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TITLE: Pulmonary rehabilitation: uptake and completion profile of patients with COPD.

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ABSTRACT

Background: Pulmonary rehabilitation (PR) is effective in the management of **chronic obstructive pulmonary disease** (COPD) patients. 33% of patients referred for PR do not start the programme.

Aim: To examine the relationship between participation in outpatient PR and baseline measures of disease severity and psychosocial variables in COPD patients.

Methods: In an observational study and prior to their first outpatient PR appointment, COPD patients completed outcome measures of depression (Brief Assessment Depression Card), social support (Duke Social Support Index), multidimensional health locus of control (MHLC) and COPD severity (Medical Research Council dyspnea score). Data on attendance at the PR appointments were obtained from the PR register.

Results: Fifty-one patients (mean age 77.2 year, male= 20), completed the study. Results indicate that in a patient, the presence of depression has a moderate, but statistically significant association ($p=0.02$) with the uptake of PR. There was no significant correlation between uptake status and any of the domains of MHLC, DSSI or MRC ($p>0.005$).

Conclusion: Patients with COPD and depression are less likely to take up a referral to PR compared to those without depression. None of social support, HLC and COPD severity has a relationship with the uptake or completion of outpatient PR.

KEYWORDS

COPD, respiratory rehabilitation, uptake, drop-out, exercise

INTRODUCTION

Evidence suggests that there are major factors that influence non-completion of (or drop-out from) pulmonary rehabilitation (PR) by patients with chronic obstructive pulmonary disease (COPD) (Boutou et al, 2014). There is however insufficient evidence to enable identification of the possible causes of non-uptake. The study reported here investigated **some** of the factors which correlate with participation **[uptake and completion]** in PR, by patients with COPD.

'Non-uptakers' are patients who have been referred to PR but who do not enrol in the programme (Garrod et al., 2006). A previous randomized control trial (RCT) (Sewell et al., 2006) (n=100, 56 male) asserted that a 4-week PR, requiring twice weekly attendance is effective in improving walking ability in patients with COPD ($p<0.05$) and the IMPRESS **guidelines (Williams et al, 2011)** defined 'drop-outs' as patients who, after initial assessment, failed to attend at least four weeks of twice weekly outpatient PR sessions.

Outpatient PR service can be provided as a 'cohort' PR programme or 'rolling' PR programme. Boutou et al (2014) (n=787) identified that 57.1% of patients completed PR and baseline quality of life independently predicted completion of PR ($p=0.003$). A study by Garrod et al. (2006) (n=74) indicates that, 33% of patients with COPD referred for PR, **do not start the programme, also that only 46% of patients referred complete PR.** These authors also identified four factors (quadriceps strength, smoking pack years, St George's Respiratory Questionnaire [SGRQ] score and depression) that independently discriminate between completers and non-completers. An earlier study by Singh et al. (1998) (n=267) reported that only 52% of patients referred to PR completed the programme. Young et al. (1999) (n=91) reported that only 60% of patients that attended initial PR assessment completed the programme. These authors indicated that current smokers and individuals that are socially isolated are more likely to be non-completers of PR programme.

Although various factors have been found to influence non-completion of PR, the factors which influence the uptake of PR following referral are not well understood. Consequently, the current study investigated whether the COPD disease severity and psychosocial profiles of patients with COPD influence their uptake and completion of PR.

Based on the published studies **(Williams et al., 2011;** Sewell et al, 2006) this study defined **completers** as those participants who attended at least eight sessions of PR (i.e. 50% of the 16 sessions offered).

Each of the measures of depression, social support, health locus of control and MRC COPD disease severity score are indicated to be of importance in patients with COPD. Garrod et al.

(2006) (n=74, mean age=68 year), investigated whether patient's baseline disease severity score is a predictor of significant change in walking ability following PR i.e. as a change of 54m in six-minute walk test distance (6MWD) following PR. Results indicated that baseline MRC score is not a predictor of significant change in walking ability. However, participants with MRC score 5 demonstrated a smaller degree of improvement compared to individuals with other MRC scores.

Cote et al. (2008) prospectively observed 1,379 (male=1,221) patients with COPD and identified that a 6MWD < 350m is significantly associated with mortality (r=0.93). Al-shair et al. (2009) and Spruit et al. (2010) reported depression as significant and an independent predictor of poor 6MWD performance (defined as "less than 350m" walk) in patients with COPD.

Fischer et al. (2009) (n=217, male=122) indicated that 'living alone' is not **an independent predictor of drop-out from PR (p > 0.05)**, but identified that patient's belief in the effectiveness of PR is an independent positive predictor of attendance.

While COPD disease severity, depression score, health locus of control and social support have been identified as important clinical screening tools in patients with COPD, no known prospective study has investigated a relationship between these screening tools and non-uptake of PR (i.e. patients been referred to PR, but with failure to enrol in the programme). Fischer et al. (2009) defined social support as a dichotomy of living-alone versus cohabitation and evaluated this against completion of PR but the authors definition of social support is not representative of the multidimensional nature of social support (Koenig et al., 1993).

RESEARCH QUESTION

The research **question** is stated as 'Is there a relationship between each of baseline measures of depression, social support, health locus of control or COPD disease severity and uptake of, or completion of PR?'

METHODS: SUBJECTS

Individuals who met the following inclusion criteria and were referred to the Trust PR programme were invited to participate in this study. The inclusion criteria were in line with the NICE guidelines (NICE, 2004; NICE, 2016) and were as follows.

- Clinical diagnosis of COPD based on the patient's spirometry ($FEV_1 \geq 70\%$ predicted value) as defined by European Respiratory Society (ERS, 1993; NICE, 2004).
- Dyspnoea level of Medical Research Council (MRC) scale 3 and above on referral to PR. The MRC 3 is defined as "walks slower than contemporaries on level ground or has to stop for breathing when walking at own pace" (Fletcher et al., 1959; NICE, 2004).

Individuals with the following criteria were excluded:

- Cognitive impairment which **may have compromised** informed consent being obtained, interest in the research, **or would affect their or their family members management by the Trust.**
- Critical cardiac, musculoskeletal condition or others that severely affect walking which excludes participation in PR.
- Lack of a good understanding of English (since the questionnaires employed were only available in English).

METHODS: SCREENING TOOLS

Various screening tools were reviewed for the current study with considerations of their suitability, validity, reliability, responsiveness and acceptability in the population of study. Subsequently, the screening tools indicated below were used.

- Brief assessment depression card (BASDEC) (Adshead et al., 1992) was used to score depression. Individuals with BASDEC score < 7 are defined as non-depressed. Individuals with BASDEC score ≥ 7 are defined as depressed.
- The sub-scales of the 11-item Duke social support index (DSSI) (Koenig et al., 1993) were used to score social support. These are the social support and social interaction subscales.
- The Multidimensional health locus of control (MHLC) scales B and C were used to score health locus of control. Scale B has domains of internal, external and powerful others. Scale C has domains of internal, external, doctors and others (Wallston & Wallston, 1981).
- The Medical research council (MRC) scale (Fletcher et al., 1959) was used to score COPD severity.

Further, the data on attendance of patients at the outpatient PR assessment and PR sessions were obtained from the PR outpatient attendance register of the trust. This was in order assess non-uptake and drop-out.

METHOD: STUDY SETTING, RECRUITMENT AND MANAGEMENT OF BIAS

The study setting was the PR unit of the Whittington Health NHS Trust (formerly Haringey Teaching PCT). Each outpatient PR session lasted 2 hours. The routine PR session involved 1 hour of exercises which included walking exercise, leg, arm and trunk exercises (including strengthening and endurance exercises). In addition to the exercise component, each routine PR session involved a one hour self-management class. In compliance with the IMPRESS guidelines (Williams et al., 2011) and NICE guidelines (2004; 2016), the PR programme consisted of two supervised outpatient PR sessions each week for 8 weeks and participants were also advised to do one self-directed exercise session at home each week. It was advised that the self-directed exercise session at home should last for 15 to 30 minutes and patients should do exercises similar to the ones that they did at the outpatient PR sessions. Two PR staff (a nurse and a physiotherapist) were present and supervised every exercise session and staff: patient ratio at each exercise session was consistently below 1:8. In compliance with the British Thoracic Society (BTS) standards (Bolton et al, 2013), the PR education sessions were combinations of talks on managing breathlessness, breathing retraining, managing exacerbation, energy conservation techniques, importance of exercise in COPD, chest clearance techniques, medications, inhaler techniques and information on the Breathe Easy arm of the British Lung Foundation (BLF).

The NHS ethics approval for the study was obtained in July 2008 from the Barnet, Enfield & Haringey Research Ethics Committee (reference 08/H0723/55). Participants were recruited over a year (September 2008 to September 2009) covering four cycles of referrals and four PR cycles in order to accommodate for any seasonal effect.

Patients with COPD who were on the PR waiting list of the Trust were informed of the study by the hospital staff when first contacted for their first PR appointment. Details of patients who indicated that they were interested in the study were given to the principal researcher. An information sheet and a consent form for the study were posted to each patient. The principal researcher contacted patients by telephone to discuss the study and respond to any questions. A home visit was arranged prior to the initial outpatient PR appointment. Following signed consent, each participant completed screenings for the following

- depression using BASDEC
- level of social support using DSSI
- Health Locus of Control using MHLC

- COPD disease severity using MRC score.

Each assessment lasted about 35 minutes. Data on subsequent attendance or non-attendance at the initial PR assessment and classes was taken from the hospital's PR attendance record.

Various steps were taken to prevent and manage bias. No additional contact was made with the patients between the home assessment and the first PR session. This was to ensure that there was no motivation, towards uptake or otherwise, from additional contact with the principal researcher. No participant was informed that attendance at the PR initial assessment or completion of PR programme were measures of interest to the researcher. The depression screenings were carried out in the same half of the day (between 12 noon and 4pm), to enhance the reliability of the data collected, since there are indications that this accounts for diurnal variation which may affect manifestations of depressive symptoms (Bhagwagar, Hafizi & Cowen, 2005).

METHODS: DATA ANALYSIS

The SPSS programme version 21 was used for analysis of data in this study.

The relationships between the independent variables which were ordinal and non-dichotomous (scores of disease severity, 2 domains of social support, 3 domains of MHLC scale B, 4 domains of MHLC scale) and the participants' uptake status or PR completion status were evaluated using the Spearman Rho correlation. The relationships between the only dichotomous independent variable (depression i.e. depressed versus non-depressed) and the participants' uptake status or PR completion status were evaluated using the Chi-square analysis (Altman, 1991; Myers & Well, 2003). Association scores range from 0 to 1. Scores above 0.5-1 represent a strong association, scores between 0.3-0.5 a moderate, scores between 0.3-0.1 a weak association. Scores of <0.1 represent little if any association (Crewson, 2014).

When more than one statistical test is conducted, the chance of type 1 error increases in the multiples of the number of tests (McLaughlin & Sainani, 2014). It was important to evaluate the possible impacts of multiple testing since this research involved the use of multiple variables (Altman, 1991). Due to unequal group size [participants with depression (n=21) versus participants with no depression (n=30)], a Bonferroni correction was employed in preference to Holm's step-down and Hochberg's step-up correction (McLaughlin & Sainani, 2014).

Ten variables were used in the Spearman Rho correlation (Table 2); Bonferroni correction was applied, hence p was set at 0.005 (Mundfrom et al., 2006). Chi-square 2x2 analysis was conducted for the only independent dichotomous variable (depression status); p was set at 0.05.

RESULTS

One hundred and fifty three patients were referred to the Trust during the recruitment period. Fifty-two volunteered, one withdrew consent to participate at the point of data collection. Fifty-one participants (mean age 77.2 year, male= 20) completed the study.

Twenty-two of the 51 participants (43.1%) who were referred to PR did not uptake. Based on the criteria employed in this study, 15 of the 29 patients who commenced (51.7%) PR dropped out. Only 14 of the 51 patients referred (27.4%) completed their PR programme (Figure 1).

Figure 1 here - Flow chart and participation profile of patients in the study indicating the association between depression and uptake of PR.

Analysis of data demonstrated that there was a statistically significant moderate and inverse association between depression status and PR uptake (Phi 0.32, n=51, p=0.02, 2- tailed).

Analysis of the cell frequencies indicated that 70% (21 out of 30) of the patients who were not depressed did uptake PR, while only 38% (8 out of 21) of the patients who were depressed did uptake PR (odds ratio=3.11, 95% confidence interval = 0.97 to 9.97) (Table 1).

Analysis of the data demonstrated that there was no statistically significant association between depression status and PR completion (n=29, p=0.54, 2- tailed). Analysis of the cell frequencies indicated that 52.4% (11 out of 21) of the non-depressed patients who commenced PR did complete the programme. while 37.5% (3 out of 8) of the patients with COPD and depressive symptoms who commenced PR did complete the programme (Table 1).

Table 1 here: Table considering the relations between depression and each of PR uptake and PR completion

There was no significant correlation between uptake status and any of the HLC, DSSI interaction, DSSI social support or MRC domains (based on statistical significance alpha <0.005, 2-tailed). Also, there were no significant correlation between drop-out and any of the HLC, DSSI interaction, DSSI social support or MRC domains (based on statistical significance alpha <0.005, 2- tailed) (Table 2). Since none of the variables in the correlation analysis demonstrated significant relationship with uptake or drop-out, it was not appropriate to conduct a regression analysis.

Table 2: Spearman Rho Correlations of PR uptake and PR completion versus psychosocial and disease variables.

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DISCUSSION

Evidence from our study indicates a moderate and negative statistically significant association between depression status and uptake of PR. High depression levels are associated with non-uptake of PR referral. The square of the Phi value is 0.10 which suggests that the data explains the relationship in about 10% of the study population. Though the result is statistically significant, 90% of this relationship is not explained by the analysis of this study. Patients with COPD who were not depressed were twice as likely to uptake PR compared with those who were depressed. The current study did not find a significant association between drop-out from PR and depression. A non-randomised study by Tselebis et al. (2013) (n=101, male=80) indicates that participation in PR results in benefits of improvement in anxiety and depression ($p < 0.05$). Therefore, it may be that the relationship between **drop-out** and the baseline depression status in our study was insignificant since participants may have benefited by relief of depression symptoms **during** the PR. Further, the data from this study did not demonstrate a significant correlation between participation in PR (uptake and drop-out) and any of MRC disease severity, HLC domains or DSSI social support domains.

Our study categorised participant's COPD severity according to the MRC dyspnoea scale. Lung function tests are of diagnostic relevance; however, the GOLD Committee stated that specific spirometry severity cut points are "for the purposes of simplicity and have not being clinically validated" (GOLD, 2010, p. 3). Joo, Au, Fitzgibbon, McKell and Lee (2011) demonstrated clinician bias in favour of conducting spirometry in patients with symptoms of exertional dyspnea and chronic cough rather than patients with current or past history of smoking and that diagnosis based on spirometry was accurate only in 50.9% of cases. Paladini, Hodder, Cecchini, Bellia and Incalzi (2010) (n=200, 146 male, MRC disease severity domains [53 with MRC 2/3, 74 with MRC 4/5]) established the reliability of the MRC dyspnea score as a surrogate marker of COPD severity. However, their study was limited in generalisability due to underrepresentation of females.

The proportion of patients with COPD in our study who manifested symptoms of depression is close to that in the study by Yohannes, Connolly and Baldwie (2000); 41.18% and 42% respectively. Furthermore, the Trust PR programme conforms to the standards of PR programme (Bolton et al, 2013; Williams et al., 2011; NICE, 2004; NICE, 2016). These facts suggest that the findings of this study may be generalisable.

The single visit by the principal researcher to the participants at home and the assessment conducted may still have influenced their behaviour and responses. However, effort was made

to minimise the effect of **such a visit** by making sure the number of visits/contacts was the same for all participants. The 51 patients who volunteered for the study may not be representative of the entire 153 patients with COPD who were referred to the Trust during the period of the study. They may be the more strongly motivated members of the population. It is not possible to know the PR participation profile of non-participating patients since the ethical approval granted for the study only allowed data collection from consenting participants.

Respondents in a patient survey are more likely to be those who are married, employed, have higher education and a greater usage of healthcare services than non-respondents (Etter and Perneger, 1997; Rupp et al, 2002; Shahar et al., 1996). Thus, the result in our study may be biased towards patients in the categories identified by previous studies. Also, due to the small sample (n= 51), the result may be tentative.

Jacobson et al. (2013) indicated that gender, socioeconomic status and frequency of the use of COPD-specific medication were associated with enrolment into PR. This report is interesting considering that our study did not find a significant correlation between COPD disease severity and uptake of PR. The study by Jacobson et al. (2013) (n=3592) **was larger than** our study (n=51). However our study was a prospective study of patients referred to PR while the study by Jacobson et al. (2013) was a retrospective analysis of data from National COPD Patient Register. Also, Jacobson et al. (2013) investigated the differences in socio-demographic and medical characteristics of the two groups (i.e. patients with COPD who enrolled and completed PR versus those who did **not), but** no direct assessment of participants' mood and depression status was conducted. Therefore, while there was some overlap between the two studies, they did not essentially investigate the same thing.

Hayton et al. (2013) (n=711), indicated that social support is an independent predictor of drop-out from PR; but not of commencement of PR. Hayton et al. (2013) reported an inverse relationship between participants' COPD severity and completion of PR (p<0.05). Further, Hayton et al. (2013) identified depression as an independent predictor (p<0.05) of drop-out from PR. The differences between the study by Hayton et al. (2013) and our study could be because our study was a prospective study while that by Hayton et al. (2013) was a retrospective study. Also Hayton et al. (2013) evaluated social support in their study as a **dichotomy** of living alone versus not living alone, whereas our study evaluated social support as a multidimensional scale which included social support and social interaction. Hayton et al. (2013) used participants' spirometry (FeV₁) as a measure of disease severity while our study used MRC score. Hayton et al. (2013) used the HADS score as measure of depressive symptoms while our study used the BASDEC score.

The findings of non-significant correlation between completion of PR and social support in our study is in agreement with the findings by Fischer et al. (2009) (n=217, drop-out = 23%). These authors indicated that living alone had no significant association with completion of PR. While our study was conducted with a PR protocol of 8 weeks of twice weekly sessions, the study by Fischer et al. (2009) combined PR programmes that vary largely in protocol; some thrice weekly and some five times weekly outpatient PR sessions. While the protocol of our study involved a home visit to each participant, the study by Fischer et al. (2009) involved sending questionnaires to the participants at home prior to commencement of PR and only the questionnaires that were returned were analysed. While our study did not find significant correlation between participation in PR and participants' health locus of control, Fischer et al. (2009) reported that patient's belief in the effectiveness of PR was an independent positive predictor of attendance.

Our study is the first prospective quantitative investigation of drop-out in PR within the protocol of eight sessions of twice weekly attendance as advanced by guidelines (NICE, 2004; Williams et al., 2011). Also, it is the only prospective study to investigate factors that affect uptake of PR in patients with COPD.

A systematic review (Keating et al., 2011) identified 11 studies that investigated attendance and drop-out from PR in patients with COPD.; 5 based on a qualitative design (Arnold, Bruton & Ellis-Hill, 2006; Fischer et al, 2007; Fischer et al, 2009; Harris, Hayter & Allender, 2008; Taylor et al, 2007) and 6 based on a quantitative design (Fan et al, 2008; Garrod et al, 2006; O'Shea et al, 2007; Sabit et al, 2008; Steele et al, 2008; Young et al, 1999). The qualitative studies adopted different definitions of 'drop-out' (which varied between attendance of seven and sixteen PR sessions), probably since these studies were conducted before the guidelines by IMPRESS was produced.

The definition of completers as patients that attended 16 (Steele et al., 2010), 10 (Fan et al., 2008; Garrod et al., 2006) or 7 (Young et al., 1999) PR sessions is not consistent with the PR guidelines and the evidence that 8 PR sessions were required to achieve improvement in walking ability in patients with COPD (Sewell et al., 2006; Williams et al., 2011). This suggests that participants were required to attend less than or in excess of the number of PR sessions recommended by guidelines. Moreover all participants in the study by Young et al. (1999) were 50 years and above and had a history of at least twenty smoking pack years. 140 of the 146 participants in the study by Steele et al. (2008) were male which limits the application of its

finding to female patients with COPD. In the study by O'Shea et al, (2007), only one of the three sessions each week was an outpatient supervised session while the other two were self-supervised. This is not in line with guidelines (NICE, 2004; Williams et al., 2011) which recommend that patients with COPD should participate in two supervised PR sessions each week. The study by Sabit et al., (2007) was a retrospective analysis of attendance at PR and did not evaluate depression as a research variable.

The finding of significant association between depression and non-uptake of PR in the current study is not an indication that depression is the cause of non-uptake of PR. However, it does support the co-existence of depression and respiratory conditions as seen in the literature and highlight the impact. Previous prospective studies indicated a significant positive correlation between depression score and disease symptoms as well as between depression score and frequency of admission ($p < 0.05$) (Ng et al, 2007) (n=376 COPD patients); between depression score and the number of breathlessness attacks at rest and between depression score and reported wheezing ($p < 0.05$) (Janson et al., 1994) (n=715 asthma patients). Furthermore, large studies (Al-shair et al., 2009; Spruit et al., 2010) reported depression as a predictor of poor 6MWD performance in patients with COPD ($p < 0.05$). Since depression is a risk factor for some other baseline factors or phenomenon like hospital admission and breathlessness attacks, low exercise performance, non-uptake or drop-out in PR by patients with COPD may have been the direct result of some of these other factors. It was not the aim of our study to investigate the cause and effect relationship between the screening tests and uptake of PR or between the screening tests and completion of PR. Investigating cause and effect relationships between depression and participation in PR may require randomising a number of patients with COPD into two arms, seeking to introduce depressive symptoms into one arm while participants in the other arm would not have depressive symptoms. It was considered that such a study was not ethically viable.

The current study demonstrates that patients with depression are less likely to take up their PR referral. Previous studies by Garrod et al. (2006) (n=74), Al-shair et al. (2009) (n=122) and Spruit et al. (2010) (n=1795) established that depression was a significant and independent risk factor for drop-out and poor exercise performance in patients with COPD. Therefore, patients with COPD and depression are less likely to derive benefit from their PR programme and there is a need to assess their depression status and manage the depression before referral to PR or simultaneously with the referral.

CONCLUSION

The current study demonstrates that there is a significant moderate and negative association between the uptake of outpatient PR and patient baseline measures of depression status. The study did not find significant correlation between the uptake of outpatient PR and any of social support, HLC and COPD severity.

The current study did not find a significant association between drop-out from PR and depression. Also, the study did not find a significant correlation between drop-out from outpatient PR and each of social support, HLC and COPD severity. Though, the lack of significant relationship between drop-out and the baseline depression status observed may be because participants already benefited by relief of depression symptoms during PR.

The findings from our study add to the existing body of knowledge on how a patient's baseline psychosocial or disease factors may influence participation in PR programme. Currently, assessment for depression is carried out at the first PR outpatient appointment. The findings of the **current study suggest** that a brief assessment for depression at the point of referral to PR may be beneficial. The outcome of the depression assessment by the person doing the referral may indicate whether depression management is required to increase the chances of participation in PR by the patients being referred. This is an important point to have demonstrated because the probability that a patient with COPD would attend the initial PR assessment is significantly reduced by the presence of depression.

CONFLICTS OF INTEREST: The authors have no conflict of interest to declare.

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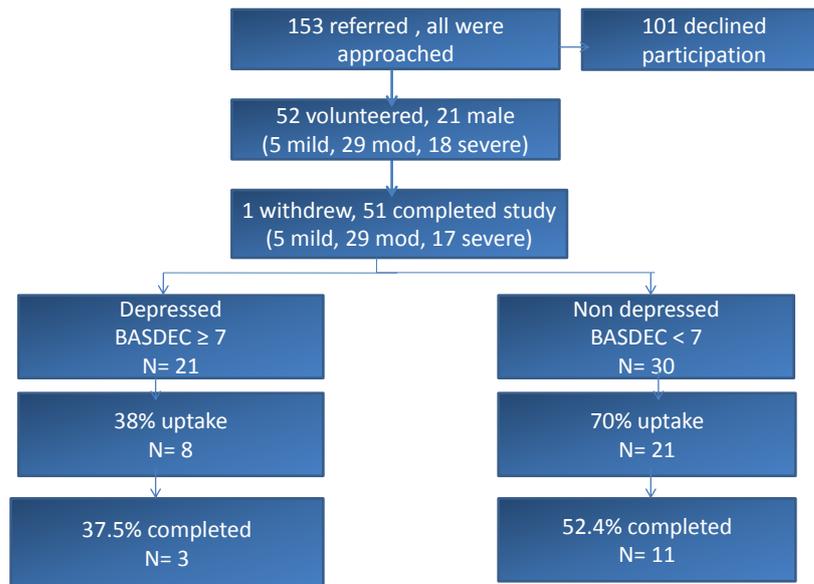


Figure 1: Flow chart and participation profile of patients in the study indicating the association between depression and uptake of PR.

	Participants who were referred and uptake Pulmonary Rehabilitation	Participants who were referred but who did not uptake Pulmonary Rehabilitation	Participants who uptake and completed Pulmonary Rehabilitation	Participants who uptake but did not complete Pulmonary Rehabilitation
Non depressed	70%	30%	52.4%	47.6%
Depressed	38%	62%	37.5%	62..5%

Table 1: Table considering the relations between depression and each of PR uptake and PR completion

Baseline variables	Correlation Coefficient with PR uptake (N=51)	Sig. (2-tailed at 0.005 level) with PR uptake	Correlation Coefficient with PR completion (N=29)	Sig. (2-tailed at 0.005 level) with PR completion
COPD severity	0.273	0.052	0.096	0.614
Social interaction	-0.206	0.146	-0.028	0.884
Social support	-0.123	0.392	-0.299	0.108
MHLC internal B	-0.062	0.665	-0.124	0.513
MHLC Chance B	0.182	0.202	0.085	0.655
MHLC Powerful Others B	0.139	0.331	-0.116	0.541
MHLC Internal C	0.042	0.771	-0.220	0.242
MHLC Chance C	0.043	0.764	0.031	0.871
MHLC Doctors C	-0.041	0.777	-0.160	0.400
MHLC Other C	-0.026	0.858	0.093	0.625

Table 2: Spearman Rho Correlations of PR uptake and PR completion versus psychosocial and disease variables.

* Relationships which are statistically significant