Protocol

COPD Pal Phase 2: Assessing the uptake, engagement, and safety of a self-management app for Chronic Obstructive Pulmonary Disease. A pilot expediency study in a real-world setting.

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Abstract

Chronic Obstructive Pulmonary Disease (COPD) is a widespread condition that accounts for 3 million deaths worldwide annually. In the UK, the condition costs the NHS over £500 million. However, despite people with COPD being extensive healthcare users, they only spend approximately 1% of their time with a healthcare professional. The rest of the time, people with COPD need to self-manage their condition, which includes exercising, taking medication, and being aware of their symptoms. To encourage better self-management, Bond Digital Health have created a mobile phone app called COPD Pal that helps people with COPD keep track of their condition.

We have designed this study to enable us to investigate the uptake, engagement, and safety of this app, in addition to help design larger, future studies. We aim to recruit 30-50 people with COPD and prescribe them COPD Pal over 6 weeks to answer the research question. A questionnaire measuring self-management will be used at baseline and at follow-up, in addition to us collecting hospital data to assess the safety of the app. Lastly, participants will be asked to complete a feedback form giving us valuable data on how they experienced the app. Averages will be calculated and visually displayed for the quantitative measures in addition to a thematic analyses conducted on the free-text boxes of the feedback form.

A final report will be provided to research participants, the creators of COPD Pal, and the funders of the project.

Introduction

Chronic Obstructive Pulmonary Disease (COPD) is a global problem, with 210 million sufferers and 3 million deaths annually (Quaderi & Hurst, 2018). It is predicted to become the third most common cause of death worldwide by 2030 (World Health Organisation, 2016). There are 1.2 million people on COPD registers in the UK, but this is likely to be an underestimate. People with COPD have daily symptoms, a poorer health status, reduced exercise capacity, and impairment in lung function. A sustained worsening of symptoms above day-to-day variation, in response to infection or pollution, is termed an acute exacerbation. Exacerbations of COPD are the second most common cause of emergency admission in the

UK, being responsible for one in eight (130,000) of the total, as well as 1 million bed days and an annual NHS expenditure of over £500M in 2015. (National Institute for Health and Care Excellence; NICE, 2018).

Despite people with COPD being extensive users of the National Health Service (NHS; Department of Health, 2012; Dhamane, et al., 2015), approximately only 1% of their time is spent with healthcare professionals (NHS England, 2014). The rest of the time, people with COPD are encouraged to self-manage their condition; where, such behaviours include regular exercise, taking medication, being aware of symptoms, and attending healthcare appointments (NICE, 2018).

Improving self-management has been identified as a possible method to reduce hospital admissions (Jonkman, et al., 2016; Zwerink, et al., 2014); a principle factor responsible for the large financial burden caused by COPD (Parikh, Shah, & Tandon, 2016). Research has also found that self-management interventions on average save £671.59 per person and are underneath the NICE threshold for cost-effectiveness (£20k-£30k per quality adjusted life year gained; Khdour, et al., 2011). Supporting self-management behaviours has been highlighted as crucial for the care of people with COPD (Kielmann, et al., 2010).

Despite the positive association between self-management and health outcomes (Benzo, Abascal-Bolado, & Dulohery, 2015), these behaviours are seldom taught, and rarely followed over prolonged periods (Russell, et al., 2018); for example, adherence to COPD medication is historically low (Bourbeau & Bartlett, 2008; Restrepo, et al., 2008).

To enable greater awareness of the change of his symptoms (i.e. better self-management), Ian Bond – who lives with COPD – created a simple diary (figure 1) which allowed him to identify when he was likely to have an exacerbation and thus take preventative action. Creating Bond Digital Health Ltd. (BDH; Cardiff, UK; https://bondhealth.co.uk/) he transformed this paper tool into a basic electronic diary (figure 2). This quickly evolved into the development of an easy to use smart phone app. 'COPD Pal' aims to allow people with COPD to track and manage their condition. It enables patients to log symptoms, wellness, and medications, with the potential to help them become more engaged in their own care.

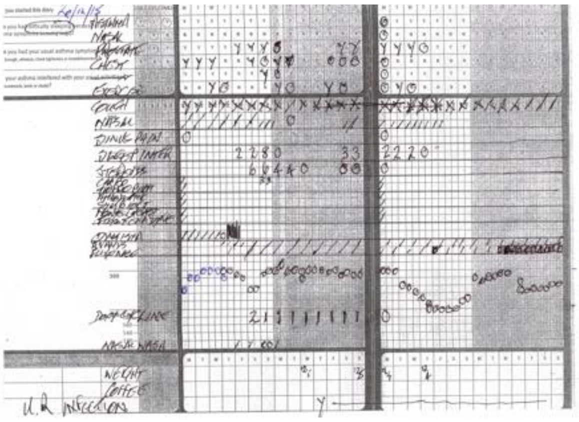

Figure 1: BDH CEO Ian Bond's original paper-based record system.

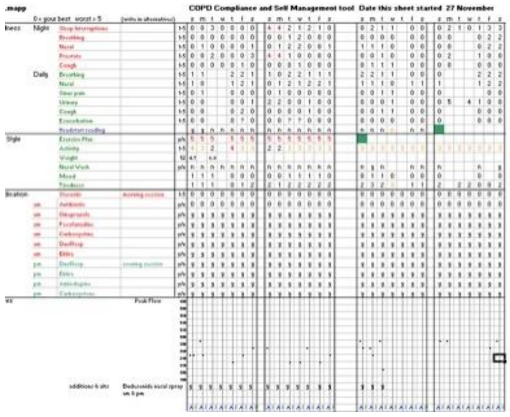

Figure 2: First generation of COPD Pal.

Showing their digitalised (health) data to a healthcare professional, during their consultation (by the patient), has the potential to guide the clinician better, open-up more communication, and empower the patient to lead their clinic appointment; thus, becoming more positively involved in their own care. It should also help any healthcare professional in looking at trends and changes (or consistencies) from baseline health status that is personal for that patient. It is akin to a patient bringing a paper diary, warfarin INR booklet or blood pressure recordings to show their healthcare professional the day-to-day variation in their chronic disease.

By improving self-management, illness understanding, and confidence in people with COPD, COPD Pal has the potential to allow greater locus of control and hopefully will lead to reduced GP contacts, number and length of hospitalisations, and present real and immediate cost-savings to the NHS.

This is a collaborative project between BDH and Hywel Dda University Health Board (HDUHB), with BDH and their specialist software engineers developing the prototype of the app and HDUHB undertaking feasibility analysis. This project has received funding from the Welsh Government through the Efficiency through Technology Programme (ETTP; Social Research Number: 51/2017).

Aim and objectives

This project aims to answer the research question: *'For people with COPD, is a self-management mobile phone app safe and feasible and do people engage?'*

Secondary objectives include:

1. Determine feasibility of large-scale trial based on recruitment to and completion of the study.
2. Determine user engagement and frequency of use of app
3. Safety of using the app in terms of impact on clinical outcomes
4. Usability and acceptability of using the app

Health-related Quality of Life (HRQoL) is collected as part of the self-management diary within the app at set time points using the CAT (Jones, et al., 2009) and the EQ-5D (Herdman, et al., 2011). Effect sizes will be calculated for HRQoL to facilitate power calculations for a future research study. Additionally, the Understanding COPD (UCOPD) questionnaire (appendix 2; O'Neill, Cosgrove, MacMahon, McCrum-Gardner, & Bradley, 2012) will be used to assess any impact of the app on self-management confidence. Effect sizes will also be calculated for the UCOPD.

Method

This study has been approved by Research Ethics Committee and HDUHB research and development (R&D).

Participants

Recruitment will take place over a period of up to 6 months, with a target sample size of between 30-50 participants. This is the number of participants considered necessary to test the processes of data collection, and based on the recommendations of Lancaster with respect to the number of people required to yield meaningful estimates of parameters of interest (Lancaster, Dodd, & Williamson, 2004).

Inclusion criteria:

- Willing and able to sign informed consent.
- Clinical diagnosis of COPD as defined by GOLD (Vogelmeier, et al., 2018; https://goldcopd.org/wp-content/uploads/2018/11/GOLD-2019-v1.7-FINAL-14Nov2018-WMS.pdf), i.e. greater than 40 years old, ≥ 10 pack years smoking history, post-bronchodilator FEV1/FVC ratio of 0.7, with FEV1 less than 80% predicted.
-
- Life expectancy greater than 6 months

Smokers and ex-smokers, any gender, any co-morbidities, and people living in residential care are eligible to participate.

Exclusion criteria:

- Unwilling or unable to provide written informed consent.
- Cognitive, visual, or motor impairment that would affect ability to see or use a smart phone.
- Current hospital inpatient or nursing home resident.

Procedure

Patients will be identified by the HDUHB respiratory research or clinical team from hospital clinics, pulmonary rehabilitation lists, Breathe Easy groups, Respiratory Innovation Wales' Expert Patient Network, from the research COPD database.

Once identified, patients will have the research first discussed with them during a clinic visit by a member of their clinical team and provided with a Participant Information Sheet Consent Form (PISCF). Although the patient will have up to seven days to consider participating in the study, as this is a low intensity study with a simple app, they can also consent on the day should they wish. In either situation, patients will be given every opportunity to ask questions during the consenting process.

Alternatively, if a patient identified on the research database or GP registers is not due to have a clinic visit within one month, they will be posted an invitation letter and PISCF. Contact details will be provided on the PISCF in case a patient has a question concerning the research study. If willing, the patient will be asked to contact the research team via telephone to indicate they wish to participate.

Numbers and reasons for refusing the study (where offered) will be collected to consider the feasibility of a larger, future research study.

Following agreement to participate, participants will be invited to attend the research offices at their nearest Hywel Dda University Health Board Hospital or the Beacon Centre for Enterprise and asked to provide written informed consent. A mobile smart phone with the latest version of COPD Pal (see appendix 1 for current images) will be given to the participant and they will be instructed on how to use app. As this is a real world study, the app may undergo updates during the trial period, only those leading to changes in data collected will be submitted to ethics. Any changes due to layout or to resolve technical issues will not be submitted unless requested by the sponsor.

Participants will then be asked to complete a short questionnaire assessing their knowledge of COPD and self-management. The UCOPD questionnaire consists of 18 questions measured on a Likert scale marked 0 to 10 (see Appendix 2). Additionally, they will be asked to report on the number of exacerbations experienced within the past three months including hospital or GP attendances experienced (due to COPD) and use of steroids. This will be validated in the first 15 patients recruited and in an additional 10 selected at random by cross-checking the number of hospital admissions and courses of oral steroids/antibiotics from routine data sources. If 90% of self-reported data matches clinical records, no further validation will be required. If this percentage is not reached, all participants' exacerbation history for 3 months prior to consent will be obtained from clinical records.

Participants will be asked to use COPD Pal for 6 weeks. There are no lifestyle restrictions to this study and participants will be encouraged to carry on with their everyday activities in addition to using COPD Pal. The app incorporates data collection on several questionnaires at different time points to enable the participant to track their symptoms and wellbeing. The data collected includes the COPD Assessment Test (CAT; Jones, et al., 2009),the EQ-5D (Herdman, et al., 2011), and the modified Medical Research Council Dyspnoea scale (mMRC; Bestall, et al., 1999). These measures are standard questionnaires used to assess the impact COPD has on people and are presented in Appendices 3-5. The app also collects the participants' first name, gender, and date of birth.

At 6 weeks follow-up (+/- 1 week), participants will complete the same short questionnaire assessing self-management and symptom knowledge (i.e. UCOPD). At 6 week follow-up, patients will be asked to state the number of acute exacerbations, hospital or GP attendances experienced (due to COPD), and use of steroids/antibiotics. Engagement data will be extracted from the app and number of hospitalisations over the six weeks will be collected from hospital databases by the research team. Participants will also be asked to complete a feedback questionnaire on usability and acceptability of using COPD Pal (see appendix 6). This will mark the end of the study.

Data entered in the app will be used to develop mathematical models for app development.

Outcomes and analysis

This study aims to assess the safety, expediency of, engagement with, and usability/acceptability of COPD Pal.

For the following outcomes the, ACCEPT model (Charlesworth, et al., 2013) guidelines will be used.

1. Acceptable recruitment is defined as >50% of eligible people consenting to participate and follow-up data available for the self-management questionnaire (UCOPD) for >60% of enrolled participants.
2. Engagement will be measured in terms of active use of the App. Participant use will be automatically collected by COPD Pal and acceptable engagement defined as over 70% using app daily.
3. Safety will be measured as the mean number of exacerbations or hospitalisations and deemed acceptable if not 20% more in the 3 months whilst using the app than the 3 months immediately pre-app. GP contact and steroid/antibiotic use may increase as a result of better patient awareness of symptoms and as such will not be used as an indicator of safety.

Usability and acceptability of using the app and study participation will be reported using frequencies and thematic analysis of free text from the feedback questionnaire (i.e. Appendix 3; Braun & Clarke, 2006). Thematic Analysis focuses on examining and identifying explicit and implicit themes within the data. The method emphasises organisation and rich description of the data using a coding process that recognises important messages in the data.

HRQoL is collected as part of the self-management diary within the app at set time points using the EQ-5D (Herdman, et al., 2011) and CAT (Jones, et al., 2009). Effect sizes will be calculated for HRQoL to help power calculations for a future research study. Additionally, the UCOPD questionnaire will be used to assess any impact of the App on self-management confidence. Effect sizes will also be calculated for the UCOPD.

Schedule of events of research measures

	Baseline (Day 0)	6 weeks follow-up
Demographics Age Gender	 x x	
FEV1	x	
Smoking history	x	x
Exacerbation Hx	x	x
Medication use	x	x

Health care contacts	x	x
UCOPD	x	x
Feedback questionnaire		x

Patient and Public Involvement

Patients and the public have been invited to give their personal views on this research project at a HDUHB Respiratory Advisory Group meeting and Breathe Easy Carmarthenshire meeting. The project was received positively and questions were asked concerning which health boards would be involved in the project, in addition to how will people with COPD access this app if the research is successful and rolled out across Wales. Unfortunately, due to funding, we can only deliver this project within HDUHB; however, the app will be released across Wales if successful. Lastly, participants expressed that the app should be provided in addition to current care and not be used as a replacement of services provided.

The study was presented to Breathe Easy Carmarthenshire and the app modified in response. The results of this project will enable further COPD Pal development based upon the quantitative findings of feasibility and engagement and qualitative questions on the feedback form. All participants will be offered a summary of the findings from this project.

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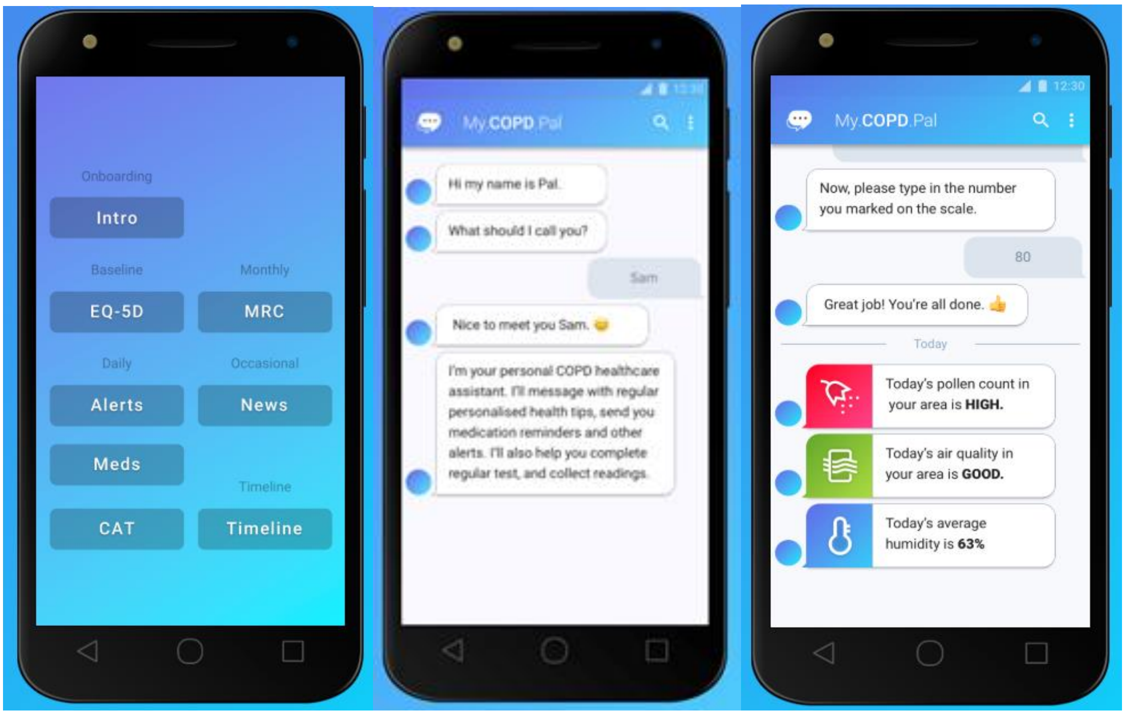
Appendix 1 – Current COPD Pal Screenshots



Hi my name is Pal.

What should I call you?

Sam

Nice to meet you Sam. 😊

I'm your personal COPD healthcare assistant. I'll message with regular personalised health tips, send you medication reminders and other alerts. I'll also help you complete regular test, and collect readings.

Now, please type in the number you marked on the scale.

80

Great job! You're all done. 👍

Today's pollen count in your area is **HIGH.**

Today's air quality in your area is **GOOD.**

Today's average humidity is **63%**

Today's pollen count in your area is **HIGH.**

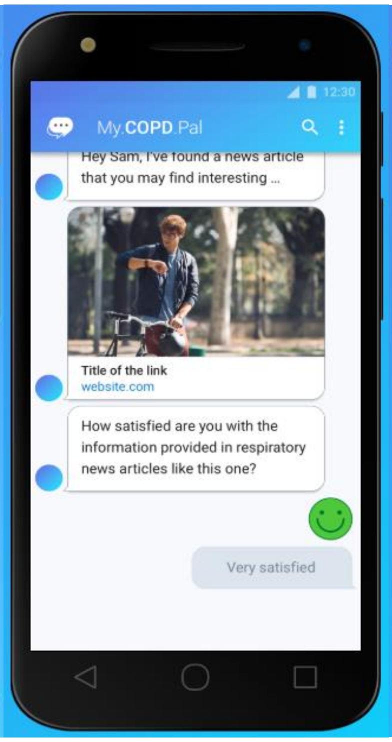
Today's air quality in your area is **GOOD.**

Today's average humidity is **63%**

Hey Sam, have you taken your morning meds yet?

Yes I have

Great! Shall we update your medication diary?

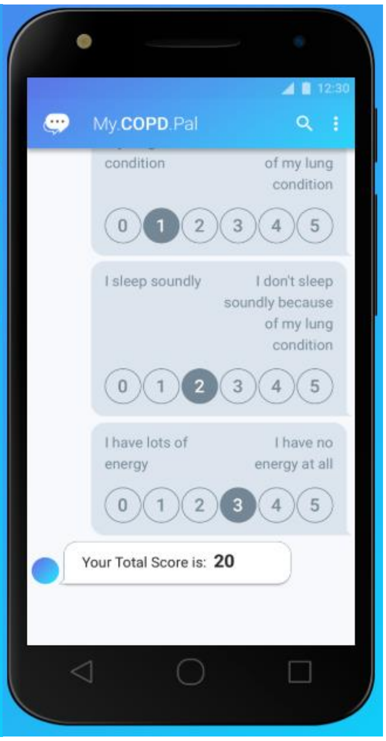


Hey Sam, I've found a news article that you may find interesting ...

Title of the link
website.com

How satisfied are you with the information provided in respiratory news articles like this one?

Very satisfied



condition — of my lung condition: 0 ● 1 2 3 4 5

I sleep soundly — I don't sleep soundly because of my lung condition: 0 1 ● 2 3 4 5

I have lots of energy — I have no energy at all: 0 1 2 ● 3 4 5

Your Total Score is: **20**

☑ Dymista Spray

Thanks! Should I remind you later about remaining meds?

Yes please

Are you ready to take the COPD Assessment Test (CAT)?

How is your COPD today?

I never cough — I cough all the time

0 1 2 3 4 5

Tap to select your answer

1 of 8 NEXT

My.COPD.Pal

Appendix 2 – UCOPD

For each question please **circle the number** on the scale to show your understanding, confidence or use with each topic. If there are topics you do not know much about, feel less confident with or don't use often, then you should circle a low score. If there are topics you know more about, feel more confident with or use often then you should circle a higher score.

Example:

0 1 2 3 4 5 [✓ 6] 7 8 9 10

ABOUT COPD

1. How well do you understand what COPD is?

0 1 2 3 4 5 6 7 8 9 10

No understanding Full understanding

2. How well do you understand how COPD changes over time?

0 1 2 3 4 5 6 7 8 9 10

No understanding Full understanding

3. How confident are you that you can recognise an exacerbation (a significant worsening of your usual symptoms)?

0 1 2 3 4 5 6 7 8 9 10

Not confident Very confident

4. How confident are you that you know how to alter your therapy during an exacerbation (a significant worsening of your usual symptoms)?

0 1 2 3 4 5 6 7 8 9 10

Not confident Very confident

5. How confident are you that you know when to seek help during an exacerbation (a significant worsening of your usual symptoms)?

0 1 2 3 4 5 6 7 8 9 10

Not confident Very confident

6. How confident are you that you know **how** to use your COPD medication (e.g. inhaler, nebuliser, and tablets)?

0 1 2 3 4 5 6 7 8 9 10

Not confident Very confident

7. How confident are you that you know **why** you use your COPD medication?

0 1 2 3 4 5 6 7 8 9 10

Not confident Very confident

MANAGING SYMPTOMS OF COPD

8. How often do you use breathing techniques to manage your symptoms (e.g. slowing your breathing down and pursed lip breathing)?

0 1 2 3 4 5 6 7 8 9 10

Never Always

9. How often do you pace yourself to conserve energy (e.g. plan activities, alternate light and heavy tasks)?

0 1 2 3 4 5 6 7 8 9 10

Never Always

10. How often do you use positions of ease (e.g. body positions to reduce shortness of breath)?

0 1 2 3 4 5 6 7 8 9 10

Never Always

11. How well do you understand the benefits of exercise?

0 1 2 3 4 5 6 7 8 9 10

No understanding Full understanding

12. How confident are you that you can take part in exercise?

0 1 2 3 4 5 6 7 8 9 10

Not confident Very confident

13. How confident are you that you can manage the low mood or depression sometimes associated with COPD?

0 1 2 3 4 5 6 7 8 9 10

Not confident Very confident

14. How confident are you that you can manage the anxiety and panic sometimes associated with COPD?

0 1 2 3 4 5 6 7 8 9 10

Not confident Very confident

ACCESSING HELP AND SUPPORT

15. How confident are you that you know how to get aids and appliances if you need them (e.g. shoe horn, shower seat)?

0 1 2 3 4 5 6 7 8 9 10

Not confident Very confident

16. How confident are you that you know how to get information about welfare and benefits that you might be entitled to?

0 1 2 3 4 5 6 7 8 9 10

Not confident Very confident

17. How confident are you that you know how to access facilities for exercise (e.g. gym, pool, walking clubs)?

0 1 2 3 4 5 6 7 8 9 10

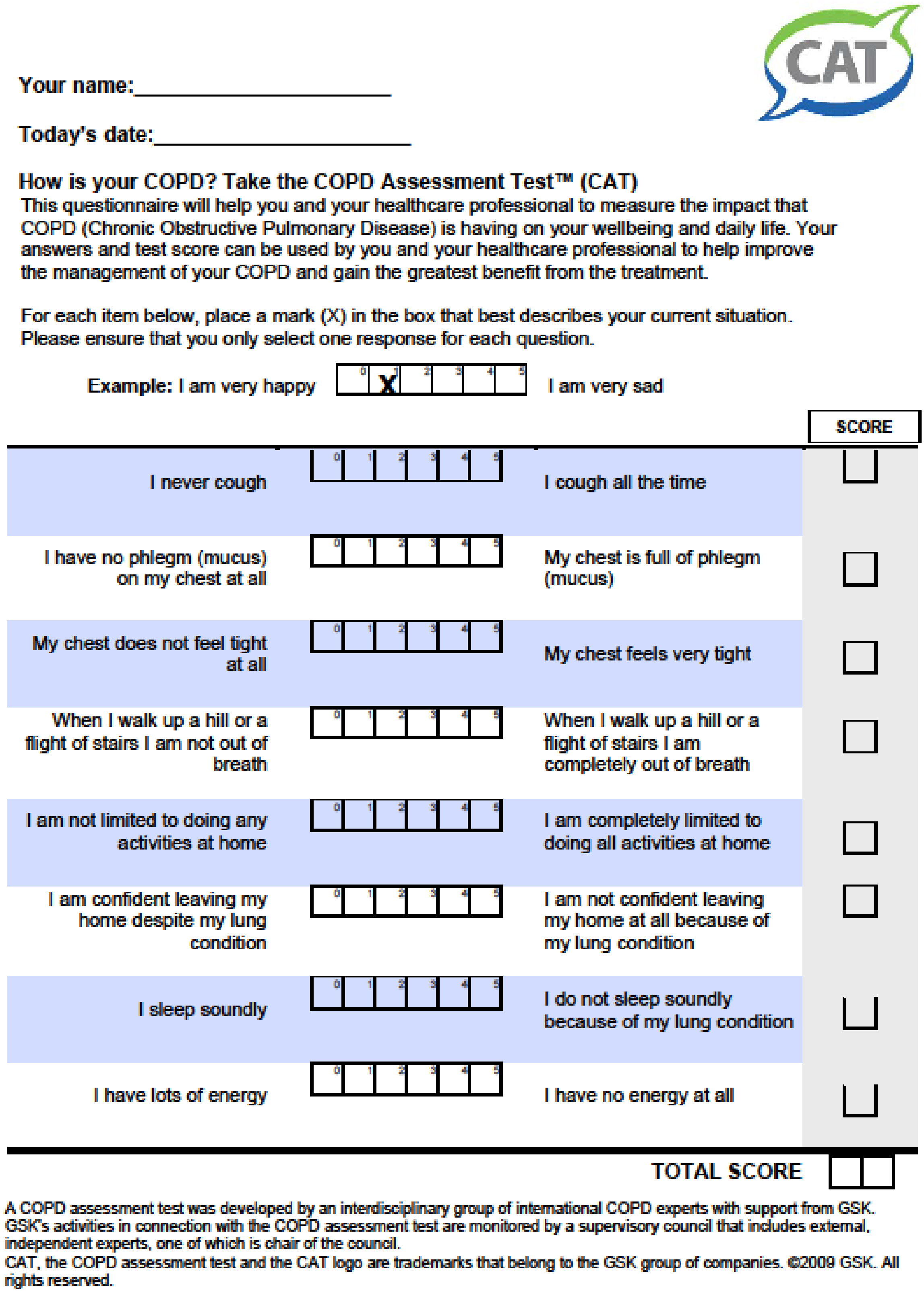
Not confident Very confident

18. How confident are you that you know how to get information about local support groups for people with respiratory conditions?

0 1 2 3 4 5 6 7 8 9 10

Not confident Very confident

Appendix 3 – COPD Assessment Test



Your name:______________________

Today's date:______________________

How is your COPD? Take the COPD Assessment Test™ (CAT)

This questionnaire will help you and your healthcare professional to measure the impact that COPD (Chronic Obstructive Pulmonary Disease) is having on your wellbeing and daily life. Your answers and test score can be used by you and your healthcare professional to help improve the management of your COPD and gain the greatest benefit from the treatment.

For each item below, place a mark (X) in the box that best describes your current situation. Please ensure that you only select one response for each question.

Example: I am very happy ☐0 ☒1 ☐2 ☐3 ☐4 ☐5 I am very sad

			SCORE
I never cough	☐0 ☐1 ☐2 ☐3 ☐4 ☐5	I cough all the time	☐
I have no phlegm (mucus) on my chest at all	☐0 ☐1 ☐2 ☐3 ☐4 ☐5	My chest is full of phlegm (mucus)	☐
My chest does not feel tight at all	☐0 ☐1 ☐2 ☐3 ☐4 ☐5	My chest feels very tight	☐
When I walk up a hill or a flight of stairs I am not out of breath	☐0 ☐1 ☐2 ☐3 ☐4 ☐5	When I walk up a hill or a flight of stairs I am completely out of breath	☐
I am not limited to doing any activities at home	☐0 ☐1 ☐2 ☐3 ☐4 ☐5	I am completely limited to doing all activities at home	☐
I am confident leaving my home despite my lung condition	☐0 ☐1 ☐2 ☐3 ☐4 ☐5	I am not confident leaving my home at all because of my lung condition	☐
I sleep soundly	☐0 ☐1 ☐2 ☐3 ☐4 ☐5	I do not sleep soundly because of my lung condition	☐
I have lots of energy	☐0 ☐1 ☐2 ☐3 ☐4 ☐5	I have no energy at all	☐

TOTAL SCORE ☐☐

A COPD assessment test was developed by an interdisciplinary group of international COPD experts with support from GSK. GSK's activities in connection with the COPD assessment test are monitored by a supervisory council that includes external, independent experts, one of which is chair of the council.

Appendix 4 – EQ-5D-5L

Under each heading, please tick the **ONE** box that best describes your health **TODAY**

B1) MOBILITY

I have no problems in walking about ☐

I have slight problems in walking about ☐

I have moderate problems in walking about ☐

I have severe problems in walking about ☐

I am unable to walk about ☐

B2) SELF-CARE

I have no problems washing or dressing myself ☐

I have slight problems washing or dressing myself ☐

I have moderate problems washing or dressing myself ☐

I have severe problems washing or dressing myself ☐

I am unable to wash or dress myself ☐

B3) USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ☐

I have slight problems doing my usual activities ☐

I have moderate problems doing my usual activities ☐

I have severe problems doing my usual activities ☐

I am unable to do my usual activities ☐

B4) PAIN / DISCOMFORT

I have no pain or discomfort ☐

I have slight pain or discomfort ☐

I have moderate pain or discomfort ☐

I have severe pain or discomfort ☐

I have extreme pain or discomfort ☐

B5) ANXIETY / DEPRESSION

I am not anxious or depressed ☐

I am slightly anxious or depressed ☐

I am moderately anxious or depressed ☐

I am severely anxious or depressed ☐

I am extremely anxious or depressed ☐

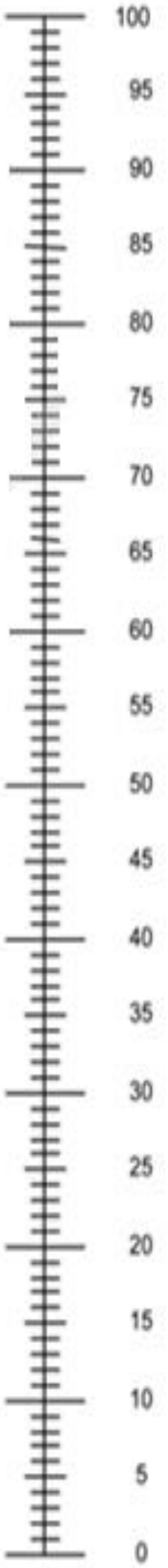
B6) We would like to know how good or bad your health is **TODAY.**

- This scale is numbered from **0** to **100.**
- **100** means the best health you can imagine.

  0 means the worst health you can imagine.
- Mark an **X** on the scale to indicate how your health is **TODAY.**
- Now, please write the number you marked on the scale in the box below.

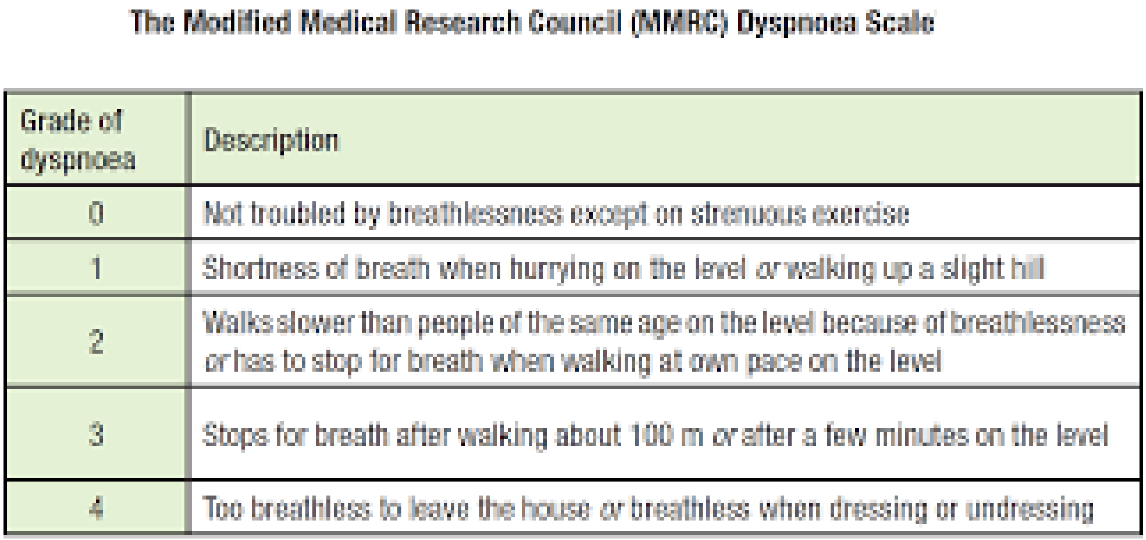
YOUR HEALTH TODAY =

The best health you can imagine



The worst health you can imagine

Appendix 5 – mMRC



The Modified Medical Research Council (MMRC) Dyspnoea Scale

Grade of dyspnoea	Description
0	Not troubled by breathlessness except on strenuous exercise
1	Shortness of breath when hurrying on the level *or* walking up a slight hill
2	Walks slower than people of the same age on the level because of breathlessness *or* has to stop for breath when walking at own pace on the level
3	Stops for breath after walking about 100 m *or* after a few minutes on the level
4	Too breathless to leave the house *or* breathless when dressing or undressing

Appendix 6 – COPD Pal Feedback Questionnaire

Please respond to each question below by circling the answer that indicates how you feel. There are no right or wrong answers to this questionnaire and we only wish to understand your views on COPD Pal. There are free-text boxes at the end of the questionnaire, which you may use to provide any further comments you wish.

a) How did you find using the app?

Very Easy   ***Easy***   ***Neutral***   ***Hard***   ***Very Hard***

b) How useful was the app to you?

Very Useful   ***Useful***   ***Neither***   ***Not That Useful***   ***Not At All Useful***

c) How likely are you to use the app longer term?

Very Likely   ***Likely***   ***Not Sure***   ***Unlikely***   ***Very Unlikely***

d) What would you like to change about the app?

e) Any other comments: