relating to hospital admissions.[3] The UK National Institute for Health and Care Excellence (NICE) recommends that PR, providing supervised exercise and education, can be offered to patients functionally disabled by COPD.[4] PR improves symptoms, exercise capacity and quality of life[5] and leads to fewer repeating exacerbations requiring admission or hospital attendance.[6 7] It plays an important role in fostering self-management skills.[8]

The National COPD Audit Programme[9] estimated that the number of COPD patients eligible for PR in England and Wales in 2013/14 was 446,000; however, despite evidence-based guidelines,[10 11] there were only 68,000 referrals (15% of normative need) during that period and only 69% of those attended an initial assessment (10% of normative need).[9] Referral and attendance figures in the East of England are not available but we have no reason to believe that the local figures are significantly different from the national figures. The audit highlighted the need to improve referral and uptake rates. It recommended that PR referral pathways, healthcare professional training, information for patients and referrers and barriers to patient access should be reviewed. The audit also demonstrated that the availability of COPD treatment for the full range of severity of disability is not inclusive.[12]

The evidence gap

Several studies have been carried out to identify barriers that prevent access to PR.[13–21] Most of these barriers have been identified as relating to the context or environment, people's knowledge, and patients' and clinicians' beliefs.[22] For example, referral to PR can be influenced by a difficult referral process and a lack of knowledge about PR; while uptake can be affected by the lack of transport and geographic distance to a program, as well as the quality of the healthcare professional's conversation with patients about PR. There is little understanding of how patients' own physical and cognitive capabilities (including mobility, dexterity, reach and stretch, vision, hearing, thinking and communication) relate to their ability to access PR and affect implementation of the care service. People's personal capability to access a healthcare service is a prerequisite for them to use it. Moreover, patients with COPD are likely to have limited mobility. Hence, it is very important to consider patients' capabilities in order to improve access to PR services. Insight into the capability demand within the COPD care pathway (i.e., the demands that the care pathway makes on people's capability) would help care providers to better understand the needs of patients and to support their engagement in PR. Therefore, this research will focus on understanding people's capability-related needs while accessing PR within the community.

Study aim

The aim of the study is to provide recommendations for how primary care PR services in the East of England could improve and increase patients' access to PR services. An Inclusive Design approach will be used to estimate the system demands on patients with COPD and evaluate PR services' exclusion, identifying ways in which the care pathway excludes patients and ways in which the care pathway design can be modified to provide inclusive access to PR for as many eligible patients as possible.

The research question is: how can Inclusive Design be used to improve patients' access to PR services within the community?

METHODS AND ANALYSIS

Overview of methods

Three central concepts will be characterised, namely, a) Inclusive Design; b) people's capabilities; and c) the care pathway/journey. In addition, the link between Inclusive Design and patients' access to PR will be considered.

a) Inclusive Design

Inclusive Design can be defined as: i) "the design of mainstream products and/or services that are accessible to, and usable by, people with the widest range of abilities within the widest range of situations without the need for special adaptation or design",[23] and ii) ensuring that the demand made on an individual in a given environment does not exceed their capability to respond.[24] In this study, Inclusive Design refers to the latter definition.

The Inclusive Design approach is a rigorous user-centred approach, where the fundamental premise is that accessible and usable products or services can only be developed or implemented by first knowing the intended users.[25] By understanding the user's capability-demand in a healthcare context, it is easier to understand their capability-related needs for care and enhance the implementation of the healthcare services.

b) People's capabilities

Capabilities in this context refer to people's abilities to access health services. There are mainly two factors that cause a change in people's capability: one is an age-related change in capability and the other is a change in condition-related capability. Regarding patients with COPD, a large proportion are older people[2] and the condition of COPD, as well as the ageing process, may significantly impact their capability. People with COPD may be more frail, weaker and have reduced exercise and activity levels.[26] Moreover, they may be burdened by high levels of anxiety and depression as well as recognised cognitive impairment, particularly at the time of exacerbation.[27] Many patients have significant differences in their functioning compared to peers. While some of these manifestations relate solely to the presence of COPD, multi-morbidity is common and clearly could further impact on patients' capabilities.

c) Care pathway/journey

'Care pathway' or 'care journey' are both terms used to describe the process of healthcare service delivery. Care pathways are more generic and described from an organisational perspective. A pathway may take the form of an integrated management plan that provides a sequence and timing of actions necessary to achieve a standard care process and optimal efficiency for clinicians.[28] For example, the main stages in the NHS primary care pathway of COPD rehabilitation are shown in figure 1.

A patient's care journey refers to the process that he or she goes through in order to receive the care. As shown in figure 2, we define the care journey as a series of tasks. For example, the first stage in figure 1, i.e., COPD diagnosis, can be further broken down into four tasks: i) make an appointment with a General Practitioner (GP); ii) go to the GP practice; iii) have a GP consultation; vi) obtain a diagnosis. The detailed care journeys that patients experience in accessing the PR service would be more easily identified in the context of a deeper understanding of COPD services.

The connection between Inclusive Design and patients' access to PR

Any service makes demands on patients, and patients have to have sufficient capabilities in order to respond to these demands and access the service (figure 3).[29] If the demands of accessing the PR service exceed the capabilities of the patients then exclusion or difficulty in using the service will arise. Taking the task "go to the GP practice" as an example, if the home of a patient with COPD is relatively far from the GP surgery and the patient's mobility is limited, then he or she may not be able to get to the GP practice. In this case, this patient is excluded from the PR service as he or she cannot even see the doctor. With a better understanding of the tasks in the patient care journey, we are able to estimate the service's system demands on patients' capabilities and analyse the extent of system inclusion.

Study procedures

As illustrated in figure 4, the research is divided into four steps: semi-structured interviews will be used in Step 1 (Mapping pathway); Step 2 (Estimate exclusion) and Step 3 (Identify challenges) are mainly data analysis; and interviews and focus groups will be used in Step 4 (Propose recommendation).

Step 1: Mapping pathway

a) Interviews with healthcare professionals (HCPs):

We will conduct interviews with HCPs (including GPs, practice nurses, and physiotherapists) who refer patients to PR, as well as PR service managers and healthcare commissioners (see section *sampling and recruitment* for details).

The interviews with HCPs will gather insight into their experiences and perception of the COPD care pathway. The main stage of the NHS primary care pathway (see figure 1) will be presented to HCPs and the detailed primary care clinicians' pathways for PR will be identified based on the interview data. This understanding of the care pathway from the clinicians' perspective will be used to help map patients' care journeys. Specifically, we will focus on the pathway from diagnosis to PR programme attendance, while recognising the number of possible different routes to PR referral. Patients' ability to do exercises and take part in PR once they have accessed the service is not the focus of this research. The questions are shown in Supplementary Appendix 1.

b) Interviews with patients:

Three categories of patients with COPD will be interviewed: patients who have accepted a PR offer, patients who have declined a PR offer and patients who have never been referred to PR (see section *sampling and recruitment* for details).

The interviews with patients with COPD will capture the detailed COPD care journey from patients' perspectives, gather insight into patients' experiences of PR and their care needs, and assess the capabilities of patients with COPD. The questions are shown in Supplementary Appendices 2 and 3.

Data analysis: i) Transcriptions and field notes will be managed and analysed using NVivo software. ii) The detailed care journeys that patients go through to receive COPD treatment and the detailed care pathway that HCPs engage in when delivering COPD treatment will be summarised and represented as a hierarchical task analysis[30] (figure 5). For example, the stage 1 *COPD diagnosis* in figure 1 could be further broken down into the following steps: make an appointment with a GP, go to the GP Practice, have a GP consultation, and obtain diagnosis (figure 2). Making an appointment with a GP can be done by telephone or computer, could be booked by dropping in or could be booked by others. Making an appointment by telephone can be further broken down into the following steps: make a telephone call, request an appointment, agree on details and mark in diary. iii) The similarities and differences between the care pathway from the HCPs' perspectives and the care journey from the patients' perspectives will also be explored.

Output: A map of the patients' care journey will be defined. This will be used in Step 2 to estimate the reasons and levels of exclusion.

Step 2: Estimate exclusion

a) Estimate how demanding the COPD care journey is for patients

Tasks will be analysed to determine the demands of the COPD care journey on patients. Specifically, the demand of every task will be rated by pre-defined scales. These scales were constructed based on the questions in the Disability Follow-up to the Family Resources Survey, which was originally performed to help plan welfare support for disabled people.[31] The survey of more than 7000 people included many with respiratory conditions including COPD. Subsequently, these data have been used to assess numerous products and services.[31–33] Examples of assessing hearing, reach and speech comprehension demand scales are shown in figure 6. Higher demand on peoples' capabilities causes higher scale ratings, and the symbol ">" off scale means it is excessive for a mainstream service.

With the pre-defined scales, the demand on every task will be assessed. For example, the task 'to make a telephone call' places demands on patients' sensory capabilities (to hear clearly throughout the call and see the number buttons), motor capabilities (to hold the phone and press the number buttons), and cognitive capabilities (to remember/know the telephone number to call and communicate with the receptionist). The demand of this task on patients' hearing capability is close to the scale 8, i.e., use telephone without special adaptations for hearing impairment, so the hearing demand is rated scale 8 (figure 7). The level of the tasks' description is matched against the details of pre-defined scales.

b) Estimate the number of people excluded from PR on the basis of their capabilities

The "Exclusion Calculator" (an Inclusive Design tool) produced by the University of Cambridge Engineering Design Centre uses a large database of British users with a range of disabilities to estimate the proportion of the British population (Great Britain) that is unable to use a product or service because of the demands that it places on the users' capability.[34] A version of this calculator is freely available on the Inclusive Design Toolkit website.[34] By inputting the estimated demands of each task along the COPD care journey, the "Exclusion Calculator" can estimate the number of people within general population excluded from accessing PR (in every task and on the whole care journey). Figure 8 shows an example of measuring the hearing exclusion for the task 'make a telephone call'.

The original population data (sample size n=7618) is from the Disability Follow-up to the Family Resources Survey[31]. Among these participants, there were nearly 1000 participants who self-reported that they have a respiratory issue and it is likely that a significant number of these people could benefit from PR. Although the exclusion numbers from the calculator are based on the general population (rather than those with COPD), we can still obtain insights about challenges raised by the COPD care journeys from the exclusion levels predicted. For some tasks, the calculator will overestimate the level of exclusion but still give useful insights as a loss in capability may not be due to COPD. Nonetheless, changes in the demand of PR on the patients with COPD will be reflected by changes in exploration from the whole population.

Output: The patient care journey map, enhanced by the types and levels of exclusion, will be used to evidence the relationship between people's capabilities and their ability to access PR in Step 3.

Step 3: Identify challenges

Understand the most challenging part of PR and analyse the relationship between people's capabilities and their access to PR services. The interviews, rated demand and the excluded number of people will provide clues to identify the most challenging issues linked to PR and develop initial recommendations. It will also help to analyse the relationships between people's capabilities and their potential to access PR.

Data analysis: An inductive Framework Analysis[35] will be used to structure the data analysis (including interview transcript and exclusion data). First, initial categories/themes will be identified and put in the coding matrix; then, the relationship among the different coded data will be analysed. Finally, the core categories to propose the initial recommendations will be established.

Output: The initial recommendations that helps identify patients' needs will be proposed, which contains a set of questions that prompts patients to consider their potential needs along their COPD care journey, in particular those needs that are caused by reduced capabilities when trying to access PR. The initial recommendations will be refined in Step 4.

STEP 4: Propose recommendation(s)

Propose and refine recommendations that aims to help patients understand their needs and manage their COPD care. These recommendations could be used as an interactive tool between HCPs and patients to help HCPs to better understand patients' needs, especially the capability demand within the process of PR.

i) Further interviews with HCPs (including GPs, practice nurses, or physiotherapists) will be conducted to obtain the views of HCPs on the proposed recommendations. Potential participants (new or existing interviewees) will be invited to participate by email or via a phone call.

ii) Two focus groups will be organised that include both patients with COPD and HCPs to obtain the views of patients and HCPs on the proposed recommendations.

iii) The recommendations will be further refined based on the data from the interviews and focus groups.

Data analysis: The interview and focus group data will be transcribed and coded in an inductive coding structure to help refine the recommendations.

Output: The data analysis from the interviews and focus groups, will help to better understand the needs of COPD patients accessing PR. The refined recommendations that contains the key points of the COPD care journey will be available to inform the delivery of the PR service.

Study setting

Interviews with HCPs will take place at their place of work or other NHS premises by arrangement.

Interviews with patients will take place on community premises where PR classes are conducted, where Breathe Easy group meetings are held or at a location of choice (i.e., the Engineering Department of University of Cambridge or their home with someone accompanying the researcher or in a coffee shop). Interviews that are conducted in a PR setting will be on a one-to-one basis to minimise any bias or any external influence. Overall the researchers will need to be pragmatic about the timing, location and other environmental factors; however, the analysts will formally reflect on the influence of contextual factors on the interpretation of the results.

Sampling and recruitment

Sampling sites

Sampling will be carried out in a single region, the East of England in the UK, that covers both urban and rural areas. The sites available to the researchers will be limited; however, sites in both urban and rural setting will be included to encourage a broad selection of professionals and patients to enrol in the study.

Eligibility Criteria

- HCPs who can refer to PR programmes from their primary care annual review, physiotherapists who provide PR, PR service managers, and the CCG strategy managers in Cambridgeshire and Peterborough.
- People resident in the East of England, aged 18 or over, with a diagnosis of COPD, free from exacerbation or hospitalisation within the preceding four weeks, eligible for PR as defined by the guideline recommendations and able to read/write in English.

Size of sample

Warren (2002) suggested that the minimum number of interviews needs to be between twenty and thirty for an interview-based qualitative study to be published.[36] Mason reported that the interview number range was 1 to 95 (with a mean of 31 and a median of 28) for interview-based qualitative studies in doctoral theses.[37] Adler also advised the best number of people for a qualitative research is between a dozen and 60, with 30 being the mean.[38] The size of sample in this study will be consistent with these recommendations and the details are shown in table 1. The size of the sub-groups will be adjusted as necessary to reach data saturation to ensure the validity of the results. This approach complements the sampling techniques as described below.

Table 1 The size of sample

Category	Healthcare professionals (HCPs)	Patients with COPD	Total
Mapping pathway: Semi-structured interview	6 HCPs (including GPs, practice nurses, or physiotherapists) and 1-2 service managers and 1-2 commissioners. (face-to-face or by telephone)	11-17 patients with COPD including those accepted an PR offer, declined an PR offer, and never referred. (face-to-face or by telephone)	18-25
Validation: Interviews	face-to-face interview 2-4 HCPs and email 5-10 HCPs to seek comments.	Not applicable	2-4 interviews 5-10 emails
Validation: Focus groups	1 physiotherapist × 2 groups who attend the Breathe Easy Support group	8-10 patients × 2 groups who attend the Breathe Easy Support group	10-24 (focus groups)

Sampling technique

Data saturation refers to a process of data collection whereby no substantial new insight data are generated. This sampling strategy will be used to gather data in Cambridgeshire and Peterborough. Sampling will be informed by the interview results to represent a range of care pathways/journeys and their experiences along the care pathways/journeys. A stakeholder map will be used to help identify a representative sample and gather adequate data. The researcher will seek advice from the interviewees to ensure all the key stakeholders are covered. If any role within the stakeholder map is missing or affects the data analysis, the researcher will try to find appropriate interviewees. The detailed plan is shown in table 2 and table 3 (where *n* refers to the number of people):

Table 2 Recruitment plan for healthcare professionals

Healthcare professionals' role	Understanding of PR pathway
GPs/ Practice nurses (n=6)	Familiar with the process of diagnosis, annual review, and referral
Physiotherapists (n=4-6)	Familiar with the process of referral, assessment for PR, PR programme, and annual review
PR service manager (n=1-2)	Familiar with the whole PR pathway process and having connections with other professionals
Commissioners & manager (n=1-2)	Familiar with the process of designing or supporting the COPD care pathway

Table 3 Recruitment plan for patients

	PR programme	Age group	Capability
People with COPD	Accepted PR offer (n=5-7) Declined PR offer (n=3-5) Never referred (n=3-5)	16-49 50-64 65-74 (n≥5) 75+ (n≥2)	Hearing, Vision, Mobility, Dexterity, Reach and Stretch, Communication, Thinking. Ensure a full range of capability loss is covered by the samples

Sampling identification

Access methods have been discussed with Clinical Research Network (CRN) Eastern.

HCPs will be identified by:

i. working with CRN Eastern locality managers to access HCPs;
ii. accessing HCPs through visiting or emailing GP Practices;
iii. accessing PR providers through East of England (EoE) PR network.

In terms of identifying patients with COPD:

i. people who have accepted a PR offer will be identified through PR provider registers.
ii. people who declined a PR offer may be challenging to engage. HCPs and PR providers will be asked to identify people they know and we will work with the British Lung Foundation to engage this group, e.g., through telephone interviews/ home visits, or interviews while people are visiting their practice for an annual review.
iii. people who have never been referred to PR will be identified through COPD registers in participating GP practices. We will sample one GP practice in a city centre and another in a rural area.

Patient and Public Involvement (PPI)

The aim of our PPI activities is to ensure that we bring patients, accompanying carers and healthcare professionals (HCPs) together to deliver the research collaboratively so that it comprehensively addresses patient needs. Patients' enthusiasm has been encouraged and we welcome their continuing contribution.

Five patients with COPD have contributed to the research questions, aim, participant sheets, interview schedule, consent forms and the plain English summary. Several discussions were held with three physiotherapists who provided clinicians' perspectives on the research questions, aim, participant sheets, interview schedule and consent forms for HCPs. The lay summary and interview materials (participant information sheets) were reviewed by nine members of the PPI panel, Cambridge University Hospitals. They have confirmed the language used is understandable and have provided useful comments to refine the research.

The study results will be disseminated to study participants by post or email based on their preferences.

Research bias

The interviews and focus groups will be used to gain multiple perspectives on the understanding of HCPs' and patients' experiences. The research has been carefully designed and has been reviewed by experts to ensure it will inform us of the current challenges that patients experience when accessing PR. The research protocol has been reviewed by the Research Advisory Committee (RAC) of Cambridge University Hospitals and advice has been received from the members of the Patient and Public Involvement (PPI) panel, Cambridge University Hospital (NHS Foundation Trust).

To reduce the risk of bias during data analysis the work will be supervised by a senior researcher. A second researcher will independently analyse the data at each stage of the analysis. The primary and secondary analysts will compare results and resolve any discrepancies. Should any discrepancies not be resolved, the supervising senior researcher shall adjudicate.

DISCUSSION

In this protocol, we describe a novel approach to service improvement which takes a structured and rigorous stance towards analysing barriers to PR referral and uptake. An Inclusive Design approach has been widely used to understand customer diversity and respond to this diversity with informed design decisions.[39] The Inclusive Design methods used in this study have been adapted from their original context (measuring the exclusion of consumer products) and applied to care journey analysis. Specifically, one of the Inclusive Design tools, exclusion calculator estimates the proportion of the British population who would be unable to use a product or service because of the demands that it places on the users' capabilities. The tool has been widely used in measuring the exclusion of consumer products. For healthcare setting, similar to products setting, it is also important to understand use's capability and demand, so that healthcare service can be better developed and benefit more people, i.e. more inclusive. A strength of the approach is that it has both qualitative and quantitative perspectives that give not only insight into how and where changes can be made but also what impact the changes might have on the uptake of PR. As the exclusion calculator data is sampled based on general British population rather than people with COPD, the exclusion levels may be overestimated, but it can still give clues and insights about the needs of people with COPD. How using general population data affects the results will be subtle, depending on the specific tasks where the greatest exclusion occurs and the capabilities needed to perform those tasks. The analysist will need to apply some care in interpreting the details of the exclusion results.

We focus on the primary care journey for people with COPD. We recognise that referrals for PR stem from a multiplicity of sources (e.g. at exacerbation, by community specialist teams, through secondary care). However, the learning applied to one specific route, e.g. from an annual review, is likely to identify at least some of the capability issues arising in other routes. This protocol is part of a first study into the application of Inclusive Design to healthcare processes. The authors have published one research that explores the role of Inclusive Design in improving people's access to back pain treatment.[40] The protocol can be adapted and applied to other PR pathways and indeed pathways for other conditions.

In this study, we enquire about people's self-reported capabilities, rather than test them in practice to determine capabilities. This methodology of seeking self-reported capabilities is validated[41] and more feasible than extensive field testing.

The protocol focuses on physical and cognitive factors that contribute to preventing people from accessing PR services. We recognise that factors such as mental health, social exclusion and other factors may also affect the uptake of PR. Hence this protocol is only a partial answer to identifying PR service exclusions.

However as previously stated, it is a prerequisite for accessing a healthcare service in which the service demands made do not exceed the capability of patients.

ETHICS AND DISSEMINATION

Assessment and management of risk

Participants may be vulnerable due to age/frailty. In order to manage this risk, they will be identified via GP practices or PR services to whom they are known and who can ensure participants are aware of their diagnosis of COPD prior to the researcher approaching them. Sources of support will be identified to whom participants can be directed.

If there is a concern about a person's health or safety the researcher may contact the relevant GP; however, as this would mean breaking confidentiality it would only be done if the person were clearly at risk. When making appointments for patients to attend research activities, researchers will ensure that the time and location are acceptable to the participant.

It is recognised that interviews may involve discussion of sensitive topics regarding the patients' health, lifestyle or quality of life. To address this:

- All study materials, including interview questions, have been developed in collaboration with a patient and public involvement group to ensure topics are addressed in a sensitive way.
- Participants will be directed to sources of support and information.

Data protection and patient confidentiality

The Patient Information Sheet will detail the data to be collected and how it will be stored.

The study will comply with the Data Protection Act, which requires data to be anonymised as soon as it is practical to do so. The study staff will ensure that participants' anonymity is maintained. Staff seeking consent will ask patients only for personal data that confirms their eligibility for the study and at no point will study staff have access to patients' medical records.

On entering the study, participants will be assigned an ID. Participant names will only be identifiable on a cross-referenced list of IDs and names, which will be stored in a locked filing cabinet on Trust premises. When recordings of interviews or focus groups are transcribed, only the ID will be used as an identifier.

Data collected will be entered onto secure computers in the Engineering Design Centre (EDC) at the University of Cambridge and will only be accessible to the study team. Paper documents will be stored in a locked cupboard in the EDC and will only be accessible to the study team.

All electronic files will be password protected and access restricted to the study team. Participants will be identified only by a participant ID number on any electronic database. The name and any other identifying details will not be included in any study data electronic file. Data sharing and storage will meet the requirements of the National Institutes of Health Research. Data will be securely stored in the University of Cambridge Research Repository.

Ethical approval

This research has been ethically reviewed and approved by Cambridge Central Research Ethics Committee. The study' REC reference number is 17/EE/0136. It has two work packages: work package 1 which uses an Inclusive Design approach is presented above; work package 2 is to develop a toolkit to increase referral to and uptake of PR in primary care.

Dissemination

We will work closely with the British Lung Foundation (BLF), who have a track record of disseminating innovation through patient networks, publications, online information, service development and HCP engagement. Two academic papers will be published in peer-reviewed journals compliant with policy on open access on: i) capabilities of patients with COPD, ii) comparison of COPD care pathways between HCPs and patients with COPD. Presentations will be given at regional, national and international academic and professional conferences, e.g. East Anglian Thoracic Society, British Thoracic Society and European Respiratory Society. The output will also comprise a part of a doctoral thesis by the lead author. The study started in June 2017 and will continue until April 2018.

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Acknowledgements
The authors would like to acknowledge Lucy Bennett at Cambridge University Hospitals NHS Foundation Trust for her help and support in developing the research; The authors would like to thank the Patient and Public Involvement (PPI) panel of Cambridge University Hospital, patients with COPD and physiotherapists involved in this study, Nicola Cavaleri and Denise Chappell from the Language Unit who helped review and refine the protocol. The Exclusion Calculator was produced by the Cambridge Engineering Design Centre, as part of the ID-3 Inclusive Design Consortium run by the Centre for Business Innovation which will be used in this research.

Contributors
YL initiated the protocol. TD and PJC provided supervision for the research and reviewed as well as finalised the protocol. FE drafted the background, ethics and dissemination and reviewed the protocol. JF was involved in the design of the protocol, clinical guidance for delivery of the study and revision of the manuscript.

Funding statement
The research is part funded by the NIHR Collaboration for Leadership in Applied Health Research & Care (CLAHRC) East of England and Buchanan Fund of Downing College. The China Scholarship Council provided funding for the researcher’s PhD study. The views expressed are those of the authors and not necessarily those of the NHS, NIHR or Department of Health and Social Care.

Competing interests
The authors declare that they have no competing interests.

Provenance and peer review
Not commissioned; peer reviewed by the Research Advisory Committee (RAC) of Cambridge University Hospitals

Data sharing statement
The Inclusive Design methods and tools are available from our website: http://www.inclusivedesigntoolkit.com

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FIGURE LEGENDS

Figure 1 The main stages in the NHS primary care pathway of COPD rehabilitation

The main stages in the NHS primary care pathway of COPD rehabilitation are: 1) COPD diagnosis, 2) annual review, 3) referral for pulmonary rehabilitation, 4) assessment for pulmonary rehabilitation, and 5) pulmonary rehabilitation programme.

Figure 2 Care journeys consist of specific tasks

The first stage of the NHS primary care pathway of COPD rehabilitation, COPD diagnosis, can be further broken down into four tasks: i) make an appointment with a General Practitioner (GP); ii) go to the GP practice; iii) have a GP consultation; vi) obtain a diagnosis.

Figure 3 Interaction Context-Demand and Capabilities. (Persad et al. 2007)
The example is of a physical product but this applies equally to services.
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Figure 4 Study design

Figure 5 Example for care journey represented in a hierarchal task analysis, not all tasks and sub tasks are shown for clarity.

Figure 6 The standard of measuring hearing (left), reaching forward and up (middle) and speech comprehension (right)

Examples of assessing hearing, reach and speech comprehension demand scales are shown.

Figure 7 Demand on capability of making a phone call

Figure 8 Calculating exclusion (i.e., the hearing exclusion for the task ‘make a telephone call’)

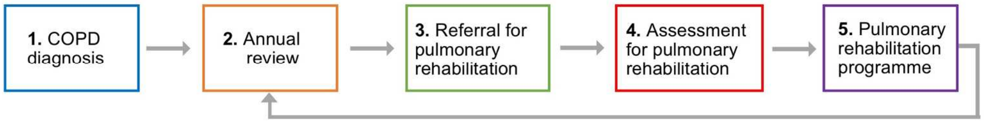

Figure 1 The main stages in the NHS primary care pathway of COPD rehabilitation

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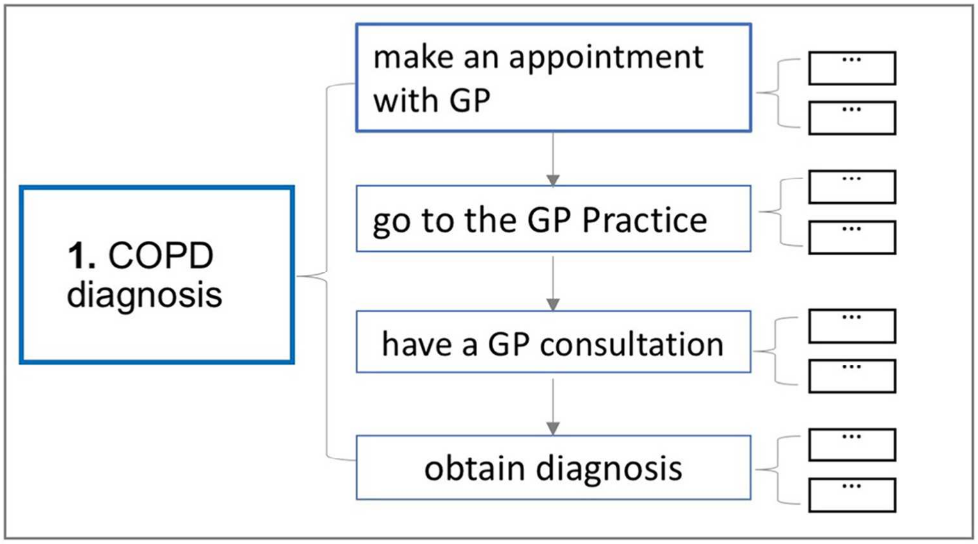

Figure 2 Care journeys consist of specific tasks

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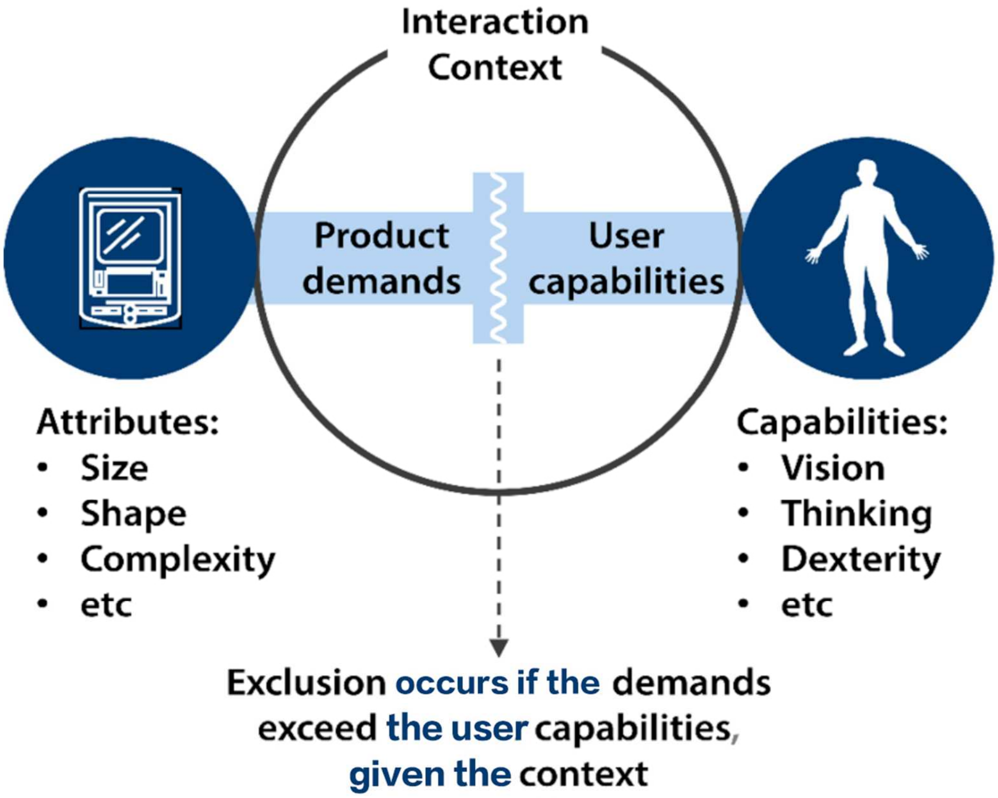

Figure 3 Interaction Context-Demand and Capabilities. (Persad et al. 2007)
The example is of a physical product but this applies equally to services.
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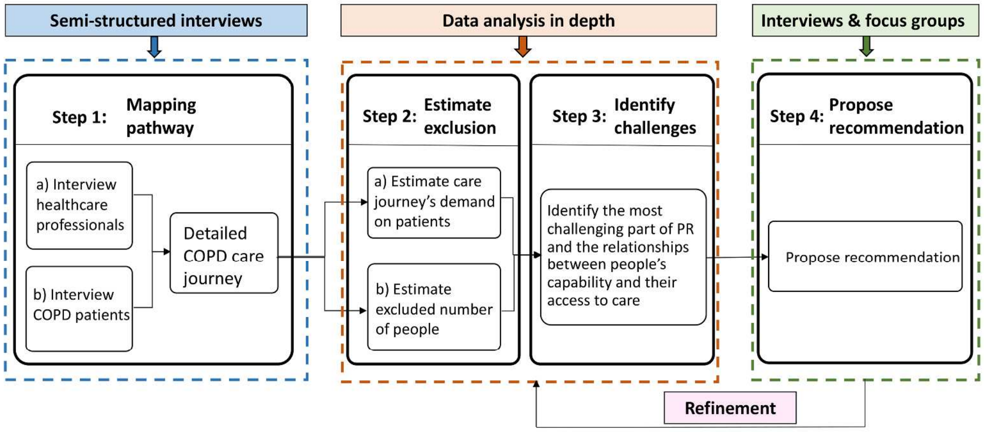

Figure 4 Study design‼ ┼

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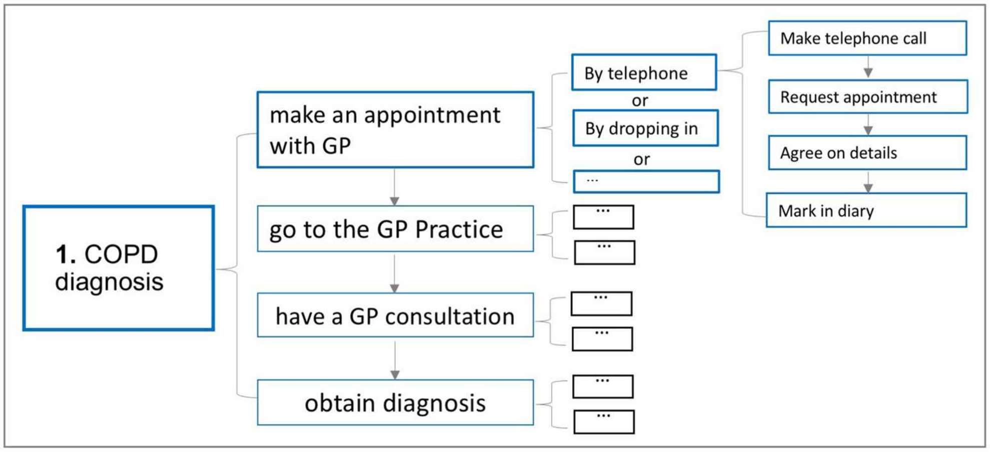
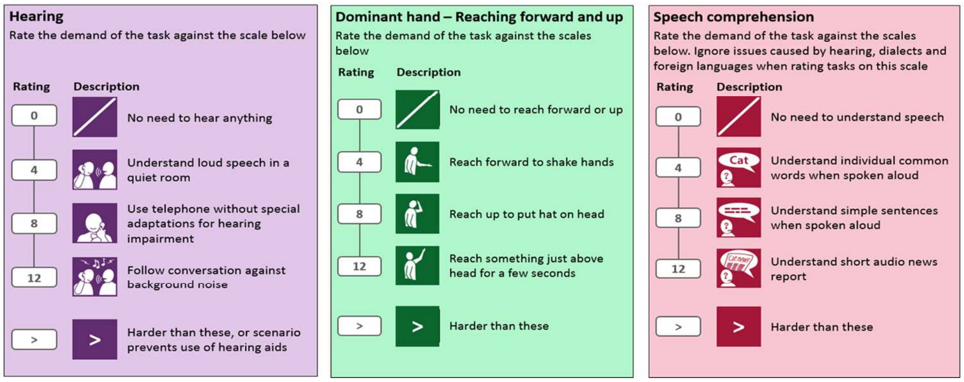


Figure 5 Example for care journey represented in a hierarchal task analysis, not all tasks and sub tasks are shown for clarity.

150x69mm (300 x 300 DPI)



Hearing

Rate the demand of the task against the scale below

Rating	Description
0	No need to hear anything
4	Understand loud speech in a quiet room
8	Use telephone without special adaptations for hearing impairment
12	Follow conversation against background noise
>	Harder than these, or scenario prevents use of hearing aids

Dominant hand – Reaching forward and up

Rate the demand of the task against the scales below

Rating	Description
0	No need to reach forward or up
4	Reach forward to shake hands
8	Reach up to put hat on head
12	Reach something just above head for a few seconds
>	Harder than these

Speech comprehension

Rate the demand of the task against the scales below. Ignore issues caused by hearing, dialects and foreign languages when rating tasks on this scale

Rating	Description
0	No need to understand speech
4	Understand individual common words when spoken aloud
8	Understand simple sentences when spoken aloud
12	Understand short audio news report
>	Harder than these

Figure 6 The standard of measuring hearing (left), reaching forward and up (middle) and speech comprehension (right)‼ ┼

150x56mm (300 x 300 DPI)

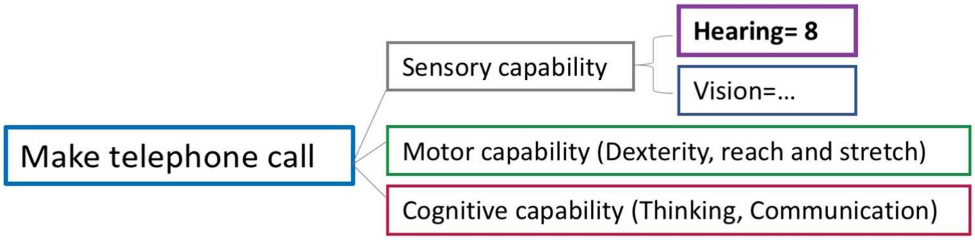


Figure 7 Demand on capability of making a phone call

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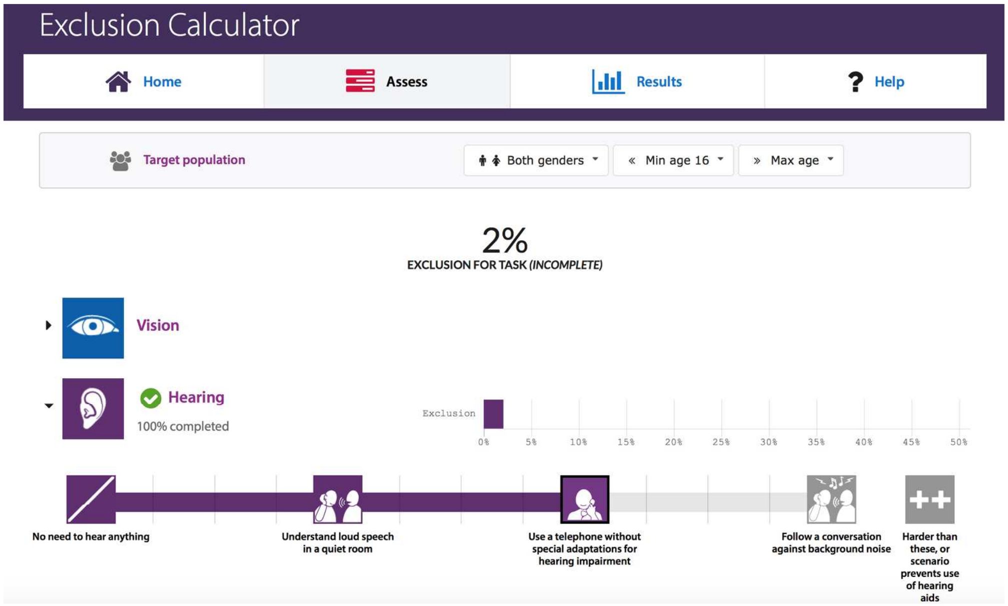


Exclusion Calculator

Target population: Both genders, Min age 16, Max age

2%
EXCLUSION FOR TASK *(INCOMPLETE)*

Hearing: 100% completed

Figure 8 Calculating exclusion (i.e., the hearing exclusion for the task ‘make a telephone call’)

209x126mm (300 x 300 DPI)

Appendix 1: Questions for semi-structured interview with HCPs

Icebreaker

- Are you happy to start?
- How long have you been working here?
- Could you brief introduce your team? e.g., how many people in your team, what kind of services you offer to patients.

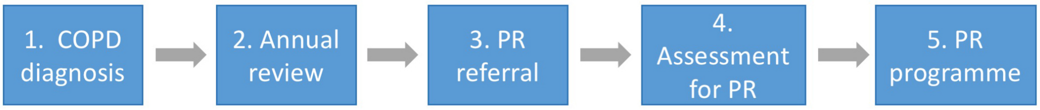
The purpose of this interview is to understand your perceptions and experiences of providing COPD care.

- **COPD journey/ Pathway**
- Have you ever used the phrase “care pathway” or “care journey” during your working? Which one (pathway or journey) do you use more frequently?

  A care journey refers to the process that patients go through in order to receive care, for example. When patients would like to see their GP, they will have to book an appointment, go the GP surgery and probably waiting a while and then do the consulting with GP. This whole process we call it care journey.

- Looking at the picture, do you agree with this primary care pulmonary rehabilitation pathway? Is there any difference in the pathway you have known?

  Probes: Can you describe a more detailed care pathway of PR? I am interested in all the professionals that are involved, i.e., what they do for the people with COPD and the information they need.



- What is your main role along the primary care pulmonary rehabilitation (PR) pathway?

  Probes: what other professionals do you have to work with? Can you describe what they do for you?
- What information do you expect to receive from other professionals you work with?

  What information will you pass to the next stage’s healthcare professionals?

  Probes: Could you tell me more about------?

- Does the COPD patient have some knowledge about the PR pathway? / Do they know where they can get support?

  Probes: Could you tell me more about------?

- Can you recall the last time you talked with a new patient with COPD? Can you describe what you did for him or her? Perhaps it may be useful to think of how things happened along the care pathway. How did you feel at that moment?

  Probes: Could you tell me more about------?

- **Perception and experience of Pulmonary rehabilitation service:**
- From your perspective, what is the purpose of pulmonary rehabilitation?

  Probes: Can you tell me more about------?

- Can you recall a person with COPD who was reluctant to take up PR? What factors do you think affected his/ her uptake and attendance?

  What factors do you think may affect people’s uptake and attendance of the PR pathway?

  Probes: Which (three) factors do you think are most important?

- Do you know someone who declined PR because they think the course does not provide what they need?
  Probes: Could you tell me more about------?

- How do you know whether or not a patient who took up the PR programme or quit at a later stage?
  Probes: How do you communicate with your patients? What information do you expect your patients to tell you? What information do you convey to the patients?
- Does PR always work? Can it be further improved?
  Probes: Could you tell me more about------?

- **The relationship between capabilities and accessibility**
- Do you think there are any connections between people’s personal capabilities (physical and cognitive abilities) and their uptake and attendance of PR?

- What affect those people cannot access pulmonary rehabilitation (any stage of the pathway)?

- Do people give up PR because they think their capabilities are not sufficient to manage the PR programme?
  Probes: Can you tell me more about------?

Appendix 2: Questions for semi-structured interview with patients

- **COPD journey of people with COPD:**
- Have you ever heard someone mentioned care journey or pathway to you?
- Can you share your COPD care journey, from how you diagnose to the pulmonary rehab?
- Looking at the picture, do you agree with this primary care pulmonary rehabilitation pathway? Can you possibly help me identify your care journey? Is there any difference in the pathway you have experienced?

- From your perspective, which part of the care journey do you think is most challenging? And which part would be relatively easier for you?
  Probes: Could you possibly tell me more about your needs along the journey?

- **Needs of people with COPD**
- Have you ever been referred to pulmonary rehabilitation?

- For people who have not been referred to PR:
  Have you ever heard about pulmonary rehab?

- For people declined an PR offer:
  I know you was referred to pulmonary rehab but declined, I wonder why you declined your PR offer?

For people accept an PR offer:

- Can you recall your experience when you had just been referred to pulmonary rehabilitation? Is this your first time to do pulmonary rehabilitation or not? If not, are there any differences between the 1st and 2nd time?
  Probes: What was your feeling at that time? Can you tell me more about------?
- Can you remember the first time you talked with your physiotherapist in the rehab centre? Can you remember what they told you?
  Probes: How you communicate with your physiotherapist/GP/practice nurse/doctor?

- How do you feel about pulmonary rehabilitation? Do you think it is helpful?
  Probes: Could you tell me more about------?

- In your experience of accessing pulmonary rehabilitation, which things do you think do you think good? And what things do you think could be better?
  Probes: What about------ is it that made it so bad? Why do you think ----- is bad?

- Are there things that you think would have improved your pulmonary rehabilitation experience?
  Probes: Could you tell me more about------?

- **The relationship between capabilities and accessibility**
- Here we are going to do a capability measure test. There will be about 6 sets of questions.
  The details questions can be seen in Appendix 3: Questions for measuring people's capability.
- How long have you been diagnosed with COPD? Have there been any significant changes in your life since your diagnosis?

- Do you think your capabilities (i.e., how well your vision, hearing, mobility, reach and stretch, dexterity, thinking and communication) will affect your access to pulmonary rehabilitation or not?

- Have there been any changes in your capabilities (vision, hearing, mobility, reach and stretch, dexterity, thinking and communication) since you were diagnosed? Do these changes affect your pulmonary rehabilitation especially the uptake and attendance process?

- **Personal information**
- Would you mind me asking you some personal information?
- What is your occupation?
- Please select your Age group
    - Under 16
    - 16-19
    - 30-44
    - 45-59
    - 60-74
    - Over 75
    - Do not wish to disclose

Appendix 3: Questions for measuring people's capability

Here we are going to do a capability measure test. There will be about 6 sets of questions.

1. VISION

- Do you use glasses?
- Can you see well enough to read a newspaper headline (with your glasses)?
- Can you see well enough to read a large print book (with your glasses)?
- Can you see well enough to read the ordinary newspaper print (with your glasses)?
- Can you see well enough to read GP's letter or medication instruction (with your glasses)?
- Has your vision affected your access to (get to) COPD care treatment or not?

2. HEARING

- Can you understand loud speech in a quiet room?
- Can you use the telephone without special adaptations for hearing impairment?
- Do you have great difficulty following a conversation if there is background noise – for example, a T.V., radio or children playing?
- Can you see hear your GP or physiotherapists' words clearly?
- Has your hearing affected your access to (get to) COPD care treatment or not?

3. THINKING

- Can you concentrate on a short TV ad without getting distracted?
- Can you concentrate enough to make toast without getting distracted?
- Can you concentrate enough to run a bath without getting distracted?
- Can you think clearly, or do your thoughts tend to be muddled or slow?

THINKING - Memory

- Can you remember your name?
- Can you remember your best friend's name?
- Can you remember names of people in your family or friends whom you see regularly?

THINKING - Literacy

- Can you read and understand individual common words, e.g. cat, house?
- Can you read and understand a sentence, i.e., in a tabloid newspaper?
- Can you read and understand a short newspaper article, i.e., in a tabloid newspaper?

THINKING - Speaking comprehension

- Can you understand individual common words when spoken aloud?
- Can you understand simple sentences when spoken aloud?
- Can you understand short audio news report?

THINKING - speaking

- Can you speak common words clearly enough that others can understand?
- Can you ask a simple question clearly enough that others understand it?
- Can you speak clearly enough that others understand you in typical everyday conversations?
- Do you have any difficulty to answer questions and talk with your GP or physiotherapists?
- Has your thinking and communication affected your access to (get to) COPD care treatment or not?

4. DEXTERITY

- Can you turn a tap or the control knob of a cooker?
- Can you pick up a small object, like a safety pin from a table-top using your fingers
- Can you use a pen or pencil to write without difficulty?

DEXTERITY - Lifting strength

- Can you pick up and hold a mug of coffee or tea by the handle?
- Can you pick up and carry a bottle of wine or a glass bottle of milk without condensation?
- Can you pick up and carry four pints of milk or a 2.5kg bag of potatoes?
- Has your dexterity affected your access to (get to) COPD care treatment or not?

5. REACH AND STRETCH - reach forward and up

- Can you reach forward to shake hands with your friends?
- Can you reach up to put a hat on head?
- Can you reach something just above head for a few seconds?

REACH AND STRETCH - reach down

- Can you reach down to knee level with one arm, supporting yourself with other arm if needed?
- Can you reach down to the floor level with one arm, supporting yourself with the other arm if needed?
- Can you get down to floor level to use dustpan& brush, supporting yourself on the way if needed?
- Has your reach and stretch affected your access to (get to) COPD care treatment or not?

6. MOBILITY

- What is the furthest you can walk on your own without stopping and without severe discomfort?

☐ I am able to walk only a few steps.
☐ I am able to walk 50m without help and without stopping, with aids if needed.
☐ I am able to walk 175m without help and without stopping, with aids if needed.
☐ I am able to walk 350m without help and without stopping, with aids if needed.
☐ Not sure

- What is the longest stairs you can climb on your own without stopping and without severe discomfort?

☐ I am able to climb 12 stairs without help and without using a handrail.
☐ I am able to climb 12 stairs without help, using a handrail if necessary.
☐ I am able to climb one step without help.
☐ I always require assistance.
☐ Not sure.

- Which one is more match your Standing and balancing ability?

☐ I am able to stand momentarily, without holding on to anything
☐ I am able to stand for a minute, without holding on to anything.
☐ I am able to stand for 10 minutes, without holding on to anything
☐ Not sure.

- Has your mobility affected your access to (get to) COPD care treatment or not?

Checklist

No	Item	Description	Page
1	Planned or ongoing studies	Manuscripts that report work already carried out will not be considered as protocols. The dates of the study must be included in the manuscript and cover letter.	12-13
2	Protocols for studies that will require ethical approval	Protocols for studies that will require ethical approval, such as trials, are unlikely to be considered without having received that approval.	12
3	Title	This should include the specific study type, e.g. Randomised controlled trial.	1
4	Abstract	This should be structured with the following sections. Introduction; methods and analysis; ethics and dissemination.	2
		Registration details should be included as a final section, if appropriate.	Not applicable
5	Strengths and limitations of this study	A section, placed after the abstract, consisting of the heading 'Strengths and limitations of this study', and containing up to five short bullet points, no longer than one sentence each, that relate specifically to the methods.	3
6	Introduction	Explain the rationale for the study and what evidence gap it may fill. Appropriate previous literature should be referenced, including relevant systematic reviews.	4-5
7	Methods and analysis	Provide a full description of the study design, including the following:	5-11
		i. how the sample will be selected;	9-10
		ii. interventions to be measured;	Not applicable
		iii. the sample size calculation (drawing on previous literature) with an estimate of how many participants will be needed for the primary outcome to be statistically, clinically and/or politically significant;	9
		iv. what outcomes will be measured and how;	6-8
		v. a data analysis plan.	6-8
8	Ethics and dissemination	Ethical and safety considerations and any dissemination plan (publications, data deposition and curation) should be covered here.	11-13
9	Full references		13-14
10	Authors' contributions	State how each author was involved in writing the protocol.	13
11	Funding statement	Preferably worded as follows. Either: 'this work was supported by [name of funder] grant number [xxx]' or 'this research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors'.	13
12	Competing interests statement		13