Development of a questionnaire to measure self-conscious emotions in patients with COPD

Thesis submitted in part fulfilment of the degree of Doctorate in Clinical Psychology

(DClinPsy)

University of Leicester

By

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Declaration

I confirm that this thesis and the research reported within it is an original piece of work and was written and submitted in part-fulfilment of the degree of Doctorate in Clinical Psychology. It has not been submitted for any other piece of work.

Elizabeth Pike

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Abstract

Chronic obstructive pulmonary disease (COPD) is a respiratory condition which can severely limit physical and social activities. Self-management and pulmonary rehabilitation programmes are commonly used to enhance clinical outcomes and quality of life in patients with COPD. However, completion rates for treatment programs are low and psychological factors remain poorly understood.

The current literature review aimed to explore the impact of self-management programmes on psychological wellbeing in individuals with COPD. Four electronic databases were searched and fifteen studies met the inclusion criteria. Findings suggested that self-management programmes appeared to have some beneficial effect on psychological wellbeing, however due to the lack of good quality studies and methodological limitations, strong conclusions could not be drawn. Conclusions suggested a need for a more standardised and theoretically driven approach to be taken, and for future research to look at a wider definition of psychological wellbeing factors.

The current empirical study aimed to develop a brief and clinically-based questionnaire that could be self-administered in outpatient settings to assess the level of self-conscious emotions experienced by patients with COPD. An empirical approach to scale development was utilised across four phases to develop the COPD Self-conscious Emotion Scale (CSES). Principal Component Analysis of the CSES suggested an 11-item measure comprising an underlying two subscale structure of 'guilt and embarrassment', and 'shame-based avoidance', best fitted the data. Findings were discussed in relation to previous literature, and clinical implications and recommendations for future research were suggested.

The critical appraisal presents a reflective account of the research process, including the trainees' professional and personal development, with the aim of maximizing transparency.

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Word count

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Non-mandatory appendices	**2291**
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PART ONE: LITERATURE REVIEW

Psychological wellbeing in those living with COPD: How is it affected by self-management interventions?

LITERATURE REVIEW

Psychological wellbeing in those living with COPD: How is it affected by self-management interventions?

By Elizabeth Pike

Abstract

Background: Chronic obstructive pulmonary disease (COPD) is a respiratory condition and a leading cause of chronic morbidity and mortality worldwide. Self-management programmes (SMP) have been widely adopted in the developed world to improve patients' skills and confidence in managing their COPD, and thus enhance clinical outcomes and quality of life. However, evidence of SMP effectiveness appears equivocal, with benefits for psychological wellbeing still unclear.

Method: This systematic review evaluated the impact of SMP on psychological wellbeing in individuals with COPD through a literature search of four databases: PsychINFO, Medline, Embase and CINAHL. Manual searches of references of key reviews and studies were also completed. Fifteen quantitative studies were deemed appropriate for inclusion. Included studies assessed psychological wellbeing via measures of quality of life, anxiety, depression and self-efficacy.

Results: Appraisal of included studies suggest variable quality, with three rated as 'strong', five rated as 'moderate' and seven rated as 'weak'. Evidence examining impact of SMP on psychological wellbeing was mixed, with six studies reporting a positive effect of SMP on wellbeing in comparison to usual care group. Outcome measures were found to be limited in their scope and based largely on deficit models, rather than asset-focused well-being.

Conclusion: SMP appears to have some beneficial effects on psychological wellbeing, however due to the lack of good quality studies and methodological limitations, strong conclusions cannot be drawn. There is a need for SMP to be standardised and more theoretically driven, and for future research to look at a wider definition of psychological wellbeing factors.

1. Introduction

1.1 Chronic Obstructive Pulmonary Disease

Chronic obstructive pulmonary disease (COPD) is a respiratory condition and a leading cause of chronic morbidity and mortality worldwide, accounting for 6% of all deaths globally (Global Initiative for Chronic Obstructive Lung Disease, 2016). COPD is characterized by progressive airflow limitation, with wheezing, increasing breathlessness on activity, a persistent cough with phlegm, and increased frequency of chest infections. Diagnosis of COPD requires a combination of history taking, physical examination and confirmation of airway obstruction with post-bronchodilator spirometry. Estimates of COPD global prevalence vary considerably, from between 1.5-10.1% (Halbert *et al.,* 2006), with under-recognition and under-diagnosis likely corollaries of variation in data collection methods, diagnostic criteria, and analytic approaches (van den Boom *et al.,* 1998). Primary care estimates of COPD prevalence in the UK suggest rates of 5.38% (Rayner *et al*., 2017), likely to increase alongside social and economic costs in coming decades because of continued exposure to COPD risk factors (notably tobacco smoking and air pollution) and population aging (Lopez *et al.,* 2006).

1.2 COPD Treatment

Dominant interventions to mitigate symptoms of COPD and enhance clinical outcomes and quality of life, are both pharmacological and behavioural. Pharmacological interventions include bronchodilators, antimuscarinic drugs, combined bronchodilator therapy and anti-inflammatory agents (Global Initiative for Chronic Obstructive Lung Disease, 2016). Notable behavioural interventions include smoking cessation, pulmonary rehabilitation and self-management education.

Smoking cessation can help to slow or halt the progression of COPD and embraces pharmacological and psychosocial approaches. Interventions often include advice, self-help materials, individual and group behavioural support, nicotine replacement therapy and antidepressants (Thabane & COPD Working group, 2012). However, around 40% of patients remain smokers (Jiménez-Ruiz e*t al.,* 2015). Challenges to smoking cessation include lack of motivation, lack of social support, and presence of mental health difficulties (Thabane & COPD Working Group, 2012).

Furthermore, patients may disengage with these programs because of perceived opprobrium regarding smoking and associated feelings of guilt and shame (Halding *et al.,* 2011).

Pulmonary rehabilitation (PR), through its deployment of exercise training, aims to reduce symptoms, improve quality of life, and increase physical and emotional participation in everyday activities, for groups of eight to sixteen people with a chronic respiratory disease experiencing severe breathlessness. PR also addresses non-pulmonary issues such as weight loss, social isolation and mood changes (Ries *et al.,* 2007). Programs most often take place within a hospital setting run by physiotherapists, nurses and occupational therapists, for two-hour sessions over six to eight weeks. Systematic assessment of the benefits of PR have concluded that adherence to programmes are associated with improvements in exercise capacity, health related quality of life and longevity, as well as reduced hospital admissions and psychological morbidity (notably anxiety and depression) (McCarthy *et al.,* 2015). Although evidence has shown the effectiveness of pulmonary rehabilitation, there is significant attrition, with completion rates for larger samples between 20-40% (Cockram *et al.,* 2006; Garrod *et al*., 2006). PR appears to incorporate some self-management, such that the support and encouragement within the group setting may lead to an increase in patients' self-efficacy (Effing *et al.,* 2012). However, this is not routinely focused on or measured, and it may be that the focus on exercise training is off-putting for some people.

Therefore, specific self-management programmes (SMP) have been developed with the aim of improving COPD patients' clinical outcomes and quality of life (Cameron-Tucker *et al*., 2014). Whilst there is currently no research consensus about what constitutes SMP or PR, a crude distinction is that PR focuses on exercise, and SMP include education that focus on self-efficacy (Lomundal & Steinsbekk, 2007). In enhancing self-efficacy, SMP seeks to promote patients' skills and confidence in managing their condition themselves and improve their outcomes. For COPD, SMP usually involves health care professionals imparting disease specific information, a focus on goal setting and regular progress reviews, discussion of exercise and medications, and how best to manage exacerbations in order to maintain health and reduce hospital admissions (Spruit *et al.,* 2013).

1.3 SMP Development

Self-management, as a psychosocial intervention, has evolved over the last three decades since its initial parameters were informed by Corbin and Strauss's (1988) framework for addressing patients' perceptions of chronic ill health. The framework suggested that to fully address outcome improvement, interventions should explicitly focus on self-management with content that addresses medical and behavioural management, role management and emotional management. Growth of self-management programmes incorporating these principles has burgeoned, as technological advances have led to increased patient access to health information and the financial burden of chronic disease management has absorbed more of health budgets and increased emphasis on patient participation in healthcare (Holman & Lorig, 2000).

Application of self-management in diverse chronic conditions (including arthritis, diabetes and heart disease) has identified common challenges (Grady & Gough, 2014); notably managing symptoms and medication, monitoring physical indicators, maintaining appropriate diet and exercise, and adjusting to the psychological and social demands that accompany chronic illness. Reviews of SMP and diabetes, for example, have shown positive effects of SMP on a range of physical and psychological outcomes (Vas *et al*., 2017; Steed *et al*., 2003). Vas *et al*. (2017) assessed fourteen studies that explored the effectiveness of SMP in people with Type 2 diabetes, reporting a reduction in body weight, blood pressure, cholesterol, anxiety, depression and diabetes-related distress. Furthermore, they found an improvement in quality of life, self-efficacy, self-care levels, self-management skills and treatment satisfaction. However, the authors acknowledged that further research was needed to confirm the findings given the limited number of studies investigating each outcome. Furthermore, Steed *et al.* (2003) reviewed twenty-one studies investigating the impact of SMP on psychological outcomes or quality of life in people with diabetes. They found a generally positive impact of SMP on anxiety, depression, emotional adjustment and quality of life. However, they highlighted the diverse definitions of self-management, variety of interventions and dominant focus of studies on the negative aspects of wellbeing, rather than including more positive dimensions.

1.4 COPD SMP Outcome Measurement

There appear few reviews of efficacy and effectiveness for SMP and COPD, with the majority typically examining the impact of SMP on clinical outcomes such as lung function and disease severity, and functional outcomes such as exacerbations of disease or pain, and healthcare burden. Only three reviews to date have assessed the efficacy of SMP on psychological outcomes (Zwerink *et al.,* 2014; Wang *et al.,* 2017; Jonsdottir, 2013). Zwerink *et al.* (2014) examined the impact of SMP versus treatment as usual (TAU) on health related quality of life (HRQoL) in 23 randomised controlled trials (RCTs), 18 of which found attendees at SMP showed significant improvements in HRQoL in comparison to TAU. The specific active elements of SMP were unable to be discerned given the heterogeneity of programs, and wider measures of psychological wellbeing were not examined. Wang *et al.* (2017) looked at the impact of SMP on quality of life, anxiety and depression in 17 RCTs and found improvement of QoL and disease-specific knowledge, and reduction of respiratory-related hospital admissions and emergency visits. They concluded SMP had a positive impact on quality of life and emotional wellbeing. However, only SMP with face-to-face interaction were included, excluding other interventions deploying, for example, internet technology such as using the internet which may limit generalisability and disregard patient preference and access issues.

Jonsdottir (2013) completed a synthesis of four systematic reviews and an integrated review on nine papers published between January 2007 and June 2012, finding some evidence of an increase in HRQOL and reduction in use of healthcare resources. However, they concluded that the effectiveness of these interventions remained inconclusive due to few studies, variation in methodological approaches and small sample sizes. As psychological wellbeing was driven by morbidity in these reviews, rather than a eudemonic focus, a broader understanding of wellbeing is warranted.

1.5 The impact of psychological wellbeing in COPD

Growing evidence has revealed the need to consider psychological domains of wellbeing in COPD outcomes. Whilst earlier work has alighted on self-efficacy, Kaptein *et al's.* (2008) review revealed reduced efficacy (little control of symptoms or management), and Khdour *et al.* 2012 found patient appraisals of medication effectiveness are amongst the strongest predictors of adherence in COPD treatment.

Further factors affecting outcomes included COPD-specific catastrophic cognitions and personality factors such as neuroticism and pessimism (Hynninen *et al.*, 2005), and these researchers suggest likely multiple causal pathways between psychological status, functional disability, reduced quality of life, and disease severity, warranting far wider construction of psychological wellbeing.

Whilst comprehensive understanding of psychological well-being is difficult given it is a broad construct with numerous definitions, Ryff's (1989) six-domain model suggest positive wellbeing emerges through self-acceptance, purpose in life, autonomy, personal growth, positive relationships and environmental mastery. Houben *et al.* (2015) have argued that positive indices of psychological adjustment such as happiness, high self-esteem and life satisfaction, and absence of negative emotions and psychopathological symptoms, constitute wellbeing, and this review adopts the Houben *et al.* (2015) definition. Support comes from Boehm *et al.* (2015) who found positive psychological well-being such as life satisfaction, emotional vitality and optimism appear associated with up to a 15% decrease in diagnosed diabetes. Similarly, Kubzansky and Thurston (2007) found that emotional vitality, characterized by a sense of energy, positive well-being, and effective emotion regulation, were associated with reduced risk of developing coronary heart disease over a 15-year period of study.

1.6 Rationale and aims of the current review

The current review thus aimed to provide an up-to-date synthesis of research evidence examining the impact of self-management programmes on psychological wellbeing for people with COPD. The review sought to 1) provide a critical appraisal of most recent literature, including uncontrolled trials 2) include a broader range of conceptualisation and measurement of psychological wellbeing

2. Method

2.1 Inclusion and Exclusion criteria

The inclusion criteria for this review comprised; peer-reviewed journal articles written in the English language, which investigated the impact of a self-management programme for adult participants (at least 18 years old) with a diagnosis of COPD , and incorporated a measure of psychological wellbeing (administered pre- and post-intervention).

Articles were excluded if they were review papers and if they looked at outcomes of self-management programmes for disorders linked to COPD, such as asthma, or focused only on physical health outcomes.

2.2 Search Strategy

Prior to the main search, a scoping exercise was carried out to gauge the amount and type of literature within this area and to identify any previous reviews. This exercise informed the development of the inclusion criteria and search terms of the review, such as the need for the search terms to be kept broad and no limits put on the publication period due to a limited number of studies in this area.

A systematic review was conducted in November 2017 using four electronic databases (Medline, PsycINFO, Embase and CINAHL), which were selected to ensure a range of medical and psychological literature were explored. Databases were searched using combinations of search terms for Chronic Obstructive Pulmonary Disease and self-management (see Appendix A). Searches were limited to peer-reviewed papers in English language. Results by database are presented in Appendix B.

2.3 Study Selection

The initial search revealed 802 titles, which were then screened for relevance. This elicited 65 papers. Any duplicates were removed, abstracts were obtained and read for salience to the question, from which 22 papers were deemed relevant and full papers sought. Reference sections of relevant articles were also hand searched to ensure all potential studies were identified. Inclusion and exclusion criteria were applied to the 22 remaining papers, resulting in two papers being removed. Furthermore, five studies were removed because of concerns about extraneous variables. One study was found to

have a significantly longer follow up period of 5 years and was not felt to be directly comparable to the usual 6-12 months measured by the majority of studies. Furthermore, four studies were removed as they compared usual care with two self-management interventions, and it was decided that this would potentially add further variables that could not be directly compared with the majority of studies that had compared only one intervention with a control group. Therefore,15 articles were left to review. Figure 1 details the search process and number of studies found at each stage.
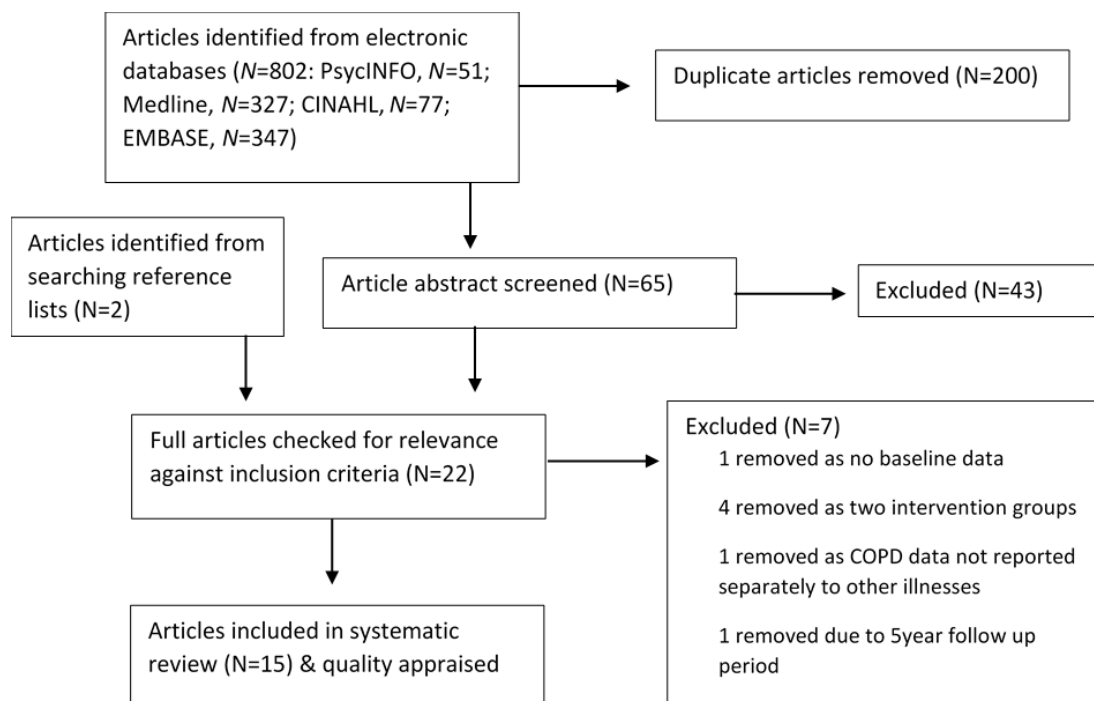
Figure 1. Flow chart of search strategy

2.4 Data Extraction

Data were extracted from the 15 articles and entered onto a table in Microsoft Word. Column headings were based on key characteristics indicative of quality for later ease of reference and reporting. These included study design; sample; measures; and results (see Appendix C).

2.5 Quality Appraisal

Articles were then assessed for quality using 'The Effective Public Health Practice Project (EPHPP) Quality Assessment Tool for Quantitative Studies' (Appendix D, Thomas *et al.,* 2004). The tool was selected as it enabled comparisons across study designs of included papers, particularly RCTs and uncontrolled trials. The EPHPP has been found to have good construct validity and inter-rater reliability (Thomas *et al.,* 2004). The tool assessed quality in six domains: selection bias; study design; confounders; blinding; data collection method; and withdrawals and dropouts. Each domain is then rated as weak, moderate or strong. The authors suggest the use of a global rating across all domains: 'strong' if all six domains are strong; 'moderate' if one domain is rated as weak; or 'weak' where two or more domains are considered weak.

3. Results

3.1 Types of studies and interventions

Most studies reported data collected either via randomised controlled trials (n=9) or controlled trials (n=5), the latter in which there was one intervention group and one control group, comprising 'usual care'. There was one uncontrolled trial. Inferential statistics were used for all studies, with a t-test, or non-parametric equivalent, most commonly used (n=7) to analyse data. However, p values were not reported by Taylor *et al*. (2012) due to the study being a pilot. No significant differences were reported in any studies between intervention and control groups, indicating appropriateness of controls.

Interventions ranged from clinic-based group self-management workshops (n=9) to home-based individual focused self-management interventions (n=6): education about managing COPD formed the main component. Intervention duration ranged from two weeks to 12 months, both relatively constrained periods to evaluate change. Studies included elements beyond education; use of a digital health system (Farmer *et al*., 2017), a fitness programme (Monninkhof *et al.,* 2003 & Ninot *et al.,* 2011), a handbook analysing physiological data to increase understanding of condition and to set goals (Moriyama *et al.,* 2015 and Ng & Drummond-Smith, 2017) and keeping a daily diary (Wood-Baker *et al.,* 2012). Jonsdottir *et al.* (2015) also additionally provided patient

and family member discussions, smoking cessation and meetings between the team, patient and their partner.

3.2 Participants and setting

Table 1 displays summaries of sample populations, psychological wellbeing variables and findings, listed in alphabetic order. Sample sizes for controlled studies (n=14) ranged from 15 to 232 per group, with a mean of 64.5 per group. Participant mean ages ranged from 58.67 to 72 years. Five studies originated from the UK, two from Canada and one study each from Sweden, France, The Netherlands, Iceland, Egypt, Japan, China and Australia. Studies recruited participants with COPD from either primary care (n= 3), secondary care (n=8) or both (n=4). No studies used remuneration. All studies specified a diagnosis of COPD most often defined as a Forced Expiratory Volume in 1 second (FEV1) spirometry test of <0.70.

3.3 Quality Appraisal

Appendix E displays the quality assessment ratings. Quality of the studies was variable : with three studies (Efraimsson *et al.*, 2008; Jonsdottir *et al.,* 2015 & Moullec *et al.,* 2012) being assessed globally on the EPHPP (Thomas *et al.*, 2004) as 'Strong' (no weak ratings), five studies assessed as 'Moderate' (1 weak rating; Farmer *et al.,* 2017; Labrecque *et al.,* 2011; Mitchell *et al.,* 2014; Ninot *et al.,* 2011 & Taylor *et al.,* 2012), and seven studies assessed as 'Weak' (2 or more weak ratings; Alsayed *et al.*, 2014; Bucknall *et al.,* 2012; Monninkhof *et al., 2003*; Moriyama *et al.,* 2015; Ng & Drummond-Smith, 2017; Turner *et al.,* 2014 & Wood-Baker *et al.,* 2012). The major distinction between strong and weak studies appeared within the blinding and data collection methods, with weak studies reporting outcome assessors as aware of the group to which participants were allocated, and with no mention of validity and reliability of outcome measures used. Due to the heterogeneity within study methodology and analysis, a meta-analysis was deemed not appropriate.

3.4 Psychological wellbeing measures

Studies reported a very circumscribed range of variables that encapsulated wellbeing; quality of life, anxiety, depression and self-efficacy. Results are grouped within these areas of wellbeing and the measures used.

1.4.1   Health related Quality of Life

Twelve studies looked at the impact of SMP on quality of life in people with COPD using four different measures – the St George's Respiratory Questionnaire (SGRQ; Jones, 1991), St George's Respiratory Questionnaire for COPD Patients (SGRQ-C; Meguro *et al*., 2006), the Short-form 36 Health Survey (SF-36; Ware & Sherbourne, 1992) and the EuroQol 5-Dimension Questionnaire (EQ5D, EuroQol Group, 1990). Five studies found a statistically significant group difference for the intervention in HRQoL.

St George's Respiratory Questionnaire (SGRQ)

The SGRQ (Jones *et al.,* 1991) is a 50-item disease specific self-report measure designed to measure the impact of respiratory symptoms on overall health, daily life and perceived well-being in patients with COPD and asthma across three domains – symptoms, activity, impact - and a total score. Six studies used the SGRQ (Efraimsson *et al.,* 2008; Labrecque *et al.,* 2011; Monninkhof *et al.,* 2003; Moriyama *et al*., 2015; Ninot *et al*., 2011; Moullec *et al.,* 2012). Four studies reported statistically significant improvement for SGRQ scores for the intervention vs. control group; Effraimsson *et al*. (2008) reported a significant group difference across all domains after 3-5 months, Ninot *et al.* (2012) found a significant group difference across symptoms, impact and total score after twelve months, Labrecque e*t al.* (2011) found a significant group difference across all domains after twelve months, and Moullec *et al.* (2012) found a significant group difference for activity and impact domains after twelve months. However, two studies found no significant group difference in SGRQ scores (Moriyama *et al.,* 2015, Monninkhof *et al.,* 2003). Moriyama *et al.* (2015) found SGRQ scores reduced slightly for both groups after six months, but there was no significant group difference across any of the domains. Monninkhof *et al*. (2003) found no significant differences for both groups on any domains after twelve months and no significant group difference.

St George's Respiratory Questionnaire for COPD Patients (SGRQ-C)

The SGRQ-C (Meguro *et al.,* 2006) is a shorter version of the SGRQ developed using COPD data only and comprising 40 items. It was developed following detailed analysis of data from large studies in COPD and reports scores in symptoms, activity, impact and a total score. Two studies used the SGRQ-C (Farmer *et al.,* 2017; Jonsdottir

et al., 2015). Farmer *et al.* (2017) reported the total SGRQ-C score and found that scores improved after twelve months for both intervention and usual care, but there was no significant group difference. Jonsdottir *et al.* (2015) found that SGRQ-C scores across all domains worsened slightly for both groups after twelve months, with no significant group difference.

Short-form 36 Health Survey (SF-36)

The SF-36 (Ware & Sherbourne, 1992) is a 36-item questionnaire which measures quality of life across four physical domains (physical functioning, role physical, bodily pain and general health) and four emotional domains (vitality, social functioning, role emotional and mental health). The emotional domains are grouped into 'mental component summary' and the physical domains are grouped into 'physical component summary'. Two studies used the SF-36 (Moullec *et al.*, 2012; Wood-Baker *et al.*, 2012). Moullec *et al.* (2012) found a statistically significant group difference on both the 'mental component summary' and 'physical component summary' domains, with the intervention group scores significantly improving after twelve months. Wood-Baker *et al.* (2012) did not find a significant group difference on any of the emotional domains after twelve months. However, physical functioning and general health improved significantly for the intervention group.

EuroQol 5-Dimension Questionnaire (EQ-5D)

The EQ-5D (EuroQoL Group, 1990) is a self-reported general measure of health status and health related quality of life. It is made up of two sections, firstly the EQ-index score, where health status is measured across five domains, which are self-care, usual activities, pain/discomfort and anxiety/depression. The second section evaluates respondents' ratings of their overall health status using a visual analogue scale (EQ-VAS). Three studies used the EQ-5D (Bucknall *et al.,* 2012; Turner *et al*., 2014; Taylor *et al,* 2012). Taylor *et al.* (2012) reported only EQ-index scores and found a group mean difference after six months, where the intervention group improved, however no p values were reported. Turner *et al. (*2014) found no significant difference in either domain after six months, and Bucknall *et al.* (2012) reported no significant overall EQ-5D score after six months.

Table 1. Study characteristics

Study & country	Aims & Design	Sample (%male, M age)	SM program	Wellbeing Outcome Measures	Analysis	Findings
Alsayed et al. (2014) Egypt	- Examine the impact of a SMP on health outcomes & healthcare utilisation on patients with COPD - Controlled trial	Intervention: N=20 (65%, 64.45) Control: N=20 (65%, 67.3)	Weekly group educational lectures for 7 weeks to meet pulmonologist, psychiatrist and internist for 60–90 min.	BAI	t-test & Chi-square	Significant improvement seen in intervention group (p<0.05). No significant change in BAI scores in control group (p>0.05)
Bucknall et al. (2012) Scotland	- Test whether supported SM could reduce hospital readmissions in UK of patients with COPD - RCT	Intervention: N=232 (38%, 70.0) Control: N=232 (35%, 68.3)	Four 40 minute individual training sessions at home from a nurse, fortnightly. Then further home visits at least every six weeks for a total of 12 months.	HADS, CSES & EQ-5D	ANCOVA, estimated differences	Significant treatment effect seen on HADS anxiety scores (p<005). No significant treatment effect on CSES scores (p>0.05), HADS depression scores (p>0.05) and EQ-5D scores (p>0.05)
Efraimsson et al. (2008) Sweden	- To examine the effects of a nurse led structured SMP on QoL, knowledge about COPD & smoking cessation in patients with COPD - RCT	Intervention: N=26 (50%, 66) Control: N=26 (50%, 67)	Four individual visits to the COPD clinic, within 3–5-months interval with focus on self-care education	SGRQ	Mann-Whitney U-Test	Statistically significant improvement of SGRQ scores in intervention group compared to control group (p<0.001)
Farmer et al. (2017) UK	- To determine the efficacy of an internet-linked computer based system of monitoring & SM support on QoL and clinical outcomes in patients with COPD - RCT	Intervention: N=110 (61.8%, 69.8) Control: N= 56 (60.7%, 69.8)	12 month use of internet computer-based system of monitoring and self-management support (EDGE, sElf-management anD support proGrammE)	SGRQ-C, SCL-20, SCL-10A	Linear mixed-effects model	Improvement seen in SGRQ-C scores for both treatment and intervention groups at 6 and 12 months.

						No significant treatment effect seen for SGRQ-C, SCL-20 or SCL-10A scores (p>0.05)
Jonsdottir *et al.* (2015) Iceland	- To evaluate the effectiveness of a partnership-based SMP for mild-moderate COPD - RCT	Intervention: *N*= 48 (39.6%, 59.41) Control: *N*= 52 (51.9%, 58.67)	6-month partnership-based self-management programme with group meetings, 3-4 conversations between nurse and patient-family member, smoking cessation & interdisciplinary team meeting	SGRQ-C, HADS	Independent group t-test & Chi-square	Improvement seen in SGRQ-C and HADS anxiety and depression scores for both intervention and control group. No significant group difference (p>0.05) for SGRQ-C or HADS
Labrecque *et al.* (2011) Canada	- To examine the efficacy of structured SM intervention on HRQoL, self-reported COPD knowledge and morbidity associated with COPD - Controlled trial	Intervention: *N*= 57 (25%, 69) Control: *N*= 45 (10%, 71)	Four 3 hour weekly group instruction sessions & individualized counselling session	SGRQ	Repeated measures ANOVA, Bonferroni correction & paired t-tests	Significant improvement in SGRQ scores at 1 year for intervention (p<0.001) and control group (p<0.05). Significant group difference (p<0.001) found.
Mitchell *et al.* (2014) UK	- To evaluate the effectiveness of SMP to people with COPD being managed by family physician - RCT	Intervention: *N*= 89 (60.67%, 69) Control: *N*= 95 (49.47%, 69)	6-week home-based individual programme structured around Self-Management Programme of Activity, Coping and Education (SPACE) FOR COPD manual. Initial consultation then 2 phone calls from physiotherapist	HADS	Independent t-test & ANCOVA	Improvement seen in HADS anxiety and depression scores for intervention group. No improvement for control group. Significant group difference (p<0.05) for anxiety. No significant group difference (p>0.05) for depression.
Monninkhof *et al.* (2003)	- To evaluate the effectiveness of a comprehensive SMP for patients with COPD - RCT	Intervention: *N*=127 (66.92%, 65)	Four weekly 2 hour group education sessions & one feedback session after 3	SGRQ	Repeated Measures ANOVA	No significant group difference for SGRQ scores for intervention and control groups at 1year. No p values reported.

The Netherlands		Control: N=121 (69.42%, 65)	months. Patient partner also invited to attend			
Moriyama et al. (2015) Japan	- To examine the effectiveness of a nurse-led 6 month SMPfor stage IV COPD patients receiving home oxygen therapy - Controlled trial	Intervention: N=15 (80%, 74.7) Control: N=15 (80%, 72.0)	2 individual sessions with nurse to analyse behaviour & set goals. Then home-based workbook and monthly reporting of data by mail or telephone	SGRQ	Repeated Measures ANOVA	Improvements seen in SGRQ for intervention and control groups. No significant group difference (p>0.05) found.
Moullec et al. (2012) Canada	- To assess the efficacy of a SMP on the emotional subscale of SGRQ in patients with COPD - Controlled trial	Intervention: N=60 (43%, 72) Control: N=50 (56%, 69)	Four 3 hour weekly group instruction sessions & individualized counselling session	SF-36 SGRQ	Fixed effect regression model	Intervention group SF-36 'mental component' scores & SGRQ 'impact scale' improved after 1 year, p<0.001.
Ninot et al. (2011) France	- To determine the 1 year beneficial effect of a SMP which included supervised exercise sessions on patients with COPD - RCT	Intervention: N=20 (90%, 65) Control: N=18 (78%, 61)	Two 2 hour weekly group education sessions for 4 weeks. Telephone support provided.	SGRQ	Regression analysis	Significant improvement in SGRQ scores at 1 year for intervention (p<0.05). No significant improvement for control group (p>0.05). Significant group difference (p<0.05) found.
Ng & Drummond-Smith (2017) China	- To compare the self-efficacy of Chinese COPD patients before and after the delivery of a newly initiated SM intervention tailored for COPD patients in Macau - RCT	Intervention: N=26 (not reported) Control: N=24 (not reported)	Three weekly 1.5-hour group self-management education group workshops. Plus a patient handbook and a monthly telephone follow-up	CSES	Mann–Whitney U-test and Wilcoxon signed-rank test	Significant improvement in CSES scores for intervention group (p<0.05) at 6 months. No significant improvement for control group (p>0.05) at 6 months.

Taylor *et al.* (2012) UK	- To explore the feasibility, effectiveness and cost effectiveness of a novel, layperson-led theoretically driven COPD SMP - Pilot RCT	Intervention: *N*=78 (51.28%, 69) Control: *N*=38 (34.21%, 70.5)	Seven weekly 3-hour group education sessions addressing five core self-management skills	EQ-5D HADS	ANCOVA	EQ-5D utility scores deteriorated from baseline to follow-up in both groups. HADS anxiety scores reduced for intervention group, no change for control. HADS depression increased for intervention and control groups. No p-values reported as it is a pilot study.
Turner *et al.* (2014) UK	- To see whether attending the SMP improved activation, health status, QoL, psychological distress & self-management ability in patients with COPD - Uncontrolled trial	*N*=205 (44.1%, 68.3)	Seven weekly 3 hour group sessions grounded in social learning theory and included four efficacy enhancing strategies	HADS, EQ-5D	Paired t tests and general linear model for repeated measures.	No significant improvement seen in HADS anxiety or depression scores (p>0.05). No significant improvement seen in EQ-5D (p>0.05)
Wood-Baker *et al.* (2012) Australia	- To evaluate the effect of a nurse-led SMP on HRQoL & health care utilization in people with COPD following hospitalisation - Controlled trial	Intervention: *N*=55 (55%, 69.7) Control: *N*=51 (43%, 66.5)	Home mentoring individual program where nurses and patients collaboratively developed self-management strategies over 12 months	HADS, SF-36	Student's t-tests for continuous data & linear mixed models	No significant group difference for HADS anxiety and depression scores or SF-36 (p>0.05)

* BAI – Beck Anxiety Inventory, HADS – Hospital Anxiety and Depression Scale, CSES – COPD Self-Efficacy Scale, EQ-5D – EuroQol 5-Dimension Questionnaire, EQVAS – EuroQol Visual Analogue Scale, SGRQ – St George's Respiratory Questionnaire, SCL-20 - Standard Checklist 20-item Questionnaire for depression, SCL-10A - Standard Checklist 10-item Anxiety Measure, SF-36 – Short-form 36 Health Survey

1.4.2 <u>Anxiety</u>

Eight studies examined impact of SMP on anxiety using three measures – the Hospital Anxiety Depression Scale (HADS, Zimond & Smith, 1983), the Beck Anxiety Inventory (BAI, Beck *et al.,* 1988) and Standard Checklist 10-item Anxiety Measure (SCL-10A).

Hospital Anxiety Depression Scale (HADS)

The HADS (Zigmond & Snaith, 1983*)* is a 14-item self-report screening measure widely used to identify levels of anxiety and depression in people attending hospital outpatient clinics and was used by six studies (Bucknall *et al*., 2012; Jonsdottir *et al*., 2015; Mitchell *et al.,* 2014; Taylor *et al.,*2012; Turner *et al.,* 2014; Wood-Baker *et al*., 2012). After six months, Bucknall *et al.* (2012), *Mitchell et al.* (2015) and Taylor *et al.* (2012) found a reduction in anxiety scores for the intervention group, with Bucknall *et al.* (2012) and Mitchell *et al.* (2015) reporting a significant difference to the usual care group. Jonsdottir *et al.* (2015) reported an improvement in anxiety scores for both groups after twelve months, but no significant group difference. Turner *et al.* (2014) found no significant improvement in anxiety scores after six months, and Wood-Baker *et al.* (2012) found no significant group difference after twelve months for HADS anxiety scores.

Beck Anxiety Inventory (BAI)

The BAI (Beck *et al.,* 1988) is a 21-question multiple-choice self-report measure used to measure levels of anxiety in children and adults. Alsayed *et al.* (2014) found a significant improvement in anxiety scores after seven weeks for the intervention group but no significant change for the control group.

The Symptom Checklist-10A (SCL-10A)

The SCL-10A *(*Derogatis, 1977*)* is a 10-item self-report measure derived from a 90-question standard measure (The Symptom Checklist-90-R, Derogatis, 1977) and has been used extensively to measure anxiety. Farmer *et al.* (2017) found that after twelve months, anxiety levels remained the same in the intervention group and increased in the control group, but there was no significant group difference.

1.4.3   Depression

Seven studies examined the impact of SMP on levels of depression using the HADS (Zimond & Smith, 1983) and SCL-20 (Derogatis, 1977).

HADS

Six studies used the HADS to measure depression (Bucknall *et al.,* 2012; Jonsdottir *et al.,* 2015; Mitchell *et al.*, 2014; Taylor *et al.,*2012; Turner *et al.,* 2014; Wood-Baker *et al.,* 2012). Bucknall *et al.* (2012) found a significant group difference after six months, with depression scores reducing in the intervention group. Mitchell *et al.* (2015) found no significant group difference for depression scores after six months. Jonsdottir *et al.* (2015) reported an improvement in depression scores for both groups after twelve months, but no significant group difference. Taylor *et al.* (2012) found that after six months depression scores increased for both intervention and control groups, with no significant difference. Turner *et al.* (2014) found no significant improvement in depression scores after six months, and Wood-Baker *et al.* (2012) found no significant group difference after twelve months for depression scores.

The Symptom Checklist-20 (SCL-20)

The SCL-20 (Derogatis, 1977) is a 20 item self-report measure derived from a 90-question standard measure (The Symptom Checklist-90-R, Derogatis, 1977) and is used to measure depression with people who have long-term conditions. Farmer *et al.* (2017) found that after twelve months depression levels reduced in the intervention group and increased in the control group, however no significant group difference was found.

1.4.4   Self-efficacy

Two studies (Bucknall *et al.,* 2012 & Ng & Drummond-Smith, 2017) looked at the impact of SMP on self-efficacy using the COPD Self-efficacy Scale (CSES, Wigal, 1991)

The COPD Self-Efficacy Scale (CSES)

The CSES (Wigal, 1991) is 34-item self-report measure comprising five dimensions of self-efficacy. Bucknall *et al*. (2012) found that after twelve months self-

efficacy scores improved in both groups, but no significant group difference was evident. Ng and Drummond-Smith (2017) found a significant improvement in CSES scores at six months for intervention group and no significant improvement for control group. No significant group difference was found.

4. Discussion

4.1 Summary of findings

The aim of the current review was to systematically examine the impact of self-management programmes on psychological wellbeing in patients with COPD. Of the fifteen studies reviewed, almost as many studies revealed SMP to have a significant beneficial effect on psychological wellbeing (Alsayed *et al.,* 2014; Efraimsson *et al.,* 2008; Labrecque *et al.,* 2011; Moullec *et al*., 2012; Ninot *et al.,* 2011; Ng & Drummond-Smith, 2017), as those that revealed no significant effect (Farmer *et al.,* 2017; Jonsdottir *et al.,* 2015; Monninkhof *et al.,* 2003; Moriyama *et al.,* 2015; Wood-Baker *et al*., 2012) or mixed effects (Bucknall *et al.,* 2012; Mitchell *et al.,* 2014; Taylor *et al*., 2012) when compared to 'usual care'. A complex picture of the impact of SMP on psychological wellbeing is thus revealed.

A common factor identified in all but one of the studies finding a beneficial effect of SMP, was that a clinic or hospital sited group intervention was used (Alsayed *et al.,* 2014; Labrecque *et al.,* 2011; Moullec *et al*., 2012; Ninot *et al.,* 2011; Ng & Drummond-Smith, 2017). By contrast of studies that found no significant effect of SMP, all but one provided an individual intervention in the participant's home (Farmer *et al.,* 2017; Jonsdottir *et al.,* 2015; Moriyama *et al.,* 2015; Wood-Baker *et al.,* 2012). Therefore, it may be that the impact of SMP is mediated by other factors, such as reduced isolation or increased social interaction, and it would therefore be advantageous for future studies to assess the impact of the group interaction. However, it must be considered that other factors may have affected this group difference, such as participants physical ability at baseline. It may be that those who were able to attend clinic-based interventions were more physically able to leave the house, and also may have had higher levels of motivation at baseline. Therefore, other individual factors such as physical ability and motivation may have been higher for the clinic based group and could provide an alternative explanation for the group differences seen.

The current review highlighted continued over-reliance on assessing psychological outcomes via morbidity, such as HRQoL, anxiety and depression, as opposed to positive well-being. This is in contrast to studies focusing on positive measures of psychological wellbeing in other areas of health such as diabetes (Boehm *et al.,* 2015) and coronary heart disease (Kubzansky & Thurston, 2007). This may reflect wider issues such as limited psychology input to study design within a medical context, and the focus within research on psychiatric diagnosis as a measure of psychological health. The latter forms the basis of evidence based practice in the form of National Institute for Clinical Excellence guidelines (e.g. NICE, 2015), but has been widely criticised as pathologising normal and understandable responses to adverse experiences, circumstances and events (Rapley *et al*., 2011).

Findings of the current review suggested a weak effect of SMP on HRQoL, with only seven out of twelve studies showing an increase in those HRQoL after attending SMP and only four studies showing a statistically significant difference to the usual care group. This is in contrast to previous findings (Zwerink *et al*., 2014; Wang *et al.,* 2017). Furthermore, although improvements were seen in self-efficacy scores after SMP, no significant difference was seen between those receiving SMP and usual care. That only two studies measured self-efficacy is surprising, given an expressed objective of SMP is to increase self-efficacy (Lomundal & Steinsbekk, 2007). Evidence for the impact of SMP on anxiety and depression was also equivocal. Following attendance at an SMP, an improvement was found in anxiety levels in five of eight studies, and depression levels in four of seven studies. However, it must be acknowledged that the majority of studies used the HADS to measure levels of anxiety and depression, which can be criticised as it is validated as a screening tool, rather than a diagnostic tool. It is likely that this reflects a wider issue, of clinicians in physical health settings relying heavily only on screening measures to assess for the presence of mental health problems.

The current review aimed to identify the current status of the literature, including evidence from controlled and uncontrolled trials. A large variability was seen in the quality of studies, which may have affected the results. The quality of the fifteen studies can be seen to be split relatively equally, with seven studies assessed as 'weak' and eight studies achieving a 'strong' or 'moderate' rating on the EPHPP. Although the majority of studies were RCTs, this did not appear to increase the overall quality of those studies. Results from studies achieving a strong or moderate rating may be

privileged (Efraimsson *et al*., 2008; Jonsdottir *et al.,* 2015; Moullec *et al*., 2012; Farmer *et al.,* 2017; Labreque *et al.,* 2011; Ninot *et al.,* 2011; Mitchell *et al.,* 2014), and these more methodologically robust studies suggest a positive impact of SMP on well being, with Efraimsson *et al.* (2008), Moullec *et al.* (2012), Labrecque *et al.* (2011) and Ninot *et al.* (2011) reporting significant improvement of quality of life, and Mitchell *et al.* (2014) finding a significant improvement in anxiety, compared to control. The methodological strengths and weaknesses of studies included in the current review will now be explored.

4.2 Research limitations

This review revealed several limitations within the published evidence base. Firstly, a lack of good quality literature limits the robustness and generalisability of findings. Therefore, due to a limited pool of studies, the majority of studies identified were completed in countries other than the UK and as such there are differences in health care systems. These different systems and the influence of health insurance status, could have affected the results and limit the generalisability.

The range of SMP content and delivery may also play a significant role in the variability of findings. Cannon *et al.* (2016) discuss how inconclusive results across studies may be due to the lack of standardisation within COPD SMP, particularly diverse content, delivery and duration of program, as well as inclusion of an exercise component. In response to this heterogeneity, Effing *et al.* (2016) created a conceptual definition of COPD SMP from an international panel of 28 COPD self-management experts addressing consensus. Their definition of the goals of SMP include optimising physical health, reducing symptoms, increasing emotional and social well-being and quality of life, and establishing effective alliances with healthcare professionals, family and the wider community. Although an agreed definition of COPD SMP by an international expert group is an important step forward, its adoption, implementation and impacts will take time to assess.

The variation in length of SMP and time points measured may have affected the outcome of SMP, which ranged from seven to twelve months. This is a relatively short time to measure change and future studies would benefit from a longitudinal design.

The focus on assessing psychological outcomes via morbidity, rather than positive well-being, can also be seen as a limitation. Steed *et al.* (2012) suggest that

floor effects often occur in studies that focus solely on negative wellbeing, and state that negative and positive outcomes of psychological wellbeing are independent constructs worthy of evaluation to provide a broader picture of the impact of interventions. It also limits the ability to draw strong conclusions due to the limited representativeness of psychological wellbeing.

4.3 Suggestions for Future Research

Other key areas, not included in the review, may be advantageous to measure in future studies when looking at SMP and psychological wellbeing, which include exploring the patient narrative of psychological wellbeing within COPD, the relationship between the health care provider and the patient, and identifying health beliefs and cognitions that guide self-management and health-seeking behaviours.

An alternate way to explore factors associated with psychological wellbeing is to consider research into the COPD patient narrative. Stridsman *et al.* (2015) conducted a qualitative study interviewing 11 patients with COPD about their experiences of well-being. They found that for the reported experience of wellbeing, participants described a need to accept and adapt to their diagnosis of COPD, incorporate meaningful activities into their life, have sufficient strength for self-care, and good quality sleep. Variations in illness were best managed by taking advantage of the good days and using emotional adaptation strategies. The importance of having access to containing relationships was also privileged. By allowing a focus on the patient narrative to guide measurement of psychological wellbeing, it may be that a more positive and balanced account of wellbeing can be provided.

Another area that may be worth further exploration in SMP is that of the relationship between the health care provider and the patient. Jonsdottir (2013) suggest that if staff appear authoritarian in nature during SMP they may potentially isolate patients from engaging, or make them feel less empowered. They suggest that collaboration not just between the patient and health care provider, but also the family members, may be most beneficial for the patient's self-management. Therefore, SMP could include and measure the alliance with healthcare professionals and also the impact of carers also being involved in SMP.

Finally, a focus on a more theoretical approach to understanding individual's motivations may be advantageous when evaluating SMP. Effing *et al.* (2016) discussed

the importance in SMP of identifying individual's health beliefs and working to enhance their intrinsic motivations. Health beliefs were not measured in any studies in the current review, even though this has been found to be key to management of other chronic conditions such as diabetes (Mann *et al.,* 2009) and hypertension (Horne *et al.,* 2001). Krauskopf *et al*. (2015) looked at patient's representations of COPD using the Common Sense Model of Self-Regulation, which suggests that patients develop mental models of illnesses that guide self-management and health-seeking behaviours. Their findings suggested that emotional representations of COPD may have a greater impact compared to cognitive processes as determinants of adherence. Furthermore, studies could benefit from employing behavioural techniques, such as Motivational Interviewing (MI), to increase patient's self-management skills, as MI has been found to be a very helpful tool in improving quality of life in patients with COPD up to twelve months post intervention (Benzo *et al., 2016*).

4.4 Strengths and Limitations of the Review

The current review provided a systematic and up to date review and critique of the SMP and psychological wellbeing literature. It benefited from its scope and comprehensiveness beyond a focus solely on quality of life and mood, and RCT designs. Specific inclusion criteria of a diagnosis of COPD, rather than other respiratory diagnoses, improved results' validity for the COPD population. However, a decision to review only quantitative studies, precluded examination of qualitative studies which may have alerted to other dimensions of psychological wellbeing. Furthermore, although a systematic approach was taken to the current review, it was undertaken by only one researcher, and so the potential bias must be acknowledged.

4.5 Conclusion

In conclusion, the current review has highlighted equivocal evidence for the role of SMP in improving psychological wellbeing in patients with COPD. Due to the lack of studies and methodological limitations, it is difficult to draw strong conclusions about SMP's impact on psychological wellbeing. There is a need for standardisation and a more theoretically driven approach to SMP, which would allow for a wider exploration of psychological wellbeing, taking into account more positive aspects and consideration of factors that are meaningful to people living with COPD.

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PART TWO: RESEARCH REPORT

Development of a questionnaire to measure self-conscious emotions in patients with COPD

RESEARCH PROJECT

Development of a questionnaire to measure self-conscious emotions in patients with COPD

Abstract

Background: Chronic obstructive pulmonary disease (COPD) is a respiratory condition which can severely limit physical and social activities. A dominant form of intervention is Pulmonary Rehabilitation (PR). However, completion rates for PR are low and remain poorly understood. Recent developments in the literature have suggested that patients experiencing high levels of self-conscious emotions may play an important role in treatment adherence. However, there is currently an absence of a disease specific screening measure developed to allow clinicians to identify these emotions for those living with COPD.

Method: An empirical approach to scale development was utilised across four phases to develop the COPD Self-conscious Emotion Scale (CSES). This involved running focus groups and individual interviews, item generation and consultation with experts to refine the scale, and administering the measure to a developmental sample of fifty-six participants with COPD and evaluating the psychometric properties of the scale.

Results: Principal Component Analysis of the CSES suggested an 11-item measure comprising an underlying two subscale structure of 'guilt and embarrassment', and 'shame-based avoidance', best fitted the data. The CSES was found to have high internal consistency (Cronbach's alpha = .86) and good convergent validity with a fear of negative evaluation measure (rs = .31) and a COPD specific measure of health and wellbeing (rs=.-.42).

Conclusion: The CSES was found to have a two-subscale structure consistent with previous research, and had good internal consistency and convergent validity. However, limitations were found with a small sample size and demographics. Future research is needed to further develop the measure and increase the sample size. Research could then explore links between self-conscious emotions and treatment adherence, with the aim of better supporting people at an earlier stage.

1. Introduction

1.1 Chronic Obstructive Pulmonary Disease

Chronic obstructive pulmonary disease (COPD) encompasses a group of progressive lung conditions including emphysema, chronic bronchitis and refractory asthma. Dominant symptoms, most often presenting after aged 40 years, include breathlessness, persistent cough and sputum, and recurrent chest infections, which can severely limit physical and social activities (Global Initiative for Chronic Obstructive Lung Disease, GOLD, 2016). Although a direct cause is unknown, risk factors include a history of smoking and exposure to environmental factors such as air pollutants (Salvi & Barnes, 2009). A genetic link has also been identified, such as a severe hereditary deficiency of alpha-1 antitrypsin (AATD), which manifests clinically as pulmonary emphysema, liver cirrhosis and panniculitis (Fregonese & Stolk, 2008).

The GOLD classification which calibrates airflow limitation severity in COPD, is commonly used and is based on FEV1, which is the forced expired volume a person can exhale in 1 second (GOLD, 2016). Lower percentage scores suggest greater severity of COPD, and describes four stages; Stage one is mild, FEV1 predicted >80%, Stage two is moderate, FEV1 <80% predicted, Stage three is severe, FEV1 <50% predicted, Stage four is very severe, FEV1 <30% predicted. These stages are often combined with the number of exacerbations patients have had per year to predict mortality risk.

Treatments for COPD vary dependent on the stage of the condition and can include pharmacological therapy such as bronchodilators, antimuscarinic drugs and anti-inflammatory agents, and smoking cessation programmes that involve individual and group behavioural support, nicotine replacement therapy and antidepressants (Thabane & COPD Working group, 2012). Self-management programmes are also increasingly offered, and cover a broad range of content, which includes Pulmonary Rehabilitation programmes which are further discussed below.

1.2 Pulmonary Rehabilitation (PR)

PR comprises a group-delivered programme (over six to eight weeks) usually run by physiotherapists and other healthcare professionals within a hospital setting. Its main focus seeks to improve cardiovascular functioning and muscle strength through

exercise training with the aim of reducing symptoms and increasing physical participation in everyday activities. Additional elements focus on weight loss, mood and quality of life, with the aim of increasing emotional wellbeing (Ries *et al.,* 2007). Effective PR is associated with reduced hospital admissions, diminished psychological morbidity and improved social participation (McCarthy *et al.,* 2015). However, completion rates of PR remain low (20-40%; Cockram *et al.,* 2006; Garrod *et al.,* 2006), with elevated non-attendance and attrition conferring poorer health outcomes and significant financial costs (Troosters *et al.*, 2001). Increasingly research has sought to examine factors underpinning the lack of engagement with pulmonary rehabilitation.

1.3 Factors affecting PR attendance

Patients' reluctance to engage with PR programmes remains poorly understood. Keating *et al.* (2011) suggested a wide range of complex social and psychological factors appear involved, such as poor access to transport, smoking status, lack of belief of perceived benefit and depression. Further social factors identified to have a detrimental effect include lower socioeconomic status (SES) (Gershon *et al.,* 2012), higher age (Salzman, 1995), lower education level (Tselebis *et al.,* 2014), living alone (Young *et al.,* 1999) and smoking status (Hayton *et al.,* 2013; Young *et al.,* 1999). Psychological factors associated with poor attendance in PR include high levels of anxiety and depression (von Leupoldt *et al.,* 2011; Garrod *et al.*, 2006; Tselebis *et al.,* 2014), low self-efficacy (Arnold *et al.,* 2006), patients' belief in effectiveness of treatment (Fischer *et al.,* 2009), coping style (Stoilkova *et al.,* 2013) and quality of life (Büchi *et al.,* 1997). The failure of numerous constructs to explain lack of engagement with PR has led researchers to explore other factors, notably high levels of self-conscious emotions (Harrison *et al.,* 2015; Halding *et al.,* 2011).

1.4 Conceptualisation of Self-conscious emotions

Self-conscious emotions include shame, guilt, humiliation and embarrassment. They differ from basic emotions, such as anger or sadness, since they require self-awareness and self-representations (Tracy & Robins, 2004), and can be understood as resulting from an internalising of beliefs about who an individual should be based on societal rules, and which are represented as ideal self-representations. Self-conscious emotions are key to motivating and regulating thoughts and feelings (Fischer &

Tangney, 1995) and guide behaviour by compelling individuals to undertake socially valued activities and to avoid doing things that lead to social opprobrium. These emotions thus promote behaviours that relate to social hierarchies and affirm status roles (Tracy & Robins, 2004).

1.5 The role of self-conscious emotions in COPD

Recent findings have suggested that self-conscious emotions may be prominent for those with COPD. A qualitative study of individuals declining PR after an exacerbation of COPD, elicited self-conscious cognitions associated with lowered self-worth, reduced help-seeking and increased isolation (Harrison *et al*., 2015). Indeed it has been suggested that if patients experience high levels of shame, or perceived culpability for their disease, health advice that censures smoking or other health-undermining behaviours, may be seen as further societal moralising, increasing the patients' fear of disgrace and hindering further engagement with services (Halding *et al.,* 2011).

Such shame-induced withdrawal could easily be misinterpreted as a lack of motivation to change. Odencrants *et al.* (2007) suggested that shame and guilt have been found to influence contacts between healthcare professionals and patients due to the perception of COPD as being a self-inflicted disease.

Although there is growing awareness and evidence for a relationship between self-conscious emotions and COPD, there exists little research, particularly examining their potential impact on PR programme attendance. It would be valuable to capture this information to increase understanding of the psychological impact of COPD and further refine the approach taken by healthcare professionals towards PR and patient engagement. Self-conscious emotions are not monitored routinely within COPD due to the lack of outcome measures available. Although the measurement of self-conscious emotions within physical health also appears to be limited, other areas within physical health have developed tools to measure the highly related concept of health-related stigma.

1.6 The measurement of health-related stigma (HRS)

HRS encompasses perceived stigma characterized by rejection, blame or devaluation from anticipating an adverse judgement based on an enduring feature of

identity conferred by a health issue (Weiss & Ramakrishna, 2006). This judgement is medically unwarranted and may adversely affect health status. Although HRS is a related, but different concept, it is useful to consider the measures that have been developed to identify it within physical health.

HRS has been studied extensively within the HIV population, leading to several measures being developed, including the HIV Stigma Scale (Berger *et al.,* 2001), which consists of 40 items, divided into four subscales: personalized (enacted) stigma, disclosure concerns, negative self-image, and concern with public attitudes. The scale was found to be a reliable and valid instrument when used with a large, diverse sample of people who had HIV.

Lung cancer has also historically been associated with high levels of stigma (Greene & Banerjee, 2006) and as with COPD, patients with lung cancer are often assumed to have smoked heavily in the past. To capture stigma, the Cataldo Lung Cancer Stigma Scale (Cataldo *et al.,* 2011) was developed which consisted of 31 items with four subscales: stigma and shame, social isolation, discrimination and smoking. Seven experts in stigma were asked to serve as content reviewers. The authors modified Berger *et al.* (2001) model of perceived stigma in people with HIV to use with people with lung cancer. Items were removed and then added, taking the total items from 45 to 46. The measure was also administered with three other scales looking at depression, quality of life and self-esteem and social support and conflict. One hundred and eighty-six participants were recruited online. The authors employed an exploratory factor analysis approach with alpha extraction and varimax rotation. However, limitations with this scale development are acknowledged, particularly around the online nature of recruitment. Thus restricting participation to those with internet access, but also limiting the clinical information that could be collected about the sample. Therefore, although this measure highlights the importance of stigma and shame within a lung related condition, it is limited in it's ability to generalise to a COPD population.

1.7 Summary and Study Rationale

Patients declining PR programmes have been found to report self-conscious emotions associated with low self-worth, and potentially unconstructive behaviours such as reduced help-seeking and isolation (Harrison *et al.,* 2015). Being able to identify elevated levels of self-conscious emotions in patients with COPD and make

subsequent adaptations to their care, such as further discussion with a clinician before PR is offered, has the potential to benefit both patient outcomes and reduce the financial costs for the healthcare system.

Currently no condition specific instrument exists to measure these emotions within the COPD population. This is significant for capturing disease-specific functioning since measures must be sensitive to the complexity of patients' experience and day-to-day condition management (Penny *et al*., 1994). Furthermore, measures designed to capture self-conscious emotions outside of a physical health setting, are unlikely to capture responses encompassing the increasing social shift to personal responsibility for physical health; arguably a significant factor in experiencing stigma when chronically ill (Guttman & Salmon, 2004). The development of a novel measure to capture levels of self-conscious emotions could better describe the experience for those with COPD, enable increased understanding for healthcare professionals, and provide a tool for further research examining how self-conscious emotions present and interact with COPD.

1.8 Study aims and objectives

The aim of this research project was to develop and evaluate a scale to measure self-conscious emotions within the COPD population. More specifically, the aim was to develop a brief and clinically-based questionnaire that can be self-administered in outpatient settings to assess the level of self-conscious emotions experienced by patients with COPD. It was hoped that such a measure would provide healthcare professionals with further information about the psychological impacts of COPD on individuals that may affect treatment adherence/engagement, enabling them to be offered earlier and additional support. It would also facilitate further research into the presence and impact of self-conscious emotions within COPD.

2. Method

2.1 Procedure overview

The development of the COPD Self-conscious Emotion Scale (CSES) involved four phases (see Figure. 1) where an empirical approach to scale development was utilised. Initially, self-conscious emotions were operationalised and the research base pertaining to these emotions and their measurement was scrutinised. A focus group and five individual interviews were conducted with patients with COPD to discuss their experiences of self-conscious emotions related to their COPD.

This data was then analysed, along with a review of existing literature, empirical studies and other measures used to assess self-conscious emotions, and an initial pool of thirty-eight items was generated by the trainee. These items were then examined and amended by research staff and two experts in the field. The final version of the questionnaire, containing twenty items, was then administered to a developmental sample of fifty-six participants, alongside two existing questionnaires. In the final stage of scale development, the scale items were evaluated for psychometric properties and factorial structure and refined as appropriate.

Phase 1
- **Operationalising the construct of self-conscious emotions within COPD**
- Review of literature
- Focus groups and individual interviews to identify narrative from patients with COPD

Phase 2
- **Item development**
- Item generation using themes from focus group, discussion with supervisors and experts and review of other self-conscious emotion measures

Phase 3
- **Questionnaire administered to developmental sample**
- Trial scale items & questions on usability administered to clincal sample

Phase 4
- **Evaluation of scale items**
- Scale structure and psychometric properties examined and refined to create final scale
- Correlation of CSES scale with FNE & CRQ

Figure 1. Phases of scale construction

2.2 Ethical approval

Ethical Approval was obtained from a Research Ethics Committee (Appendix F). Approval was granted from the Health Research Authority (HRA; Appendix G) and the hospital trusts' research and development department (Appendix H). It was acknowledged there was a risk for participants to experience distress related to the emotional content of the study, and if participants showed any signs of distress, they were asked if they would like to continue and advised of their right to withdraw. They were then either advised to go to A&E, or a referral to medical psychology considered following discussion with the participant and MDT. All participants were given contact details for the trainee and for the Patient Information and Liaison Service (PILS). Interviews were kept securely on an encrypted USB and questionnaires were anonymous, identifiable only through the unique study ID. Principles of ethical practice were adhered to throughout recruitment, data storage, analysis and dissemination.

2.3 Phase 1 - Operationalising the construct

2.3.1 Participants

Seven patients with COPD were recruited to participate in either a focus group in clinic (n=3) or individual interview at home (n=4). Demographics are presented in Table 1. Participants' medical notes were screened for eligibility.

2.3.2. Eligibility criteria
Inclusion criteria

Participants had to have a diagnosis of COPD confirmed by a spirometer, be able to speak English and be able to provide informed consent.

Exclusion criteria

Exclusion criteria for this study included if participants had a primary respiratory condition other than COPD and if they had an inability to communicate because of language skills, hearing or cognitive impairment.

2.3.3 Procedure

Forty patients with COPD who had consented to be approached for research purposes by the respiratory research unit, were written to by the trainee asking if they would be interested to take part in a focus group looking at self-conscious emotions in COPD. Participants received the Participant Information Sheets (Appendix I) regarding the study at least 24 hours prior to a focus group taking place. Seven patients replied and two focus groups were facilitated by the trainee and a member of research staff. However only two participants attended the first group and only one attended the second – thus this was treated as an individual interview. Consent forms (Appendix J) were completed with the trainee prior to the focus group. Patients who had opted in but not attended the focus groups were approached by the trainee via telephone to ask if they would be interested to participate in an individual interview in their homes with the trainee, and four agreed. They were then sent the Participant Information Sheet (Appendix K) and given at least 24 hours notice to consider and withdraw. Consent forms (Appendix L) were completed prior to the interview with the trainee.

The focus group and interviews were semi-structured around potential feelings of shame, embarrassment and guilt based on how self-conscious emotions have been operationalised in the research literature (Tracy & Robins, 2004), seen in Appendix M. Initially an opening statement and question were posed to participants before key areas were addressed based on the literature. This included others' knowledge of COPD, effects of symptoms and previous lifestyle choices. The CSES as an idea was then discussed with participants to gather their views about completing this type of questionnaire.

Responses were recorded on a Dictaphone. Data were not transcribed due to time limitations and due to the nature of the analysis being to generate items from the data, rather than describing phenomena. Data were analysed using an adapted thematic analysis framework (Braun & Clarke, 2006), where the trainee familiarised themselves with the data, listened to interviews several times and then generated initial ideas. These were written down alongside quotations from interviews, which were written down verbatim to aid in statement development. This was then added to from further interviews and any common themes were noted. The trainee then looked again at the self-conscious emotion literature and also at two similar measures (the HIV Stigma Scale, Berger *et al.,* 2001; the Cataldo Lung Cancer Stigma Scale, Cataldo *et al.,* 2011). The themes were then defined and named.

2.3.4 Results of interviews

Through the process of interviews, several common themes emerged related to embarrassment, guilt and shame that were felt to be relevant to a measure of self-conscious emotions in COPD. These were:

1) Embarrassment due to symptoms and using aids, avoidance of certain situations

2) Guilt about previous and current lifestyle choices, the effects of COPD on family life and outings social engagement, impact on partner or children

3) Shame related to culpability of developing COPD, negative judgements from others, avoidance of people or healthcare appointments due to feeling bad about self

2.4 Phase 2 –Development of statements and consultation with experts

2.4.1 Selecting a scaling method

To help identify the most appropriate scaling method, research supervisors were consulted and existing measures of self-conscious emotions with good psychometric properties were reviewed (HIV Stigma Scale: Berger *et al.*, 2001; The Cataldo Lung Cancer Stigma Scale: Cataldo *et al.*, 2011; FNE: Watson & Friend, 1969). Following review of other similar measures (HIV Stigma Scale: Berger *et al.*, 2001; The Cataldo Lung Cancer Stigma Scale: Cataldo *et al.*, 2011) a five-point Likert scale was identified as being appropriate to measure participants ratings of self-conscious emotions, which allowed responses of strongly disagree, disagree, agree, strongly agree and not applicable.

2.4.2 Procedure

Themes were taken from the focus group/interview analysis and viewed alongside statements from similar measures used in other areas of health (HIV Stigma Scale: Berger *et al.*, 2001; The Cataldo Lung Cancer Stigma Scale: Cataldo *et al.*, 2011). Statements were initially written based on the underlying emotions – shame, embarrassment, guilt. They were then randomised. A resultant questionnaire containing thirty-four items was reviewed and modified in consultation with research supervisors, notably to include an introductory sentence to make sure that participants were aware they may or may not have experienced these emotions before. Two clinical experts in

COPD then provided feedback about the readability and statement content, suggesting reducing length and complexity of language of preliminary questionnaire. A readability checker was also suggested to improve the readability of the introductory paragraph. Based on this feedback the introductory paragraph was further refined and items that were low on readability or repetitive were removed, eliciting a final number of twenty items (Appendix N).

2.5 Phase 3 - Administering scale to developmental sample

2.5.1 Participants

Participants with COPD were recruited from the advanced COPD research database, the advanced COPD clinic and the pulmonary rehabilitation clinic at a single hospital site. Participants' medical notes were screened for eligibility.

2.5.2 Eligibility criteria

Inclusion criteria

Participants were eligible if they were over 18 years of age, had a diagnosis of COPD confirmed by a spirometer, could provide informed consent and could understand English.

Exclusion criteria

Exclusion criteria for this study included if participants had a primary respiratory condition other than COPD and if they had an inability to communicate because of language skills, hearing or cognitive impairment.

2.5.3 Procedure

Postal recruitment

One hundred potential participants were selected at random from the advanced COPD clinic research database (n=400), and sent questionnaire packs containing the Participant Information Sheet (Appendix O), consent form (Appendix P), the CSES, FNE, CRQ, usability questionnaire and sociodemographic information sheet. A stamped addressed envelope was provided.

Recruitment in clinic

Participants recruited at the COPD clinic were approached about the research by their physician in clinic. If they agreed to discuss the project, the trainee spoke to them after their appointment and issued the Participant Information Sheet to read through. If they decided to participate, they were given the option to complete the questionnaires in clinic for their ease, with the trainee taking informed consent, or to take them away and post back in a stamped addressed envelope.

Participants recruited at the pulmonary rehabilitation class were approached by the trainee and took questionnaire packs away to complete and post back if they wanted to participate giving them the option of 24hours to consider whether they would like to participate.

Consent forms

In questionnaire packs two copies of the consent form were included, with instructions for participants to sign and complete one and sign and post the other back. A copy was then put in the site file and the participants' medical notes. For participants recruited in clinic, a copy of the participant's consent form was taken for the site file and medical notes. Consent forms were stored separately to questionnaires to maintain anonymity of participants.

2.5.4 Additional measures

Usability of questionnaire

Participants were asked to provide feedback on the usability of the questionnaire (see Appendix Q).

Sociodemographic information

Participants were asked to provide sociodemographic information to assess representativeness of the developmental sample. Data on gender, age, ethnicity, relationship status, smoking status and prior attendance at a PR programme were collected.

Fear of Negative Evaluation

The Fear of Negative Evaluation (FNE; Watson & Friend, 1969) was used to assess convergent validity. The FNE is a 30-item self-report questionnaire that was designed to assess feelings of apprehension about others' evaluations, distress over these negative evaluations, and the expectation that others will evaluate one negatively. The higher the score the higher the level of fear of negative evaluation. It has been found to have good psychometric properties (Cronbach's α = .94 to .98).

Physical and emotional aspects of chronic respiratory disease

The Chronic Respiratory Disease Questionnaire (CRQ; Guyatt *et al.*, 1987) was used to assess the convergent validity of the self-conscious measure. The CRQ is a 20-item disease specific self-report questionnaire designed to assess Dyspnoea, fatigue, emotional function and mastery of disease. The higher the score, the better a person feels. It has good psychometric properties within the COPD population (Cronbach's α = .80 to .90).

2.6 Phase 4– Evaluation of scale items

2.6.1 Sample size

Initially the study was designed for the trainee to develop and validate the CSES. The literature suggested that a minimum of 100 participants were required to meet the underlying assumptions of factor analysis (Fabrigar & Wegener, 2011). Furthermore, Gorsuch (1983) suggested it is adequate to have five times the number of participants per item in the scale. As the CSES contained 20 items, a sample size of 100 participants for this study was felt to be adequate.

However, research data from only 56 participants were collected for the questionnaire construction phase. Therefore, the decision was made to run the study as a pilot study and exploratory factor analysis was still arguably warranted, despite the small sample size, to identify the presence of any underlying factors or components. Evidence suggests that factor analysis can yield good quality results for small *N,* and exploratory factor analysis can be reliable even in sample sizes below 50, when high level of loadings, low number of factors and high number of variables are evident (De Winter *et al*., 2009).

2.6.2 Summary of analysis

Factor Analysis (Principal Components Analysis)

The project aimed to explore the factor structure of a new scale that was developed to identify self-conscious emotions such as shame, embarrassment and guilt. Therefore, the analysis needed to identify any factors or coherent components that might underlie the scale, determine the number of these factors and identify any patterns between variables. It was felt that an exploratory factor analysis was most appropriate, more specifically principal component analysis (PCA) with a straightforward empirical summary of a data set (Tabachnick & Fidell, 2013). Oblique rotation was selected initially rather than orthogonal rotation, since the former allows for factors (or components) to be correlated which was felt more appropriate for the CSES.

Analyses were performed using SPSS statistical software, Version 24 (SPSS Inc., 2016), with statistical significance set at $p < .05$. Initially descriptive statistics were gathered to describe the demographic information of the sample. Data were assessed for suitability for a PCA, through considering the sample size and the strength of the relationship between the items, and reviewing whether the inter-correlations among items were above .3 (Tabachnick & Fidell, 2013). The Kaiser-Meyer-Olkin measure of sampling adequacy (Kaiser, 1974) and Bartlett's test of sphericity (Bartlett, 1954) were also used to help assess the factorability of the data set.

Factor extraction was carried out using Principal Components. Eigenvalues above 1 (Kaiser Criteria), factor loadings above 0.3, and the scree plot examined to identify how many factors should be retained. Parallel analysis was also used (Horn,1965) comparing the size of the eigenvalues with those from a randomly generated data set of the same size. An oblique rotation (Oblimin; delta=0) was specified as any resulting factors might be expected to correlate.

Reliability

Scale reliability was investigated through internal consistency using Cronbach alpha procedure (Cronbach, 1951), with a lower acceptable cut off of 0.7 used (Nunally, 1978). Assessment of test-retest reliability was not able to be utilised due to the limited time frame.

Validity

The CSES validation analysis was carried out by correlational analysis to assess convergent validity, by examining the relationship between the total item scores of each factor of the CSES with the total FNE and CRQ scores. It was expected that there would be a correlation between ratings of self-conscious emotions and fear of negative evaluation and that there may be a correlation between ratings of self-conscious emotions and other ratings of health and wellbeing in the CRQ. The effect sizes were estimated using Cohen's (1988) criteria.

3. Results

3.1 Participants

3.1.1 Interviews and focus group

Forty-five participants were approached in May 2017 and seven took part (15%). One participant was excluded as they had had a recent lung transplant. Frequencies and percentages for sample characteristics of focus groups/interviews are shown in Table 1. It can be seen that the majority of participants were female (57.1%) with a mean age of 65 years. All participants were White British.

Table 1. Focus group and interview sample characteristics

		Frequency	Percentage
Total no. of participants	7		
Age (years)	Median= 65 (SD=6.8)	Range = 51-70	
Gender	Male	3	42.9
	Female	4	57.1
Ethnicity	White British	7	100
Relationship status	Married	3	42.9
	Divorced	4	57.1
Smoking status	Current smoker	1	14.3
	Former smoker	6	85.7
Attended PR program	Attended	4	57.1
	Did not attend	3	42.9
Recruitment method	Focus groups	3	42.9
	Interview	4	57.1

3.1.2 Questionnaires

The sampling frame comprised a four-month period from October 2017 to February 2018. The trainee sent 100 questionnaire packs by post, yielding 30 positive responses, with sixty-nine non-responders and one person declining to take part. The trainee attended eight clinics and all participants who spoke to the trainee took part in the study (n=16). The trainee attended eight rehab classes, issuing questionnaire packs to eighteen patients, with 56% participating. Participants were not asked to disclose reasons for non-participation. No participants were excluded. The majority of participants were White British (80.4%), male (58.9%) and married (42.9%). Frequencies and percentages for sample characteristics of questionnaires are shown in Table 2.

Table 2. Questionnaire Sample characteristics

Total no. of participants	56		
Age (years)	Median= 73.5 (SD=8.31)	Range = 42-86	
Gender		*Frequency*	*Percentage*
	Male	33	58.9
	Female	23	41.1
Ethnicity	White British	45	80.4
	Indian	1	1.8
	Unknown	10	17.9
Relationship status	Single	6	10.7
	Married	24	42.9
	Divorced	4	7.1
	Widowed	12	21.4
	Unknown	10	17.9
Smoking status	Current smoker	6	10.7
	Former smoker	40	71.4
	Unknown	10	17.9
Attended PR program	Attended	35	62.5
	Did not attend	11	19.6
	Unknown	10	17.9
Recruitment method	Postal from advanced clinic list	30	53.6
	Advanced clinic	16	28.6
	PR class	10	17.9

3.2 Preliminary checks

3.2.1 Missing values and outliers

Twelve item responses were missing from the CSES and 220 item responses were coded as missing, as participants had selected 'not appropriate'. Ten participants had not completed the CRQ and there were no missing data from the FNE. Due to the small sample size and missing data, pairwise deletion was used for analysis. Data were explored for outliers using histograms and box plots and none were identified.

3.2.2 Suitability for FA

Data were assessed for suitability for factor analysis via sample size and the strength of the relationship between the items (Pallant, 2016). The inter-correlations among items were reviewed and inspection of the correlation matrix revealed the presence of many coefficients of .3 and above. The Kaiser-Meyer-Olkin measure of sampling adequacy was .78, which exceeded the recommended value of .6 (Kaiser, 1974). However, Bartlett's test of sphericity was not significant ($p > .05$), and therefore did not support the factorability of the correlation matrix. Given the exploratory nature of the study, different items and factors were explored to elicit a satisfactory solution (Tabachnik & Fidell, 2013).

3.3 Factor structure of the scale

3.3.1 Process of PCA to reach final solution

Initially, PCA revealed the presence of five components (Appendix R) with eigenvalues exceeding 1, explaining 33.1%, 11%, 7.9%, 5.9%, 5.4% of the variance respectively. An inspection of the screeplot (Appendix S) revealed a clear break after the second component. Using Cattell's (1996) scree test, it was decided to retain two components for further analysis, further supported by the results of a Parallel Analysis, which also indicated that there were only two components with eigenvalues exceeding the corresponding criterion values for a randomly generated data matrix.

The PCA was re-run with two components forced. The resulting solution explained a total of 44.1% of the variance, with Component 1 contributing 33.1% and Component 2 contributing 11%. To aid in the interpretation of these two components, an oblique rotation was specified. The rotated solution revealed the presence of a simple structure with both components showing a number of strong loadings. However, seven

items (items 3, 4, 7, 16, 18, 19, 20) were found to have low cross-loadings. These items were found to be complex and on inspection one might expect them to load on more than one factor. Furthermore, items 7, 18,19 and 20 were found to generate high levels of 'not applicable' responses from the vast majority of participants. These items had been included in order to be 'comprehensive', however it is likely that they were too specialist. Therefore, the decision was made to remove these items and re-run the analysis without forcing a particular number of components, with the understanding that removal of these items would permit the scale to be more amenable for general use.

After removal of these seven items, the output revealed that Bartlett's test was now significant, suggesting their exclusion had led to an improvement in the factorability of the correlation matrix. Three components were revealed with eigenvalues over 1, which explained a total of 60% of variance, with Component 1 contributing 36.1%, Component 2 contributing 16.4% and Component 3 contributing 7.7%. However, when the Oblimin rotated component scores were reviewed, it was seen that Component 3 had many low cross-loadings (Appendix T). Therefore, the PCA was re-run with thirteen items but two components were forced. Two further items were then identified as cross-loading (items 8 and 13) and were removed. These items were considered to be too complex and unlikely to load onto only one factor.

The remaining eleven items of the CSES were subjected to PCA. This revealed the presence of two components with eigenvalues exceeding 1, explaining 33.6% and 18.2% of the variance respectively. However, when the component correlation matrix was reviewed it showed very low correlation (r=0.17) between components, suggesting the underlying constructs were relatively independent. Tabachnick and Fidell (2013) have suggested that oblique rotation should only be employed if component correlations exceed .32, therefore the decision was made to use a varimax rotation at the next stage.

3.3.2 Final PCA solution

The remaining eleven items of the CSES were subjected to PCA. Inspection of the correlation matrix revealed the presence of many coefficients of .3 and above. The Kaiser-Meyer-Olkin value was .741, exceeding the recommended value of .6, and Bartlett's Test of Sphericity reached statistical significance, supporting the factorability of the correlation matrix. PCA revealed the presence of two components with eigenvalues exceeding 1, explaining 33.57% and 18.18% of the variance respectively, with a total of 51.76% variance explained. This was further supported by the scree plot

revealing a clear break after the second component, and Parallel Analysis, which showed only two components with eigenvalues exceeding the corresponding criterion values for a randomly generated data matrix.

To facilitate interpretation of these two components, varimax rotation was performed. The rotated solution revealed that both components showed a number of strong loadings and all variables loaded substantially on only one component. Rotated component coefficients can be seen in Table 3. Seven items loaded on component 1 (items 1, 2, 5, 9, 10, 15, 17), explaining 31.59% of the variance, and four items loaded on component 2 (items 6, 11, 12, 14), explaining 20.17% of the variance.

Table 3. Rotated component coefficients for PCA with varimax rotation of Two factor solution of CSES Items

Item no.	Item	Rotated Matrix C1	Component C2	Communalities
5	I feel guilty about my lifestyle choices that may have contributed to COPD	**.772**	.005	.596
9	I feel guilty when I am admitted to hospital because of the worry it gives my family and friends	**.761**	.224	.630
15	I feel guilty that I am not able to engage in sexual activities anymore, or as often, with my partner	**.718**	.153	.539
10	I blame myself for developing COPD	**.684**	-.151	.491
2	I'm glad COPD is not visible, so I do not have to deal with people making negative judgements	**.681**	-.011	.464
17	I feel guilty about the impact of my COPD on my partner's life	**.645**	.133	.433
1	It's embarrassing when I need to move quickly and can't, such as getting to the toilet	**.608**	.173	.400
12	I have not attended healthcare appointments in the past because I was worried I would be told off for not doing as they advised	-.065	**.789**	.627
11	I was diagnosed with COPD under the age of 60 and have felt that people have made negative judgements about me	.228	**.707**	.552
6	I have cut short or avoided visits with certain family or friends because they have made me feel bad about myself	.077	**.702**	.499
14	People have made negative judgements about me because I have COPD, which has made me feel bad about myself	.059	**.676**	.461
	% Variance Explained	**31.59%**	**20.17%**	

3.4 Conceptualising the factor structure

Seven items loaded on Component 1 (Item 5, 9, 15, 10, 2, 17, 1) and were interpreted as comprising items that were related to feelings of guilt and embarrassment. Specifically guilt around developing COPD and the impact on others, and embarrassment with others noticing their COPD, it was therefore labelled as 'Guilt, embarrassment'. Four items loaded on Component 2 (Item 12, 11, 6, 14) that were related to shame-based avoidance and not engaging with others, and was labelled as 'Shame-based avoidance'.

3.5 Reliability of the scale

Cronbach alpha was run for the total CSES and the two subscales. However, it must be acknowledged that due to listwise deletion, a different number of cases were run each time. For the final total scale Cronbach alpha was .86 (.87 for males, .76 for females) with only 16 cases. For the 'Guilt, embarrassment' subscale the Cronbach alpha was .88 (Male .90, Female .81) with 22 cases, and the 'Shame-based avoidance' subscale was .76 (Male .80, Female .77) with 37 cases. It can be seen that the Cronbach's alpha shows more of a variation for males. Overall, results suggest a strong relationship among the items, but given missing data this must be interpreted with caution.

3.6 Convergent validity

Convergent validity of the CSES was assessed through correlations with the FNE total and CRQ total (Table 4). A one-tailed Spearman's rank-order correlation identified a moderate statistically significant positive relationship between the CSES total score and the FNE total score (rs (56) = .31, p <.05) and a moderate statistically significant negative relationship between the CSES total score and the CRQ total score (rs (46) = -.42, p <.001). This suggests that a higher score on the CSES correlates with higher levels of fear of negative evaluation and lower levels of emotional function and mastery of disease.

The 'Guilt, embarrassment' subscale did not appear to have a strong relationship with either measure as it had a small non-significant correlation with the FNE (rs (56) = .12, p >.05) and a small significant negative correlation with the CRQ (rs (46) = -.29, p < .05). However, the 'Shame-based avoidance' subscale had a large positive significant

relationship with the FNE (rs (54) = .60, *p* <.001) and a large negative significant relationship with the CRQ (rs (44) = .50, *p* <.001).

Table 4. Correlations with FNE and CRQ to assess convergent validity

	CSES total	CSES 'guilt, embarrassment' subscale	CSES 'shame based avoidance' subscale
FNE total	.31*	.12	.60**
CRQ total	-.42**	-.29*	.50**

*p <.05; ** p <.001

3.7 Assessment of potential confounding variables

Participants' demographics were investigated to identify possible confounding variables of the CSES. Participants' gender, age, recruitment method, smoking status, marital status and attendance at PR programme were examined. No significant relationships or differences were found between participants' variables and the total CSES score, suggesting that these factors did not confound their scoring of the CSES (Table 5).

Table 5. Investigation of potential confounders

Potential confounders	N	Statistical Test	Test result	P value
Age	56	Spearman's rho	r= .151	.268
Gender	56	Mann-Whitney U Test	U= 306.5	.223
Smoking status	46	Kruskal-Wallis Test	χ^2=.428	.513
Marital status	46	Kruskal-Wallis Test	χ^2=3.28	.351
Recruitment method	56	Kruskal-Wallis Test	χ^2= 2.35	.309
Attendance PR program	56	Mann-Whitney U Test	U=188.5	.919

3.8 Assessment of usability of the measure

Participants' ratings of the usability of the measure were explored. This included rating how easy the CSES was to use, whether the statements made sense, how acceptable it would be to complete the CSES routinely in clinic and whether the CSES was too long (Table 6). It can be seen that overall participants rated the usability of the CSES favourably.

Table 6. Usability of the CSES

	Easy to complete (n=55)	Statements made sense (n=55)	Acceptable to complete in clinic (n-54)	Didn't take too long to complete (n=48)
Strongly agreed	39.3%	28.6%	26.8%	35.4%
Agreed/agreed somewhat	51.7%	67.8%	62.5%	50%
Neither agreed/disagreed	3.6%	1.8%	5.4%	N/A
Disagreed/somewhat disagreed	3.6%	N/A	1.8%	2.1%
Strongly disagreed	N/A	N/A	N/A	4.2%

4. Discussion

4.1 Aims of the present study

The aim of the present study was to develop and evaluate a new measure of self-conscious emotions for people with COPD that could be used as a brief self-administered clinically-based screening questionnaire in outpatient clinics. More specifically, it was hoped that the CSES would provide healthcare professionals with further information about the psychological effects of COPD that impact on their treatment engagement, enabling further support at an earlier stage.

4.2 Summary of study findings

4.2.1 Scale construction

The CSES was developed through a systematic process over four phases, which included discussion about self-conscious emotions in COPD with patients through focus groups and individual interviews, consultation with experts on preliminary items, piloting the scale with a clinical sample, and assessment of the underlying factor structure and the reliability and validity.

In the first phase, several themes emerged that were felt to be relevant to a measure of self-conscious emotions in COPD. These were: Embarrassment due to symptoms and using aids, avoidance of certain situations; Guilt about previous and current lifestyle choices, the effects of COPD on family life and outings with friends, impact on partner or children; and Shame related to culpability of developing COPD, negative judgements

from others, avoidance of people or healthcare appointments due to feeling bad about self. Items were developed based on these themes, and then refined through discussion with experts. It was hoped that by including patient views and expert opinion from the start of the process, content and face validity of the scale would be maximised.

4.2.2 Psychometric evaluation of CSES

The 20-item CSES was administered to fifty-six participants, along with the FNE and CRQ measures. This was done via three methods, postal recruitment of the advanced COPD research database, attendance at an advanced COPD clinic and attendance at pulmonary rehabilitation classes. Unfortunately, even though multiple sources of recruitment were utilised, recruitment was limited. Therefore, this led to some difficulties in completing a factor analysis on the data, such as having low power, due to significantly falling short of the minimum 100 participants recommended to meet the underlying assumptions for a factor analysis (Fabrigar & Wegener, 2011). Indeed, Bartlett's assumption was found to be non-significant initially. However, as the study was being run as a pilot study, it allowed some scope to take an exploratory approach to investigate the underlying factor structure by forcing factors and removing items.

PCA initially offered a five component solution and a three component solution, however after further exploration of multicollinearity, scree plot and power analysis, it was decided that a two component model appeared to more appropriately fit the data. This was further enhanced by the removal of nine items. Four of the nine items were removed based on the high level of 'not applicable' missing data, which had been included to be 'comprehensive' but were likely too specialist, such as embarrassment related to personal hygiene assistance, guilt over still smoking and COPD having a genetic link.

Previous scales investigating similar concepts have generally found a higher number of factors, however have also comprised many more items. The HIV Stigma Scale (Berger *et al.,* 2001) found that four factors emerged for their 40-item scale, defined as; personalized stigma, disclosure concerns, negative self-image, and concern with public attitudes and people with HIV. Furthermore, the Cataldo Lung Cancer Stigma Scale (Cataldo *et al.,* 2011) found four underlying factors for their 43-item scale and described four subscales: stigma and shame, social isolation, discrimination and smoking. However, they acknowledge a limitation of their study as replication of items

across subscales, as five items were included in three of the subscales, with twenty items in total assigned to more than one subscale, thus suggesting they did not have four distinct factors.

In the current study, the CSES offered two subscales, interpreted as 'guilt and embarrassment' and 'shame-based avoidance', both of which are supported by previous research (Gilbert, 2000; Harrison *et al*., 2015; Halding *et al.,* 2011; Odencrants *et al.,* 2007). In particular, the shame-based avoidance subscale provides further evidence to support Harrison *et al.'s* (2015) findings that self-conscious cognitions in people with COPD were associated with increased isolation and reduced help-seeking behaviour, and Halding *et al's.* (2011) findings that levels of shame may increase the COPD patients' fear of experiencing disgrace and hinder further engagement with services. The results of the analysis provide further evidence of the complexity of capturing complex emotions and behaviours for people with COPD.

4.2.3 Reliability and validity of CSES

The internal consistency of the total final scale was high ($\alpha = .86$), which confirmed the inclusion of the final items for the scale. Both subscales also had high Cronbach alpha (factor 1, $\alpha = .88$; factor 2, $\alpha = .76$), suggesting there was a significant overlap between items, and which would be expected if the measure was measuring a latent construct such as self-conscious emotions. However, due to missing data the total scale and the subscales were only compared for 16-37 cases. Therefore, it cannot be said to represent the whole data set and strong conclusions about the reliability of the scale cannot be drawn.

Convergent validity was assessed via exploration of the relationship between the CSES total and subscale scores, and the total scores on a fear of negative evaluation scale and a COPD health and wellbeing measure. The correlation between total CSES and the FNE (Watson & Friend, 1969) and CRQ (Guyatt *et al.*, 1987) scores were significant and moderate. The CSES was found to correlate positively with the FNE, suggesting that higher levels of self-conscious emotions correlate with higher levels of fear of negative evaluation. The CSES was found to correlate negatively with the CRQ, suggesting higher levels of self-conscious emotions correlate with lower levels of difficulties relating to COPD health and wellbeing. This therefore suggests high

convergent validity, as the CSES is measuring similar concepts to the two related measures.

4.3 Study limitations and strengths

4.3.1 Limitations

There remain a number of study limitations. The sample may not truly be representative of the overall COPD population, as most participants were recruited from the advanced COPD clinic (n=46), rather than settings in which diverse stages of the disease would be captured. Furthermore, eighty percent of participants were White British, suggesting the sample was not representative of the multicultural society within the UK. However, Gilkes e*t al.* (2016) carried out a retrospective cross-sectional study and found that all minority ethnic groups, but especially black people, were significantly less likely than white people to have a diagnosis of COPD when controlling for age, sex, smoking and deprivation. They suggested that reasons for these differences could be due to broad categories of ethnic differences in access to care, ethnic differences in normal spirometry, ethnic differences in susceptibility to COPD, or ethnic differences in smoking patterns.

Finally, the effectiveness of the factor analysis may have been affected by the small sample size and large amount of missing data. The analysis was approached as an exploratory process to try to make sense of the scale as a pilot measure, however more data would be needed to be more confident about findings. This therefore impacts negatively on the generalisability of results. Therefore, to enhance the robustness of the study further recruitment would be needed, particularly with a more diverse representation of COPD patients.

4.3.2 Strengths

The study developed a new measure to screen for self-conscious emotions within the COPD population based on a gap in the research that had been clearly identified. The study being run as a pilot study enabled a more exploratory approach to the measure and analysis. Therefore, issues such as place of recruitment, and how specific or general items should be, have been given consideration. This then enables the measure and methodology to be further refined and improved in future research.

As the measure is disease specific, it may be more sensitive to the complexity of patients' experience and day to day management of the disease (Penny *et al.,* 1994) than more generic shame-assessing measures and captures responses related to society's increasing emphasis on personal responsibility for physical health (Guttman & Salmon, 2004). Furthermore, as the measure was developed based on discussion with patients and experts, it can be seen as representative of patient's experiences with self-conscious emotions in COPD. It showed good levels of convergent validity with other related measures, and the interpreted subscales were consistent with previous research.

4.4 Clinical implications

Given that the prevalence of COPD is set to increase in the coming decades due to exposure to COPD risk factors and an ageing population (Lopez *et al.,* 2006), improvements in patient engagement and care are vital to maximising treatment adherence and reducing financial costs for the healthcare system. The development of the CSES permits healthcare professionals to gather information about patient's self-conscious emotions related to their COPD. Armed with a better understanding of patients' emotional functioning and motivations, clinicians may be able to normalise these feelings and discuss whether they would like further psychological support. This could then enable patients to engage better with COPD treatments. Furthermore, it also provides a tool that could be utilised by clinicians for further research looking at the effects of self-conscious emotions and COPD.

4.5 Suggestions for future research

Due to the limited sample size, this study was run as a pilot study taking an exploratory position. Therefore, to allow for more confidence in the findings, the CSES needs to be administered to a larger sample size of 100-150 participants. Furthermore, it would be advantageous to recruit participants at different stages of COPD (GOLD, 2016) to create a more representative sample, such as from a range of COPD clinics held within the hospital, or through primary care.

During the analysis nine items were removed to create the final scale. It was identified that these were either too general, being appropriate for several components, or too specific, eliciting many 'N/A' responses. Therefore, further consideration is needed as to whether the specific items are included as a subsection in any future

versions of the CSES. This could help capture the range and variation of experiences and maintain a record of a patient experiencing a self-conscious emotion related to less common difficulties.

Although assessment of gender as a potential confounding variable was found to be non-significant, it can be seen that the Cronbach's alpha shows more of a variation for male data which may have further clinical significance, suggesting that women may respond around a tighter band of response variance. Indeed, several studies have reported gender differences in self-reported emotional expressivity (Hess et al., 2000; Fischer, 1993). This could have important clinical implications and requires further consideration, particularly when considering the development of interpretative guidelines for clinicians administering the measure. It may be that the measure would benefit from two separate 'cut offs' for men and women, with men requiring a higher cut-off with very good sensitivity and specificity. Further research may look to investigate links between self-conscious emotions and adherence to treatment and attendance at PR and SMP courses, by administering the CSES at the start of programmes and comparing to attendance outcomes. The use of the CSES would allow quantitative comparison with other factors, such as mood, quality of life and health beliefs.

4.6 Conclusion

The CSES was developed to identify levels of self-conscious emotions in people with COPD. It was administered to patients with COPD as a pilot study, with preliminary evidence suggesting that the revised 11-item scale had an underlying two component structure, of 'guilt and embarrassment' and 'shame-based avoidance'. Findings also indicated good internal consistency and convergent validity with other related measures. However, limitations were found with the sample size and demographics, and future research is needed to give further consideration to the measure and recruitment.

It is hoped that the focus of this study on exploring the impact of self-conscious emotions within COPD, will contribute to increased understanding and identification of more complex emotions within this population. Further research could then look to focus on the links between these emotions and treatment adherence, with the aim of better supporting people at an earlier stage.

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PART THREE: CRITICAL APPRAISAL

Critical Appraisal

1. Introduction

In this paper I will reflect on my experiences of completing doctoral-level research. I was aided in this reflection by a research diary that I kept throughout the course of study. I will initially discuss the origins of the two aspects of this thesis, before describing the process of completing the literature review and then the empirical project. Finally, I will discuss learning outcomes and conclusions.

2. Origins of the empirical project and literature review

Empirical project

My interest in understanding the link between physical health conditions and psychological adjustment started several years ago when I worked in a sexual health service with people with HIV. There were often high levels of stigma and shame associated with the condition, which had a big impact on how patients viewed themselves and also their engagement with services. Since starting clinical training, I had also become very interested in compassion focused therapy theory and noticed how effective it could be to work therapeutically with people to help identify and work with their self-conscious emotions, such as shame and guilt.

Therefore, when the research supervisors initially presented their research interests, I was keen to pursue a project looking at the link between shame and chronic obstructive pulmonary disease (COPD). Through reading around the topic and discussion with supervisors, it became apparent that a link had been identified between high levels of self-conscious emotions and poor treatment adherence. However, there existed no measure to screen for these emotions routinely in COPD clinics.

Literature review

As the literature review had to be related to the empirical project, I was keen to identify a topic that also had enough scope to explore with a systemic review. In my first year of training I had completed a literature review that looked at psychosocial predictors of outcomes of pulmonary rehabilitation (PR) in COPD, and was keen to develop further understanding of factors that affect COPD outcomes. Initially I ran a search on the impact of self-efficacy on outcomes in people with COPD but struggled to

obtain enough papers. I then decided to change focus and look at the extent that social support predicts psychological wellbeing, but had to abandon this idea as I found a recent review paper that was very similar. Finally, I decided to focus my search on the impact of self-management programmes on psychological wellbeing.

3. Completing the literature review

At the start of the searches, I consulted a university librarian to discuss my search terms and strategy. This was invaluable and enabled me to better structure my search and maximise the amount of relevant papers. Due to the time needed to complete a literature review, combined with the delay in finding an appropriate topic for the literature review I was concerned about completing a first draft on time.

Whilst reading through the literature, I found it interesting to learn more about self-management programs, particularly as I was on placement in medical psychology and was working with patients with chronic health problems who struggled with motivation to make changes to the way they managed their condition. I was also quite surprised at the lack of good quality papers available in this area, which further highlighted the importance of completing psychological research within COPD.

4. Completing the empirical project

Initial thoughts

When I began my empirical project, I was aware that I had a lot to complete within a relatively short amount of time. This led me to create a plan of when I needed to complete each part by. I did not, however, set myself any deadlines for drafts which in hindsight I wish I had. I was excited to develop a measure of self-conscious emotions, but was also aware that I had never attempted to create and evaluate a scale before and this at times felt quite overwhelming. I was also keen to build relationships with staff that worked at the hospital who would help to identify potential participants, but conscious I did not have much contact time in which to do this.

Obtaining ethical and other approvals

The process of gaining ethical and other approvals for the research was a more lengthy process than I had anticipated, particularly as the system was relatively new and so it wasn't always obvious what to do. The sponsor representative that I worked with was extremely helpful with this and provided plenty of guidance and support.

I was required to attend a Research Ethics Committee (REC) meeting. Although daunting, I found it to be a really interesting process, particularly as some of the points raised highlighted the difficulty people have talking about self-conscious emotions. For example, I was asked whether participants may find being asked these questions too difficult and could I describe embarrassment, guilt, shame as 'difficult emotions' instead. I was really pleased to be able to respond to this point and justify the importance of being transparent and clear with participants, so as to avoid confusion. It highlighted the importance of increasing psychological research within physical health settings so this language and discussion can become more normalised.

Following some changes to my research proposal and participant information, I was granted NHS ethical approval and HRA approval and was then granted R&D approval. This was a lengthy and new process for me, but I feel I really benefited as I learnt a lot about the process of obtaining NHS and other approvals, which I can draw on for any future research I may be involved in.

Recruitment for focus groups and interviews

To help with recruitment for the focus groups, I worked with the research manager at the respiratory unit. I was very grateful for her time, as it was a difficult system to navigate and I only had limited access to patient information. She helped me to access patient notes from the advanced COPD clinic, and I sent out forty letters asking patients to respond if they wanted to participate in a focus group at the unit. However, seven registered interest and only three people attended. This was very disappointing and I tried to understand what I could have done differently. Following later discussion with participants about their day to day lives with advanced COPD, I began to understand some of the challenges they face, such as how difficult it can be to leave the house if the weather is bad or if their symptoms are particularly bad that day. Therefore, I think asking participants to travel to the clinic was one of the main barrier for focus group attendance. I also think due to the higher levels of self-conscious emotions that this patient group may experience, the prospect of discussing their COPD within a group setting may have felt quite threatening.

Therefore, following discussion with my supervisors, I submitted a substantial amendment to the ethics board to conduct 1:1 interviews instead. This meant a further delay whilst waiting for the approval, and required me to spend time travelling between participants homes. However, I was pleased to get a rich account from several people

about their experience of self-conscious emotions and I wonder whether in their own homes and not in a group setting, they felt able to be more honest. Although there were some difficulties, I really enjoyed this phase of data collection, as I was able to have open and honest conversations with participants about their experiences of living with COPD, and gauge their opinions about the measure I was intending to develop. It also allowed me to draw on my clinical skills of empathy, building rapport and structuring the interviews/focus groups to keep them on task.

Constructing the scale

It had been agreed that I did not need to transcribe the focus group and interviews given the time restrictions and given the aim of developing quantitative items rather than an in depth understanding of the phenomenon. Therefore I listened to the recordings and noted ideas and themes. This worked well and enabled me to generate a lot of general and more specific items.

After the first draft was developed, it was shared and discussed with the research supervisors and two professors that work clinically in COPD. I was really keen to gather feedback on the scale, as I had not designed one before, and at times felt a bit overwhelmed working on this on my own. It was therefore very useful to have feedback from supervisors encouraging me to develop the items to think about the length and readability of the resulting measure. This highlighted to me the benefits of conducting research within a team.

The next stage was submitting the measure to the ethics committee for approval as previously agreed. In response to feedback from the committee I was required to write a letter to make it clear why we had been so explicit with the naming of emotions and how important it was to do this. Following this approval was granted. Again, I reflected on the difficulty with having so many different phases to complete with the project and the impact of a delay at any stage.

Recruitment for questionnaire

Due to the delays in the first two phases, recruitment for the questionnaire began later than hoped. Therefore, the decision was made to try to maximise recruitment by initially sending out 100 questionnaire packs before I started attending clinics. This required many hours at home to make the questionnaire packs up and then addressing them in the respiratory unit. Again, the support of the staff there was invaluable. Only

30 questionnaires packs were returned, which was initially disappointing but staff said this was a good return rate for this population.

I began recruitment in the advanced COPD clinic in December and was initially surprised to be told that I would not be able to approach patients as they waited for their clinic appointments (which were often delayed and presented an ideal opportunity to complete questionnaires). Instead the doctors were required to ask them in their appointment if they wanted to talk to me about participating in my research. Looking back, I wish I had discussed this procedure earlier and more thoroughly with field supervisors, as I believe it impacted on the number of participants I was able to recruit. In total I was only able to recruit sixteen participants from this clinic. I think the difficulty recruiting from this clinic was likely down to several factors, such as the doctors being very busy and not always having the time to discuss the study with patients, and another study recruiting at the same time.

Given that recruitment was likely to be limited in that clinic, I spoke to my other field supervisor who was involved with PR classes, and it was suggested that I liaise with the staff running those classes. I was grateful for their help and managed to recruit ten additional participants. Again, this form of recruitment was not straightforward, as I had to give participants packs to take away as they did not have time to complete during or after the classes. However, it enabled me to observe PR classes, and I could understand how beneficial they could be but also how some people may feel quite embarrassed at attending and may drop out. Overall, I found recruitment of the COPD population quite difficult and frustrating at times, particularly as I was the only person able to take consent and recruit participants. For future research I think it would be important to have several people able to take consent to maximise recruitment.

Data analysis

As I had never done any scale development before, I found the analysis quite daunting. I did some reading and invested in some different books before deciding that Palant (2016) was the most clear and helpful to follow as a guide. After meetings with my research supervisor I felt more confident and spent time experimenting with different ways of approaching the factor analysis. I was nervous about the impact of the small sample size on my analysis, but with guidance from my supervisor I was able to develop an understanding of the scale appropriate for a pilot study. The process enabled

me to learn more about factor analysis and the theory behind it and I feel glad that I have done it.

5. Learning outcomes

If I were to run the study again, I would do a few things differently, such as focus more time initially to design the focus groups with an emphasis on maximising attendance. This may include running them at a local GP practice. Secondly, I would have allocated more time to develop the questionnaire and get it approved. Finally, I would gather more information from staff working in the advanced COPD clinic in terms of how the clinic worked and what my recruitment opportunities might be in practice. However, although I think I could have done things differently, I think the large scale, multi-stage nature of the project and the time restrictions for a DClinPsy might always have led to time pressures. The ethics and recruitment issues which arose meant that I learnt how to be more flexible with my time and asking others for help where I could. I was also really pleased to be able to increase my statistical knowledge and general research skills.

6. Conclusions

Through undertaking this project I have learnt a lot personally and professionally. I really enjoyed the opportunity to work with MDT colleagues and to meet participants and discuss their experiences. I think that my self-management and organisational skills have improved. I also further developed my team working, communication and problem solving skills. I feel proud to look back and reflect on how I managed the major setbacks. It has also highlighted to me that whilst I enjoy conducting research, it is really beneficial to conduct research as part of a team to share tasks.

References

Pallant, J. (2016). *SPSS Survival Manual: A Step By Step Guide to Data Analysis Using SPSS Program* (6th ed.). London, UK: McGraw-Hill Education.

APPENDICES

Appendix A - Search terms used

"Self-management" OR "Self management" OR "education"

AND

"Chronic Obstructive Pulmonary Disease" OR COPD OR "pulmonary disease" OR "emphysema" OR "bronch"

Appendix B - Table of databases & hits

Database	No. of papers found	Abstracts read	Full papers read	Final selection
PsycInfo	51	16	4	4
Medline	327	31	14	10
Embase	347	11	3	1
CINAHL	77	7	1	0
Total	**802**	**65**	**22**	**15**

Appendix C - Data Extraction Pro-Forma

Article Number:	Publication Date:	Country:

Title:

Authors:

Journal:

Volume:	Number:	Pages:

Aims:

Sampling / Participants: *Sample size, age range & mean, gender, recruitment method, drop out*

Study Design: *Randomized allocation? Control group? RCT?*

Self-management program: *What was the structure & content of the self-management program?*

Outcomes: *What psychological wellbeing outcomes are being measured? What assessment tools are used, are they validated? Administered pre & post?*

Analysis: *What statistical methods were used? Was power calculated?*

Findings:

Strengths: *Validity, reliability*	Weaknesses:

Conclusions: W*hat do the findings mean? Generalisability? Implications & Recommendations?*

Additional Comments:

Appendix D - Quality Appraisal Tool

QUALITY ASSESSMENT TOOL FOR QUANTITATIVE STUDIES

EPHPP
Effective Public Health Practice Project
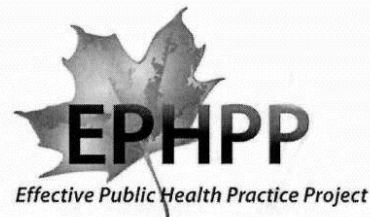
COMPONENT RATINGS

A)   SELECTION BIAS

(Q1)   Are the individuals selected to participate in the study likely to be representative of the target population?
1   Very likely
2   Somewhat likely
3   Not likely
4   Can't tell

(Q2)   What percentage of selected individuals agreed to participate?
1   80 - 100% agreement
2   60 – 79% agreement
3   less than 60% agreement
4   Not applicable
5   Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

B)   STUDY DESIGN

Indicate the study design
1   Randomized controlled trial
2   Controlled clinical trial
3   Cohort analytic (two group pre + post)
4   Case-control
5   Cohort (one group pre + post (before and after))
6   Interrupted time series
7   Other specify _____
8   Can't tell

Was the study described as randomized? If NO, go to Component C.
No   Yes

If Yes, was the method of randomization described? (See dictionary)
No   Yes

If Yes, was the method appropriate? (See dictionary)
No   Yes

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

1

C)   CONFOUNDERS

(Q1)   Were there important differences between groups prior to the intervention?

        1   Yes
        2   No
        3   Can't tell

        The following are examples of confounders:
        1   Race
        2   Sex
        3   Marital status/family
        4   Age
        5   SES (income or class)
        6   Education
        7   Health status
        8   Pre-intervention score on outcome measure

(Q2)   If yes, indicate the percentage of relevant confounders that were controlled (either in the design (e.g. stratification, matching) or analysis)?

        1   80 – 100% (most)
        2   60 – 79% (some)
        3   Less than 60% (few or none)
        4   Can't Tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

D)   BLINDING

(Q1)   Was (were) the outcome assessor(s) aware of the intervention or exposure status of participants?

        1   Yes
        2   No
        3   Can't tell

(Q2)   Were the study participants aware of the research question?

        1   Yes
        2   No
        3   Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

E)   DATA COLLECTION METHODS

(Q1)   Were data collection tools shown to be valid?

        1   Yes
        2   No
        3   Can't tell

(Q2)   Were data collection tools shown to be reliable?

        1   Yes
        2   No
        3   Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

2

F) WITHDRAWALS AND DROP-OUTS

(Q1) Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group?
1 Yes
2 No
3 Can't tell
4 Not Applicable (i.e. one time surveys or interviews)

(Q2) Indicate the percentage of participants completing the study. (If the percentage differs by groups, record the lowest).
1 80 -100%
2 60 - 79%
3 less than 60%
4 Can't tell
5 Not Applicable (i.e. Retrospective case-control)

RATE THIS SECTION	STRONG	MODERATE	WEAK	
See dictionary	1	2	3	Not Applicable

G) INTERVENTION INTEGRITY

(Q1) What percentage of participants received the allocated intervention or exposure of interest?
1 80 -100%
2 60 - 79%
3 less than 60%
4 Can't tell

(Q2) Was the consistency of the intervention measured?
1 Yes
2 No
3 Can't tell

(Q3) Is it likely that subjects received an unintended intervention (contamination or co-intervention) that may influence the results?
4 Yes
5 No
6 Can't tell

H) ANALYSES

(Q1) Indicate the unit of allocation (circle one)
community   organization/institution   practice/office   individual

(Q2) Indicate the unit of analysis (circle one)
community   organization/institution   practice/office   individual

(Q3) Are the statistical methods appropriate for the study design?
1 Yes
2 No
3 Can't tell

(Q4) Is the analysis performed by intervention allocation status (i.e. intention to treat) rather than the actual intervention received?
1 Yes
2 No
3 Can't tell

3

GLOBAL RATING

COMPONENT RATINGS
Please transcribe the information from the gray boxes on pages 1-4 onto this page. See dictionary on how to rate this section.

A	SELECTION BIAS	STRONG	MODERATE	WEAK	
		1	2	3	
B	STUDY DESIGN	STRONG	MODERATE	WEAK	
		1	2	3	
C	CONFOUNDERS	STRONG	MODERATE	WEAK	
		1	2	3	
D	BLINDING	STRONG	MODERATE	WEAK	
		1	2	3	
E	DATA COLLECTION METHOD	STRONG	MODERATE	WEAK	
		1	2	3	
F	WITHDRAWALS AND DROPOUTS	STRONG	MODERATE	WEAK	
		1	2	3	Not Applicable

GLOBAL RATING FOR THIS PAPER (circle one):

1	STRONG	(no WEAK ratings)
2	MODERATE	(one WEAK rating)
3	WEAK	(two or more WEAK ratings)

With both reviewers discussing the ratings:

Is there a discrepancy between the two reviewers with respect to the component (A-F) ratings?

No   Yes

If yes, indicate the reason for the discrepancy

1	Oversight
2	Differences in interpretation of criteria
3	Differences in interpretation of study

Final decision of both reviewers (circle one):   1   STRONG
2   MODERATE
3   WEAK

4

Appendix E - Quality appraisal

Reference	Study Design	Randomisation described	Drop-out rate (%)	Selection bias	Study design	Confounders	Blinding	Data collection method	Withdrawals and dropouts	Global rating for paper
Alsayed *et al.* (2014)	Controlled trial	n/a	n/a	Weak	Strong	Weak	Moderate	Weak	Strong	Weak
Bucknall *et al.* (2012)	RCT	Yes	11%	Weak	Strong	Strong	Weak	Weak	Weak	Weak
Efraimsson *et al.* (2008)	RCT	Yes	38%	Strong	Strong	Strong	Moderate	Strong	Strong	Strong
Farmer *et al.* (2017)	RCT	Yes	12.7%	Moderate	Strong	Strong	Moderate	Weak	Strong	Moderate
Jonsdottir *et al.* (2015)	RCT	Yes	15.9%	Moderate	Strong	Strong	Moderate	Strong	Strong	Strong

Labrecque *et al.* (2011)	Controlled trial	n/a	7.2%	Moderate	Strong	Strong	Moderate	Weak	Strong	Moderate
Mitchell *et al.* (2014)	RCT	Yes	21.7%	Moderate	Strong	Strong	Moderate	Weak	Moderate	Moderate
Monninkhof *et al.* (2003)	RCT	Yes	4.8%	Strong	Strong	Strong	Weak	Weak	Strong	Weak
Moriyama *et al.* (2015)	Controlled trial	n/a	14.2%	Moderate	Strong	Strong	Weak	Weak	Strong	Weak
Moullec *et al.* (2012)	Controlled trial	n/a	7.3%	Strong	Strong	Strong	Moderate	Strong	Strong	Strong
Ninot *et al.* (2011)	RCT	Yes	15.5%	Moderate	Strong	Strong	Moderate	Weak	Strong	Moderate

Ng & Drummond-Smith (2017)	RCT	Yes	16%	Strong	Strong	Weak	Weak	Weak	Strong	Weak
Taylor *et al.* (2012)	Pilot RCT	Yes	21.5%	Moderate	Strong	Strong	Moderate	Weak	Moderate	Moderate
Turner *et al.* (2014)	Uncontrolled trial	n/a	48.7%	Moderate	Moderate	Weak	Weak	Weak	Weak	Weak
Wood-Baker *et al.* (2012)	Controlled trial	n/a	35.8%	Moderate	Strong	Strong	Weak	Weak	Moderate	Weak

Appendix F - Research Ethics Committee Approval Letter

NHS
Health Research Authority

> Please note: This is the
> favourable opinion of the
> REC only and does not allow
> you to start your study at NHS
> sites in England until you
> receive HRA Approval

30 March 2017

Mrs Elizabeth Pike

███████████████████████

Dear Mrs Pike

Study title:	Development of a questionnaire to measure levels of self-conscious emotions in patients with COPD.
REC reference:	17/EM/0092
Protocol number:	0606
IRAS project ID:	214503

Thank you for your submission of 28 March 2017 responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter.   Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Appendix G - HRA approval letter

NHS
Health Research Authority

Mrs Elizabeth Pike

███████████████████████
███████████████████████
███████████████████████

Email: hra.approval@nhs.net

06 April 2017

Dear Mrs Pike

Letter of HRA Approval

Study title:	Development of a questionnaire to measure levels of self-conscious emotions in patients with COPD.
IRAS project ID:	214503
Protocol number:	0606
REC reference:	17/EM/0092
Sponsor	

I am pleased to confirm that HRA Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. Please read *Appendix B* carefully, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

Appendix H - Sponsor green light letter

3 May 2017

Mrs Elizabeth Pike
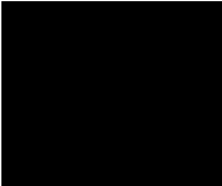
Dear Mrs Elizabeth Pike

Ref:	UOL 0606/ IRAS 214503
Title:	Development of a questionnaire to measure levels of self-conscious emotions in patients with COPD.
Status:	Approved
End Date:	31/05/2018
Site	

I am pleased to advise you that following confirmation of a Favourable Opinion from an Ethics Committee, HRA, NHS Trust R&D Approval, and where relevant regulatory authority agreements have been received, the University are able to confirm sponsorship for the above research at the above site.

Please note you are required to notify the Sponsor and provide copies of:

- Changes in personnel to the Study
- Changes to the end date
- All substantial amendments and provisional and favourable opinions
- All minor amendments
- All serious adverse events (SAEs) and SUSARS
- Annual progress reports
- Annual MHRA (DSUR) safety reports (if applicable)
- End of study declaration form
- Notifications of significant breaches of Good Clinical Practices (GCP)or Protocol

Please copy the Sponsor into all correspondence and emails by using uolsponsor@le.ac.uk.

Please note it is essential that you notify us as soon as you have recruited your first patient to the study.

I would like to wish you well with your study and if you require further information or guidance please do not hesitate to contact me.

Yours sincerely

Acting Research Governance Manager

Appendix I - Focus group Participant Information Sheet

<u>Focus Group Participant Information Sheet</u>

Study Title: Development of a questionnaire to measure levels of self-conscious emotions in patients with COPD

Chief Investigator: Liz Pike

You are being invited to volunteer to take part in a research study. Before you decide whether to take part you should fully understand why the research is being done and what it will involve. Please read the following information carefully and discuss it with your family and friends. If there is anything that is not clear or if you would like more information please contact us at the address at the end of this leaflet.

What is the purpose of this study?

The aim of this study is to develop a new questionnaire to investigate levels of self-conscious emotions, such as embarrassment, that people with Chronic Obstructive Pulmonary Disease (COPD) may experience. Other studies have shown that these emotions are associated with low self-worth and coping behaviours such as reduced help-seeking and isolation. Currently there is no questionnaire available to identify possible self-conscious emotions in people that have COPD, so it can be difficult to offer people support with these feelings. This is the first phase of this study, where information is collected from a discussion with participants with COPD to help to develop questions for the questionnaire. This study is also being carried out in partial fulfilment of the Chief Investigator's (Liz Pike) completion of a Doctorate in Clinical Psychology.

Why have I been invited?

You have been invited to take part in this study as you have a diagnosis of COPD and the service involved in your care is committed to carrying out research.

Do I have to take part?

It is your right to decide whether or not you would like to take part in this study. Your medical care will not be affected by whether you take part. You can withdraw from the study at any point by contacting the Chief Investigator using the contact details below. You do not need to give a reason to withdraw. If you were to lose the ability to consent during the study, then you would be withdrawn from the study and, depending on the stage of data analysis (as discussed below), your data may be withdrawn.

What will be involved if I do take part?

You will be asked to sign a form to say that you have agreed to take part (this is not a contract and does not mean you definitely have to take part, you can stop taking it at any point during the study). This is called 'informed consent'.

If you agree to participate in the study you will be asked to attend a focus group, which would be a group of 6-10 people with COPD and the chief investigator. This will be held at ▮ and last for up to 1 hour. There will be discussion around issues related to self-conscious emotions with COPD, for example how your symptoms make you feel in public. Your views will help us to develop questions for the questionnaire. This discussion will be audio recorded using a discrete audio recording device.

Will my taking part remain confidential?

All information collected about you as part of this study, including the audio recordings, will be kept confidential. All data will be anonymised and held on an encrypted memory stick which will be stored securely in a locked filing cabinet at the ▮. Only the Chief Investigator will have access to the passwords and data. Due to the difficulties in identifying individual participants from the audio recordings, it will not be possible to withdraw individual data. Some verbatim quotes might be used in the research write up to illustrate themes in the data, but these will be annonymised to comply with protecting participant anonymity. Annonymised data will be stored electronically for 5 years before being deleted. The study may be examined by representatives from University Hospitals of Leicester and University of Leicester, as sponsor, for auditing and monitoring purposes.

If you disclose any intention to harm yourself or others then this will need to be discussed with healthcare staff within the ▮ and may need to be shared further, but every effort will be made to discuss this with you first.

What are the potential risks and disadvantages of taking part?

Due to the sensitive nature of the discussion there is a risk that some of what is spoken about may be upsetting. If you do become upset during the study then you will be reminded of your right to withdraw at any time and offered further support.

Potential benefits of taking part in this research

By taking part in this study you have the opportunity to share some of your experiences of how living with COPD makes you feel. The information gathered from this study will help to inform healthcare professionals about the needs of people with COPD and may lead to developments or improvements in treatment options that could be made available to people with COPD.

We cannot promise that the study will directly help you, but the information we get from this study will contribute to the growing literature on COPD, and participation is greatly valued.

Will I get any payment and/or travel expenses reimbursed?

Participants will not be paid to participate in this study. However, travel expenses of up to £10 from the participants' home to the ██ and back will be reimbursed upon production of a receipt.

How long will the study last?

The focus group will run for up to 1hour. After completion of the focus group no further involvement is required from study participants.

What will happen to the results of the study?

The results of this research will be published in a scientific journal and presented at research meetings or conferences. Data will be analysed and displayed collectively. If you would like to receive a summary of the results once the project has been completed please let the Chief Investigator know.

Who has reviewed this study?

This study has been reviewed by the Chief Investigator's academic supervisors, ██ and a service user reference group.

What if I would like to make a complaint about the research?

If you want to make a complaint please contact the researcher at the end of this leaflet and the Patient Advice and Liaison Service:

██

How do I volunteer?

If you would like to take part in the study please contact the researcher by calling the number below, emailing the email address or returning the reply form in the pre-paid envelope.

What if I have more questions?

If you have any questions about the study or if you would like to request feedback of the study results, please contact:

Mrs Liz Pike

██████████
██████████
███
████████
███████

Thank you for taking the time to read this leaflet

Appendix J: Focus group consent form

Participant Identification Number:

FOCUS GROUP CONSENT FORM

<u>Title of Project:</u> Development of a questionnaire to measure levels of self-conscious emotions in patients with COPD

<u>Name of Researcher</u>: Liz Pike

Please <u>initial</u> all boxes

1. I confirm that I have read and understood the information sheet dated 20.03.17 (version 1.2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

3. I understand that the focus group will be audio recorded for analysis purposes. The audio recording will be kept electronically for 5 years and then deleted.

4. I understand that I will be unable to withdraw my data as it will not be possible to individually identify me from the recording.

5. I understand that my data will be anonymised and kept confidentially in line with research ethics guidance.

6. I understand that while the researcher will maintain confidentiality, this cannot be promised on behalf of other participants, although it will be requested.

7. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the study team, the sponsor, NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

8. I understand that if I disclose intention to harm myself or others whilst taking part in this research, confidentiality may need to be broken, however every effort will be made to discuss this with me first.

9. I agree to take part in the above study.

_____   _____   _____
Name of Participant   Date   Signature

_____   _____   _____
Name of Person   Date   Signature
taking consent

Page 1 of 1

Version 1.2 dated 20.03.2017   IRAS number: 214503   Focus group PIS Version 1.2 dated 20.03.2017
Development of a questionnaire to measure levels of self-conscious emotions in patients with COPD

<u>Interview Participant Information Sheet</u>

Study Title: Development of a questionnaire to measure levels of self-conscious emotions in patients with COPD

Chief Investigator: Liz Pike

You are being invited to volunteer to take part in a research study. Before you decide whether to take part you should fully understand why the research is being done and what it will involve. Please read the following information carefully and discuss it with your family and friends. If there is anything that is not clear or if you would like more information please contact us at the address at the end of this leaflet.

What is the purpose of this study?

The aim of this study is to develop a new questionnaire to investigate levels of self-conscious emotions, such as embarrassment, that people with Chronic Obstructive Pulmonary Disease (COPD) may experience. Other studies have shown that these emotions are associated with low self-worth and coping behaviours such as reduced help-seeking and isolation. Currently there is no questionnaire available to identify possible self-conscious emotions in people that have COPD, so it can be difficult to offer people support with these feelings. This is the first phase of this study, where information is collected from a discussion with participants with COPD to help to develop questions for the questionnaire. This study is also being carried out in partial fulfilment of the Chief Investigator's (Liz Pike) completion of a Doctorate in Clinical Psychology.

Why have I been invited?

You have been invited to take part in this study as you have a diagnosis of COPD and the service involved in your care is committed to carrying out research.

Do I have to take part?

It is your right to decide whether or not you would like to take part in this study. Your medical care will not be affected by whether you take part. You can withdraw from the study at any point by contacting the Chief Investigator using the contact details below. You do not need to give a reason to withdraw. If you were to lose the ability to consent during the study, then you would be withdrawn from the study and, depending on the stage of data analysis (as discussed below), your data may be withdrawn.

What will be involved if I do take part?

You will be asked to sign a form to say that you have agreed to take part (this is not a contract and does not mean you definitely have to take part, you can stop taking it at any point during the study). This is called 'informed consent'.

If you agree to participate in the study you will be asked to participate in an individual interview with the chief investigator. This will take place either at your home or at the █ dependent on your preference. The interview will last for up to 1 hour. There will be discussion around issues related to self-conscious emotions with COPD, for example how your symptoms make you feel in public. Your views will help us to develop questions for the questionnaire. This discussion will be audio recorded using a discrete audio recording device.

Will my taking part remain confidential?

All information collected about you as part of this study, including the audio recordings, will be kept confidential. All data will be anonymised and held on an encrypted memory stick which will be stored securely in a locked filing cabinet at the █. Only the Chief Investigator will have access to the passwords and data. It will not be possible to withdraw data once it has been collected. Some verbatim quotes might be used in the research write up to illustrate themes in the data, but these will be anonymised to comply with protecting participant anonymity. Anonymised data will be stored electronically for 5 years before being deleted. The study may be examined by representatives from █ for auditing and monitoring purposes.

If you disclose any intention to harm yourself or others then this will need to be discussed with healthcare staff within the █ and may need to be shared further, but every effort will be made to discuss this with you first.

What are the potential risks and disadvantages of taking part?

Due to the sensitive nature of the discussion there is a risk that some of what is spoken about may be upsetting. If you do become upset during the study then you will be reminded of your right to withdraw at any time and offered further support.

Potential benefits of taking part in this research

By taking part in this study you have the opportunity to share some of your experiences of how living with COPD makes you feel. The information gathered from this study will help to inform healthcare professionals about the needs of people with COPD and may lead to developments or improvements in treatment options that could be made available to people with COPD.

We cannot promise that the study will directly help you, but the information we get from this study will contribute to the growing literature on COPD, and participation is greatly valued.

Will I get any payment and/or travel expenses reimbursed?

Participants will not be paid to participate in this study. However, travel expenses of up to £10 from the participants' home to the ▉ and back will be reimbursed upon production of a receipt.

How long will the study last?

The interview will last for up to 1hour. After completion of the interview no further involvement is required from study participants.

What will happen to the results of the study?

The results of this research will be published in a scientific journal and presented at research meetings or conferences. Data will be analysed and displayed collectively. If you would like to receive a summary of the results once the project has been completed please let the Chief Investigator know.

Who has reviewed this study?

This study has been reviewed by the Chief Investigator's academic supervisors, ▉ as sponsor, ▉ Research Ethics Committee and a service user reference group.

What if I would like to make a complaint about the research?

If you want to make a complaint please contact the researcher at the end of this leaflet and the Patient Advice and Liaison Service:

▉

How do I volunteer?

As you had agreed to be approached for research within ▉, you have been contacted by telephone and the study has been explained to you and what would be required from your participation. You then agreed to participate in this study and for this information sheet to be sent out to you. However, if after reading through this information sheet you decide you do not want to take part please contact the chief investigator on the number listed below.

What if I have more questions?

If you have any questions about the study or if you would like to request feedback of the study results, please contact:

Mrs Liz Pike

▉

Thank you for taking the time to read this leaflet

Appendix L - Interview consent form

INTERVIEW CONSENT FORM

<u>Title of Project:</u> Development of a questionnaire to measure levels of self-conscious emotions in patients with COPD

<u>Name of Researcher:</u> Liz Pike

Please <u>initial</u> all boxes

1. I confirm that I have read and understood the information sheet dated 20.06.17 (version 1.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that the interview will be audio recorded for analysis purposes. The audio recording will be kept electronically for 5 years and then deleted. ☐

4. I understand that I will be unable to withdraw my data ☐

5. I understand that my data will be anonymised and kept confidentially in line with research ethics guidance. ☐

6. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the study team, the sponsor, NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

7. I understand that if I disclose intention to harm myself or others whilst taking part in this research, confidentiality may need to be broken, however every effort will be made to discuss this with me first. ☐

8. I agree to take part in the above study. ☐

_____   _____   _____
Name of Participant   Date   Signature

_____   _____   _____
Name of Person   Date   Signature
taking consent

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Appendix M - Focus group/Interview Schedule

Opening statement: Thank you for agreeing to attend this group/interview. As previously shared with you, I am a trainee psychologist and my research is aiming to develop a questionnaire that can be used for people with COPD to look at self-conscious feelings that may be coming up for them. To help me to develop the most effective questionnaire I am meeting with you to hear about your experiences and opinions. This session will last for up to 1 hour. I'm going to ask some questions around your experience of symptoms of COPD, of lifestyle choices and how you feel that COPD is viewed by others. I will also give you a questionnaire used to measure self-conscious emotions in another area of health to think about. Then we'll think about your thoughts of a questionnaire being used in COPD.

In order to analyse data I will be recording this interview today. As stated in the consent form, this information will be kept securely and will be annonymised. Please can we respect the confidentiality of comments that are brought to the group today.

Group opening questions: please say your name, when you were diagnosed with COPD and something you do to relax

Key areas & questions

- Knowledge of COPD
    - o Do you think people understand what COPD is?
    - o What have others said to you about your COPD?
    - o Do you hear COPD reported in the media?
- Effect of symptoms
    - o What symptoms do you have from your COPD that other people might notice (i.e. mucus, phlegm, sputum)?
    - o Has anyone ever made any negative comments about your symptoms?
    - o Have you ever tried to hide your symptoms or avoided going out because of them?
    - o How has this changed things at work/family life?
    - o Has having COPD changed how attractive you feel?
    - o Are there things you cannot do anymore and have had to ask for help from others?
- Previous lifestyle choices
    - o Do you think you've done anything to contribute to developing COPD?
    - o Have other people judged you about this?
    - o Do you think healthcare professionals have judged you because of this?

- COPD self-conscious emotion questionnaire
    - o If you were given a questionnaire to ask about feeling self-conscious or embarrassed about your COPD when would you want to have this?
    - o Where would you want to be given it?
    - o Would you feel able to be honest?
- The focus of this study is to understand your experiences of COPD in relation to self-conscious emotions. With this in mind is there anything else we should have talked about?
- Think back on what we've discussed today, which aspects are most important to you?

Appendix N - COPD Self-Conscious Emotion Scale (CSES)

COPD Self-Conscious Emotion Scale

This questionnaire is looking at emotions such as guilt, embarrassment and shame. The following statements are thoughts and feelings that are sometimes reported by people with COPD; you may or may not have experienced these. Please put a mark indicating how much you agree with the statement. If a statement does not apply to you, please tick 'not applicable'.

		Strongly disagree	Disagree	Agree	Strongly agree	Not applicable
1	It can be embarrassing when I need to move quickly and can't, such as getting to the toilet					
2	I am glad COPD is not visible, so I do not have to deal with people making negative judgements					
3	I have been embarrassed when I have had to be admitted to hospital because of my COPD					
4	I find it embarrassing if I become breathless in public					
5	I often look back and feel guilty about my lifestyle choices that may have contributed to COPD					
6	I have cut short or avoided visits with certain family or friends because they have made me feel bad about myself in relation to my COPD					
7	It is embarrassing having to have help with personal hygiene and self-care because of my COPD					
8	I don't often tell people about my COPD as I worry it will change the way they think about me					
9	I feel guilty when I am admitted to hospital because of the worry it gives my family and friends					
10	I blame myself for developing COPD					
11	I was diagnosed with COPD under the age of 60 and have felt that people have made negative judgements about me, such as that I am 'work shy'					
12	I have not attended healthcare appointments in the past because I was worried I would be told off for not doing as they advised					
13	I find myself avoiding certain situations where I know I may feel embarrassed because of my COPD					
14	People have made negative judgements about me because I have COPD, which has made me feel bad about myself					
15	I feel guilty that I am not able to engage in sexual activities anymore, or as often, with my partner					
16	Meal times can be embarrassing because of my symptoms, such as coughing					
17	I feel guilty about the impact of my COPD on my partner's life					
18	I find it embarrassing when I have to go out in public and use a wheelchair/oxygen tank/inhaler					
19	I feel guilty that I still smoke					
20	I have been told there is a genetic link with my COPD and I feel guilty that my children/grandchildren may develop this in the future					

Appendix O - Questionnaire Participant Information Sheet

Questionnaire Participant Information Sheet

Study Title: Development of a questionnaire to measure levels of self-conscious emotions in patients with COPD

Chief Investigator: Liz Pike

You are being invited to volunteer to take part in a research study. Before you decide whether to take part you should fully understand why the research is being done and what it will involve. Please read the following information carefully and discuss it with your family and friends. If there is anything that is not clear or if you would like more information please contact us at the address at the end of this leaflet.

What is the purpose of this study?

The aim of this study is to develop a new questionnaire to investigate levels of self-conscious emotions, such as embarrassment, that people with Chronic Obstructive Pulmonary Disease (COPD) may experience. Other studies have shown that these emotions are associated with low self-worth and coping behaviours such as reduced help-seeking and isolation. Currently there is no questionnaire available to identify self-conscious emotions in people that have COPD, so it can be difficult to offer people support with these feelings. This study is also being carried out in partial fulfilment of the Chief Investigator's (Liz Pike) completion of a Doctorate in Clinical Psychology.

Why have I been invited?

You have been invited to take part in this study as you have a diagnosis of COPD and the service involved in your care is committed to carrying out research.

Do I have to take part?

It is your right to decide whether or not you would like to take part in this study. Your medical care will not be affected by whether you take part. You can withdraw from the study at any point by contacting the Chief Investigator using the contact details below. You do not need to give a reason to withdraw.

What will be involved if I do take part?

You will be asked to sign a form to say that you have agreed to take part (this is not a contract and does not mean you definitely have to take part, you can stop taking it at any point during the study). This is called 'informed consent'. If you agree to participate in the study you will be

asked to complete some questionnaires. You will be given the self-conscious emotions questionnaire and alongside that you will also be asked to complete two other short questionnaires which look at similar issues. You will also be asked to provide some basic demographic information such as time since diagnosis, gender, age and ethnicity. The questionnaires should take approximately 15minutes to complete.

Will my taking part remain confidential?

All information collected about you as part of this study will be kept confidential. All data will be anonymised and held on an encrypted memory stick which will be stored securely in a locked filing cabinet at the █. Only the Chief Investigator will have access to the passwords and data. If you chose to withdraw whilst completing the questionnaire your data will not be used for the study and will be appropriately destroyed. Anonymised data will be stored electronically for 5 years before being deleted. The study may be examined by representatives from █ for auditing and monitoring purposes.

If you disclose any intention to harm yourself or others then this will need to be discussed with healthcare staff within the █ and may need to be shared further, but every effort will be made to discuss this with you first.

What are the potential risks and disadvantages of taking part?

As the questionnaires are asking you to respond about sensitive issues, there is a small risk that you may become upset after completing the questionnaires. If you do become upset during the study then you will be reminded of your right to withdraw at any time and advised to contact your GP for further support.

Potential benefits of taking part in this research

The information gathered from this study will help to inform healthcare professionals about the needs of people with COPD and may lead to developments or improvements in treatment options that could be made available to people with COPD.

We cannot promise that the study will directly help you, but the information we get from this study will contribute to the growing literature on COPD, and participation is greatly valued.

Will I get any payment and/or travel expenses reimbursed?

Participants will not be paid to participate in this study.

How long will the study last?

It is estimated completing the questionnaires will take no longer than 15 minutes. After completion of the questionnaires no further involvement is required from study participants.

What will happen to the results of the study?

The results of this research will be published in a scientific journal and presented at research meetings or conferences. Data will be analysed and displayed collectively, so a single person's data will not be presented. If you would like to be informed about the results of the study please let the Chief Investigator know by indicating on the 'Additional information' sheet when prompted.

Who has reviewed this study?

This study has been reviewed by the Chief Investigator's academic supervisors, ■ and a service user reference group.

What if I would like to make a complaint about the research?

If you want to make a complaint please contact the researcher at the end of this leaflet and the Patient Advice and Liaison Service:

■

How do I volunteer?

If you have been approached before your appointment in clinic you will be asked by the researcher if you would like to take part in the study. If you say yes you will be given a consent form and a questionnaire pack to complete and hand back in when you are finished.

If you have been approached via letter then please complete the consent form and questionnaire pack and post back to the researcher in the pre-paid envelope enclosed.

What if I have more questions?

If you have any questions about the study or if you would like to request feedback of the study results, please contact:

Mrs Liz Pike

Thank you for taking the time to read this leaflet

Appendix P - Questionnaire consent form

Participant Identification Number:

QUESTIONNAIRE CONSENT FORM

<u>Title of Project:</u> Development of a questionnaire to measure levels of self-conscious emotions in patients with COPD

<u>Name of Researcher:</u> Liz Pike

Please <u>initial</u> all boxes

1. I confirm that I have read and understood the information sheet dated 20.03.17 (version 1.2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

3. I understand that I will be able to withdraw my data prior to data analysis. Following data analysis all individual questionnaires will be destroyed, but the anonymised data will be stored electronically for 5 years.

4. I understand that my data will be anonymised and kept confidentially in line with research ethics guidance.

5. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the study team, the sponsor, NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

6. I understand that if I disclose intention to harm myself or others whilst taking part in this research, confidentiality may need to be broken, however every effort will be made to discuss this with me first.

7. I agree to take part in the above study.

_____   _____   _____
Name of Participant   Date   Signature

_____   _____   _____
Name of Person   Date   Signature
taking consent

Page **1** of **1**

Appendix Q - Usability questionnaire

Feedback on the usability of the questionnaire

We would appreciate if you could give some feedback on how easy you found filling out the questionnaire please.

Please rate how much you agree with the following statements.

1) It was easy to complete the questionnaire

1	2	3	4	5	6	7
Strongly disagree	Disagree	Disagree somewhat	Neither agree nor disagree	Agree somewhat	Agree	Strongly agree

2a) The statements made sense

1	2	3	4	5	6	7
Strongly disagree	Disagree	Disagree somewhat	Neither agree nor disagree	Agree somewhat	Agree	Strongly agree

2b) Which, if any, of the statements were unclear?

3a) The questionnaire took too long to fill out

1	2	3	4	5	6	7
Strongly disagree	Disagree	Disagree somewhat	Neither agree nor disagree	Agree somewhat	Agree	Strongly agree

3b) If so, how many statements would you have preferred?

4) I think this would be an acceptable questionnaire to complete routinely in clinic

1	2	3	4	5	6	7
Strongly disagree	Disagree	Disagree somewhat	Neither agree nor disagree	Agree somewhat	Agree	Strongly agree

5) Please provide any further feedback below

Appendix R - Initial Pattern & Structure Matrix for PCA with Oblimin Rotation of five factor solution of CSES items

Pattern Matrix[a]

	Component				
	1	2	3	4	5
6 cut short or avoided visits with certain family or friends because they have made me feel bad about myself	**-.655**	.186	-.012	.292	.402
10 blame myself for developing COPD	**.509**	-.060	.189	.024	.399
15 guilty that I am not able to engage in sexual activities anymore, or as often, with my partner	**.502**	.306	.239	.128	.165
5 feel guilty about my lifestyle choices that may have contributed to COPD	.434	-.012	.116	.249	.370
11 diagnosed with COPD under the age of 60 and have felt that people have made negative judgements about me	-.060	**.760**	.187	.023	-.060
14 People have made negative judgements about me because I have COPD, which has made me feel bad about myself	-.099	**.728**	-.258	-.046	.034
13 avoid certain situations where I know I may feel embarrassed because of my COPD	.264	**.637**	.104	.149	.149
4 embarrassing if I become breathless in public	.340	**.552**	-.096	.126	.150
12 not attended healthcare appointments in the past because I was worried I would be told off for not doing as they advised	-.462	**.529**	.154	-.029	.121
19 feel guilty that I still smoke	.045	-.122	**.835**	.099	-.025
20 genetic link with my COPD and I feel guilty that my children/grandchildren may develop this in the future	.022	.225	**.556**	-.157	.498

7 embarrassing having to have help with personal hygiene and self-care	-.252	-.135	-.210	**.781**	.209
3 embarrassed when I have had to be admitted to hospital because of my COPD	-.111	.171	.370	**.748**	-.213
2 glad COPD is not visible, so I do not have to deal with people making negative judgements	.216	-.149	-.019	**.647**	.150
9 feel guilty when I am admitted to hospital because of the worry it gives my family and friends	.248	.161	.219	**.624**	-.007
8 don't often tell people about my COPD as I worry it will change the way they think about me	-.186	.353	.096	**.534**	.160
1 embarrassing when I need to move quickly and can't, such as getting to the toilet	.350	.322	-.250	.503	.023
17 I feel guilty about the impact of my COPD on my partner's life	.122	-.157	-.014	.185	**.735**
16 Meal times can be embarrassing because of my symptoms	-.142	.129	.050	-.089	**.673**
18 I find it embarrassing when I have to go out in public and use an aid	.068	.219	-.176	.185	**.529**

Extraction Method: Principal Component Analysis.   Rotation Method: Oblimin with Kaiser Normalization.

a. Rotation converged in 44 iterations.

Note: major loadings for each item are bolded

Structure Matrix

	Component				
	1	2	3	4	5
10 blame myself for developing COPD	**.592**	.091	.284	.262	.481

|					
15 guilty that I am not able to engage in sexual activities anymore, or as often, with my partner	**.563**	.414	.369	.385	.416
6 cut short or avoided visits with certain family or friends because they have made me feel bad about myself	**-.555**	.430	.013	.378	.481
5 feel guilty about my lifestyle choices that may have contributed to COPD	**.544**	.186	.226	.471	**.534**
11 diagnosed with COPD under the age of 60 and have felt that people have made negative judgements about me	-.073	**.775**	.286	.220	.222
13 avoid certain situations where I know I may feel embarrassed because of my COPD	.298	**.735**	.256	.440	.472
14 People have made negative judgements about me because I have COPD, which has made me feel bad about myself	-.159	**.693**	-.162	.133	.223
4 embarrassing if I become breathless in public	.351	**.612**	.050	.390	.423
12 not attended healthcare appointments in the past because I was worried I would be told off for not doing as they advised	-.454	**.603**	.191	.097	.244
19 feel guilty that I still smoke	.157	.017	**.828**	.135	.072
20 genetic link with my COPD and I feel guilty that my children/grandchildren may develop this in the future	.117	.432	**.635**	.144	.583
7 embarrassing having to have help with personal hygiene and self-care	-.102	.137	-.167	.758	.395
9 feel guilty when I am admitted to hospital because of the worry it gives my family and friends	.375	.358	.323	.729	.342

3 embarrassed when I have had to be admitted to hospital because of my COPD	.025	.368	.422	**.728**	.152
2 glad COPD is not visible, so I do not have to deal with people making negative judgements	.355	.074	.056	.697	.369
8 don't often tell people about my COPD as I worry it will change the way they think about me	-.073	**.580**	.191	**.669**	.466
1 embarrassing when I need to move quickly and can't, such as getting to the toilet	.402	.422	-.118	**.644**	.343
17 I feel guilty about the impact of my COPD on my partner's life	.263	.140	.076	.435	**.765**
16 Meal times can be embarrassing because of my symptoms	-.063	.348	.122	.178	**.670**
18 I find it embarrassing when I have to go out in public and use an aid	.147	.424	-.060	.441	**.663**

Extraction Method: Principal Component Analysis.

Rotation Method: Oblimin with Kaiser Normalization.

Note: major loadings for each item are bolded

Appendix S - Scree Plot

Scree Plot
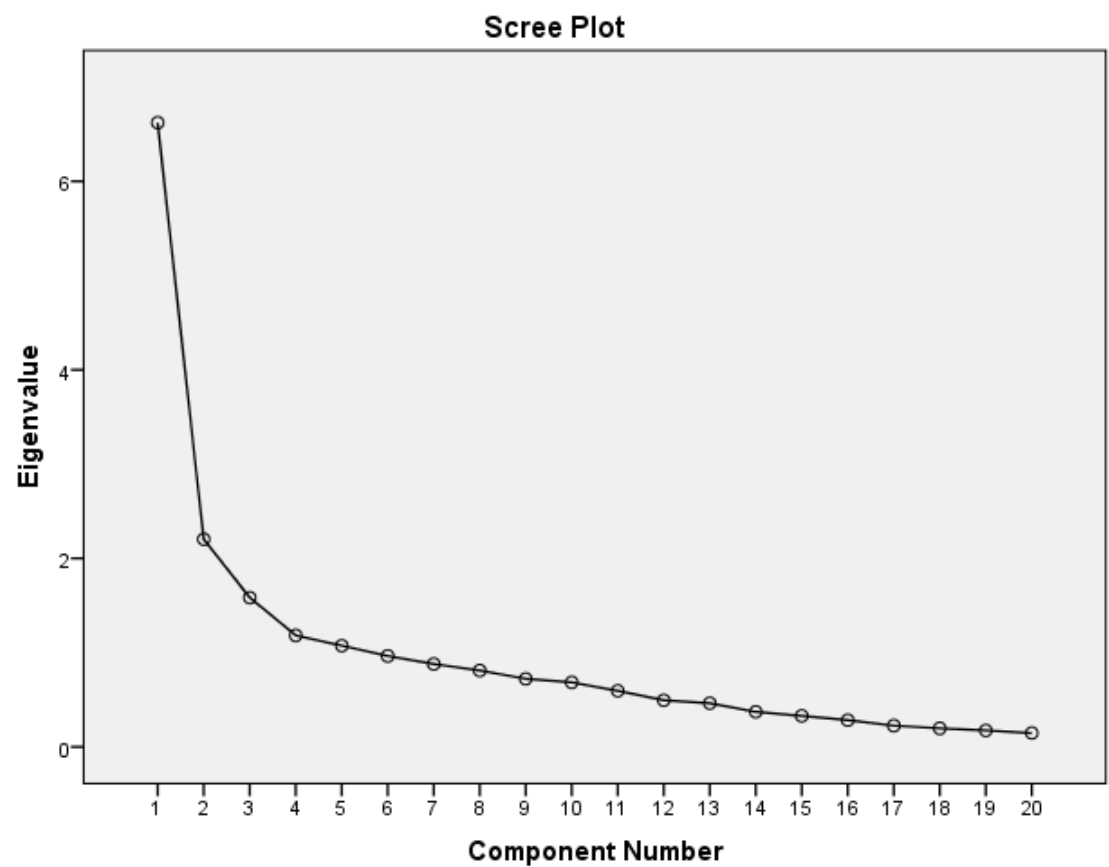
Appendix T - Pattern & Structure Matrix for PCA with Oblimin Rotation of three factor solution of CSES items

Pattern Matrix[a]

	Component		
	1	2	3
5 feel guilty about my lifestyle choices that may have contributed to COPD	**.775**	-.058	.043
9 feel guilty when I am admitted to hospital because of the worry it gives my family and friends	**.744**	.083	-.134
10 blame myself for developing COPD	**.717**	-.221	.023
15 guilty that I am not able to engage in sexual activities anymore, or as often, with my partner	**.716**	-.290	-.446
2 glad COPD is not visible, so I do not have to deal with people making negative judgements	**.675**	.296	.443
17 I feel guilty about the impact of my COPD on my partner's life	**.623**	.112	.077
1 embarrassing when I need to move quickly and can't, such as getting to the toilet	**.600**	.145	-.023
13 avoid certain situations where I know I may feel embarrassed because of my COPD	**.525**	.186	-.441
6 cut short or avoided visits with certain family or friends because they have made me feel bad about myself	-.020	**.846**	.016
8 don't often tell people about my COPD as I worry it will change the way they think about me	.439	**.644**	-.068

	-.016	**.598**	-.263
14 People have made negative judgements about me because I have COPD, which has made me feel bad about myself	-.016	**.598**	-.263
11 diagnosed with COPD under the age of 60 and have felt that people have made negative judgements about me	.152	.219	**-.715**
12 not attended healthcare appointments in the past because I was worried I would be told off for not doing as they advised	-.169	.414	**-.576**

Extraction Method: Principal Component Analysis.

Rotation Method: Oblimin with Kaiser Normalization.

a. Rotation converged in 42 iterations.

Note: major loadings for each item are bolded

Structure Matrix

	Component		
	1	2	3
9 feel guilty when I am admitted to hospital because of the worry it gives my family and friends	**.775**	.251	-.241
5 feel guilty about my lifestyle choices that may have contributed to COPD	**.759**	.074	-.035
15 guilty that I am not able to engage in sexual activities anymore, or as often, with my partner	**.716**	-.054	-.463
2 glad COPD is not visible, so I do not have to deal with people making negative judgements	**.678**	.317	.293
10 blame myself for developing COPD	**.674**	-.094	-.011
17 I feel guilty about the impact of my COPD on my partner's life	**.634**	.209	-.022

Item			
1 embarrassing when I need to move quickly and can't, such as getting to the toilet	**.630**	.261	-.128
13 avoid certain situations where I know I may feel embarrassed because of my COPD	**.612**	.386	-.546
6 cut short or avoided visits with certain family or friends because they have made me feel bad about myself	.133	**.839**	-.180
8 don't often tell people about my COPD as I worry it will change the way they think about me	**.565**	**.740**	-.270
14 People have made negative judgements about me because I have COPD, which has made me feel bad about myself	.125	**.656**	-.400
11 diagnosed with COPD under the age of 60 and have felt that people have made negative judgements about me	.277	.414	**-.784**
12 not attended healthcare appointments in the past because I was worried I would be told off for not doing as they advised	-.025	**.517**	-.653