Reducing the time before consulting with symptoms of lung cancer: a randomised controlled trial in primary care

INTRODUCTION
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The alternative is to attempt to diagnose cancer early through rapid identification and investigation of those with symptoms. Lung cancer has been targeted for this by the National Awareness and Early Diagnosis Initiative in England and the Detect Cancer Early Programme in Scotland.8,9 Achieving this will be challenging, but there are some grounds for optimism.10 Most individuals with lung cancer have unrecognised symptoms for several months before seeking medical help and there are indications that consulting behaviour is modifiable; for example, the wait before consulting is shorter for those with particular experiences, including previous chest infections.11 There have been encouraging findings from a recent public awareness campaign in Doncaster, including increases in symptom awareness and referrals for chest X-ray.12 Few interventions, however, have been evaluated in randomised trials. A systematic review found only five randomised trials of interventions to promote cancer awareness and early presentation.13 None of the interventions targeted lung cancer and only one included lung cancer symptoms.14 These trials reported modest effects on cancer awareness and attitudes, but none reported effects on consulting behaviour: Interventions that have been developed using research evidence and theory to understand fully the underlying problem and how it may be targeted, and use behaviour change techniques found effective in other situations, are more likely to work.

Sarah Smith, Shona Fielding, Peter Murchie, Marie Johnston, Sally Wyke, Rachael Powell, Graham Devereux, Marianne Nicolson, Una Macleod, Phil Wilson, Lewis Ritchie, Amanda J Lee and Neil C Campbell

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to be effective. A previous article described the development of a theory-based primary care intervention that seeks to reduce the time taken by individuals at high risk of lung cancer to consult. This study evaluates the effect of this intervention on actual and intended consulting behaviour.

METHOD
A parallel-group randomised controlled trial was carried out in two general practices in north-east Scotland.

Participants
Participants were long-term smokers (at least 20 pack-years) aged ≥55 years, including ex-smokers if their cessation date was within 10 years. Smokers and ex-smokers were identified from practice computerised records and a sample selected (every nth name from an alphabetical list, where \( n = \frac{\text{number eligible}}{\text{number required}} \)); these individuals were sent a letter from their general practice, inviting them to take part in the study. Two waves of recruitment were conducted, the first to establish recruitment rates and the second to achieve the target sample size.

Intervention
A consultation with a trained nurse guided each participant through a self-help manual, which the participant took home, and developed ‘if–then’ action plans (full details are published separately). The manual provided information, used behaviour-change techniques and sought to: engage high-risk individuals, using logos, celebrity endorsement by Liz Dawn (from Coronation Street), and ‘special attention’ messages; increase the salience and personal relevance of symptoms; reinforce the benefits of early intervention in lung cancer and other chest diseases using patient stories and frequent positive messages; sanction early consultation using messages from doctors, other patients, and Liz Dawn; provide prompts to self-monitoring; provide simple symptoms checklists linked to ‘if–then’ action plans; and tackle barriers to consultation using ‘if–then’ coping plans. Participants allocated to the intervention group who did not attend the nurse consultation were sent the self-help manual by post. The intervention was appraised at, and refined after, focus groups and interviews with patients from the target group, GPs, and individuals with lung cancer. The control group received usual care at their general practice, which included patient-initiated consultations, opportunistic smoking-cessation advice and, if applicable, annual reviews for chronic obstructive pulmonary disease (COPD).

Outcomes
The primary outcome was the number of general practice consultations, within target times, for individuals with new chest symptoms (≤3 days for haemoptysis and ≤3 weeks for other symptoms) in the year after the start of intervention. However, data on symptom duration were missing for most consultations, so the primary outcome was analysed in two parts: first, number of general practice consultations with new chest symptoms and, secondly, the proportion of those who consulted (and for whom duration data were available) that were within the target time. The secondary outcome was intention to consult with symptoms by a given time. This was assessed using four items: intervention, self-efficacy, knowledge, and mood; each requiring forced-choice direct estimation of the time taken before making an appointment to see a doctor for a given chest symptom scenario. Each item had 11 options ranging from <1 day to >6 months. Internal consistency (Cronbach’s alpha) was 0.78. These were converted into ‘number of days’ to give the analysis more meaning (for example, 3 weeks to 21 days), with <1 day converted to 1 day and >6 months to 180 days. The a priori decision was for the main outcome to be a single measure of intention combining all four items, but with the four items also presented separately for clinical relevance.

Additional measures of process were:
- self-efficacy for consulting without delay; 10 items each with a 10-point scale (from ‘not at all confident’ to ‘totally confident’) summed to give scores ranging from 10 to 100, Cronbach’s alpha was 0.85;
- knowledge of symptoms of lung disease; 21 symptoms with ‘yes’, ‘no’, ‘not sure’

How this fits in
Most individuals with lung cancer have symptoms for several months before seeking medical help. This study developed a general practice-based intervention to be delivered to individuals at high risk of lung cancer. The intervention reduced the time individuals reported they would wait before consulting with various chest symptoms. Although this is encouraging, increased rates of consulting within target times were not statistically significant, so larger trials are needed.
answers, expressed as a percentage of
answers correct;
• risk perception; ‘how would you rate your
chance of getting lung disease?’, with a
five-point scale ranging from ‘very low’ to
‘very high’;
Adverse effects were assessed by:
• the Hospital Anxiety and Depression
Scale (HADS), a validated scale
measuring anxiety (7 items, range 0–21)
and depression (7 items, range 0–21),
with minimal confounding by somatic
symptoms;18
• the Cancer Worry Scale, a six-item scale
(range 6–24) with internal consistency
(Cronbach’s alpha) of 0.88 in this
study;19,20 and
• general practice consultation rates with
anxiety or depression.

Wider health service effects were
measured by total general practice
consultations, and chest radiograph and
respiratory medicine referrals.
Respiratory fitness for treatment was
assessed by spirometry, which was
measured for participants attending nurse
consultations and categorised using Global
initiative for chronic Obstructive Lung
Disease (GOLD) criteria for COPD.21

Self-report data were collected by
questionnaires at recruitment (pre-
treatment) and 1 and 6 months after the
nurse consultation. For the control group,
who did not have a nurse consultation,
matching dates were allocated by pairing
each control participant at randomisation
to an intervention participant and using
the latter’s date of nurse consultation.
For intervention-group participants who
did not attend the nurse consultation, the
date of posting their manual was used.
Data on consultations and referrals during
the years before and after the nurse
general practice consultation were collected by review
of general practice case notes. Data on
duration of symptoms were collected from
both records of consultations in case notes
and short questionnaires that participants
were asked to complete if they consulted.

Sample size
It was estimated that, without intervention,
35% of participants would consult for
respiratory symptoms,22 of whom 20% (7% of
the total) would consult within target times.11
It was judged that an increase to 25% would
be clinically worthwhile; a sample of 200 (100
in each group) would provide 90% power
at 5% two-sided significance to detect this
difference.

Randomisation
Invitations to participate and randomisation
in equal numbers to intervention and control
groups were both conducted at the start
of the trial. Responses from consenting
participants were stratified by general
practice and given a unique identification
number as they were received. When blocks
of 24 had accumulated, random numbers
were generated by the project senior
statistician and assigned to the previously
ordered identification numbers.

Blinding
Data entry from questionnaires was blind
to group allocation. Detailed protocols and
rules were used for abstraction of data from
case notes, but blinding was not possible
because indicators of nurse consultations
were present in the case notes.

Statistical methods
Analysis was by intention to treat, with
participants analysed according to the trial
arm to which they were randomised. For
counts of consultations by participants,
Poisson regression was used to produce
an estimate of the ratio of consultation
rates between the two treatment groups.
The proportion of consultations within the
target time was analysed using a generalised linear model with a binomial distribution and logit link function. For outcome measures from questionnaires, linear mixed effects models were used to estimate the treatment differences at 1 month and 6 months, taking into account the correlation between the repeated outcomes. Main analyses were of all observed data adjusted for baseline count or score, age (in years), sex, and practice. This assumes that missing data were at random, therefore sensitivity analyses were conducted with all participants using multiple methods of missing value imputation, including the median value from completers, median values within a scale, hot-deck of completers (random selected value from completers), and last value carried forward, to check for important differences.23

RESULTS
Recruitment took place between 26 May 2008 and 28 February 2009. Of 2780 smokers and ex-smokers initially approached, 212 were eligible, consented, and randomised into two equal groups (Figure 1). There were no important differences between groups (Table 1). Of 82 intervention group participants, spirometry was normal (forced expiratory volume in one second/forced vital capacity [FEV1/FVC] ≥ 0.7) for 40 (49%). The remainder had spirometric criteria for COPD: five (6%) mild (FEV1 ≥ 80% of predicted); 24 (29%) moderate (FEV1 < 80% and ≥ 50% of predicted); eight (10%) severe (FEV1 < 50% of predicted); and five (6%) very severe (FEV1 < 30% of predicted). Follow-up took place between 29 October 2008 and 10 June 2010, with 206 (102 intervention, 104 control) participants completing the trial (Figure 2).

The adjusted ratio of consultation rates with new chest symptoms in the intervention versus control group was 1.19 (95% confidence interval [CI] = 0.92 to 1.53) (Table 2). Data on symptom duration were available for 105 of 250 (42%) consultations in the year after intervention commenced. In the intervention group, 52 of 65 (80%) consultations were within the target time, compared with 31 of 40 (78%) for the control group. Adjusted for age, practice, sex, and number within target time in the pre-intervention period, the rate ratio in the intervention versus control group was 1.11 (95% CI = 0.41 to 3.03; P = 0.83).

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The intervention group reported their intention to consult as statistically significantly sooner: 31 days (95% CI = 7 to 54) earlier at 1 month, and 25 days (95% CI = 1.5 to 48) earlier at 6 months. Of individual scenarios, the biggest difference was that concerning weight loss (Table 3). Re-analyses using multiple methods of imputation of missing data did not make meaningful changes to the findings (data not shown).

There was strong evidence that the total consultation rate was higher in the intervention group (Table 2); the median number of consultations for any reason increased from six in the year before intervention to eight in the year after, while remaining unchanged at seven in the
control group. The adjusted consultation rate ratio was 1.15 (95% CI = 1.04 to 1.27).
There was no evidence of a difference between groups in self-efficacy or perceived risk at 1 month or 6 months. Knowledge scores were significantly higher for the intervention group compared to controls at 1 month, but not after 6 months (Table 3). Cancer Worry Scores were not statistically different at 1 month, but were found to be higher in the intervention group at 6 months (0.79, 95% CI = 0.16 to 1.41) (Table 3). HADS scores were not affected by the intervention, nor were there differences in GP consultation rates for anxiety or depression (Table 2).

The number of chest radiograph referrals from the intervention group increased from eight (for eight participants) in the pre-intervention year to 17 (for 15 participants) in the year after the intervention commenced. From the control group, there were 11 referrals (10 participants) pre-intervention and 13 (12 participants) afterwards. Numbers of participants with respiratory medicine referrals increased from one in the pre-intervention year to 11 in the year after the intervention commenced. Respective figures for the control group were one and four. The numbers were too small to permit formal statistical testing.

**DISCUSSION**

**Summary**

For individuals at risk of lung cancer, a theory-based intervention in primary care shortened the intended time to consultation with new chest symptoms but, while consultation rates increased, this was not statistically significant. The intervention caused a small increase in cancer worry, but this did not translate into anxiety or depression.

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**Table 2. Consultation rates during the year before and after the nurse consultation or matched control date**

<table>
<thead>
<tr>
<th>General practice consultations</th>
<th>Intervention (n = 102)</th>
<th>Control (n = 104)</th>
<th>Adjusted analysis(^a)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Consultations, n</td>
<td>Consulters, n (%)</td>
<td>Consultations, n</td>
</tr>
<tr>
<td>New chest symptom</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Year before</td>
<td>98</td>
<td>45 (44)</td>
<td>118</td>
</tr>
<tr>
<td>Year after</td>
<td>138</td>
<td>56 (55)</td>
<td>112</td>
</tr>
<tr>
<td>Any chest symptom</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Year before</td>
<td>137</td>
<td>45 (44)</td>
<td>145</td>
</tr>
<tr>
<td>Year after</td>
<td>188</td>
<td>56 (55)</td>
<td>139</td>
</tr>
<tr>
<td>Anxiety or depression</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Year before</td>
<td>22</td>
<td>8 (8)</td>
<td>27</td>
</tr>
<tr>
<td>Year after</td>
<td>22</td>
<td>13 (13)</td>
<td>33</td>
</tr>
</tbody>
</table>

\(\text{Median (IQR)}\) and \(\text{Median (IQR)}\)

\(^a\)Unadjusted analysis included age, sex, and practice.
Strengths and limitations
The primary outcome was analysed in two parts because data on symptom duration were missing for most consultations, despite the fact that data were collected from both case notes and questionnaires. This approach meant the findings on numbers of consultations for new chest symptoms were unaffected by missing data, but the data on proportions of consultations within target times should be viewed cautiously. Missing data on symptom duration may have been due to patients not remembering or GPs not recording the information. The former may be more likely for symptoms of long duration and this could explain the higher rates of symptoms within the target time that were found, compared to previous research.11

<table>
<thead>
<tr>
<th>Table 3. Intention, self-efficacy, knowledge, and mood before intervention and 1 and 6 months afterwards</th>
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<tbody>
<tr>
<td><strong>Intention to consult (days before consulting)</strong></td>
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<tr>
<td></td>
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<tr>
<td>All four scenarios combined</td>
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<tr>
<td>Baseline</td>
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<tr>
<td>1 month</td>
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<tr>
<td>6 months</td>
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<tr>
<td>New persistent dry cough</td>
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<tr>
<td>Baseline</td>
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<tr>
<td>1 month</td>
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<tr>
<td>6 months</td>
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<tr>
<td>Newly short of breath in day-to-day activities</td>
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<tr>
<td>Baseline</td>
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<tr>
<td>1 month</td>
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<tr>
<td>6 months</td>
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<tr>
<td>Coughing up phlegm with signs of blood</td>
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<tr>
<td>Baseline</td>
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<tr>
<td>1 month</td>
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<tr>
<td>6 months</td>
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<tr>
<td>Losing weight</td>
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<tr>
<td>Baseline</td>
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<tr>
<td>1 month</td>
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<td>6 months</td>
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<tr>
<td>Self-efficacy (score from 10 to 100)</td>
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<td>Baseline</td>
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<tr>
<td>1 month</td>
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<tr>
<td>6 months</td>
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<td>Knowledge (% correct)</td>
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<tr>
<td>Baseline</td>
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<tr>
<td>1 month</td>
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<td>6 months</td>
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<tr>
<td>Perceived risk (score out of 5)</td>
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<td>Baseline</td>
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<td>1 month</td>
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<td>6 months</td>
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<tr>
<td>Cancer Worry Scale (score from 6 to 24)</td>
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<td>Baseline</td>
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<td>1 month</td>
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<td>Anxiety (HADS score from 0 to 21)</td>
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<td>1 month</td>
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<td>6 months</td>
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<td>Depression (HADS score from 0 to 21)</td>
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<td>Baseline</td>
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<td>1 month</td>
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<td>6 months</td>
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*aAdjusted analysis included baseline score, age group, sex, and practice. DD = days difference. HADS = Hospital Anxiety and Depression Scale.*
splitting in two the effect size upon which the sample size was based, study power was lost and the study was, in the first place, only powered to detect a large difference. Thus while effects on consultations appeared encouraging, they were not statistically significant.

The secondary outcome, self-reported consulting intentions, is not equivalent to behaviour, but is the most proximal preceding factor and gives a strong indication of the likelihood that a behaviour will be performed.24 Translation of intentions into action is particularly likely when there are high levels of self-efficacy for early consultation, as has been found.25 By identifying and approaching potential participants from general practice, full data were obtained at all stages of recruitment. Initial recruitment rates were low, as is typical in this population; it is possible that participants are more interested in health, but their characteristics, weighted towards higher levels of deprivation, are typical of the wider high-risk group.

Comparison with existing literature
This trial adds weight to the limited existing research on interventions to reduce the time before consultation with symptoms of cancer. The recently reported public awareness campaign in Doncaster had encouraging effects but the authors called for randomised trials and the first of these are provided for lung cancer symptoms.12 Regarding other cancers, a systematic review of five randomised trials and three more recent randomised trials shows they have reported increased knowledge and awareness from various interventions on symptoms of colorectal, breast, prostate, and oral cancer, and melanoma.13,26–28 One randomised trial in the Netherlands included some lung cancer among other cancer symptoms and reported benefits to consulting intentions,16 but previous trials have not measured behaviour. Most interventions in these randomised trials have been leaflets and booklets but one trial on breast awareness showed that one-to-one interaction, as in the present intervention, is more effective than literature alone.29

Implications for research and practice
The findings of this study provide encouragement that intervention in primary care may lead to earlier consultation with symptoms of lung cancer, but fall short of proof. Evidence of an effect on actual consulting behaviour and its size is needed and will require a larger trial with more complete recording of symptom duration. The latter may require participants to be contacted after each consultation. Some additional observations from the present study are encouraging. The data collected on dyspnoea and spirometry show that severe lung disease is uncommon among the target group, so many would have been fit for aggressive treatment (surgery and radiotherapy). Rates of attendance at the intervention were high, suggesting that members of the target group are receptive. Furthermore, consultation rates with GPs and practice nurses averaged seven per year, so there are plenty of opportunities to engage patients.

By intervening in primary care, it is possible to shorten the time individuals at high risk of lung cancer intend to take before consulting with important symptoms. More research is needed to determine whether there is an effect on actual consulting behaviour and whether this is large enough to translate into improvements in prognosis.

Funding
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Ethical approval
Full ethical approval for the study was granted by the North of Scotland Research Ethics Committee (REC reference number: 08/S0801/13) on 15 February 2008.

Provenance
Freely submitted; externally peer reviewed.

Competing interests
The authors have declared no competing interests.

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Trial registration
UKCRN 3804; ISRCTN 22421875. The full protocol is available from the corresponding author.

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