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Does additional support by nurses enhance the effect of a brief smoking cessation intervention in people with moderate to severe chronic obstructive pulmonary disease? A randomised controlled trial

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Abstract

Background: Smoking cessation is the primary disease modifying intervention for chronic obstructive pulmonary disease (COPD).
Setting: A Regional Respiratory Centre (RRC) out-patient department in Northern Ireland.
Methods: A randomised controlled trial (RCT) evaluated the effectiveness of brief advice alone or accompanied by individual nurse support or group support facilitated by nurses. Smoking status was biochemically validated and stage of change, nicotine addiction and dyspnoea were recorded at 2, 3, 6, 9 and 12 months.
Participants: Ninety-one cigarette smokers with COPD were enrolled in the study (mean age 61years, 47 female).
Results: After 12 months cessation rates were not significantly different between groups ($p = 0.7$), but all groups had a significant reduction in their nicotine addiction ($p = 0.03$–0.006). No changes in subjects' motivation or dyspnoea were detected over the 12 months.
Conclusion: Patients with COPD were unable to stop smoking regardless of the type of support they received. Harm reduction may be a more appropriate goal than complete cessation for intractable smokers and nurses must evaluate their role in this arena.

Keywords: Chronic obstructive pulmonary disease; Nursing interventions; Randomised controlled trial; Secondary care; Smoking cessation

What is already known on this topic?

- Smoking cessation is the only disease modifying intervention available for individuals with chronic obstructive pulmonary disease.

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- There is a dearth of evidence evaluating nursing interventions for smokers with COPD.
- As the largest group of healthcare providers, nurses have an important role to play in smoking cessation.

What this paper adds

- Harm reduction may be a more appropriate outcome for recalcitrant smokers.
- Nurses need to develop and test specific interventions with respiratory populations.

0. Introduction

The World Health Organisation predicts by 2020 chronic obstructive pulmonary disease (COPD) will be the 5th most prevalent disease worldwide (Murray and Lopez, 1996). Susceptible smokers experience dyspnoea and frequent chest infections (Brooker, 2005). Health professionals should encourage smoking cessation as the primary management of COPD (BTS, 1997; GOLD, 2003) because it is the only intervention that can slow the disease trajectory (Anthonisen et al., 1994; Doll et al., 1994; Fletcher and Peto, 1977; NICE, 2004; Pauwels et al., 2001).

1. Background

The Health Education Authority guidelines recommend a series of interventions to help smokers stop smoking (Raw et al., 1998). Brief advice (10 min) given by a physician increases smoking cessation by 3% (Raw et al., 1998). Similar results have been found in systematic reviews of primary and secondary care (Lancaster and Stead, 2004). The use of nicotine replacement therapy (NRT) doubles cessation rates from 10% to 20% in intensive settings (Raw et al., 1998). A systematic review concluded that individual and group support were equally effective in a variety of populations and settings (Lancaster and Stead, 2005; Stead and Lancaster, 2005). The role of nursing in smoking cessation is less clearly defined (Jonsdottir et al., 2004), but studies suggest cessation rates range from 5% to 29% in general populations (Canga et al., 2000, Hollis et al., 1993; Quist-Poulsen and Gallefoss, 2003; Tonnesen et al., 1996). There are only five studies that meet the requirements of systematic review evaluating smoking cessation interventions for COPD (van der Meer et al., 2001, updated in 2003). Cessation rates range from 7% to 20%, but subjects often had mild disease and wanted to stop smoking. This provides little insight into interventions that may help smokers with COPD requiring secondary care to stop smoking, as their disease is typically more severe and smoking habit more entrenched.

The current study was undertaken to gain an insight into the nurse's role in changing the smoking behaviour of adults with COPD requiring secondary care. The primary outcome measure was complete cessation confirmed by biochemical validation over 12 months. The aim of this study was to test the hypothesis that intensive nursing interventions (individual or group support) would increase cessation rates at twelve months compared to usual care consisting of brief advice. The Theory of Planned Behaviour (Ajzen, 1991; Ajzen, 1985) was used as the conceptual framework for the study. Attitudes towards smoking, subjective norms and perceived behavioural control were conceptualised to be directly related to intention to quit smoking (Bursey and Craig, 2000).

2. Methods

2.1. Design and setting

To determine the effectiveness of the interventions a randomised controlled trial (RCT) was performed at Northern Ireland's Regional Respiratory Centre (RRC), which is an out-patient facility. All eligible and consenting patients ($n = 91$) in the study had baseline assessment data collected. After the patients received brief advice to stop smoking from a physician, the researcher opened a sequentially sealed envelope which placed patients into one of three treatment groups. Patients in the Usual Care group (UC, $n = 35$) did not receive further intervention (control group). Patients allocated to Individual Support (IS, $n = 27$) and Group Support (GS, $n = 29$) were offered 5 weeks of further intervention. Follow-up visits were scheduled for all patients at 2, 3, 6, 9 and 12 months where smoking status was biochemically validated.

2.2. Sample

Patients were included in the study if they were self-reported cigarette smokers attending the RRC with a diagnosis of COPD. They were excluded if they had any alcohol/drug related problems, contra-indications to nicotine replacement therapy or they stated they had no intention to stop smoking. Subjects included in the study were allocated to one of three treatment groups by a computer-generated list of random numbers. All study personnel were blind to the randomisation sequence.

2.3. Power analysis and sample size

Brief advice was not expected to help this long-term, heavily addicted population to stop smoking. It was

anticipated that a new treatment, e.g. individual or group support would increase cessation by 13% (Anthonisen et al., 1994). A power calculation estimated that 101 patients per group were required (significance 0.05, power 0.8), therefore 303 patients were required (Dupont and Plummer, 2003).

2.3.1. Interventions

Individual support (IS) and group support (GS) were delivered by experienced respiratory nurses who had approximately 6 h of standardised training from a Health Promotion Officer and Pharmacist. The doctors giving brief advice received standardised training at each medical rotation.

Standardised intervention: All patients received brief medical advice to stop smoking (5–10 min) in accordance with the Health Education Authority smoking cessation guidelines (Raw et al., 1998). This included assessing patients' interest in stopping smoking based on their Stage of Change (Prochaska and DiClemente, 1988), advising on the personal benefits of cessation and discussing the potential benefits of NRT. Patients were encouraged to set a date to stop and to enlist the support of family and friends. Education material consisted of the leaflet "Stopping Smoking Made Easier" (Raw, 1998) was provided as recommended in the guidelines (Raw et al., 1998).

Intensive interventions: Stage of change (Prochaska and DiClemente, 1988) was used to categorise motivation and assist nurses to stage-match interventions for each patient. In addition Stage of Change (Prochaska and DiClemente, 1988) was also used as a secondary outcome measure for the study. Interventions were informed by the Theory of Planned Behaviour (TPB) (Ajzen, 1991; Droomers et al., 2004; Puffer and Rashidian, 2004). This included discussing the positive and negative aspects of smoking, particularly on their health (attitudes). Subjects were encouraged to discuss the social desirability to stop (or continue) smoking and the impact this had on their behaviour (subjective norms). Subjects were asked to recall previous attempts to stop smoking and identify factors that contributed to relapse. They then planned how they would address similar situations in the future to increase their confidence about future attempts (self-efficacy).

The interventions were performed by nurses, so that if effective they could be implemented as part of the hospital protocol. Both interventions consisted of five (maximum 60 min) weekly sessions with carbon monoxide measurements performed at each visit. They were designed to be flexible in order to tailor information and make it personally relevant to the smoker's need (Kreuter et al., 1999). The nurses offered help to patients regarding their smoking habit in a caring and dignified way (Benner and Wrubel, 1989; Miller and Rollick, 2002). The interventions were developed from an extensive review of the research literature and adapted to the needs of the study population. The content and format of both interventions are outlined in Fig. 1.

During the 2nd week patients in either intervention (IS and GS) who wanted to make an immediate attempt to stop smoking were offered NRT. This was considered an adjunct to the interventions, as free NRT was recommended in the guidelines (Raw et al., 1998), but was not available on NHS prescription at the commencement of the study. The study is not a NRT evaluation study, as this was not considered a compulsory part of the interventions. Each NRT patch administered 16 h of nicotine (8 weeks 15 mg, 2 weeks 10 mg and 2 weeks 5 mg).

2.4. Measures

All measures were collected at 2, 3, 6, 9 and 12 months. Abstinence from smoking was the primary outcome measure and was defined as: (a) self-report of complete cessation (CC) at all follow-up visits, confirmed by biochemical validation or (b) self-report of intermittent cessation (IC) at any follow-up visit confirmed by biochemical validation. Two biochemical measures were used at each visit. Carbon monoxide (CO) was measured using the piCO Smokerlyzer, (Bedfont Scientific Limited, 1998; Clark et al., 1998). The cut-off value of $\leqslant$10 parts per million was used to identify non-smokers (Humerfelt et al., 1998; Paoletti et al., 1996; Tashkin et al., 2001; Waage et al., 1992). Salivary cotinine was measured using the SDS Omni-Sal® collector. A cut-off of $\leqslant$10ng/ml was used to identify non-smokers (Abrams et al., 1987; Cozart Bioscience Limited, 2000). Patients lost to follow-up were documented as smokers (Sackett et al., 2000).

The secondary measures are as follows. Stages of change was categorised by asking two questions about patients smoking status and their timetable for stopping (Prochaska and DiClemente, 1988). The five categories ranged from precontemplation (those who did not want to stop smoking), contemplation (thinking about stopping), preparation, action and an ex-smoker for over 6 months. Nicotine addiction was recorded using the Heaviness of Smoking Index (HSI) (Heatherton et al., 1989). The researcher asked each patient two questions and scored the HSI as 0–2 for "very low," and scores of 3, 4, 5 and 6 are "low," "moderate", "high" and "very high" nicotine addiction, respectively (Fagerstrom et al., 1991). Patients' perceived dyspnoea was assessed at each visit using the MRC Dyspnoea Scale (1966). Patients were asked to choose one of the five statements, these were ranked one (least severe) to five (severe breathlessness). Patients' disease was classified in accordance with the NICE Guidelines (2004).

Key components of the nursing interventions		
	Individual Support (IS)	**Group Support (GS)**
Setting	Regional Respiratory Centre	Regional Respiratory Centre
Duration	Five weekly hour long sessions	Five weekly hour long sessions
Flexibility	Mutually suitable day and time	Predetermined day and time
Health professionals involved	Researcher, chest clinic Sister and Respiratory Nurse Specialist, allocated patients chronologically	Researcher and Respiratory Nurse Specialist
Structure	One to one sessions between patient and nurse	Group of patients and two nurses
Key components	Based on readiness and intention to change behaviour. Benefits, structure and content of intervention explained. Patient centred approach, motivational interviewing. Review of smoking history and current habit. Education concerning smoking behaviour, COPD, composition of a cigarette, addictive properties, perceived advantages and disadvantages of smoking, health benefits of smoking cessation, techniques to stop smoking, withdrawal and relapse prevention, quit tips, relaxation techniques, healthy eating, benefits of NRT. 12 week course of NRT (patches) for patients wanting to stop smoking. Weekly carbon monoxide testing.	

Fig. 1. Key components of the nursing interventions.

2.5. Ethical considerations

The study was approved by the University Research Ethics Committee as part of the researcher's doctorate. Each patient gave informed written consent at the beginning of the study and continued verbal consent at each data collection point.

2.6. Data analysis

Pillai's criterion was selected to confirm homogeneity of the treatment groups at baseline (Tabachnick and Fidell, 2001). Mean and SD were calculated for most parameters. Prior to analysis, patients' age, FEV_1 (lung function), nicotine addiction and stage of change at visit 1 were selected as covariates (Rice and Stead 2004; Rigotti et al., 2002; Tonnesen et al., 1996), as small non-statistically significant differences between groups could be clinically important. A one-way between groups analysis of covariance (ANCOVA), compared the effectiveness of the interventions on patients' smoking habits and cigarette consumption. Due to the levels of attrition throughout the study as demonstrated in Fig. 2, repeated measures ANOVA were not performed. Statistical Package for Social Sciences Inc. (2004) version 11.0 was used and a p-value of $\leqslant 0.05$ was considered statistically significant. Intention-to-treat was applied.

3. Results

The scheme for patient recruitment and randomisation is shown in Fig. 2. A total of 516 patients with COPD were identified. From these, a number of subjects were excluded because they failed to meet the inclusion criteria ($n = 80$). Others were excluded because they were ex-smokers ($n = 284$) or they refused to participate in the study ($n = 61$). Patients refused because they did not want to stop smoking or did not want to commit to the follow-up schedule.

A total of 91 patients participated in the study (44 male and 47 female) with an age range of 38–80 years. Many were retired (50%, 55%) or registered long-term sick (29%, 32%) and 18 (20%) reported taking prescribed anti-depressants at baseline. As classified by the NICE Guidelines (2004), 48 (53%) had mild disease, 31 (34%) had moderate disease and 12 (13%) had severe disease. Many patients (38%, 42%) stated they lived with another smoker at baseline. The sample consisted of long-term heavy smokers as demonstrated in Table 1.

Smoking cessation: At 1 year none of the patients in any of the treatment groups achieved complete cessation (CC), as verified by self-report, carbon monoxide and salivary cotinine. Two patients (6%) in the UC group and 3 patients (10%) in the GS group achieved intermittent cessation (IC) ($p = 0.7$, ns).

Smoking habit: No significant differences were detected between the intervention groups and aspects of the patients' smoking habit or motivation over 12 months (Table 2). When pre and post-treatment values were compared within groups using Paired-Samples *t*-tests, all groups had a significant reduction in nicotine addiction (HSI) over 12 months (UC and GS $p = 0.006$, IS $p = 0.03$).

Comparisons of dyspnoea: No significant differences between the intervention groups and patients' perceived dyspnoea or lung function were detected over 12 months (Table 2).

Attendance to the nursing interventions was poor in both groups (Fig. 2). Only 10 patients (37%) in the IS group and 7 patients (24%) in the GS group attended at least 3 weeks of the 5-week intervention. Only 16 (59%) patients in the IS group and 12 (41%) patients in the GS group used the free NRT patches offered (Fig. 1).

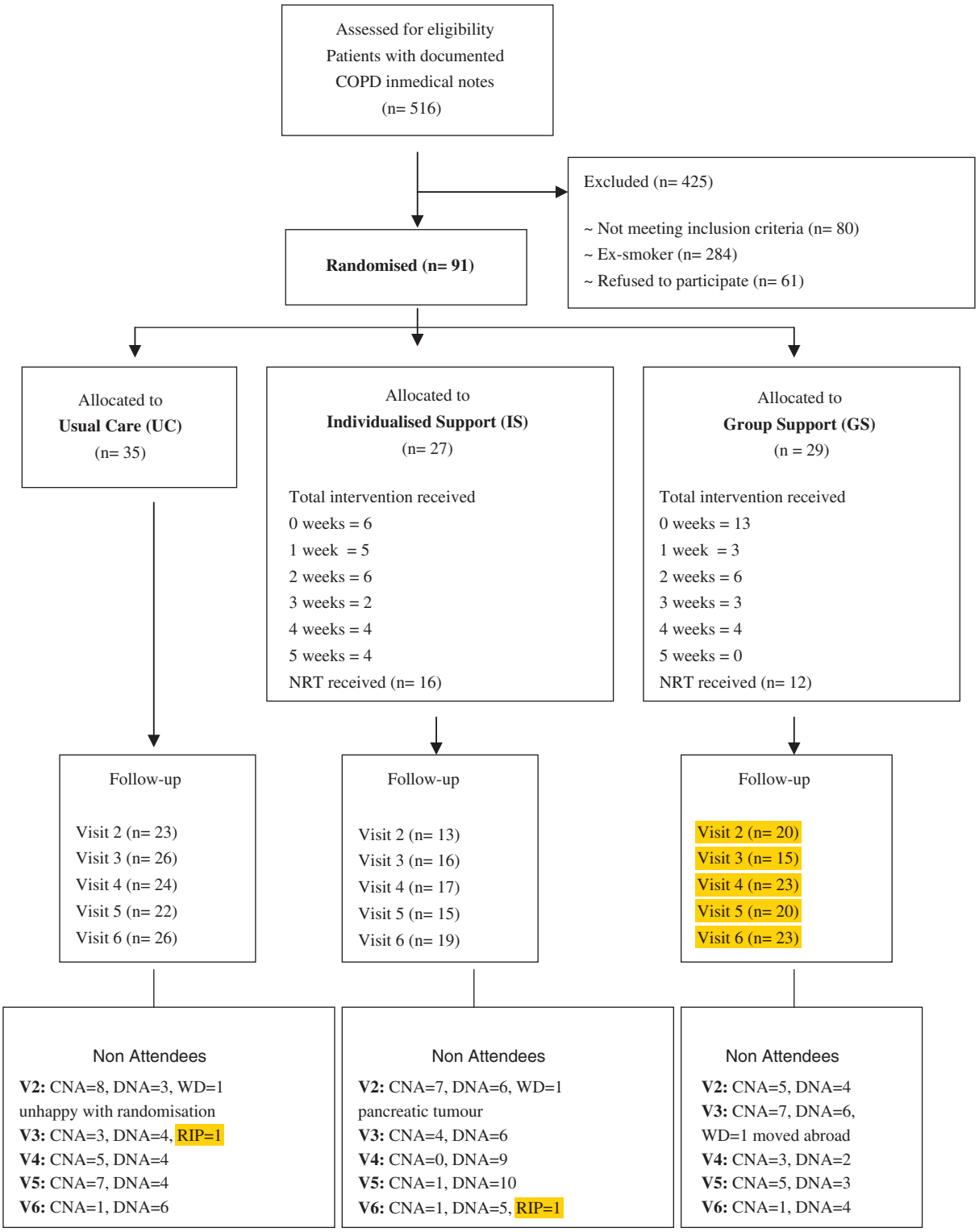
4. Discussion

This study has demonstrated only a few patients with COPD can stop smoking abruptly, even after they have received a highly resourced, intensive treatment. While this is disappointing it is not entirely unexpected as other studies have found it difficult to help such patients to stop smoking (Anthonisen et al., 1994; Crowley et al., 1995; Lancaster and Stead, 2004; Tonnesen and Mikklesen, 2000; van der Meer et al., 2001). The results suggest that brief advice may be the most appropriate intervention for smokers with moderate to severe COPD attending secondary care. Physicians administered the brief advice, as this is recommended in the guidelines (Raw et al., 1998). Further research is required to assess if nurses can produce similar cessation rates with brief advice, as this more accurately reflects current practice (Rice, 2006). Other studies have found high cessation rates in minimal smoking intervention groups (Froelicher et al., 2004; Hollis et al., 1993). As the Global Initiative for COPD (2003) recommends brief advice (3 min) for all smokers at every health care visit, the merit of nurses, (as the largest group of healthcare workers), providing low intensity interventions may have clinical and cost benefits but needs to be further explored.

The high proportion of ex-smokers at screening suggests that many smokers had stopped smoking earlier in their disease trajectory, leaving a sub-group of recalcitrant smokers. The stability of participants' lung function and dyspnoea during the study may have provided little incentive to stop smoking. It is important to highlight the biochemical cut-off for salivary cotinine was more stringent than in other studies (Griebel et al., 1998; Hajek et al., 2002), which may have lead to false positives. Throughout the study 36% of participants were reclassified as non-smokers when carbon monoxide was used alone.

Since attendance to the nursing interventions was poor, we cannot conclude that these are ineffective, rather, intensive intervention did not appeal to this population. Further research is required to explore why interventions recommended through systematic review failed to engage this population. Low participation rates for group support is not unique to this population, as it is often cited as problematic in smoking cessation interventions (Lancaster and Stead, 2005). As the interventions where hospital based, it may be advantageous to evaluate their effectiveness in community settings.

There is no dispute that sustained abstinence from cigarette smoking is the most important therapeutic intervention for patients with COPD, as health benefits occur at any age. But as there is a cumulative risk associated with both malignancy and airflow obstruction, reducing cigarette consumption should lower this risk (Murray et al., 1998; Pelkonen et al., 2001; Peto et al., 2000). Smokers having difficulty stopping should be helped to gain control over their smoking habit by gradual cigarette reduction (Fagerstrom, 2002). Overall this sample demonstrated a reduction in carbon monoxide levels over 12 months from 17ppm (SD 11) to 10ppm (SD 8), and all groups had a significant reduction in nicotine addiction. Whilst changes in smoking behaviour cannot be attributed to a particular interven-



CNA= subject unable to attend,DNA= did not attend, WD= withdrawn from study, V= visit, RIP = subject died.

Fig. 2. Flow diagram of the progress of patients through each phase of the study.

Table 1
Patients' baseline characteristics

	UC ($n = 35$) Mean (SD)	IS ($n = 27$) Mean (SD)	GS ($n = 29$) Mean (SD)	Total ($n = 91$) Mean (SD)
Female *n* (%)	17 (49%)	13 (48%)	17 (59%)	47 (52%)
Age (yr)	61.4 (8)	61.0 (8)	60.4 (9)	61 (84)
FEV_1	54.3 (20)	52.1 (20)	54.6 (23)	53.1 (21)
Pack years	38.9 (13)	45.5 (25)	40.8 (21)	41.4 (20)
Current cigarettes/day	17.5 (7)	20.8 (11)	20.1 (11)	19 (9)
Carbon monoxide (ppm)	17.2 (12)	16.2 (9)	18.0 (12)	17.2 (11)
First cigarette (min)	18.4 (26)	19.6 (37)	24.3 (48)	20.6 (37)
Previous attempt (months)	55.0 (71)	45.9 (81)	52.8 (91)	52 (80)
HIS	3.4 (1)	3.6 (2)	3.4 (1)	3.5 (1)
MRC Dyspnoea Scale	3.0 (1)	3.4 (1)	3.6 (1)	3.3 (1)
Stage of Change	4.8 (1)	4.8 (1)	4.7 (1)	4.8 (1)
Precontemplation *n* (%)	1 (3%)	3 (11%)	4 (14%)	8 (9%)
Contemplation *n* (%)	7 (20%)	14 (52%)	18 (62%)	59 (65%)
Preparation *n* (%)	27 (77%)	10 (37%)	7 (24%)	24 (26%)

Table 2
ANCOVA pairwise comparisons of variables at visit 6 ($n = 91$)

Variable	Comparisons		Mean difference	*p*-value	CI
Carbon monoxide	UC	IS	−2.49	0.30	−7.98, 3.01
	UC	GS	−0.79	0.73	−6.09, 4.5
Time to first cigarette	UC	IS	0.86	0.94	−23.84, 25.54
	UC	GS	5.48	0.61	−18.8, 29.76
Cigarettes smoked per day	UC	IS	0.18	0.94	−5.26, 5.63
	UC	GS	0.99	0.67	−4.34, 6.32
Stage of change	UC	IS	−0.15	0.68	−0.99, 0.86
	UC	GS	0.33	0.36	0.49, 1.14
HSI	UC	IS	−0.13	0.73	−0.99, 0.73
	UC	GS	−0.04	0.92	−0.88, 0.81
MRC dyspnoea scale	UC	IS	0.07	0.78	−0.50, 0.64
	UC	GS	0.02	0.95	−0.56, 0.59
FEV_1	UC	IS	3.09	0.35	−4.49, 10.67
	UC	GS	−1.21	0.69	−8.22, 5.79

tion, it demonstrates that this population is capable of making positive changes to their smoking habit. This has been observed in another study of smoking cessation and COPD (Crowley et al., 1995).

The treatment of depression is recommended as a primary intervention for COPD (NICE, 2004), at baseline 20% of the sample self-reported taking prescribed anti-depressants. In future research, it may be advantageous to include the assessment and treatment of depression, as this may have contributed to the low attendance to the nursing interventions, high attrition throughout the study and poor cessation rates. NICE (2004) recommend a bi-annual assessment of depression for patients with severe COPD. Nurses must clarify their role in the screening and treatment of depression in this population. There was also a poor response to the offer of free NRT. Whilst the optimal duration of NRT is unknown, previous studies have demonstrated an increase in cessation rates when NRT was used (Campbell et al., 1998; Molyneux et al., 2003; Raw et al., 1998; van der Meer et al., 2001). Whilst bupropion has demonstrated increased cessation in

mild-moderate COPD (Tashkin et al., 2001), the incidence of depression amongst this population may restrict its prescription. Systematic review found pharmacological interventions increased cessation in this population (van der Meer et al., 2001).

The nursing interventions incorporated components of the TPB (Ajzen, 1991), with limited effect. This population has resisted previous smoking cessation messages and patients continue to smoke despite having a smoking-related disease, suggesting their behaviour is firmly entrenched. As many patients (42%) lived with another smoker, cessation may not be perceived as a valued behaviour by patients or their loved ones. During the study few patients attempted to stop smoking, they may have lacked confidence in their ability to stop smoking successfully and further research is required to explore the self-efficacy of this population. The Stage of Change Model (Prochaska and DiClemente, 1988) may have limited application when trying to assess smoker's intention to stop smoking, as it does not consider patient's previous experience, which may impact on future behaviour. A systematic review found stage-based interventions had limited effectiveness (Riemsma et al., 2003). It may be an efficient categorisation tool, if nurses are to give brief advice as part of standardized care (Froelicher and Kozuki, 2002). Motivation to stop smoking remained high during the study, therefore, failing to stop smoking was not considered a negative experience by participants. A greater understanding of this populations' smoking behaviour is required before more apt interventions can be developed (Jonsdottir et al., 2004; Schofield et al., 2006). Increased cessation was demonstrated in smokers with COPD who gradually reduced their consumption before stopping (Jimenez-Ruiz et al., 2002). Smoking cessation research differs to other addictions, such as illicit-drug dependence programs, which do not focus exclusively on abstinence (Reuter, 2000). Cigarette reduction may be a pragmatic outcome for smoking cessation programs with this population and nurses must evaluate their role in this arena.

4.1. Limitations

The estimated sample size was not achieved. Nursing research is often criticised for inadequate sample sizes (Polit and Beck, 2002; Raw et al., 1998), however strong attempts were made in this study to ensure an optimal sample size was achieved, such as extending the recruitment period. If the current recruitment rate was to persist, it is estimated that it would have taken many years for the sample size to be achieved and the current results suggest the effect size would have been small. Participants were expected to attend five follow-up visits during the study; these may be interpreted as an intervention as participants may have received positive reinforcement concerning their behaviour. This schedule was applied to all groups as multiple follow-up was recommended in the guidelines for increased interventions (Raw et al., 1998).

4.2. Future research

More research is required evaluating brief smoking cessation interventions provided by nurses. Further research is also required to explore smokers' attitudes to harm reduction and whether this would be a more acceptable outcome for this population. As little is known about the efficacy of specific interventions, further research is required to identify which components of smoking cessation interventions actually contribute to cessation.

5. Summary

Despite offering smokers with COPD interventions recommended by systematic review (Raw et al., 1998), no nursing intervention increased cessation significantly. This finding suggests that the provision of brief advice is clinically and cost effective compared to more intensive interventions. Nursing input into harm reduction may be a more appropriate outcome for the long-term care of this population and further research is required.

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