Short communication

General practice counseling for patients with chronic obstructive pulmonary disease to quit smoking: Impact after 1 year of two complex interventions

Sander R. Hilberink, Johanna E. Jacobs, Marinus H.M. Breteler, Hein de Vries, Richard P.T.M. Grol

1. Introduction

The main cause of chronic obstructive pulmonary disease (COPD) is smoking [1,2]. Smoking cessation does not reverse respiratory function loss, but it slows down lung function deterioration and contributes to greater life expectancy [3–8]. Treatment guidelines name smoking cessation support as the most important intervention [1].

Motivating COPD patients to abstain from smoking proved to be very complex [9–12]. Many COPD patients are treated in primary care, where various cessation aids can be used: simple advice to quit [13], pharmacological therapies [nicotine replacement therapy (NRT), antidepressants, and varenicline] [14–16], minimal intervention (counseling) [17], and proactive telephone counseling [18]. Combinations of pharmacological and behavioral strategies are recommended for COPD smokers [19]. We investigated the impact of a combined intervention (counseling + NRT) and additional bupropion-SR, specifically aimed at COPD smokers in different motivational stages who were treated in routine general practice.

2. Methods

2.1. Design

Cluster randomized controlled trial, with two intervention arms and one control arm. General practices assigned an intervention received support for implementing a smoking cessation program consisting of a counseling strategy plus the recommendation of NRT (CN; [20]) or a counseling strategy plus the prescription of bupropion-SR (CNB). Both strategies used the same counseling protocol. The control practices continued their usual care (UC). A convenience sample was recruited in nine Dutch districts from general practices using one of four widely used general practice electronic record systems (Fig. 1). Power analysis (alpha = 0.05 and beta = 0.20) showed that each arm should.
contain at least 25 practices to find a 10% difference in cessation figures

A software program using the prescription codes of Anatomical Therapeutic Chemical Classification System and diagnosis codes of the International Classification of Primary Care (ICPC) was used to select patients. The criteria were: age 35 years or more, diagnosis recorded as COPD (or relevant ICPC code), and at least three prescriptions of bronchodilators and/or anti-inflammatory medication in the preceding year. The general practitioners (GPs) had to confirm the diagnosis before inviting patients to participate. For detailed information, see Hilberink et al. [20,21].

Table 1
Aspects of the intervention.

<table>
<thead>
<tr>
<th>Intervention elements</th>
<th>Preparers</th>
<th>Contemplators</th>
<th>Precontemplators</th>
</tr>
</thead>
<tbody>
<tr>
<td>The first appointment</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Leaflet and videotape</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Self-efficacy-enhancing information</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Information about NRT (depending on nicotine dependency)</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>New appointment in 2 weeks</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Planned quit day and follow-up visits</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proactive telephone calls</td>
<td>X</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Preparers: intention to quit smoking within 1 month; contemplators: intention to quit smoking within 6 months and precontemplators: no intention to quit smoking within 6 months.

NRT: nicotine replacement therapy.
2.2. Intervention and protocol

The general practice team received a 4-h group training session about COPD and smoking cessation. An outreach visitor provided additional individual support at the practice location (three visits). The patient-directed intervention tailored to general practice patients with COPD carried out in 2001–2002 was based on the minimal intervention strategy [17]. The patient education tools consisted of a leaflet especially developed for COPD smokers and a videotape. Patients in the CNB program were also advised to use bupropion-SR. The patients paid for the pharmacological aids themselves. Table 1 summarizes the aspects of the intervention for the different motivational stages. The first visit to the GP took place within 1 month after baseline measurement.

2.3. Outcomes

The outcome measure was point prevalence abstinence after 12 months. Self-reported quitters were invited to produce a urine sample at the practice location. The sample was biochemically verified by cotinine levels (measured by radioimmunoassay). Patients with no 12-month data, patients with more than 50 ng/mL in their urine [22] and patients not providing a sample were considered to smoke.

2.4. Instruments

The patients received three questionnaires: at baseline and 6-month and 12-month follow-ups. We collected data about smoking, background characteristics, motivation to quit [23,24], nicotine dependence (FTND; [25]), attitude scales, self-efficacy expectations [26–29], COPD symptoms [30], and self-reported exposure to the intervention.

2.5. Analyses

Several bivariate techniques tested differences between the programs. Cohen’s $h$ reflected the effect size [31]. We used multilevel analyses to test treatment effects because of the study’s hierarchical structure, along with SPSS 14.0 and SAS V8.2 (PROC MIXED and GLIMMIX MACRO).

3. Results

3.1. Sample

The participants were 753 COPD smokers, and there were 56 nonparticipants (Fig. 1). No reasons for nonparticipation were obtained. Table 2 shows the baseline characteristics. Five hundred and thirty-nine participants (80.8%) returned the 12-month questionnaire (123 controls and 416 intervention participants). Dropout was associated with being assigned to the CNB program, and, at baseline, little motivation to quit and less positive attitude towards quitting ($\chi^2 = 23.0$, $df = 5$, $p < 0.001$, and $R^2 = 0.06$).

3.2. Comparison of the interventions

More CNB participants than CN participants used bupropion-SR with or without NRT, although few of them used both (Table 3). The

<table>
<thead>
<tr>
<th>Variable</th>
<th>UC</th>
<th>CN</th>
<th>CNB</th>
</tr>
</thead>
<tbody>
<tr>
<td>n = 148</td>
<td>n = 243</td>
<td>n = 276</td>
<td></td>
</tr>
</tbody>
</table>

Demographics
- Percentage of men: 55.4, 46.5, 47.8
- Mean age in years (SD): 60.1 (11.5), 58.0 (12.2)$^*$, 60.7 (11.2)
- Percentage with partner: 73.6, 76.1, 74.3
- Percentage with partner who smokes: 33.8, 41.2, 31.5

Education in percentages
- Primary level: 48.0, 47.7, 47.1
- Secondary level: 38.5, 41.6, 41.7
- Advanced level: 7.4, 7.4, 6.2
- Percentage with job (voluntary or otherwise): 34.5, 37.9, 31.5

Smoking
- Stages of change in percentages:
  - Preparer (intention to quit within 1 month): 17.6, 25.9, 24.3
  - Contemplator (intention to quit within 6 months): 28.4, 32.1, 29.3
  - Precontemplator (no intention to quit within 6 months): 50.7, 39.9, 43.1
- Mean nicotine dependence$^b$ (SD): 19.5 (9.3), 21.5 (10.5), 21.2 (10.5)
- Mean number of cigarettes/shag per day (SD): 16.8 (9.7), 16.9 (10.3), 16.9 (9.1)
- Percentages of participants who ever attempted to quit smoking: 71.6, 75.3, 76.8
- Mean number of cigarettes/shag per day (SD): 17.8 (4.6), 17.6 (4.7), 17.9 (4.3)
- Mean anticipated regret for smoking (SD): 19.7 (9.1), 21.4 (9.4), 20.5 (9.3)

Health
- Mean dyspnea$^c$ (SD): 1.6 (1.2), 1.5 (1.2), 1.4 (1.2)
- Chronic coughing$^d$ in percentages: 35.1, 33.3, 30.8
- Chronic sputum$^c$ in percentages: 35.1, 35.0, 27.5
- Coughing or dyspnea as reaction to tobacco smoke in percentages: 31.1, 35.0, 32.2


$^b$ Fagerström test of nicotine dependence.

$^c$ Derived from the Medical Research Council.

$^d$ Sum-score range: 0–3.

$^*$ $p = 0.028$, mean age in CN program lower than in CNB program.

$^*$ $p = 0.022$, mean score in usual care program lower than in CN program.
1. Motivated and unmotivated COPD smokers were included; other studies included motivated participants only [4,8,32]. Including smokers in different motivational stages better reflects the potential effectiveness in real-life settings.

2. The intervention was less intensive than in other studies due to the integration in routine care. Intensive counseling [4,10,11] combined with pharmacotherapy [4,8,32] in more controlled environments may result in better success rates, as studies of programs embedded in hospital care show [8,11,33].

3. We did not monitor the exact protocol performance of the GP. The training of the GPs and their team might have had only a restricted influence on counseling behavior.

4. The lower success rates after biochemical verification were partly caused by some participants' noncompliance to the verification procedure. Reasons for noncompliance were related to poor health (unable to visit the practice) in some cases.

5. The differences between the quit rates were smaller than anticipated in the power analysis, showing a lack of power.

What can we learn from the present study? One can argue that the quit rates did not differ significantly, hence the program is not effective. This confirms clinical practice and other studies reporting that COPD patients are highly nicotine dependent and have great difficulty to give up smoking [9–11,34]. But one can also claim that the intervention in a real-life, primary-care setting resulted in a quit rate twice that of the rate in UC. This might contribute to lowering the healthcare costs for these patients. From this viewpoint, the intervention can contribute to optimizing care for patients with COPD in general practice, in which smoking cessation plays a crucial role. However, a more intensive intervention might be more appropriate.

4.2. Conclusion

Both interventions resulted in similar small effects and might improve the treatment for COPD patients, but their effects are limited. We could not determine the effectiveness of the advice to use bupropion-SR. As not many patients used the pharmacological aids, the effectiveness of better compliance to the protocols (possibly encouraged by reimbursement of costs) is still to be studied.

4.3. Practice implications

General practice treats most of the patients with mild-to-moderate COPD and needs to incorporate effective strategies for smoking cessation in routine care. The protocols offer a tool, but success expectations should be modest and additional studies are needed to confirm its value in real-life practice. The protocols give directions for dealing with unmotivated or hesitant patients. For motivated patients, the protocols can be embedded in a stepped care approach, so that unsuccessfully counseled patients are subsequently referred to a more intensive smoking cessation program during routine follow-up.

Conflict of interest

None of the authors had a conflict of interest.

References


### Table 3
Use of nicotine replacement therapy and bupropion-SR and exposure to elementary parts of the protocol at the 6-month follow-up.

<table>
<thead>
<tr>
<th>Variable</th>
<th>CN</th>
<th>CNB</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Program</td>
<td>Program</td>
</tr>
<tr>
<td></td>
<td>n = 243</td>
<td>n = 276</td>
</tr>
<tr>
<td>Pharmacological (n (%))</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NRT</td>
<td>32 (13.2)</td>
<td>21 (7.6)</td>
</tr>
<tr>
<td>Bupropion-SR</td>
<td>12 (4.9)</td>
<td>46 (16.7)</td>
</tr>
<tr>
<td>Total NRT or bupropion-SR</td>
<td>44 (18.1)</td>
<td>53 (19.2)</td>
</tr>
<tr>
<td>NRT and bupropion-SR</td>
<td>0 (0)</td>
<td>7 (2.5)</td>
</tr>
<tr>
<td>Support aids + follow-up (n (%))</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leaflet</td>
<td>45 (18.5)</td>
<td>52 (18.8)</td>
</tr>
<tr>
<td>Video</td>
<td>82 (33.7)</td>
<td>74 (26.8)</td>
</tr>
<tr>
<td>Telephone counseling</td>
<td>58 (23.9)</td>
<td>53 (19.7)</td>
</tr>
</tbody>
</table>


** p < 0.01.

### Table 4
Quit rates at 12-month follow-up in the various study arms (%).

<table>
<thead>
<tr>
<th>Quit rates</th>
<th>UC</th>
<th>CN</th>
<th>CNB</th>
<th>CN + CNB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leaflet</td>
<td>7.4</td>
<td>14.4</td>
<td>14.5</td>
<td>14.5</td>
</tr>
<tr>
<td>Self-report</td>
<td>3.4</td>
<td>7.4</td>
<td>7.6</td>
<td>7.5</td>
</tr>
<tr>
<td>Biochemically verified</td>
<td>3.4</td>
<td>7.4</td>
<td>7.6</td>
<td>7.5</td>
</tr>
</tbody>
</table>


### 3. Comparison of intervention and UC

Self-reported smoking cessation rates differed [14.5% (intervention) versus 7.4% (UC); OR = 2.1, 95% CI = 1.1–4.1]; p = 0.027]. After biochemical verification, these figures were 7.5% and 3.4%, respectively (OR = 2.3, 95% CI = 0.9–6.0; F = 3.02; p = 0.083)—a borderline significant effect with a small effect size (h = 0.18; Table 4).

### 4. Discussion and conclusion

#### 4.1. Discussion

The present study showed doubled quit rates favoring a smoking cessation protocol for COPD smokers over UC. After biochemical verification, these effects decreased to values of borderline significance. Thirty-one studies have shown that bupropion-SR is an effective single cessation aid [15]. In our intervention, the addition of advice to use bupropion-SR did not increase successful quitting. Poor compliance with the recommendations may be an important issue: few participants reported using bupropion-SR or both NRT and bupropion-SR. Neither the prescription nor the use of bupropion-SR had extra benefit when embedded in a multifaceted protocol aimed at smoking cessation in general practice.

The success rate in the present study is lower than in other studies. Five factors that might help explain this:

1. Motivated and unmotivated COPD smokers were included; other studies included motivated participants only [4,8,32]. Including smokers in different motivational stages better reflects the potential effectiveness in real-life settings.

2. The intervention was less intensive than in other studies due to the integration in routine care. Intensive counseling [4,10,11] combined with pharmacotherapy [4,8,32] in more controlled environments may result in better success rates, as studies of programs embedded in hospital care show [8,11,33].

3. We did not monitor the exact protocol performance of the GP. The training of the GPs and their team might have had only a restricted influence on counseling behavior.

4. The lower success rates after biochemical verification were partly caused by some participants' noncompliance to the verification procedure. Reasons for noncompliance were related to poor health (unable to visit the practice) in some cases.

5. The differences between the quit rates were smaller than anticipated in the power analysis, showing a lack of power.

What can we learn from the present study? One can argue that the quit rates did not differ significantly, hence the program is not effective. This confirms clinical practice and other studies reporting that COPD patients are highly nicotine dependent and have great difficulty to give up smoking [9–11,34]. But one can also claim that the intervention in a real-life, primary-care setting resulted in a quit rate twice that of the rate in UC. This might contribute to lowering the healthcare costs for these patients. From this viewpoint, the intervention can contribute to optimizing care for patients with COPD in general practice, in which smoking cessation plays a crucial role. However, a more intensive intervention might be more appropriate.

#### 4.2. Conclusion

Both interventions resulted in similar small effects and might improve the treatment for COPD patients, but their effects are limited. We could not determine the effectiveness of the advice to use bupropion-SR. As not many patients used the pharmacological aids, the effectiveness of better compliance to the protocols (possibly encouraged by reimbursement of costs) is still to be studied.

#### 4.3. Practice implications

General practice treats most of the patients with mild-to-moderate COPD and needs to incorporate effective strategies for smoking cessation in routine care. The protocols offer a tool, but success expectations should be modest and additional studies are needed to confirm its value in real-life practice. The protocols give directions for dealing with unmotivated or hesitant patients. For motivated patients, the protocols can be embedded in a stepped care approach, so that unsuccessfully counseled patients are subsequently referred to a more intensive smoking cessation program during routine follow-up.

#### Conflict of interest

None of the authors had a conflict of interest.


