CHEST-Australia: a phase II randomised controlled trial of a complex intervention to reduce time-to-consult for symptoms of lung cancer.

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This thesis is presented for the degree of Doctor of Philosophy at
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Thesis Declaration

I, Sonya Murray, certify that:

This thesis has been substantially accomplished during enrolment in the degree.

This thesis does not contain material which has been accepted for the award of any other degree or diploma in my name, in any university or other tertiary institution.

No part of this work will, in the future, be used in a submission in my name, for any other degree or diploma in any university or other tertiary institution without the prior approval of The University of Western Australia and where applicable, any partner institution responsible for the joint-award of this degree.

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The research involving human data reported in this thesis was assessed and approved by The University of Western Australia Human Research Ethics Committee. Approval #: RA/4/1/6018.

Written patient consent has been received and archived for the research involving patient data reported in this thesis.

The following approvals were obtained prior to commencing the relevant work described in this thesis: The University of Melbourne Human Research Ethics Committee (1441433).

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This thesis contains published work some of which has been co-authored.

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Abstract

Background

Lung cancer is the most common cancer worldwide, with 1.3 million new cases diagnosed every year. It has one of the lowest survival outcomes of any cancer because over two thirds of patients are diagnosed when curative treatment is not possible. International research has focused on screening and community interventions to promote earlier presentation to a healthcare provider to improve early lung cancer detection. The previous Scottish CHEST Trial of a behavioural intervention showed promising preliminary evidence in increasing overall consultation rates. The CHEST Australia trial is a phase II, multi-site, randomised controlled trial (RCT), powered to test the effect of an individual-level behavioural intervention on consultation rates for respiratory symptoms in people at increased risk of lung cancer.

Aims

The aims of the work presented in this thesis are to:

- Optimise the CHEST intervention, used previously in the Scottish CHEST Trial, for an Australian population.
- Measure the effect of the intervention on consultation rates for chest symptoms in a Phase II trial.
- Explore qualitatively the theoretical underpinning of the CHEST Intervention in participants who were exposed to the Intervention.

Methods

The CHEST intervention involved a primary-care consultation to discuss and implement a self-help manual, followed by self-monitoring reminders to improve symptom appraisal and encourage help seeking in patients at increased risk of lung cancer. Initially the original Scottish intervention was adapted for an Australian population. New patient information sheets, self-help manuals, and other associated materials were tested with focus groups and in a Phase I trial.

Participants were recruited from two Australian states: Western Australia and Victoria. Patients were randomised to the Intervention (a health consultation involving a self-help manual, monthly prompts and spirometry) or usual care (spirometry followed by usual care). Eligible participants were long-term smokers with at least 20 pack years, aged 55 and
over, including ex-smokers if their cessation date was less than 15 years ago. The primary outcome was consultation rate for respiratory symptoms. Secondary outcomes focused on symptom appraisal, self-efficacy, intention to consult, and psychosocial scales such as cancer worry, quality of life and Hospital Anxiety and Depression scale (HADs).

A subset of participants who received the CHEST intervention also participated in semi-structured qualitative interviews to explore their experiences of the CHEST consultation and self-help manual, their recall of main messages, their symptom appraisal and issues relating to health-seeking when they develop symptoms.

**Results**

The target sample size of 551 patients was recruited (intervention=274; usual care n=277) and 12 month follow-up completed in November 2016. There was a statistically significant increase in consultations for respiratory symptoms in the intervention arm compared to the usual care arm (RR=1.39 (1.07-1.81) p=0.0145) with treatment group and general practice as co-variates. Those in the intervention arm consulted 9 days sooner than those in the control arm, but this was not statistically or clinically significant. There was no statistically significant difference between treatment arms for total consultation rates (RR=1.01 (0.88-1.16) p=0.8998). There was also no difference on any process intermediate measures such as perceived risk of lung cancer, self-efficacy or intention to consult and knowledge of symptoms. There were no clinically important or statistically significant differences between groups on any of the harm scales.

Qualitative data from the in-depth interviews identified themes consistent with the theoretical basis of the CHEST intervention. Barriers to consultation identified in the CHEST-Australia trial participants were; smoker stigmatisation, guilt, fatalism and symptom normalisation. Similar barriers were identified in the Scottish trial. We identified a general perceived mistrust of GPs, based on previous negative experiences of visiting their GP in relation to their smoking. The intervention tackled barriers around lecturing and feelings of guilt and stigma related to smoking by being delivered in a non-judgemental environment where participants could openly talk about their smoking and lung health. We identified expected effects on salience and personal relevance of symptoms, Participants reported a clearer understanding of what to look out for and when to take action after the CHEST Intervention. Tailored prompts and reminders were seen to increase self-efficacy and sanctioned earlier consulting.
Significance of the study

This is the first Australian trial to test the effect of a behavioural intervention to reduce time to presentation with lung cancer symptoms. The trial was effective in increasing respiratory consultations in an increased risk population, it could be a cheaper, safer option in long term smokers who don’t meet any future CT screening criteria or an overall low-cost approach to early diagnosis of lung cancer.
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Authorship Declaration: Co-authored Publications

This thesis contains work that has been published.

Details of the work:

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Eleven authors collaborated on the protocol paper described in Chapter Four.
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Appendix J

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Chapter 1. Introduction

1.1. Rationale for this thesis

Lung Cancer is one of the leading causes of death globally estimated to be responsible for nearly one in five deaths (1.59 million deaths, 19.4% of the total)[1]. Lung cancer poses an enormous burden on the Australian health system and economy, causing more deaths per annum than breast, prostate, and ovarian cancers combined[2]. The symptoms of lung cancer can often be non-specific thereby hindering early diagnosis and contributing to the high mortality rate associated with late diagnosis[3]. Long intervals between a patient’s detection of symptoms and presentation in primary care are well documented in literature on lung cancer[4, 5].

Patients with symptoms of lung cancer are more likely to present to the general practitioners (GPs) as part of routine primary care or during the management of other diseases such as chronic obstructive pulmonary disease, chronic heart failure and chronic heart disease[6]. The symptoms of these diseases can present in a similar manner to early symptoms for lung cancer, which could mean an early diagnosis of lung cancer could be missed. It is therefore important to facilitate the early awareness of the symptoms of lung cancer, particularly among those high risk candidates, that is, current or ex-smokers.

1.2. Current lung cancer rates in Australia

Lung Cancer is the fourth most commonly diagnosed invasive cancer in Australian adults (excluding basal cell carcinoma and squamous cell carcinoma), accounting for approximately 8% of all cancers and is the number one cause of cancer deaths[2]. Lung cancer refers to any carcinoma that originates in the lungs (such as the trachea, bronchi, bronchioles and alveoli) and can be categorised according to two main types:

- Small cell carcinoma. This is the most aggressive form of lung cancer and spreads very quickly during the early stages of the disease. About 10% to 15% of lung cancers are classified as small cell carcinomas. Small cell lung cancer occurs almost exclusively in smokers; most commonly in heavy smokers and rarely in non-smokers[7]. Often surgery is not an effective form of treatment as diagnosis is too late. The only options are radiotherapy and chemotherapy[3].
Non-small cell carcinoma is a form of lung cancer that grows and spreads more slowly. Approximately 85 to 90 percent of lung cancer cases are classified as non-small cell carcinomas and tend to occur most often in people who smoke or in those who have smoked in the past (although it can occur in never-smokers also)[8]. The tumour tends to be confined to one region for a longer time and surgery is a more effective option[3].

In 2013, there were 11,174 new cases of lung cancer diagnosed in Australia (6,627 males and 4,548 females)[9]. In 2017, it is estimated that 12,434 new cases of lung cancer will be diagnosed in Australia (7,094 males and 5,340 females). In 2017, it is estimated that the risk of an individual being diagnosed with lung cancer by their 85th birthday will be 1 in 17 (1 in 14 males and 1 in 21 females)[9]. In 2014, there were 8,251 deaths from lung cancer in Australia (4,947 males and 3,304 females). In 2017, it is estimated that this will increase to 9,021 deaths (5,179 males and 3,842 females). Lung cancer is the leading cause of cancer deaths and it is estimated that it will remain the most common cause of death from cancer in 2017. This reflects its relatively high incidence (58 per 100,000 for males and 31 per 100,000 for females) which is still rising in women, and its low survival. Between 2009–2013, individuals diagnosed with lung cancer had a 16% chance (14% for males and 19% for females) of surviving for 5 years compared to their counterparts in the general Australian population. Between 1984–1988 and 2009–2013, 5-year relative survival from lung cancer improved from 9% to 16%[9]. See Figure 1 for an overview of the current Lung Cancer Statistics in Australia[9].
The primary risk factor for lung cancer is tobacco smoking which accounts for 90% of all diagnosis in males and 65% of all diagnosis in females[2]. There are also notable risk factors for lung cancer which include:

- Passive smoking.
- Exposure to other carcinogens (e.g. asbestos, diesel exhaust fumes).
- Radon exposure.
- Family history of lung cancer.
- A history of lung disease, (particularly non-small cell carcinoma)[2].

The relatively high incidence of lung cancer combined with the low survival rate means there is a need to identify and develop effective strategies to aid secondary prevention.
1.3. Early detection of lung cancer

Five-year survival rates are closely related to stage at diagnosis[10] suggesting that earlier, and timely diagnosis could be a critical factor in improving lung cancer outcomes. The literature examining the association between symptom duration and stage at diagnosis has conflicting results[10] some studies have shown significantly longer symptom duration for stage III and IV disease compared to earlier stage disease[10], while others have found no such association[11]. This partly reflects significant methodological challenges, not least of which is treating symptom duration as a categorical variable (short versus long delay). A recent Danish cohort study examined the impact of symptom duration, as a continuous variable, on mortality for several common cancers and this found a U-shaped association between symptom duration and mortality for colorectal, lung, and prostate cancer[12]. For lung cancer mortality begins to rise after symptoms have been present for more than 60 days before diagnosis[13].

The National Lung Screening Trial (NLST) compared two ways of detecting lung cancer: low-dose helical computed tomography (CT) and standard chest X-ray[14]. Helical CT uses X-rays to obtain a multiple-image scan of the entire chest, while a standard chest X-ray produces a single image of the whole chest in which anatomic structures overlie one another.

The study findings revealed that participants who received low-dose helical CT scans had a 15 to 20 percent lower risk of dying from lung cancer than participants who received standard chest X-rays[14]. This is equivalent to approximately three fewer deaths per 1,000 people screened in the CT group compared to the chest X-ray group over a period of about 7 years of observation (17.6 per 1,000 versus 20.7 per 1,000, respectively) (http://www.cancer.gov/types/lung/research/nlst accessed 11th of August, 2015).

This study enrolled 53,454 current or former heavy smokers ages 55 to 74. Participants were required to have a smoking history of at least 30 pack-years and were either current or former smokers without signs, symptoms, or history of lung cancer. The CHEST trial applied a slightly lower risk criteria for recruitment (20 pack-years smoking versus 30 pack years smoking) (see Chapter 4-Quantitative Methods).

While this trial shows promise, the uncertain cost-effectiveness and feasibility of implementing a national lung cancer screening program means that alternative approaches to timely diagnosis of lung cancer are still required[14].
Another uncertainty regarding lung cancer screening was shown in a study by Patel et al. (2012) which showed a general reluctance of those at high risk to take part in such programmes[15]. This UK study described that poor uptake in a screening programme was most likely attributed to smokers and ex-smokers with a pattern of high risk behaviour and with a mindset of fatalism and denial who would be less likely to take up the offer of screening. In addition the strong culture of nihilism surrounding the issue of lung cancer would also prevent those at most risk. “Worry” and fear of cancer diagnosis is also another important factor that deters people from participating in screening[15].

Molecular biomarkers for early lung cancer detection are still being developed[16]. The study of cancer epigenetics has in the last decade provided new insights in biomarker development for risk assessment, early detection and therapeutic stratification. In particular, DNA methylation and miRNAs (micro RNAs) have rapidly emerged as potential biomarkers in body fluids showing promise to assist the clinical management of lung cancer[17]. Currently, the largest randomised trial ever conducted for the early detection of lung cancer using the “EarlyCDT®-Lung test”, an autoantibody biomarker blood test is being carried out by Sullivan et al. (2017) in the UK[18]. This is a blood test that results in detection of lung cancer in high-risk, asymptomatic patients, whereby those with a positive result are further screened with a CT test. The results from this trial are expected to be published in 2018, and will be further discussed in Chapter 8 (Discussion).

While the search for useful biomarkers of lung cancer is now getting closer, an alternative strategy is to attempt to diagnose lung cancer earlier through prompt recognition and investigation of symptoms suggestive of the disease, particularly in those at higher risk.

1.4. Diagnostic delay in cancer

There is a vast amount of literature spanning several decades on the concept of ‘diagnostic delay’ in cancer[19, 20]. This recognises that patient pathways to presentation to healthcare and initial management in primary care are key determinants of cancer patient outcomes[20, 21]. Much of the research on cancer diagnostic delay has suffered from lack of a theoretical model and precise definitions of key time points along the diagnostic pathway.

Walter et al. (2012) published a systematic review of cancer diagnostic studies which applied the Andersen Model of Total Patient Delay[22]. This model developed the earlier theoretical framework developed by Safer et al. (1979)[23]. Safer et al. proposed a three-
stage model to account for the total time from first noticing a symptom to seeking treatment. The “Appraisal Delay” described the time a person takes to evaluate a symptom as a sign of illness. The illness delay is the time the person takes from the first sign of illness until deciding to seek professional medical care and the “Utilisation Delay” is the time from the decision to seek care, until the person consults a GP. Anderson *et al.* (1995) further developed this model, developing “The General Model of Total Patient Delay.” (Figure 2). In-between phases of decision-making “delay intervals” were conceptualised and were labelled “Delay Components.” Safer’s model was extended to include “Utilisation Delay” with “Behavioural Delay” to describe the time between a person deciding an illness requires medical care and deciding to act on this decision. “Scheduling Delay,” the time between deciding to act on the decision to seek help and actually attending an appointment and “Treatment Delay” the time between the first appointment with a GP and the onset of treatment (Figure 2).

The systematic review by Walter *et al.* (2012) searched any literature reporting the application of Andersen’s model of Total Patient Delay (delay stages: appraisal, illness, behavioural, scheduling, treatment) in studies which assess cancer diagnosis. The inclusion criteria consisted of primary research, cancer diagnosis and the application of one or more stages of the Anderson Model in the collection or analysis of data. Results showed that the majority of papers studying diagnostic delay did not apply a theoretical model to inform data collection or reporting. Ten papers (reporting 8 studies) met the inclusion criteria.

Results showed clearly identifiable stages between the detection of a symptom, first presentation to a health care professional, diagnosis and initiation of treatment. There was strong evidence to support the existence and importance of appraisal and treatment delay as defined by the Andersen Model, however, the treatment delay interval could have been expanded to represent the first presentation to a GP leading to diagnosis and initiation of treatment. The authors also discovered there was little evidence to support scheduling delay and illness delay was often difficult to distinguish from appraisal delay[22].
Figure 2 The general model of total patient delay

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Walter et al. (2012) also referred to Safer’s description of “stage” to not only describe delay time, but also the components of delay or phases of decision making. On the basis of their review they have modified this theoretical framework, producing The Model of Pathways to Treatment (Figure 3).
The model proposes four key intervals:

1. The **Appraisal Interval**. The review found that the nature of the symptoms was the most important factor determining the duration of the Appraisal Interval. Misattribution of symptoms either to a previous benign or concurrent condition or non-recognition of the seriousness of symptoms contribute to longer Appraisal Intervals[24].

2. The **Help-Seeking Interval**. Various factors may contribute to this interval including patient factors such as competing events (e.g. holidays), and emotional ones such as fear. This includes fear of the consultation and examination, or of the diagnosis and treatment[25]. Access to primary care and sanctioning help-seeking by family or friends, so that patients do not perceive themselves as wasting the doctor’s time, are also important factors[25].

3. The **Diagnostic Interval**. Depending on the healthcare setting this may involve a series of healthcare visits, referrals and investigations and often represents a complex process. System factors including the role of primary care as a gatekeeper and access to investigations and specialist care are key factors in this interval[22].
4. **The Pre-Treatment Interval.** The time from formal cancer diagnosis to initiation of treatment is also strongly influenced by several healthcare system factors such as access to staging investigations and specialised treatments.

The concepts and framework of Walters Model of Pathways to treatment were elaborated in a paper by Scott et al. (2012) [26] which described how the model can encompass existing psychological theory, with particular focus on the Appraisal and Help-seeking intervals. This paper reinforced the idea that the pathways taken to diagnosis are complex and dynamic and can be described using psychological theory, mainly, Leventhal’s Common Sense model (CSM) of Illness self-regulation[27] (described in further detail in Chapter 2) and Bandura’s Social Cognition Theory (also described in Chapter 2 in more detail).

Leventhal’s CSM is relevant to the Appraisal interval because when there is a bodily change there is an initial assessment of its expectedness (in relation to context) and if it is deemed unexpected or abnormal then it becomes a symptom. An explanation as to why the symptom is occurring and “coping” mechanisms are then put into place. If this is ineffective, then self-regulation mechanisms are put into place which can alter coping procedures and lead to changes in the cognitive and emotional representations which can ultimately lead to an effect on seeking help[26].

Similarly, Bandura’s Social Cognitive Theory (SCT) underpins the Help-seeking Interval because there is a reciprocal relationship between the environment, personal and social determinants which reflect the complex processes involved in the decision to seek help. The Anderson model assumed a linear stage model whereby everyone moves through stages only once, when in reality the process is more complex and involves self-regulation and also the role of emotions. Scott et al. (2012) sought to highlight some of the conceptual and operational problems in the Andersen Model and describe that the Model of Pathways to Treatment provides a useful theoretical approach using existing underlying psychological theories to lead to greater consistency in reporting and ultimately the development of a more effective intervention[26].

Primary care is often the first point of call for patients with symptoms that could possibly relate to cancer. Reducing delay in this section of the cancer care pathway may help to improve cancer survival[28]. Walter et al. (2012) suggest there is strong evidence to suggest that there are many delays that can occur in the time interval from presentation to a GP in primary care to a referral or secondary care. This can involve referrals, several
appointments and investigations and can be a very complex process for some cancers. The authors refer to a study that examined treatment delay among women with ovarian cancer where several factors were described as attributable to health care providers such as the non-investigation of symptoms, lack of follow up and referral delays. These delays are often compounded by doctors and the health system[22].

Missed opportunities in primary care have also been described in a perspective article by Lyratzopoulos et al. (2015)[29] where epidemiological ‘signals’ suggestive of missed opportunities were considered and evidence was drawn from retrospective case reviews of cancer patient cohorts to summarise factors that contribute to missed opportunities. The authors describe missed opportunities as “instances in which post-hoc judgement indicates that alternative decisions or actions could have led to more timely diagnosis. They can occur in any of the three phases of the diagnostic process (initial diagnostic assessment; diagnostic test performance and interpretation; and diagnostic follow-up and coordination) and can involve the patient, doctor/care team, and health-care system factors, often in combination.” (Lyratzoppulos et al., 2015). An example is absence of evaluation for possible gastrointestinal bleeding in a 50-year-old man with new onset iron deficiency anaemia could represent a missed diagnostic opportunity for more timely diagnosis of gastrointestinal cancer[30]. The authors state that determining the presence of missed opportunity involves a process of retrospective judgement based on patient record audits, but it helps reveal critical areas for improvements in diagnostic quality[29].

1.5. Symptom appraisal and help-seeking in lung cancer

The symptoms of lung cancer can often be non-specific, thereby hindering early diagnosis and contributing to the high mortality rate associated with late diagnosis. Patients with symptoms of lung cancer are likely to present to general practitioners (GPs) as part of routine care or during the management of other diseases such as chronic obstructive pulmonary disease, chronic heart failure, and coronary heart disease[31]. As the symptoms for the aforementioned diseases can often be similar to early lung cancer symptoms, an early diagnosis can be missed.

Several studies have explored symptom appraisal and help-seeking in people recently diagnosed with lung cancer. Smith et al. (2009) interviewed 360 Scottish patients with lung cancer; of these 50% had experienced symptoms for more than 14 weeks before presenting to a doctor (median 99 days; IQR 31-381 days) [31]. Factors associated with
longer symptom appraisal and help-seeking included living alone, a history of COPD and longer pack years of smoking. In contrast, haemoptysis, new onset of shortness of breath and cough were associated with earlier consulting. A smaller UK study showed similar findings: most patients recalled having symptoms for many months before seeking help but these symptoms were not recognised as serious, were attributed to everyday causes and therefore not acted upon[4, 32]. There was reluctance to seek help amongst some people, partly because they were unsure whether their symptoms were normal and, for some, because they felt unworthy of medical care as a smoker. This normalisation of respiratory symptoms, which contributed to later help-seeking, was also observed by Emery et al. (2013) in a study of rural lung cancer patients in Western Australia[33].

Other studies have focused on help-seeking delay between age groups. In 2012, Leprieyr et al. compared the diagnostic and treatment delays and initial symptoms for elderly patients (>70 years old) with lung cancer with younger patients[34]. Despite more comorbidity in the elderly patients, no difference was observed between delays and the initial symptoms were equivalent. Specifically, the delay between the first visit and specific treatment with a thoracic oncologist for > 70 years, was 1.6 months (median IQR 23 days – 3.3 months) compared to 1.2 months (median IQR 15 days to 2.5 months) for < 70 year olds. In this study (based in France) delays were shorter compared to those in the UK, Scotland and Canada[34].

Walter et al. (2015)[35] examined the factors associated with time to diagnosis and stage of lung cancer in a prospective cohort study. The authors reported a median total diagnostic interval (TDI) for any symptom was 117 days, and 91 days for those with lung cancer. This remains a significant period between a person first noticing a symptom and receiving a diagnosis but is also consistent with the findings from the national UK ‘Be Clear on Cancer’ lung cancer campaign[36]. Secondary analyses of a national audit of cancer diagnosis from primary care medical records also suggest that the symptoms and signs of lung cancer may be more quickly acted upon by patients than GPs: lung cancer patients had a median patient interval of just 12 days Keeble et al. (2014)[37]. In contrast, more than 30% of lung cancer patients had three or more primary care consultations before referral in the study by Lyritzopoulos et al. (2013)[29].
1.6. How well do symptoms predict cancer in primary care?

Two systematic reviews have addressed the diagnostic value of symptoms in Lung Cancer: Shapley, 2010 and Hamilton and Sharp, 2005[38, 39]. Shapely (2010) identified symptoms, signs and non-diagnostic test results that were highly predictive of specific cancers and that have a positive predictive value (PPV) of more than 5%, a figure arbitrarily determined as sufficient to warrant further investigation by a GP. The review analysed all higher quality evidence of symptoms that predicted lung cancer in an unselected primary care population and reported two studies for lung cancer[39, 40] Only haemoptysis was identified as having high PPV’s (>5%) in lung cancer diagnosis.

Hamilton’s CAPER studies examined the risk of cancer associated with single and pairs of symptoms and clinical signs from a General Practice database. He showed that as a single symptom haemoptysis had the highest PPV, but this was only 2.4%. Whereas, haemoptysis in combination with other symptoms resulted in higher PPV’s such as, weight loss (PPV of 9.2%) and haemoptysis and loss of appetite (PPV of>10)[41]. The study by Jones et al. (2007) stratified symptoms by age and this showed that haemoptysis in people aged over 55 had a PPV greater than 8%.

Hippisley-Cox (2011) developed an algorithm incorporating information on symptoms, to estimate the absolute risk of having lung cancer in a Cohort study of 375 UK general practices for development, and 189 for validation[42]. The “QCancer” lung model incorporates symptoms with baseline risk factors (age, smoking history (included smokers and non-smokers), chronic obstructive pulmonary disease, deprivation, BMI). The model also took into account family history of lung cancer, other cancers, asbestos exposure and anaemia. The primary outcome was incident diagnosis of lung cancer recorded in the following two years. Cox proportional hazards models with age as the underlying time variable were used to develop separate risk equations in males and females. The authors report 3785 incident cases of lung cancer arising from 4 289 282 person-years in the derivation cohort. Results showed the 10% of patients with the highest predicted risks included 77% of all lung cancers diagnosed over the subsequent two years. Overall, 13, 980 patients with incident haemoptysis were identified in the derivation cohort, 11 853 with loss of appetite and 30 937 with weight loss. The algorithm had good discrimination and calibration and could potentially be used to identify those highest at risk of lung cancer, however, a separate validation study of this model has not yet been published[42].
The latest systematic review of symptomatic diagnosis of lung cancer was published by Shim et al. in 2014[43]. This review aimed to overcome the lack of high-quality research in primary care populations in previous reviews as well as investigate the diagnostic value of symptoms, regardless of national healthcare seemed or spectrum of disease, and update evidence from 2010. The review also included qualitative studies to explore the symptom experience of people diagnosed with lung cancer and identify factors pertaining to patient reporting that may identify any non-classical symptoms prior to lung cancer diagnosis not investigated in diagnostic studies before.

Similar to the previous reviews, haemoptysis was the only symptom consistently indicated as a predictor of lung cancer. The diagnostic values of other symptoms were inconclusive. The review highlighted the weak methodological issues such as the lack of standardised data collection and the lack of comparability of findings across the different studies that extend beyond the spectrum of the disease. Qualitative studies indicated that patients with lung cancer experienced symptoms months before diagnosis but did not believe they were serious enough to seek health care. The study concluded that lung cancer symptoms maybe “under-represented” in primary care clinical notes and that it would be difficult to suggest a symptom profile for lung cancer[43].

While much of the evidence about which symptoms best predict cancer mainly comes from retrospective studies in people with a lung cancer diagnosis, Walter et al. (2015) published research describing a prospective cohort of patients in two English regions at the point of their referral for suspected lung cancer in order to identify symptom and patient factors that influence time to lung cancer diagnosis and stage at diagnosis[35]. Primary care and hospital records for diagnostic routes and diagnoses were also examined. Haemoptysis was the only symptom associated with lung cancer but it only occurred in 21.6% of cases and 4.6% of cases as a first symptom. Diagnostic intervals were longer for non-cancer than cancer diagnosis and for early stage rather than late stage lung cancer. Prolonged chest/shoulder pain was the only first symptom associated with a shorter diagnostic interval for lung cancer than for non-cancer diagnosis. Despite conducting such a large prospective cohort study, the author’s state they failed to identify any other strong signals of lung cancer diagnosis and that lung cancer awareness campaigns that currently concentrate on a single symptom should consider messages that reflect the multi-symptom nature and complexity of its presentation. The authors also conclude that targeted
interventions at high-risk populations aimed at symptom monitoring could be more effective at recognising symptom evolution[35].

1.7. Interventions to promote cancer awareness and early presentation

One approach to earlier presentation to the GP is the use of Public awareness campaigns in order to educate patients on symptom awareness. These campaigns have shown promise but have limited outcomes. In 2012 the Sax institute published a rapid review examining the effectiveness of “signs and symptoms” campaigns for lung cancer[3]. This identified eight lung cancer ‘signs and symptoms’ interventions: ‘I’ll tackle it soon’ (UK), ‘3 Week Cough’ (UK), ‘Be Clear on Cancer’ (UK), ‘Cough, cough, cough’ (NZ), ‘The Sooner the Better’ (NZ), ‘The Australian Lung Foundation’ (various programs; Australia), ‘Find Cancer Early’ (Australia), and ‘Detect Cancer Early’ (UK). The primary aim of all of these interventions was to raise awareness of the signs and symptoms of lung cancer, and increase help seeking behaviour (e.g. seeking help from a GP or other healthcare professional). The interventions tended to target a single symptom (i.e. a persistent cough lasting for three weeks or more). However, the ‘Be Clear on Cancer’ intervention publicised additional lung cancer symptoms such as coughing up blood, breathlessness, fatigue, chest/shoulder pain[3] (Table 1).

The authors report that the evidence for the effectiveness of these interventions was limited. Only two of the eight interventions had any evaluation data (‘I’ll tackle it soon’, and ‘3 Week Cough’).

The data did indicate that the interventions had positive effects. For example, ‘I’ll tackle it soon’[44] combined a public awareness campaign and GP education programme to increase chest x-ray referral numbers and promote lung cancer diagnosis. A public awareness campaign (including leaflets, local radio, pharmacy bags, and leaflets to beer mats) was employed in conjunction with brief intervention training in general practices (including reassurance to GPs that there was sufficient capacity to cope with increased chest x-ray referrals). It was piloted in six localities with a high lung cancer incidence. End points were intention to seek healthcare, chest x-ray referral rates in primary care, secular trends in the incidence of lung cancer, and stage at diagnosis before and after the intervention[44].
<table>
<thead>
<tr>
<th>Campaign</th>
<th>Description of Campaign</th>
<th>Country and Year</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>I’ll tackle it soon</em> (NHS)</td>
<td>This was a pilot awareness raising campaign implemented in Doncaster (UK) in early 2008. The campaign involved two complementary components. The push element involved a public awareness campaign that focused on raising awareness of the importance of seeking medical advice and requesting a chest x-ray for a cough lasting more than 3 weeks. The pull aspect involved brief interventions to prepare healthcare professionals for the intervention and to assure them that there was sufficient capacity to deal with the increased referrals.</td>
<td>UK, 2008</td>
<td>20% increase in chest x-rays. Significant increase in GP visits. 27% increase in lung cancer diagnoses. Quality of evidence: Low (controlled trial – no randomisation).</td>
</tr>
<tr>
<td><em>Be Clear on Cancer</em> (NHS)</td>
<td>This two month campaign is part of a larger national cancer awareness campaign, addressing breast, lung, bowel, and prostate cancer. The key messages of the lung cancer campaign focus on the importance of early detection of lung cancer. It also aims to increase awareness of lung cancer signs and symptoms (e.g. coughing up blood, persistent cough, breathlessness, fatigue, chest/shoulder pain).</td>
<td>UK, 2012</td>
<td>Not reported</td>
</tr>
<tr>
<td><em>Cough, cough, cough</em> (Midland Cancer Network)</td>
<td>Awareness raising campaign aimed at improving the early detection of lung cancer in Rotorua, NZ. This was based on a push-pull model. In the push element, the aim was to encourage individuals (especially smokers) with a persistent cough to see their doctor. In the pull element, health care workers were encouraged to promote the early detection of lung cancer and seek help earlier.</td>
<td>NZ, 2010</td>
<td>Not reported.</td>
</tr>
</tbody>
</table>
| **The sooner the better**  
(Northern Cancer Network)  
[http://tinyurl.com/9nk2qd8](http://tinyurl.com/9nk2qd8) | Campaign aimed at increasing awareness of lung cancer symptoms in Maori and Pacific populations. The campaign involved outlining the main symptoms of lung cancer (e.g. persistent cough, chest pain, persistent chest infection, coughing up blood). Individuals with these symptoms were encouraged to contact their nurse, doctor, local health worker, or the Health line phone number. GPs and other health care workers were advised of the program. | NZ, 2010 | Not reported. |
| --- | --- | --- | --- |
| **The Australian Lung Foundation**  
(various campaigns)  
| **Detect Cancer Early**  
(NHS)  
Scottish Government 2011 | A social marketing campaign aimed at overcoming the fear associated with cancer and improving awareness levels of cancer signs and symptoms. The campaign is targeted at breast, lung, and bowel cancer. | Scotland, lung cancer component planned for 2013 | Not reported. |

Results show that primary care chest x-ray referral rates increased by 20%, in the targeted practices in the year following the intervention compared with a 2% fall in control practices. The difference was highly significant, with an incidence rate ratio of 1.22 (95% CI 1.12-1.33, p=0.001) There was also a 27% increase in lung cancer diagnosis in the intervention area compared with a fall in the control area. The incidence rate ratio was 1.42 (95% 1.12 to 1.33).

This campaign had a significant positive effect on the targeted population in this study and their response to having a cough lasting more than 3 weeks. This led to an increase in the likelihood of presentation to a GP and requesting a chest x-ray, and this also correlated with the number of actual chest x-rays carried out. Athey et al. (2011) describe this “push-pull” approach of combining public and professional interventions to increase service access and earlier diagnosis as being an effective approach to promote symptom reporting and chest x-ray referral in primary care, with the potential to improve lung cancer outcomes through earlier diagnosis[44].

The ‘3 Week Cough’[45, 46] intervention similarly led to a 23% increase in GP attendances for patients with a cough or other symptoms of lung cancer. This was a five week pilot campaign trialled in the Midlands in the UK in 2011. The campaign aimed to increase awareness of lung cancer signs and symptoms in adults over age 50 and utilised a range of media including television, radio, out-of-home advertising (e.g. TV screens in GP surgeries) and face-to-face events. Unfortunately, in addition to being limited in quantity, the quality of the evidence was limited. There was also no indication of whether these ‘signs and symptoms’ interventions led to changes in knowledge, attitudes, or beliefs.

While the above interventions were mainly large and community based, there is evidence for raising cancer awareness using targeted interventions tailored at individuals. In 2009, Austoker et al. published a systematic review distinguishing between community and individual tailored interventions to promote cancer awareness[47]. The aim of this review was to study the evidence for the effectiveness of interventions to raise cancer awareness and promote early presentation in cancer to inform policy and future research. Five studies (including 4 RCT’s) were identified that examined the effectiveness of individual level interventions such as telephone counselling or tailored print materials. Four community-level non-randomised interventions were also identified including lectures, print material, media and posters. None of the trials identified (which was published prior to the Scottish CHEST Trial) were on lung cancer awareness. The authors found some
evidence that interventions delivered to individuals did increase cancer awareness. They found limited evidence that public education campaigns reduce stage at presentation of breast cancer, malignant melanoma and retinoblastoma but promote cancer awareness[47].

1.8. CHEST-United Kingdom. The Scottish Trial

Another targeted and tailored approach is to attempt to diagnose lung cancer earlier through prompt recognition and investigation of symptoms suggestive of the disease, targeting those individuals at high risk.

CHEST Australia is based on an exploratory trial in Scotland, funded by Cancer Research UK, led by Dr. Neil Campbell and Dr. Peter Murchie (The CHEST Trial)[48, 49]. They developed and tested a theoretically-based intervention (the psychological theories behind this are described in Chapter 2) which comprised a primary-care nurse consultation to discuss and implement a self-help manual, followed by self-monitoring reminders. Figure 4 presents a summary of the intervention.

Two hundred and twelve people at increased risk of lung cancer were recruited into the Scottish trial, of whom 206 completed the trial after one year of follow-up (102 intervention, 104 control). The total consultation rate was significantly higher in the intervention group (adjusted consultation ratio 1.16, 95% CI 1.05-1.28 p=0.004). The adjusted consultation ratio for new chest symptoms was also increased but this did not reach statistical significance (ratio 1.20, 95% CI 0.93-1.55). Participants in the intervention group intended to consult sooner with symptoms. There were non-significant increases in chest x-ray requests and referrals to respiratory medicine in the intervention group[50].

This trial therefore provided important preliminary evidence for the potential efficacy of the intervention in altering symptom appraisal and help-seeking behaviour. It represents the first ever trial to test this type of an intervention and measure its impact on health care consultations. Stronger evidence is required before this research can inform practice and policy. In particular, evidence is required on the generalisability of the intervention in other populations and the effect on clinical outcomes as well as consulting behaviours. It was therefore rationalised that the CHEST intervention could be tested in an Australian population and powered to detect a significant effect on consultation rates in general practice for respiratory symptoms (unlike the Scottish trial that had no data to inform
power calculations). A larger Australian study, based on the Scottish intervention and preliminary evidence, would form the basis of this thesis.

![Diagram of CHEST Australia study intervention summary](image)

**Figure 4 Intervention summary**

1.9. **Aims of the CHEST Australia study**

The aims of the work presented in this thesis are to:

1. Optimise the CHEST Intervention, used previously in the Scottish CHEST Trial, for an Australian population.

2. Measure the effect of the intervention on consultation rates for chest symptoms in a Phase II trial.

3. Considerations about a Phase III randomised controlled trial.
The hypotheses of the work presented in this thesis are:

1. The CHEST Australia intervention will increase consultation rates for chest symptoms in people at higher risk of lung cancer.

2. The CHEST Australia intervention will be acceptable and will reduce symptom appraisal and help-seeking intervals in people at higher risk of lung cancer.

3. The CHEST Australia intervention will not cause significant distress or cancer worry in people at higher risk of lung cancer.

The CHEST Australia Trial represents the first trial in Australia to test this type of intervention and measure its impact on health care consultations. Previous work has involved population level campaigns, whereas this trial is unique in that it is targeted at individuals in a high risk population.

The structure of this thesis follows the systematic stages in which the study was conducted.

- **Stage I** involved gaining consumer feedback and adapting the Scottish CHEST Intervention for an Australian audience (Chapter 3).

- **Stage II** involved testing the newly adapted intervention in a general practice (Chapter 3).

- **Stage III** involved running a large Phase II RCT (Chapter 4) with a qualitative component (Chapter 5).

- **Stage IV** involved assessing the impact of the Intervention both quantitatively (Chapter 6) and qualitatively (Chapter 7).

The forthcoming chapters are structured as follows;

Chapter One provides the rationale for carrying out this research and has established the context in which the CHEST Australia Trial fits.

Chapter Two explains the key objectives of the Scottish CHEST intervention with the relevant underlying health psychology theories described in detail. This sets the foundation for the CHEST Australia trial.
Chapter Three describes adapting the Scottish CHEST Intervention for an Australian audience and piloting of the Phase I trial which resulted in modifications to the material required for the Phase II trial.

Chapter Four describes the Phase II quantitative methods and design for the Australian CHEST Intervention. Practice and participant recruitment are described as well as procedures, randomisation, intervention delivery to those in the intervention and control arms, outcome analysis and the methods used to statistically analyse the primary and secondary outcomes.

Chapter Five describes the qualitative methodology used to explore the experiences of patients as high risk of lung cancer exposed to the CHEST intervention. A sub-set of patients who received the intervention in the Phase II Randomised Controlled Trial (RCT), were purposively sampled for the qualitative aspect of the study. Specifically, the objectives were to “unpack” the intervention and compliment the quantitative study. This chapter describes the semi-structured interview process, recruitment strategy, development of the Interview guide and subsequent thematic analysis.

Chapter Six, describes the quantitative outcomes including practice and patient recruitment rates, the flow of participants into and through the trial, the baseline characteristics of patient’s randomised into the trial and the primary and secondary outcome analysis.

Chapter Seven describes the findings from the qualitative thematic analysis to determine if the CHEST Australia intervention was achieving the desired objectives at the qualitative level through the proposed theoretical mechanisms.

Chapter Eight provides a discussion around the findings of each phase of the study, and assimilates these to provide insight into how the CHEST Intervention may be used in primary care in the future.
Chapter 2. Underlying Health Psychology theories used for the development of the Scottish CHEST Intervention

2.1. Introduction

The Scottish CHEST Trial tested a theoretically based complex intervention. Development of complex interventions can draw on theory, evidence, and practical issues in the following ways; theory can be used to understand the factors that might influence the clinical behaviour change being targeted, to underpin possible techniques that could be used to change clinical behaviour, and to clarify how such techniques might work[51]. Evidence can inform which clinical behaviours should be changed, and which potential behaviour change techniques and modes of delivery are likely to be effective[52]. Practical issues then determine which behaviour change techniques are feasible with available resources, and which are likely to be acceptable in the relevant setting and to the targeted health professional group[51]. Smith et al. (2012) used the 2008 well-established MRC framework for the development and evaluation of the CHEST Intervention[51]. Complex interventions are widely used in the health research and practice. Complex Interventions are conventionally defined as interventions with several interacting components, combined to produce a desired outcome. Developing, piloting, evaluating, reporting and implementing a complex intervention are critical phases of research that need to be undertaken prior to conducting a trial. The 2000 MRC Framework provides advice and guidance to researchers for this process.

The authors describe two phases in developing the CHEST intervention. Phase I involved defining the problem with reference to the empirical evidence and underlying theory, that is, there is later presentation by lung cancer patients due to various reasons such as non-recognition of symptoms or symptom seriousness. Five sequential steps were worked through by an expert multidisciplinary team including two psychologists, a sociologist, three GPs, a respiratory physician and a health services researcher. The five steps are summarised in Table 2 and clearly identifies the problem, the population at risk, the pathways by which the problem is caused and the pathways that could be amenable to change. Within step 3, informative behavioural and social models from health psychology were used to address each concept identified. Table 3 shows the theory and evidence mapped to concrete behaviour change techniques to positively impact on the causative
pathways. Finally the research team quantified the potential for improvement, estimating that 75% of people with lung cancer have the potential to consult sooner and that the intervention had the potential to cause this proportion of people with lung cancer to consult sooner (Table 4).

Table 2 Developing an intervention: defining and understanding the problem[49].

<table>
<thead>
<tr>
<th>Key Tasks</th>
<th>Commentary</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Define and quantify the problem</td>
<td>Lung cancer is usually advanced and incurable at diagnosis. If more patients had earlier stage disease at diagnosis, more could be treated curatively and survival times from palliative treatment could be lengthened. A systematic review of factors that increase patient delay in lung cancer found non-recognition of symptom seriousness, older age, and lower education and social class were associated with later presentation, which is the essential underlying problem. A previous study found that the median time between onset of symptoms and consultation was 99 days (14 weeks) (IQR 31–381).</td>
</tr>
<tr>
<td>2. Identify and quantify the population most affected, most at risk, or most likely to benefit from the intervention</td>
<td>The most important risk factors for lung cancer are pack years of smoking and increasing age. Trials of lung cancer screening have generally defined ‘low risk’ as a history of less than 20 pack years and ‘high risk’ as a history of 20 pack years or more. Among ex-smokers, increased risk persists after smoking cessation for at least 10 years. Between 1999 and 2003 in Scotland, 92% of males and females diagnosed with lung cancer were aged ≥55 years. Therefore, a Scottish population aged ≥55 years, with a history of 20 pack years or more, who are current smokers or gave up within the past 10 years, can be regarded as at high risk of developing lung cancer and as an appropriate target group for this intervention. It is estimated that approximately 5% of the population of Northeast Scotland fall into this high risk group.</td>
</tr>
</tbody>
</table>
| 3. Understand the pathways by which the problem is caused and sustained | In another study by the same authors independently predictive factors of delayed presentation were:  
  - Symptoms — those whose first symptoms were cough, shortness of breath, change in longstanding cough, haemoptysis, or loss of appetite, consulted sooner than those without. Those with a change in a longstanding cough waited longer than the median total delay.  
  - Past medical history — those with COPD waited longer, but those with renal failure or a previous chest infection went sooner. Those with known cardiovascular disease went sooner, but those with previous gastrointestinal disease waited longer.  
  - Social — increasing time between first symptom and consultation was associated with living alone. There was a non-significant trend for those without paid work to take longer ($P = 0.09$).  
  - Behavioural — Increasing pack years of smoking was associated with longer delay  
  - Health service factors — frequent consulters consulted sooner. There was a non-significant trend for those who knew
their GP well socially to take longer ($P = 0.08$).

- Knowledge — those reporting more knowledge of lung cancer took longer to consult.

Several psychological and social models can be used to conceptualise the pathways that lead from symptom onset to consultation in lung cancer. These include the Zola’s Triggers; Social Cognitive Theory; Common Sense Self-Regulation Model; Illness Prototypes; Illness Action Model; Network Episode Model. Consequently the finding is interpreted in light of these. These models are about observation rather than action so the study moved towards the Theory of Planned Behaviour and Implementation Intentions. This helped the study to clarify the pathways by which the problem was caused and sustained, and hence the targets for action.

4. Explore whether these pathways may be amenable to change and, if so, at which points

**Symptom appraisal:** could be impacted by raising salience of lung cancer as a possible cause for symptoms

**Attitudes to consultation:** could be enhanced by emphasising the potential benefits of early consultation and the acceptability of doing so

**Subjective norm:** involving others in the intervention, for example spouses, friends, may heighten subjective norm (social pressure to perform an action), influencing intention to act. Involving others may also influence symptom appraisal and attitudes to consultation.

**Perceived behavioural control or self-efficacy:** could be impacted by establishing that getting an appointment in primary care is ‘easy’ partly by training in phrases to use to get a consultation.

**Implementation intentions:** could be enhanced by clear action plans supported by the knowledge that their own practice was participating in and supportive of the study and consultation was sanctioned. Additionally, reception staff were asked to provide access to these patients reporting appropriate symptoms.

5. Quantify the potential for improvement

The study’s previous research suggests that 75% of people with lung cancer have the potential to consult sooner. They thus estimate that the intervention has the potential to cause this proportion of people with lung cancer to initially consult sooner

Table 3 Theories and evidence on how late consultation is caused and sustained[49].

<table>
<thead>
<tr>
<th>Elements</th>
<th>Theoretical model</th>
<th>Relevant construct</th>
<th>Related evidence in chest disease</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Key concept 1: reaction to symptoms</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knowledge</td>
<td>Illness Prototypes</td>
<td>Ideas of what symptom-sets are associated with particular conditions</td>
<td>Less delay if previous experience of serious acute chest disease but longer delay if previous experience of chronic chest disease and self-reported greater knowledge of lung cancer symptoms</td>
</tr>
<tr>
<td></td>
<td>Illness Action Model</td>
<td>‘Stock of knowledge’ — built up through personal experience, interacting with others and general media</td>
<td></td>
</tr>
<tr>
<td>Appraisal</td>
<td>Illness Action Model</td>
<td>Cognitive appraisal or interpretation based on what is known about symptoms</td>
<td>Systematic review found non-recognition of symptom seriousness was associated with delay. Most symptoms are not appraised as serious even in retrospect. Qualitative evidence that fear could deter consultation</td>
</tr>
<tr>
<td></td>
<td>Common Sense Self-Regulation Model</td>
<td>Identity, cause, timeline consequences, control/curability, emotional response to symptoms</td>
<td></td>
</tr>
<tr>
<td>Salience</td>
<td>Illness Action Model</td>
<td>Symptoms can be in the background, not foreground, of thinking depending on what else is happening in patient’s life unless they are force higher in ‘system of relevance’</td>
<td>Less delay with some symptoms (usually more dramatic) than others (usually vague); Longer delay if live alone</td>
</tr>
<tr>
<td></td>
<td>Zola’s Triggers</td>
<td>Salience can be affected by interpersonal crises and interference with relationships and work</td>
<td></td>
</tr>
</tbody>
</table>

**Key concept 2: approaches to coping with/action on symptoms**

<table>
<thead>
<tr>
<th>Elements</th>
<th>Theoretical model</th>
<th>Relevant construct</th>
<th>Related evidence in chest disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common Sense Self-Regulation Model</td>
<td>Continuous process of performing coping strategies/actions (for example ‘waiting to see’, self-treatment, seeing GP) as indicated by appraisal, and then reappraising the health threat</td>
<td>Qualitative evidence that symptoms appraised as minor were attributed to benign causes, managed by ‘waiting to see’ and self-treatment or put to the back of patients’ minds until they could no longer do so</td>
<td></td>
</tr>
<tr>
<td>Illness Action Model</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zola’s Triggers</td>
<td>Temporalisation — waiting to see what happened with symptoms before consulting</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Key concept 3: attitude to consulting

<table>
<thead>
<tr>
<th>Personal opinion</th>
<th>Theory of Planned Behaviour</th>
<th>Attitude to consulting at an early stage formed in response to beliefs about the consequences of consulting</th>
<th>Less delay if symptoms appraised as being serious. Qualitative evidence of smokers feeling discouraged from consulting because of doctors preoccupied with anti-smoking</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opinions of others</td>
<td>Zola’s Triggers</td>
<td>Interactions with others can lead to sanctioning of consultation or to advice for further ‘wait and see’</td>
<td>Longer delay if live alone</td>
</tr>
<tr>
<td>Theory of Planned Behaviour</td>
<td>Subjective norm: social pressure to consult at an early stage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Network Episode Model</td>
<td>Responses shaped by interacting with others, resource sharing, suggestion, support, and nagging</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Forming intentions</td>
<td>Theory of Planned Behaviour</td>
<td>Intentions to consult at an early stage formed in response to attitudes, subjective norms, and perceived behavioural control</td>
<td></td>
</tr>
</tbody>
</table>

### Key concept 4: carrying through to action

<table>
<thead>
<tr>
<th>Self-efficacy</th>
<th>Social Cognitive Theory</th>
<th>Self-efficacy — confidence that one can make an appointment. This can be based on previous experience</th>
<th>Less delay from frequent consulters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Theory of Planned Behaviour</td>
<td>Perceived behavioural control — extent to which patient feels he or she has control over the behaviour (making an appointment)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intention–behaviour gap</td>
<td>Implementation Intentions</td>
<td>Implementation intentions: forming precise intentions to enact a particular behaviour (for example making appointment with doctor) when a particular situation occurs</td>
<td>Qualitative evidence of patients saying they don’t want to waste doctor’s time</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Label</th>
<th>Definition</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health consequences</td>
<td>Record/provide information about health consequences of behaviour</td>
<td>‘It’s worth having symptoms dealt with because treatments can make you feel better, improve your quality of life, and even extend your life!’ (p13)</td>
</tr>
<tr>
<td>Salience of consequences information</td>
<td>Make information about the consequences of changing the behaviour more obvious</td>
<td>Salience is reinforced with a case study of an individual who initially ignored symptoms but finally did see the doctor. Lung cancer was diagnosed and treatment began. (p15)</td>
</tr>
<tr>
<td>Prompts/cues</td>
<td>Use environmental, social or internal stimuli to prompt or cue performance of wanted behaviour or non-performance of unwanted behaviour</td>
<td>Participants are invited to choose prompts which will remind them to check for symptoms: either a text message, postcard or stickers. (p11) Participants are given a list of prompts (for example, ‘if on one of my regular checks I have any symptoms …’) to which they suggest appropriate behavioural responses. (p11)</td>
</tr>
<tr>
<td>Social support (general)</td>
<td>Advise on or facilitate development of general social support for the behaviour from friends, relatives, colleagues or ‘buddies’</td>
<td>‘Let your family, friends or carers read this handbook; there may be ways they can help’ (p3)</td>
</tr>
<tr>
<td>Action planning</td>
<td>Prompt detailed planning of the behaviour goal including context, frequency, intensity and duration of performance</td>
<td>Participants are asked to plan the behaviours they will perform in response to prompts such as ‘if on one of my regular checks I have any symptoms …’ (p11)</td>
</tr>
<tr>
<td>Instruction on how to perform a behaviour</td>
<td>Instruct how to perform a behaviour or preparatory behaviours</td>
<td>‘Phone for an appointment’ (p6)</td>
</tr>
<tr>
<td>Vicarious reinforcement</td>
<td>Facilitate observation of the consequences for others when they perform the target behaviour</td>
<td>‘I wouldn’t be here now if it weren’t for the medication that I’m on.’ (quote from celebrity Liz Dawn, p1)</td>
</tr>
<tr>
<td>Anticipation of future rewards or removal of punishment</td>
<td>Inform that future rewards or removal of future punishment will be contingent on performance of wanted behaviour</td>
<td>A list of lung diseases are presented with information on how the illnesses can be treated (to either cure the disease or relieve symptoms) if diagnosed. (p9)</td>
</tr>
<tr>
<td>Verbal persuasion to boost self-efficacy</td>
<td>Tell the person that they can successfully perform the behaviour, arguing against self-doubts and asserting that they can and will succeed</td>
<td>‘It’s as easy as 1… 2… 3…’ (p6)</td>
</tr>
</tbody>
</table>
### Goal setting (behaviour)

Set a goal defined in terms of the behaviour to be achieved

Participants are presented with the behavioural goal *‘Phone your surgery today to make an appointment’* on experiencing symptoms (p8)

### Persuasive communication

Present verbal or visual arguments from a credible source in favour of or against the behaviour

‘It’s definitely worth your while’ (p3)

### Modelling of the behaviour

Provide an example for people to aspire to or imitate

The target of the case study models the behaviour of seeking help — *‘I said “Och I better go an see about this cough”, so I went tae my local doctor’.* (p15)


Phase II of the intervention involved “optimising the intervention” prior to implementation (Smith et al., 2012). The optimisation of the intervention was explored with focus groups composed of GPs, high risk patients, and patients with lung cancer. The final intervention comprised of a self-help manual, nurse consultation and a system of prompts. The key components of the final intervention involved the following:

- Referring to a range of lung diseases not just cancer.
- Proposing special attention rather than fear message.
- Stories and speech bubble messages from patients about early and late consultation.
- Frequent messages about the benefits of early consultation.
- A simple checklist of symptoms that need action and when.
- Prompts to self-monitoring including postcards, texts or stickers.
- If then action and coping plans based on identified barriers to consultation.
- Specific advice on what to say and expect when making appointments.
- 1,2,3 action plan logo repeated through the logo.
- Celebrity endorsement (a celebrity from Coronation Street who had emphysema)[50].
This chapter will explain in detail the key objectives of the Scottish CHEST intervention with the relevant underlying theories (noted in parentheses). Specifically the objectives were to:  

1. Increase the salience and personal relevance of symptoms (Illness Action Model)[53].  
2. Improve knowledge of symptoms by introducing chest disease prototypes (Illness Prototypes and Illness Action Model)[54].  
3. Reinforce the benefits of early intervention in lung cancer and other chest disease (Theory of Planned Behaviour)[55].  
4. Sanction early consultation (Zola’s triggers)[56].  
5. Tackle barriers to consultation (Theory of Planned Behaviour)[55, 57].  
6. Develop personalised action and coping plans (Social Cognitive Theory and Implementation Intentions)[58, 59].

Intervention components 1 and 2 aim to reduce the Symptom Appraisal Interval, while components 3-6 aim to reduce the Help-Seeking Interval. Four key concepts underlying delayed lung cancer diagnosis were elucidated and the most informative behavioural and social models from health psychology (as described in parenthesis above) were applied. This chapter seeks to explain each of these theories in more detail and understand how each theory led to the development of the Scottish CHEST model.

2.2. Increasing the salience and personal relevance of symptoms (The Illness Action Model)

Social Scientists focus on illness behaviour and how the individual responds to symptoms. Mechanic (1962) stated that “illness behaviour” encompasses “the varying ways an individual respond to bodily indications, how they monitor internal states, define and interpret symptoms, make attributions, take remedial actions and utilise various sources of formal and informal care.”[60]. Social scientists argue that a detailed understanding of the social and cognitive processes involved in responding to symptoms are essential for effective self-management and better health service use.

“Help seeking” has been defined by many models, which try to describe the process as a series of “small decisions”[61] and decisions that take place as symptoms are experienced. Biddle et al. (2007) pointed out that illness behaviour is not a simple decision, but rather “multi-faceted.” The illness action model focuses on “Illness career” or the process as well as the outcomes of decisions around how people come to feeling ill and what they do about it[62].

The intellectual origins of the Illness Action Model (Dingwall, 2001) lay in the sociology of deviance. Dingwell (2001) argued that illness can be seen as a failure of everyday life, that
“being ordinary was something we had to work at. We had to know what it would take to ‘be ordinary’ and we had to be able to command the skills and resources, including our own bodies, to do this.”[53]. He draws on Schutz’s ‘systems of relevance’[63] that places importance on the interactions between each other and their bodies. Dingwell suggests that every day we take for granted our current bodily state and are continually monitoring it. If there is a change in our physiological or biological state (such as trauma) there is a change in our personal relevance’s and “priorities” that will require a response. Knowledge plays an important role, knowledge gained from personal experience of illness, how symptoms have responded in the past, what has happened when interacting with health services will all affect how decisions are made. Knowledge can be acquired through public campaigns or through “common-sense” knowledge.

Dingwell also states that motivational forces will come into play, that is, we make decisions about what course of action to take based upon other people’s views or how our physiological state is. Furthermore, Dingwell claims that once experiencing a change, we seek to “reconcile” ourselves back to a state of normality, ensuring we present ourselves to others the way we should do. Dingwell states that Actions in response can include dismissal (it’s not important) ‘wait and see’ (I’ll see how it goes on), self-treatment and consultation with formal health services or others considered knowledgeable[53].

An important feature of Dingwell’s model is interaction with others. Other people may notice a problem that one has normalised or put down to other causes; help interpret the problem if asked, referring to their own knowledge and experience; and engage in practical help such as making a medical appointment. The process is also iterative, that is, once actions are taken they are continually monitored and evaluated until a normal state is restored. Dingwall argues that a “normal” state may not be the same as prior to getting sick and the “equilibrium” may change[53].

In a critical review by Wyke et al. (2013), three process models of response to symptoms were compared: the Illness Action Model, the Common Sense Model of the Self-Regulation of Health and Illness and the Network Episode Model[64]. This model uses self-regulation to manage, or regulate the perceived threat to health, whereas the central tenant of the Social Network Episode Model is that social networks are essential to the recognition of and the response to health problems. Wyke’s aim was to integrate all three models into an integrated network in which symptoms, responses and actions are simultaneously
interpreted and evaluated. She provides a “challenging” model for developing and applying an integrated framework and suggests some useful future work.

In discussing the Illness action model Wyke et al. (2013) believes that there are six key features of the Illness Action Model that can be identified:

1. Action is driven by the desire to be ‘ordinary’ when one's equilibrium is disturbed.

2. A ‘stock of knowledge’ is both general (shared, culturally available, common-sense) and personal (based on one's own experience of one's body and interactions with health services).

3. This knowledge is used to evaluate, label and explain experiences.

4. Then a range of actions is considered.

5. The impact of these actions is evaluated and reassessed.

6. Interactions with other people, including health professionals, directly impact on evaluations and actions[64].

Figure 5 ‘Concentric circles of influence’ representation of the integrated symptom-response framework.
The Illness Action Model can explain how late consultation can be caused and maintained. An individual’s “stock of knowledge”, their appraisal of symptoms and how relevant their symptoms are, will ultimately determine how long they delay seeking help. For example, if a symptom is not recognised as being serious, this could cause delay, or if a symptom is not seen as relevant compared to other aspects of their lives, this can cause help seeking delay. Walter’s 2012 systematic review found that non-recognition of symptom seriousness was associated with delay[22].

In order to increase the salience and personal relevance of symptoms the Illness Action Model was drawn upon to develop the CHEST Intervention in the following ways:

1. Each patient is told what symptoms to look out for so their knowledge of symptoms is expanded and reinforced. Each patient is provided a simple checklist of symptoms that need action and when.

2. Each patient is told to “look out for number 1”- only they know when something is not right. The patient knows from past experiences that they are not in a “normal” state.

3. Patients are advised to listen to family and friends if they notice a change from their normal state, and to not normalise symptoms and put them down to other causes. Therefore this draws upon the Illness Action Model of interacting with others. The role of others is important in advising, prompting and interpreting symptoms and ultimately leading to the action of seeking help.

2.3. Improving the knowledge of symptoms by introducing chest disease prototypes (the theories behind illness cognitions and illness prototypes).

Leventhal et al. (1980, 1985)[27, 65] defined illness cognition as a “patient’s own implicit common sense beliefs about their illness”. They proposed that these cognitions provide a framework for coping with and understanding their illness, and informing them what to look out for if they are becoming ill.

Leventhal et al. (1980) identified five cognitive dimensions from these beliefs: identity, perceived cause, time line, consequences and cure or control. Identity refers to the medical diagnosis and the symptoms experienced, for example, influenza and high fever. The cause can be seen as biological or psychosocial, for example, “A virus caused me to be sick” or “I am run down.” The time line refers to how long the illness will last, whether it is
short term or chronic. The consequences can be physical, such as pain related, or social, being sick will keep someone from seeing friends or family. Illness representation also can also be represented by a patient’s view of how to cure and control a medical illness. For example; “I can treat the flu with medication and I will be okay in a few days.”[27]

Leventhal et al. (1985) also carried out interviews with individuals who were chronically ill (having been recently diagnosed with cancer) and healthy adults. Participants’ descriptions of their illness suggested underlying beliefs made up of the above dimensions[66]. Other studies have provided support for these “dimensions.” Lau et al. (1989)[67] asked 20 people to sort 65 statements into piles that ‘made sense to them’. These statements had been previously made in response to descriptions of ‘your most recent illnesses’. The researchers reported that the categories that people produced reflected the dimensions of identity of the illness (diagnosis or symptoms), its consequences (the possible effects), the time line (how long it would last), the cause (what caused the illness) and cure/control (how and whether it could be treated).

Bishop and Converse (1986) suggested that lay people bring meaning to physical symptoms by relating them to certain disease prototypes. These disease prototypes provide details of particular diseases. The more symptoms a person has which corresponds to a particular disease prototype, the more likely the person is to interpret those symptoms as an indication of that disease. Two experiments tested the hypothesis that lay people cognitively organise and recall information about physical symptoms according to prototyped conceptions they have of physical diseases. Based on pilot studies that identified the extent to which symptom sets associated specified symptoms with specific diseases, symptom sets were assembled to vary in the extent to which the symptoms were perceived to be associated with a given disease. The first experiment (Experiment 1) asked 37 undergraduates to indicate whether a given set of symptoms indicated a disease and, if so, which one. The second experiment tested 72 undergraduates' recall for symptom sets varying in prototypically for given diseases and also tested the effects on recall of giving symptom sets a diagnosis[54].

It was shown in Experiment 1 that students were more likely to indicate that a list of symptoms are associated with a disease if the list was faithfully reproduced, compared to when two or more unrelated symptoms were introduced. This suggested that the student’s interpretation of the sets of symptoms was influenced by the degree of match between the symptoms and a known disease prototype. Experiment 2 showed significant differences in
the associations made by experiment participants to symptom sets as a function of the typicality of the symptoms in those sets. Participants made more category-based associations to highly prototypical symptom sets than to those lower in prototypicality, but made more associations to individual symptoms for symptom sets low in prototypicality[54].

Bishop (1986) concluded that the perceived cause of the symptoms is a critical determinant of predicted action. When a symptom is perceived as being physically caused it seems to trigger help seeking from a professional, compared to a viral cause which tends to lead to self-care. Furthermore, certain specific symptom groups seem to be more or less associated with the seeking of professional help. The symptoms most associated with professional help were those associated with the urinary tract. The symptoms associated with more serious diseases such as coronary heart disease and cancer were less likely to be associated with the seeking of professional help[54].

While qualitative research interviews have been mainly used to determine illness cognitions, quantitative questionnaires such as the Illness perception Questionnaire (IPQ) by Weinman et al. (1996) have also been used to research further an individual’s belief about illness[68]. This questionnaire asks patients to rate a series of statements about their illness and covers the 5 dimensions aforementioned. It has been used to examine beliefs about illness for diabetes, arthritis, and chronic fatigue syndrome. Ogden (2012) believes that even though questionnaires such as this are now common practice, they are not without limitations[69]. Ogden (2012) states that these questionnaires may change beliefs rather than access them and that an illness cognition could actually be a coping mechanism (for example, I believe my illness is not going to last a long time) and whether the constructs created are states or traits and how stable they are. Ogden (2012) claims overall that individuals tend to show consistent beliefs about illness which can be used to make sense of one’s illness and help their understanding of any developing symptoms[70]. The illness cognitions described have been incorporated into Leventhal’s “self-regulatory model of illness behaviour” The concept of “self-regulation” will be discussed further in relation to social cognition theory.

To increase the knowledge of patients about important respiratory symptoms, The CHEST Intervention provides a simple checklist of symptoms that need action and when. For example, symptoms that would require attention urgently included coughing up phlegm with signs of blood, chest pain and severe or sudden breathlessness. For other symptoms
the “three week rule” was applied, whereby patients were told not to let these specific symptoms linger for longer than 3 weeks. These included, cough, a worsening cough, breathlessness or worsening breathlessness, coughing up phlegm, shoulder or rib pain, wheezing, weight loss, loss of appetite and severe unusual tiredness. By introducing these prototypes or sets of symptoms it was hoped that this would increase a patient’s knowledge of symptoms and reinforce at what stage they should consult their GP.

2.4. Reinforce the benefits of early diagnosis and tackle barriers to consultation using the Theory of Planned Behaviour (TPB).

The Theory of Planned Behavior (TPB) is a theoretical model developed for the prediction of behaviour. It is an extension of the Theory of Reasoned Action by Ajzen & Fishbein (1975, 1985)[71, 72] made necessary by the original model's limitation in dealing with behaviour over which people have incomplete volitional control[71]. The TPB recognizes that attitudes towards a behaviour, social norms and behvioural control operate via behavioural intentions to predict a behaviour (but to a varying degree depending on the specific behaviour).

The Theory of Planned Behaviour puts forward three conceptually independent determinants namely attitude towards the behaviour, subjective norm and perceived behavioral control. The degree to which the determinants are important in shaping behaviour varies according to situations and behaviour. Overall, the Theory of Planned Behaviour is the most used theory to predict individuals' intention and behaviour. Researchers have used the model to investigate about drinking problems[73], leisure behaviour[74] and cigarette smoking[75].

Figure 6 is the structural diagram graphically representing the theory with its independent determinants of intention. Each determinant will then be discussed separately.
2.4.1. **Attitudes towards behaviour (Behavioral Beliefs).**

Attitude towards behaviour is defined as the sum of the salient beliefs associated with the performance of the behaviour; where salient beliefs refer to beliefs about the consequences, important to the individual of him or her performing the behaviour[76]. According to Fishbein & Ajzen (1975), in their expectancy-value model, attitudes develop reasonably from the beliefs people hold about the object of the attitude. People tend to form beliefs about an object by associating it with certain attributes, i.e., with other objects, characteristics or events[72].

To form an attitude towards a behaviour, the individual intending to perform a behaviour will make an evaluation of how good or bad the consequences would be of performing that behaviour. The consequences are the outcomes on which the individual has linked all their beliefs. The evaluation can prove to be either positive or negative depending upon the outcome of the relatively weighted dimensions[76]. Behavioral belief is the probability that behaviour will produce a given outcome, and it is upon that perceived outcome that an individual will base an intention to perform or not that particular behaviour. As shown in the TPB diagram, an example is exercise, the belief that “exercise is fun and I will improve my health.” Evaluations specific to the expected outcome of the behavior, i.e. being healthy, slim and fit is desirable and contributes towards positive attitudes about that specific action. People would generally favour behaviors which they believe have desirable
consequences and for those generating undesirable consequences, they tend to develop an unfavorable attitudes towards such behaviors.

The CHEST Intervention attempts to develop positive attitudes about consulting at an early stage. The CHEST Intervention uses the TPB to reinforce the benefits of early diagnosis for lung conditions. The booklet refers to the benefits of early diagnosis and the patient is informed about examples where lung cancer can be cured if caught early enough.

2.4.2. **Subjective norms (normative beliefs)**

Subjective norms are an important measure of an individual's intention or behaviour. Social psychology researchers like Solomon Asch, Kurt Lewin or Leon Festinger, introduced the concept of social influence as a pressure of conformity on an individual human being to conform to the behaviour of a distinct group or person[77, 78]. Social influence is an element that tunes an individual thinking or feeling concerning a specific behaviour as he communicates with another individual or a person. According to Fishbein and Ajzen (1975), subjective norm is "the perceived social pressure to perform or not to perform the behaviour as a sum of the perceived expectation of specific referent individuals and/or groups weighted by the individual's motivation to comply"[72]. Triandis (1991) further supported subjective norm by stating "that an individual's behaviour is influenced by social norms, which depend on messages received from others and reflect what individuals think they should do"[79].

Normative beliefs are an individual's belief about the extent to which other people who are important, think he or she should or should not perform a particular behaviour. An example of a normative belief would be “people who are important to me will approve if I exercise and I want their approval.”

Normative beliefs have long been used by health researchers to predict and influence health behaviors. Trafinow (1996) suggested that there might be different causal pathways to behaviour for different individuals. He further explained this by stating that some people may rely more on the attitudinal pathway to perform behaviour while some may be more influenced by the normative pathway. Therefore the focus should be laid on both the behaviour of interest and the specific person of interest[80].

The CHEST Intervention seeks to encourage participants to listen to family and friends. For example in the booklet the following quotation is “If other people notice your symptoms,
seriously think about what they are saying…” The basis of this is to promote social pressure to consult at an earlier stage.

2.4.3. **Perceived Behavioral Control (control beliefs)**

The last dimension of the theory of planned behaviour is perceived behavioral control. It plays an important part in the theory as Ajzen (1991) extended the theory of reasoned action to include its measurement as part of the variables that help predict behavioural intentions[57]. The rationale behind the addition of perceived behavioral control was that it accounts for behaviors which may not be under control of an individual. Ajzen and Madden (1986) defined perceived behavioral control as "a person’s estimate of how easy or difficult it will be for him or her to carry out the behaviour"[74]. It is also assumed to reflect "past experiences as well as anticipated impediments and consequences"[81]. Perceived behavioral control is the determinant where the resources and opportunities available to an individual determine the likelihood of the behavioral achievement. The belief is based upon a consideration of internal control factors (e.g., skills, abilities, information) and external control factors (obstacles and opportunities)[70]. An example of a control belief would be “I have no time to exercise because I am too busy looking after my children.” The CHEST Intervention also seeks to determine the extent one has control over certain behaviour, in this case, making an appointment to see their GP and gives advice to promote perceived behavioral control.

2.4.4. **Self-Efficacy**

A concept that is relevant to that of perceived behavioral control is perceived self-efficacy developed by Bandura[58, 82]. Self-efficacy "is concerned with judgments of how well one can execute courses of action required to deal with prospective situations" Bandura demonstrated that an individual’s behaviour is strongly influenced by their confidence in their ability to perform it. The concept of behavioral control was criticised due to the fact that it becomes less realistic when it comes to an individual having little information about the behaviour, when the requirements have changed, or when new and unacquainted elements have come into into the situation.

Perceived Behavioural Control may not be sufficient to predict actual behaviors, only behavioral intentions if there is limited self-efficacy to perform the behaviour[83]. For example: White, Terry and Hogg (1994) researched safer sex behaviors and they showed that perceived behavioral control only had an effect on a behavioral measure of discussing
the use of condoms with any new partner, while self-efficacy had a strong effect on intentions to discuss and intentions to use a condom[84].

Individuals do not have complete control over their behaviour, and it has been proven that the degree of confidence an individual has over which they have control helps predict a behaviour as well as intention. Schifter and Ajzen (1985) confirmed the use of the concept to influence intention and as well behavior in one of their research studies[81]. Self-efficacy will also be discussed with reference to Social Cognition Theory (Section 2.6).

2.4.5. Prediction of Intention and behaviour

Performance is one component which predicts intentions to perform a behaviour. It is found that when “behaviors pose no serious problem of control, they can be predicted from intentions with considerable accuracy”[85] Intentions represent a person's motivation in the sense of his conscious plan or decision to exert effort to enact the behaviour. Intentions and behavior tend to strongly relate to each other, when they are measured at the same level of specificity in relation to the action, target, context and time frame[72] (Fishbein & Ajzen, 1975; principle of compatibility). The limitation of the theory includes due past experience of the same behaviour and repetition of the behavior. Repetition over time leads to a behavior to be defined as a “habit.” It was found that habit had an autonomous effect on intention as compared to perceived behavioral control. Apart from this criticism, habit was deemed to be “the most important predictor of exercising behavior, above all the determinants encompassing the Theory of Planned Behavior”[86].

Research has shown that past behaviour predicted future behaviour use such as attending health checks[75] or breakfast consumption[87]. Oullette and Wood (1998) identified two possible routes that show past behaviour influences future behaviour. They postulated that this may happen indirectly through a conscious change in cognitions, for example (I had breakfast yesterday and I realise I have more energy so I will have breakfast today.”). Secondly, they argue for the role of “habit” where behaviour occurs more automatically, with no effort of conscious processing and tends to happen for regular occurring behaviours that do not offer new experiences[88]. Aarts et al. (2000) have explored ways to measure habit strength and research indicates a role for habit in explaining a number of behaviours including people’s use of information[89].

While the TPB has shaped psychological theorising, there has been no shortage of criticism directed with the theory[90]. The main focus of criticism has been the limited predictive
validity of the TPB. Reviews show clearly that the majority of variability in observed behaviour is not accounted for by measures of the TPB. In particular, the problem of ‘inclined abstainers’, individuals who form an intention and subsequently fail to act, has been a recognised limitation of the TPB that remains unaddressed by the theory (Orbell & Sheeran, 1999)[106]. It was also found that the TPB was considerably less predictive of behaviour when studies used a longitudinal rather than a ‘shortitudinal’ design, when participants were not university students and when outcome measures were taken objectively rather than as a self-report. Ogden (2012) found that authors of studies with results conflicting with TPB assumptions (e.g., null correlations between variables hypothesised to be highly related) rarely question the validity of the theory, but instead consider other explanations such as the operationalisation of their study measures [69].

Ajzen (2015) has responded to the main criticism of the predictive validity of the model[91]. He claims events occurring between assessment of intentions and observation of behaviour can produce changes in intentions and unanticipated obstacles can prevent people from carrying out their intentions. Furthermore, the beliefs that are accessible in the real situation in which a behaviour is performed can differ from the beliefs that are accessible in the hypothetical situation in which the TPB constructs are typically assessed[91].

Ajzen claims it is true that the theory also does not fully account for the variance in intentions. This can in part be attributed to the fact that measures of the theory’s constructs are fallible both with respect to reliability and with respect to construct validity. In a typical application of the TPB, a small number of items, perhaps three or four, is used to directly assess each of the major TPB constructs. Ajzen states “that such a small number of items is usually incapable of completely capturing the underlying construct, the measure’s validity is impaired. This state of affairs can not only help to account for imperfect predictive validity, but it can also help to explain the frequent finding that adding more variables to the model can improve prediction of intentions.” (Ajzen, 2012)[91].
2.5. Sanction early consultation using Zola’s Triggers.

In 1973, Irving Zola published a classic paper on a problem that he suggested:

‘... we think we know a great deal about that but, in reality, we know so little — how and why an individual seeks professional medical aid,...and what the term means to be “sick”....’(Zola, 1973)[56].

The process of identifying a problem as abnormal can be influenced by what Zola (1973) called social triggers in his analysis of “pathways to the doctor.” This relates to how directly the symptom will impact on an individual’s daily lives. If a symptom disturbs our day-to-day functioning it can disrupt ones equilibrium and help seeking is a means to re-establish this equilibrium.

Zola thought researchers made at least three assumptions about how and why a patient might present at a general practice; however, he does not believe any of them are justified. Firstly, researchers assumed that patients are asymptomatic for most periods of their lives; secondly, when patients do appear in the surgery, it is the seriousness and frequency of symptoms that prompt the visit to the doctor; and finally that when faced with such symptoms; patients who do not seek help are illogical and irrational in their thinking.

However, Zola claims that most people have symptoms most of the time; that the seriousness and frequency of symptoms are not good predictors of attendance at the doctor; and that most people make decisions to seek (or delay seeking) help that are rational, if framed in terms of their own beliefs and values[56].

Zola identified social triggers that lead to help seeking:

1. Perceived interference with work or physical activity. A symptom that disturbs this will be perceived as abnormal.

2. Perceived interference with social relations: if something interferes with our ability to interact with others then this is abnormal also.

3. An interpersonal crisis: Zola argues that people have symptoms all the time that they normalise. A sudden crisis such as a divorce may trigger increased attention to a long-standing symptom leading to help seeking that the patient appears to have had for a while.
4. Sanctioning involves other people encouraging a visit to the doctor. Other people recognise the seriousness of a symptom and encourage them to seek help.

There have been many studies in the last 40 years that support Zola’s theory (represented in Figure 7) and these will be described below.

2.5.1. Most people have symptoms most of the time

In a paper written by Mayer and Avery in 2009, they highlight two studies that support Zola’s theory that most people are symptomatic most of the time[92]. The first paper was by Koopman et al. (2004) who conducted a study concerning Type 2 diabetes, which showed that patients could identify symptoms, but often attributed the symptoms to other causes and were not aware of their significance in relation to diabetes[93]. The second study was conducted by Vahdaninia (2009) concerning women in Iran with sexual dysfunction. This study showed that most women had experienced at least one problem relating to sexual dysfunction and the majority of these women had sought no professional help due to ‘time constraints’ or denial that a problem existed[94]. Mayer and Avery (2009) suggest that these situations may highlight missed opportunities for diagnosis and improving quality of life, as well as the need to target health literacy and promotion programmes for these groups. It could also indicate that some people do not actually need to see a doctor[92].

Many cancer studies also show that symptoms don’t get reported. An example is the study by Courntey et al. (2012) who explored the factors associated with healthcare-seeking behaviour for symptoms of colorectal cancer[95]. This study attempted to determine the failure and delay in seeking medical advice for rectal bleeding and change in bowel habit in the Hunter region in NSW, Australia. Results showed that 18% of respondents experiencing rectal bleeding and 20% who reported change in bowel habit, had never consulted a doctor. The rate of delay (>1month) for each symptom was 18% and 37%. The reasons for delay included the assumption that the symptoms were not serious or that they were benign. This emphasised that the seriousness of symptoms, importance of early detection and prompt medical consultation must be clearly stated in health messages to at-risk persons.
2.5.2. Frequency and seriousness of the symptom are not good predictors

There are a number of papers that show that frequency and seriousness of a symptom is only partially predictive of seeking help. An example is a study from Sweden in 2003 where it was found that women who sought help for urinary incontinence were more likely to perceive their symptoms as socially unacceptable, rather than straightforwardly ‘serious’ or ‘frequent’[96].

Mayer and Avery highlight two papers that showed men’s help-seeking practices and health service use are also complex issues involving biological, psychological, and sociological considerations.

Smith et al. (2008) showed that four factors were found to influence the way men monitored their health and determine when they should seek help: the length of time available to monitor health and legitimise help seeking; men's previous illness experiences; the impact on their ability to maintain regular activities in the context of their daily lives; and a judgment of illness severity[97].

2.5.3. A decision to delay seeking help makes sense in the light of a person's own beliefs and values

An example of Zola’s third concept is highlighted in an English study of 22 men and women recently diagnosed with lung cancer by Corner et al. in 2006[4, 32]. Most patients recalled having symptoms (such as cough, breathing changes and pain in the chest) for many months before seeking help, but these symptoms were not recognised as serious and were attributed to everyday causes and therefore not acted upon. There was reluctance to seek help for some people in part due to the “stigma” associated with smoking or because they were unsure whether their symptoms were normal. In one case a person felt “unworthy” for medical care because they were a smoker.

These examples suggest that people do not make the decision to visit the doctor lightly. The logic that is followed is determined by a range of factors that is not medically straightforward. As Ogden (2012) states: social triggers not only influence help-seeking ability but also the cost and benefit of going to the doctor, illness cognition, symptom perception and social triggers[69].
The theory behind Zola’s Triggers can also influence a person to delay help seeking. Smith et al. (2012) noted that interaction with others can lead to sanctioning of consultation or to advice for further wait and see. Evidence shows that those living alone tend to wait longer before seeking help. Salience of symptoms can also be affected by interpersonal crises or interference with relationships and work[48].

The CHEST Intervention uses the theory behind Zola’s triggers to reinforce early consultation by people at increased risk lung cancer. Patients exposed to the CHEST Intervention are set “time limits” whereby if symptoms persist past 3 weeks they are encouraged to seek help from their GP. The basis of the 123 logo is 1. Look out for number 1; 2. Take worrying symptoms to your GP and 3. Don’t wait longer than 3 weeks. If a symptom persists for over this time frame, the patient is encouraged to seek help. They are also encouraged to seek help if these symptoms are interfering with day to day life or other people are noticing their symptoms.

Social cognitive theory (SCT) refers to a psychological model of behaviour that emerged mainly from the work of Albert Bandura[58]. Initially developed with an emphasis on the attainment of social behaviours, SCT continues to emphasise that learning occurs in a social context and that much of what is learned is gained through social learning and removed experiences. SCT has been applied broadly to areas such as organisational behaviour, athletics, and mental and physical health. SCT also has been applied extensively by those interested in understanding classroom motivation, learning, and achievement[98, 99].

SCT explains psychosocial functioning in terms of “triadic reciprocal causation”[96]. Behaviour, cognitive, other personal factors and environmental factors operate as interacting determinants that influence each other bi-directionally (Figure 8). For example, classroom learning is shaped by factors within the academic environment, especially the reinforcements experienced by oneself and by others. Learning can also be affected by a students' own thoughts and their own self-beliefs at the same time.

One assumption within SCT is that “learning can occur without an immediate change in behaviour”[82]. That is acquiring new knowledge and demonstrating this are two distinct processes. SCT also assumes that learning also involves the acquirement of new knowledge, cognitive skills, concepts, abstract rules, values, and other cognitive constructs, in addition to the attainment of new behaviours.

Figure 8 represents the core concepts of Bandura’s Social Cognition Theory.
2.6.1. **Historical origins of Social Cognitive Theory**

Bandura (1977) began a series of studies designed to examine social reasons for why and when children displayed “aggressive behaviours”[58]. In Bandura’s infamous “Bobo Doll study” in 1961 he made a video in which an adult woman was shown being aggressive to a doll, hitting and shouting aggressive words. The film was shown to groups of children. Afterwards, the children were allowed to play in the room with the same doll. The children began imitating the model by hitting the doll and using similar, aggressive words. The study was important because it “departed from behaviorism's insistences that all behavior is directed by reinforcement or rewards.”[58]. The children did not receive encouragement or incentives to act in this manner; they were merely imitating the behavior they had observed.

Through the Bobo doll experiment and others, Bandura grounded his understanding of a model’s primary function, which is to transmit information to the observer. This function occurs in any of three ways:

1. Modeled behaviors serve as cues to initiate similar behaviors in others.

2. They also serve to strengthen or weaken the learner's existing restraints against the performance of a modeled behavior.

3. They’re used to demonstrate new patterns of behavior.
These studies demonstrated the value of modelling for acquiring novel behaviours and provided initial evidence for the separation of learning and performance. They also indicated the importance of the learner's perceptions of the environment, of the person modelling behaviour specifically, and of the learner's expectations regarding the consequences of behaviour. These findings challenged assumptions within behavioural models that learning was the result of trial and error or that changes in behaviour were due primarily to the consequences of one's own actions[58].

By the mid-1970s these studies helped form the foundation for what Bandura “social learning theory”[58]. This predecessor to SCT established a feasible model for understanding how people learned through observation of models. Additional work during this time expanded aspects of the theory dealing with abstract modelling, language, and conceptual learning. SCT continued to evolve, stressing the processes of goal setting, self-efficacy, and self-regulation. The development of SCT also used ideas from information processing models of psychological functioning to describe the cognitive processes that facilitate learning. Bandura noted in his work *Social Foundations of Thought and Action: A Social-Cognitive Theory*, that, in an effort to be inclusive of these more motivational and cognitive processes, he was using the term “social cognitive theory” rather than social learning to describe his work. Since that time, SCT has continued to grow and expand especially with regard to the work on self-efficacy, self-regulation, and agency[100, 101].

### 2.6.2. The core concepts of SCT

SCT integrates a large number of sub-processes into an overall framework for understanding human functioning. Five of the central concepts are described below.

#### 2.6.2.1. Observational Learning and Modelling

One prominent feature within SCT has been that people learn through observation. This process is also described as vicarious learning or modelling because learning is a result of watching the behaviour and consequences of models in the environment. Live demonstrations of a behaviour or skill by a teacher for example, typifies the notion of modelling. Verbal or written descriptions, video or audio recordings, and other less direct forms of performance are also considered forms of modelling. There are distinctions among different types of models.
According to SCT, observational learning of new behaviours’ is dependent on four interrelated processes involving attention, retention, production, and motivation. Attentional processes are critical because one must attend to a model and the relevant aspects of behaviour in order to learn. Retention refers to “the processes necessary for reducing and transforming what is observed into a symbolic form that can be stored for later use”[69]. Production processes are necessary when students draw on their stored codes and make an effort to perform what they have observed. Finally, motivational processes determine whether they ever attempt to use or recreate the new skills they have observed[69].

Modelling is also important for understanding when or why previously learned behaviours’ are exhibited. For example smokers may model someone else trying to quit smoking by chewing nicotine gum. Finally, through a process termed “response facilitation” models can prompt others to behave in known ways[58].

The CHEST intervention provides examples for people to aspire too or imitate and model behaviour from. Throughout the intervention booklet there are speech bubbles which provide case studies of people seeking help. For example:” I had a cough and thought I better see my doctor about this.” This is different from social norms in the Theory of Planned Behaviour described previously, because there is no social pressure to perform a certain behaviour.

2.6.2.2. Outcome expectations

Outcome expectations reflect individuals' beliefs about what consequences are most likely to ensue if particular behaviours’ are performed. Outcome expectations are important in SCT because they shape the decisions people make about what actions to take and which behaviours’ to suppress. The frequency of a behaviour should increase when the outcomes expected are valued, whereas behaviours’ associated with unfavourable outcomes will be avoided.

In the CHEST Intervention, a list of lung diseases is presented with information on how the illness can be treated (cured/relieved) if the disease is diagnosed. The basis behind this being that the future rewards or removal of future punishment will be contingent on the performance of wanted behaviour.
2.6.2.3. **Perceived Self-Efficacy**

As already discussed with the Theory of Planned Behaviour, Self-efficacy has emerged as a prominent and influential concept within SCT. Self-efficacy reflects individuals' beliefs about whether they can achieve a particular task[100]. For example, Self-efficacy has proven useful for understanding students' motivation and achievement in academic contexts. Higher levels of perceived self-efficacy have been associated with greater choice, persistence, and with more effective strategy use[98].

Self-efficacy is viewed as a product of individuals' own past performances, the observation and verbal persuasion of others in the environment, and individuals' on-going physiological state[100]. Sources of information are weighed and filtered through a process known as “cognitive appraisal.” For instance in the learning environment, a prior failure may not be detrimental to self-efficacy if students believe there was some no-longer relevant reason for the poor performance (e.g., prior sickness). Interventions based on SCT are designed to increase self-efficacy in school-aged children have shown to be effective[98].

In the Chest Intervention, self-efficacy was boosted by verbal persuasion, by informing the patient that they can successfully perform the behaviour to be achieved, arguing against self-doubts and asserting that they will succeed. This is where the logo for the trial originated: “It’s as easy as 123....” (See Table 5).

2.6.2.4. **Goal setting**

Goal setting is another central process within SCT[102]. Goals reflect cognitive representations of anticipated, desired, or preferred outcomes. Therefore, goal setting within SCT shows that people not only learn, they identify desired outcomes, and generate plans of action. Goals are also closely related to other important processes within SCT such as providing models for more specific behavioural outcomes and set standards for acceptable levels of performance. Goals are also an important prerequisite for self-regulation because they provide objectives for achievement and benchmarks against which to judge progress.

The idea behind setting goals was used in the development of the CHEST Intervention. Goals were set in order to achieve the behaviour to be achieved, for example, participants are presented with the behavioural goal “phone your surgery today to make an appointment if you experience these symptom.”
2.6.2.5. Self-regulation

Research on self-regulation thrived in the 1980s and continued into the early 2000s to expand. SCT models of self-regulation assume that self-regulation is dependent on goal setting, in that people manage their thoughts and actions in order to reach particular outcomes[101]. Three sub-processes were identified by Bandura in relation to SCT views on self-regulation. Self-observation reflects a person’s ability to monitor or keep track of their own behaviours and outcomes. Self-judgment is the process through which one evaluates whether their actions are effective and allow them to make progress toward their goals. Finally, self-reaction occurs when one responds to the evaluations they have made by modifying their behaviour, rewarding it, or discontinuing it.

Self-regulation is a prominent feature of SCT that highlights the underlying assumptions regarding agency and the influence of personal factors on behaviour and the environment. As noted above, self-regulation is also dependent on other processes within SCT, including goal setting and self-efficacy. Unless people have goals and feel efficacious about reaching them, they may not activate the processes needed for self-regulation. Modelling can also affect one's self-regulated learning. The skills needed to manage one's behaviour, as well as the beliefs and attitudes that serve to motivate self-regulation, can be obtained through modelling.

2.6.3. SCT and Implementation Intentions

An implementation intention is a self-regulatory strategy in the form of an "if-then plan" that can lead to better goal attainment, as well as help in habit and behaviour modification. It is subsidiary to goal intentions, as it specifies the when, where and how portions of goal-directed behaviour[59].

To implement the goals that are selected, some individuals form “implementation intentions”[59]. In particular, some individuals form conditional plans, in which they imagine the precise behaviours they will undertake in response to specific cues. That is, they might form an image of when, where, and how they will execute the intended behaviour.

The CHEST Intervention aims to develop “If then coping plans”, for example; if you develop this symptom then you ring your GP right away. The intervention provides prompts for self-monitoring and enabling if then coping plans to occur and tackle barriers to consultation so
for example, what do you do if you ring your General Practice and the number is busy, or how does one feel about seeing an alternative doctor?

In contrast, some individuals do not form conditional plans. They might decide to execute a behaviour without specifying the time, place, or context in which this act should be implemented. This is referred to a goal intention not an implementation intention.

Many studies indicate that individuals are more inclined to fulfil their goals if they form implementation intentions, that is, if they consider the conditions under which they will execute the intended behaviours (e.g., Oettingen, Hoig, & Gollwitzer, 2000[104]).

Implementation intentions have been shown to improve the capacity of individuals to initiate and maintain behaviours that fulfil their goals in many important domains. For example, implementation intentions have been shown to initiate and maintain behaviours’ that improve health, such as screening for breast cancer[105] screening for cervical cancer[106], consuming healthy food[107] consuming vitamin C pills[108] and engaging in exercise[109-111].

Most of the studies have examined health behaviours that involve engaging in a suitable behaviour. Fewer studies have examined the capacity to override undesirable habits, such as eating unhealthy food, smoking cigarettes, or consuming excessive alcohol[59]. That is, few studies examine the capacity of individuals to change an existing, but unsuitable behaviour into a more “desirable and adaptive inclination”[59].

Adriaanse et al. (2009) attempted to address this shortcoming[112]. These authors showed that implementation intentions can inhibit the habit of eating unhealthy food. Specifically, these implementation intentions were most effective when participants connected their goal to eat healthy good with the feelings or motivations they typically experience when they eat unhealthy food. For example, they might have formed the implementation intention “If I am bored, I will eat an apple”. These goals were likely to be fulfilled if related to feelings or motivations that correspond to maladaptive habits rather than a typical setting, time, or place.

Therefore implementation intentions have been the basis for behaviour change interventions, particularly through the use of the TPB and planning.
2.7. Overall summary

In conclusion, the core tenants of each of the models described in this chapter have been summarised in Table 5, to describe the strategies used to design the Scottish CHEST Intervention.

Table 5 Overall summary of behaviour change techniques used in the CHEST Intervention.

<table>
<thead>
<tr>
<th>Aims of the CHEST Trial</th>
<th>Underlying Theory</th>
<th>How it was used in the CHEST Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increase salience/Personal Relevance</td>
<td>Illness Action Model[53]</td>
<td>A list of what symptoms to look out for to increase patient knowledge.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The slogan “Look out for number 1, only you know when you don’t feel 100%.”</td>
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<tr>
<td></td>
<td></td>
<td>“Listen to family and friends if they notice something is wrong…”</td>
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<tr>
<td></td>
<td></td>
<td>Salience is reinforced with a case study of an individual who initially ignored symptoms but finally did see the doctor. Lung cancer was diagnosed and treatment began.</td>
</tr>
<tr>
<td>Improve knowledge of Symptoms</td>
<td>Illness prototypes[54]</td>
<td>Each patient is given a simple checklist of symptoms, that need action and when.</td>
</tr>
<tr>
<td>Reinforce the benefits of early consultation</td>
<td>Theory of Planned Behaviour[55]</td>
<td>Change attitudes to early consulting “It’s definitely worth your while..” or “Its worth having symptoms dealt with because treatments can make you feel better, improve your quality of life and even extend your life…”</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Subjective norms, “my family and friends think I should stop smoking….. “ or “If other people notice your symptoms, listen to what they say…”</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Perceived control over making an appointment. “It’s as easy as 123…”</td>
</tr>
<tr>
<td>Sanction Early consultation</td>
<td>Zola’s Triggers[56]</td>
<td>Time frame set for seeking help. Patients exposed to the CHEST Intervention are set “time limits” whereby if symptoms persist longer than 3 weeks; the patient is encouraged to seek help. Patients are also encouraged to seek help if these symptoms are interfering with day to day life or other people are noticing their symptoms.</td>
</tr>
<tr>
<td>Tackle Barriers to consultation</td>
<td>Theory of Planned Behaviour[57]</td>
<td>Change attitudes to consulting, listen to friends and family and give the person control over making that appointment. Social Support: advice of general social support for the behaviour from friends, relatives, or buddies. “Let your families, friends or carers read this handbook, there may be ways they can help. Provide each patient with support helplines such as the Cancer Council.</td>
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<tr>
<td>Develop a personalised action and coping plans</td>
<td>Social Cognition Theory[58]</td>
<td>Self-efficacy – the confidence that one can make an appointment. Reinforcement of when to make that appointment. Also verbal persuasion to increase self-efficacy. The CHEST Intervention tells the patient they can successfully perform the behaviour arguing against self-doubts and asserting they can succeed. “It’s as easy as 123…..” Modelling of the behaviour, for example, in the handbook there is behaviour of seeking help- “I said crickey I better go and see about this cough, so I went to my doctor....” Prompts and cues. Use environmental, social or internal stimuli to prompt or cue performance of wanted behaviour or non-performance of unwanted behaviour. Patients are asked to choose prompts which will remind them to check for their symptoms including a text message, postcard, email or phone call. Each patient is given a magnet with the 123 slogan also.</td>
</tr>
<tr>
<td>Develop a personalised action and coping plan</td>
<td>Implementation Intentions[60]</td>
<td>“If then coping plans..” Action planning was used to prompt detailed planning of the behaviour goal including context, frequency, intensity and duration of performance. For example patients are asked to plan the behaviours they will perform in response to prompts such as “if on one of my regular checks I have symptoms I will....”</td>
</tr>
</tbody>
</table>

(Sourced from Smith et al. (2012). Developing a complex intervention to reduce time to presentation with symptoms of lung cancer[48]).
Chapter 3. Phase I-Pilot Study

3.1. Introduction

During 2012, an initial pilot study was conducted in Perth, WA to adapt the CHEST Intervention for an Australian population. This study applied the MRC framework for the design and evaluation of complex interventions as described in Chapter 2, and represents a critical phase of research that needs to be conducted prior to the undertaking of a definitive trial[51]. Piloting was necessary to test the acceptability and feasibility of the intervention and to test our electronic data extraction software for identifying eligible patients. This chapter will describe initial consumer feedback regarding the CHEST Intervention and material including the Patient Information Sheet, questionnaire and self-help manual, followed by modification of the material for an Australian audience. This chapter then describes the Phase I pilot trial which resulted in the changes for the final CHEST-Australia Phase II trial and protocol.

3.2. Initial modifications made to the Scottish Intervention

As described in Chapter One, the Scottish Intervention comprised of a consultation with a trained nurse guiding each participant through a self-help manual, which the participant took home, and developing “If then” Action plans. The ‘self-help” manual provided information and behaviour change techniques including celebrity endorsements (by Liz Dawn) from Coronation Street (Appendix A).

Initially, smokers and ex-smokers were identified from practice computerised records and a sample was invited by their general practice to take part in the study by post. Two waves of recruitment were carried out, the first to establish recruitment rates and the second to achieve the required target size.

The process for those assigned to the Intervention included taking height and weight measurements prior to going through the self-help booklet. After a nurse had gone through the self-help booklet, baseline measurements were taken, including blood pressure and a spirometry test (see Appendix A).
Those assigned to the control group received usual care at their general practice, which included patient initiated consultation, opportunistic smoking cessation advice and if applicable, annual reviews for chronic obstructive pulmonary disease.

3.2.1. **Initial consumer consultation with the Scottish material.**

This was conducted initially with one focus group who were consumers with chronic respiratory disease. They reviewed the CHEST self-help manual and provided feedback on the overall intervention. Separate feedback on the acceptability of the intervention, the length of the questionnaire, the intervention handbook and trial design were also obtained from the Joint Consumer Advisory Group of Primary Care Collaborative Cancer Clinical Trials Group (PC4) and the Psycho-oncology Group (PoCoG). This process occurred in mid to late 2012.

**Box 1 Key points from the Consumer Advisory Group**

- Consumers thought the self-help manual would be useful and should encourage those at a high risk of a lung condition to visit their GP sooner.

- Some consumers thought that for those who are already sick (for example with COPD) this intervention maybe too late to help them or it would be like “preaching to the converted.” Many already knew what symptoms to look out for.

- All consumers liked the Patient Information Sheet, although some people thought it could be simplified more. Many wanted to know what exactly happens if they participate in the study.

- Another concern was the cost of participating in the study. Many wanted to know if they had to pay to participate. We therefore made it clear in the Patient Information Sheet (PIS) that there was no cost involved in participating and that we don’t pay people to participate either. All travel expenses will be reimbursed though.

- The consumers did not seem to mind the Scottish terminology but thought the public would prefer Australian lay language to be used. The word “crikey” and “Mate” seemed relatable.

- There were some questions raised about patient confidentiality if we were to
search through electronic databases. This was given priority when designing the Patient Information Sheet and Consent Form.

- Some consumers questioned the relevance of some of the questions in the Intervention Booklet, for example: “what if you try ringing your Doctors surgery and you can’t get through.” or “What if you can’t get a doctor’s appointment within 3 days.” These questions did not seem to be relevant in Australia compared to the United Kingdom.

As a result of this initial consumer feedback the following changes were made to the trial material.

3.2.2. Modification of the self-help manual

The layout of the self-help manual was left very similar to the Scottish CHEST Trial (Scottish manual is located in Appendix A). The main changes were made to the language used, the colour of the booklet and the removal of some questions that were not relevant in the Australian setting. Also, Australian support hotlines were added to the end of the booklet (Appendix D).

Specifically the following changes were made:


Quotations from Professor Jon Emery (a Primary Care Physician) and Associate Professor David Barnes (Respiratory Physician) were used in the Australian Intervention booklet. The Scottish handbook used a “celebrity” to endorse their handbook who suffered from emphysema. We could not find a suitable celebrity in Australia.


The first sentence is changed from “Lung disease is on the rise in the UK” to “about 14% of deaths in Australia are due to lung disease.”

Page 8. The Australian emergency number 000 is used instead of the UK emergency number. The local Australian General Practice number is used and afterhours number
relevant to that area. In the Australian version we referred to a General Practice rather than a “Health centre.”

Page 10. The Scottish slang word “Och” is replaced with the Australian word “Crikey” in one of the speech bubbles.

Page 12. Part of the personalised Action Plan. The following sentence was removed: What if the receptionist at your health centre offers you the practice nurse when you really want to see the doctor.” This is not a procedure carried out in Australia. This question was replaced with “What if you cannot get an appointment within 3 days.” It was observed that even this question was not highly relevant to the Australian local population.

Page 13. Doctor’s quotes were changed.

Page 14. The Scottish terminology “didnae” was replaced with “didn’t.”

Page 15. A lot of the Scottish terminology in Mike’s story was changed to Australian lay language. Specifically:

“itsel’ to “itself.”

“Hoarseyness” to “scratchiness.”

“Och” to “Bloody Hell.”

Page 18. Support Helplines. Relevant Australian Support Helplines replaced the UK support helplines. The Australian Lung Foundation, Cancer Council and Asthma Australia contact information was used.

The Scottish Chest logo was replaced with the Australian Chest Australia logo throughout the handbook and the Australian green and gold colouring replaced the blue colouring through the Scottish Intervention handbook.

3.2.3. **Length and design of the questionnaire**

The questionnaire was tested with members from the Joint Consumer Advisory Group of PC4 and the Psych oncology Group (POCOG). We were particularly interested in the length of the questionnaire and the wording. We were concerned that the addition of the AqoL8D (Quality of Life Questionnaire which was not included in the Scottish Questionnaire) may
result in a questionnaire that took too long to complete. All members apart from one found the questionnaire took approximately 20-25 minutes to complete and was of a reasonable length.

The questionnaire was printed in a booklet orientation so it appeared compact and was easy to send. The concern was that the font was too small and this may deter people from completing the questionnaire. However, none of the members found this an issue and hence the questionnaire was left as is.

3.2.4. **Individual consent form**

Consent Forms were designed to ensure the patient knew what they were agreeing to within the study and ensures the rights of the patient. The consent point was approved through the HREC committee. In addition to what is on a standard consent form, we also asked for permission to access the patients GP medical records for 6 months after their consultation in order to check for any respiratory consultations. We also asked for permission to perform a lung function test and access Medicare and PBS claim data for outcome analysis. In addition, permission was sought to follow-up some patients in the study with a phone call (see Figure 9 for the Phase I consent form).

3.2.5. **Development of the first Patient Information Sheet**

Taking into account the comments from the consumer group and those involved in the Pilot trial the Patient Information Sheet was modified to appear simple and easy to read with the following key sub-headings: What is the purpose of the research study? Why have I been invited? Do I have to take part? What will happen to me if I take part? What will I have to do if I take part? What are the disadvantages or risks of taking part? The possible benefits of taking part. What happens when the research study stops? What will happen when I don’t want to carry on with the study? Will taking part in the study be kept confidential? Involvement of your General Practitioner (GP) and what will happen to the results of the research study. Further information and contact details and those associated with the trial were on the outside sheaf of the pamphlet. The CHEST logo and slogan “Chest Symptoms that call for action, It’s as easy as 123, special attention for people who may be at risk of lung disease” (Figure 9).
We would like to invite you to take part in a research study. Before you decide if you would like to take part it is important for you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Discuss it with relatives and friends, and your GP if you wish. Ask us if there is anything that is not clear or if you would like more information (contact details at the end). Take time to decide whether or not you wish to take part.

What is the purpose of the research study?

Approximately 14% of all deaths each year in Australia are a result of lung disease. Symptoms of lung disease, including lung cancer, are often put down to other causes, or not considered serious enough to seek advice from your doctor. We have designed this study to encourage people who are found to have reached an advanced stage of lung disease to seek medical advice early. We have designed a self-help information booklet on lung disease which aims to encourage early consultation with symptoms that require investigation. We now need to assess whether this booklet would be helpful and we would like people living in the Perth area to assist us with this.

Why have I been invited?

We have designed the study to minimise this possibility. We have designed the study to minimise this possibility. This is an exploratory study only, the usual care all participants receive would not be affected.

Do I have to take part?

No, taking part is voluntary. If you would prefer not to take part, you do not have to give a reason. The care you receive would not be affected. If you agree to take part, you are free to change your mind at any time.

What will happen to me if I take part?

Once you have agreed to take part and signed a consent form, you will be randomly allocated to one of two arms of the study. Randomisation means that you are put into a group by chance, like the toss of a coin. A computer program will choose which group you are allocated to. Neither you nor your doctor can choose the group you will be in. You will be asked to attend a consultation in your GP practice to take a group of measures to assess your lung function. A copy of this result will be given to your GP. If you are in one group of the study you will then be given through the self-help booklet.

What will I have to do if I take part?

You will be asked to attend one appointment with a health researcher at your GP practice. This appointment will last a time that suits both you and the researcher and will last about 20-45 minutes. You can bring a family member or friend along with you.

Will I be paid to take part?

We cannot pay you to take part. However, we will refund all travel expenses you pay because of taking part. In addition, everyone will have a questionnaire posted to them to complete at three different time points in the study: at the beginning, at one month, and at 12 months. Also if you consult your doctor with chest symptoms during the 12 month study period you will be asked to complete a short questionnaire about your symptoms. In the consent form we ask for permission to look at your GP medical records. This will let us check details of chest and lung consultations made over the study period.

Will my taking part in this study be kept confidential?

We have designed the study to minimise this possibility. There may be no direct benefit to you as an individual. However, the findings we obtain will be used to help save the lives of others in the future. What happens when the research study stops?

If you withdraw from the study, we will destroy all information that would identify you. If you allow us, we will use the data collected up to the time you withdraw. Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the surgery will have your name and address removed so that you cannot be identified. In order to be able to check your medical records we will need to hold some information such as your date of birth and patient identification number. All tape recordings will be stored securely and destroyed after a period of four years.

Involvement of your General Practitioner (GP)

Doctors in your general practice support this study but are not being paid for including you in the study. If you agree to take part we will let them know.

What will happen to the results of the research study?

The findings will be analysed and the results will be published. We will send you a summary of the results.

Who is in organising and funding the research?

The project is being organised by the School of Primary, Aboriginal and Rural Health Care (SPARCH) at the University of Western Australia, as well as The Department of General Practice Department, University of Aberdeen, Scotland, United Kingdom. This trial will be funded by SPARCH. Further funding has been sought from Cancer Australia and the National Health Medical Research Council (NHMRC) which, if successful, will fund a further 4 year research and development of a larger trial, led by PhD student Sonya Murray.

Who has reviewed the study?

All research in the University is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given approval by the University of Western Australia, as well as The Department of Academic General Practice and Primary Care Academic Centre, University of Melbourne. Herman Professor of Primary Care Cancer Research, Professor of General Practice, Professor Jon Emery and Sonya Murray will be keen to hear about them.

If you have any concerns about any aspect of this study, Sonya Murray or Jon Emery will be happy to talk to you. You can also complain formally, you can do this through the University. If you have any concerns about any aspect of this study, Sonya Murray or Jon Emery will be happy to talk to you. You can also complain formally, you can do this through the University. If you have any concerns about any aspect of this study, Sonya Murray or Jon Emery will be happy to talk to you. You can also complain formally, you can do this through the University. If you have any concerns about any aspect of this study, Sonya Murray or Jon Emery will be happy to talk to you. You can also complain formally, you can do this through the University. If you have any concerns about any aspect of this study, Sonya Murray or Jon Emery will be happy to talk to you. You can also complain formally, you can do this through the University. If you have any concerns about any aspect of this study, Sonya Murray or Jon Emery will be happy to talk to you. You can also complain formally, you can do this through the University. If you have any concerns about any aspect of this study, Sonya Murray or Jon Emery will be happy to talk to you. You can also complain formally, you can do this through the University. If you have any concerns about any aspect of this study, Sonya Murray or Jon Emery will be happy to talk to you. You can also complain formally, you can do this through the University. If you have any concerns about any aspect of this study, Sonya Murray or Jon Emery will be happy to talk to you. You can also complain formally, you can do this through the University.
Additional information was described in the inside leaf. This included who organised and funded the research, who reviewed the study and what if there was a problem, giving key staff contact details.

The brochure was designed in eye catching colours that resembled the Australian yellow and gold theme and the logo was placed on the front cover.

3.2.6. Changes to the delivery of the Scottish Intervention and modification of the consultation script

The following changes were made to the Scottish consultation script and Intervention procedure for the CHEST – Australia Phase I Pilot Trial: (Phase I CHEST Australia script in Appendix D).

- The Phase I trial patients were sent consent forms to sign and send back. They were then contacted for an appointment at their GP practice.

- Weight and height measurements were not taken initially like the Scottish Trial as these were in the medical records and were not so crucial to the Phase 1 pilot trial.

- Australian Relevant researchers, and contact details replaced the Scottish ones.

- After hour GP numbers relevant to Australia replaced the Scottish after hour’s number.

- Australian Support Helplines Asthma Australia, The Australian Lung Foundation, Cancer Council Australia were discussed. The question; ‘What if the receptionist at your practice offers you the practice nurse when you really want to see the doctor?’ was excluded as this was not relevant in the Australian setting when booking a Doctor’s appointment.

- The Scottish Intervention ends with blood pressure being taken and a spirometry test. Patients in the Australian Phase I pilot trial were not given a spirometry test and blood pressure was not taken.
3.3. Piloting of the CHEST Intervention (Phase I trial)

Eleven participants were recruited from Ocean Keys General Practice (Perth, WA) to pilot the CHEST consultation, self-monitoring prompts, and the outcome measures and follow-up procedures.

All patients were exposed to the intervention and followed up at one and 6 months. Some patients were followed up within two weeks of completion of the trial (by phone) to further explore how they found the intervention. Patients were randomly selected after the Canning Tool had extracted those eligible for the study and then 11 patients were approached. This work resulted in modifications to the patient information sheet, Intervention booklet and the questionnaire design and length and the consultation process itself. This will be described below.

3.3.1. Canning Tool

3.3.1.1. History behind the Canning Tool

Current General Practice software provide good storage and retrieval systems on a patient by patient basis, however retrieval for whole populations can be difficult. In response to this The Canning Division was approached by the National Primary Care Collaborative in 2005 to develop a data extraction tool for diabetes and coronary heart disease. The Bentley-Armadale Medicare local (formerly known as the Canning Division) produces a range of tools to extract data from range of GP desktop software (http://www.canningtool.com.au)[113].

3.3.1.2. Development of the Canning Tool

Potentially eligible participants were identified from computerised records using a specific version of electronic data extraction software developed for this trial. For the CHEST study, the smoking extraction tool was designed to extract smoking information from Best Practice, Zedmed and Medical Director clinical software. The tool generates a patient list with the following clinical information: surname, first name, age, smoking status, smoking quantity, smoking frequency, cigarettes smoked daily, duration, pack years, smoking cessation date, street, suburb and postcode. Extracted data from the tool can be exported to an excel file. The following inclusion and exclusion criteria are described for each specific software.
3.3.1.3. **Inclusion and exclusion criteria from the Canning Tool**

The inclusion criteria were patients aged 55 and over, including ex-smokers if their cessation dates were less than 15 years ago. Patients had to be moderate to heavy smokers (with at least 20 pack years). Participants were able to read and write English and give informed consent. Exclusion criteria were severe psychiatric or cognitive disorder or a previous diagnosis of lung cancer. Additional terms for exclusion used for the different software are described in Appendix B.

The Canning tool was originally tested in Ocean Keys General Practice. All those extracted from the tool were checked against the practice database to ensure the tool was extracting the patients following the correct inclusion and exclusion criteria described below. Patients (n=255) were extracted from the MD software of whom 86 were eligible. From these 86, 13 returned expression of interest forms. While the Canning Tool extracts an initial list of possible participants, it was discovered that further screening was necessary to determine when an ex-smoker stopped smoking and to establish the exact number of pack years. Often, the GP medical records were not up to date or accurate for smoking records, so further screening was necessary to determine those that were eligible for the CHEST Study (see Section 3.4.3.3-Development of the Expression of Interest Form). After further screening, 11 were eligible and consented to the Phase I study.

3.3.2. **Quantitative results for the phase I pilot trial**

3.3.2.1. **Participants**

Eleven participants were recruited from Ocean Keys General Practice (Perth, WA) to pilot the CHEST consultation, self-monitoring prompts, and the outcome measures and follow-up procedures. The participants were selected using the inclusion criteria specified above. Table 6 describes the baseline characteristics of patients in the Phase I pilot study.

3.3.2.2. **Procedure**

Patients eligible for the study were identified using the Smoking extraction tool for Best Practice Software. Initially 255 were found eligible for the study, further screening resulted in 86 eligible (many had stopped smoking >15 years ago). These 86 patients were sent invitations to the study of whom 13 responded. Eligible consent was obtained from 11 patients.
All patients were exposed to the intervention and were followed up at one and 6 months with the questionnaires. Follow up phone calls were made 2 weeks after the consultation process to gauge feedback on the manual, questionnaire, information sheet and month reminders. Specifically, questions were asked about their thoughts on the process, how clear the trial material was, any difficulties experienced and why they participated in the trial.

### Table 6 Baseline characteristics of patients enrolled in the Phase I Pilot Trial.

<table>
<thead>
<tr>
<th>Patient Number</th>
<th>Gender</th>
<th>Age</th>
<th>Smoking Status</th>
<th>Postcode</th>
<th>MRC Dyspnoea</th>
<th>Employment Status</th>
<th>Home Ownership</th>
<th>Lives</th>
<th>Education</th>
</tr>
</thead>
<tbody>
<tr>
<td>55</td>
<td>M</td>
<td>79</td>
<td>NS</td>
<td>6030</td>
<td>1-3</td>
<td>Retired</td>
<td>Own home</td>
<td>With spouse</td>
<td>Trade certificate</td>
</tr>
<tr>
<td>364</td>
<td>M</td>
<td>62</td>
<td>S</td>
<td>6030</td>
<td>1-3</td>
<td>Invalid</td>
<td>Lease Life</td>
<td>With spouse</td>
<td>Year 12</td>
</tr>
<tr>
<td>423</td>
<td>F</td>
<td>63</td>
<td>NS</td>
<td>6041</td>
<td>1-3</td>
<td>Retired/Invalid</td>
<td>Own home</td>
<td>With spouse</td>
<td>Year 12</td>
</tr>
<tr>
<td>508</td>
<td>M</td>
<td>61</td>
<td>NS</td>
<td>6028</td>
<td>1-3</td>
<td>Retired</td>
<td>Own home</td>
<td>With spouse</td>
<td>Undergrad University</td>
</tr>
<tr>
<td>31</td>
<td>M</td>
<td>79</td>
<td>NS</td>
<td>6030</td>
<td>1-3</td>
<td>Retired/Volunteer</td>
<td>Lease Life</td>
<td>With spouse</td>
<td>&lt;Year 11</td>
</tr>
<tr>
<td>71</td>
<td>M</td>
<td>87</td>
<td>NS</td>
<td>6030</td>
<td>1-3</td>
<td>Retired</td>
<td>Lease Life</td>
<td>With spouse</td>
<td>Teacher Certificate</td>
</tr>
<tr>
<td>263</td>
<td>F</td>
<td>58</td>
<td>S</td>
<td>6030</td>
<td>1-3</td>
<td>Nursing</td>
<td>Own home</td>
<td>With family</td>
<td>Diploma Nursing</td>
</tr>
<tr>
<td>432</td>
<td>M</td>
<td>57</td>
<td>NS</td>
<td>6030</td>
<td>1-3</td>
<td>Not specified</td>
<td>Own home</td>
<td>With spouse</td>
<td>&lt;Year 11</td>
</tr>
<tr>
<td>514</td>
<td>F</td>
<td>69</td>
<td>NS</td>
<td>6030</td>
<td>1-3</td>
<td>Retired</td>
<td>Own home</td>
<td>With spouse</td>
<td>Year 12</td>
</tr>
<tr>
<td>350</td>
<td>M</td>
<td>63</td>
<td>NS</td>
<td>6743</td>
<td>1-3</td>
<td>Volunteer</td>
<td>Rent</td>
<td>Alone</td>
<td>&lt;Year 11</td>
</tr>
<tr>
<td>569</td>
<td>M</td>
<td>63</td>
<td>NS</td>
<td>6030</td>
<td>1-3</td>
<td>Invalid</td>
<td>Own home</td>
<td>With spouse</td>
<td>&lt;Year 11</td>
</tr>
</tbody>
</table>

#### 3.3.2.3. Outcomes

The main objectives of the Phase I trial was to test the acceptability and feasibility of the intervention, recruitment and outcome measures. By assessing the feasibility of the Intervention, we could also look at an initial assessment of the primary outcome;
consultation rates for respiratory symptoms (which was captured through a review of the medical records).

Additional outcomes included;

1. **Demographics and clinical variables.** Age, gender, marital status, postcode, highest education level, occupation, MRC Dyspnoea Scale\[114\] and lung function at baseline only (Appendix D).

2. **Perceived risk of Lung Disease.** A five point self-completed scale asking “how would you rate your chance of getting lung disease?” Answers range from “very low” to “very high.” Developed for the Scottish CHEST Trial (Appendix D).

3. **Intention to Consult.** Intention to consult with symptoms by a given time. Each item has 11 options ranging from <1 day to >6months to 180 days to make an estimation of the time taken before making an appointment to see a doctor for a given chest symptom scenario. Developed for the Scottish CHEST Trial (Appendix D).

4. **Self-efficacy for consulting without delay.** A 10-item self-completed scale summed to score 10-100, developed for the Scottish CHEST Trial which showed good internal reliability (Cronbach α =0.85) (Appendix D).

5. **Knowledge of symptoms of lung disease.** A 21-item self-completed checklist of possible symptoms expressed as a percentage correctly selected as associated with chest disease (Appendix D).

6. **Hospital anxiety and depression scale (HADS)[115]** This 14-item self-completed scale has been widely used to measure distress and has been extensively validated and shown to perform well in a wide range of populations (mean Cronbach α = 0.82; sensitivity and specificity 0.80) (Appendix D). In general the HADS tool was developed as a brief measure of generalised symptoms of anxiety and fear. The purpose of the HADS was to screen for clinically significant anxiety and depressive symptoms in medically ill patients. The HADS tool includes specific items that assess generalised anxiety including tension, worry, fear, panic, difficulties in relaxing, and restlessness. A systematic review of measures of distress in patient
with cancer has concluded that the HADS performs better than other similar measures.

7. **Cancer-worry scale.** A 6-item self-completed scale, adapted from the breast cancer worry scale[14] which showed good internal reliability in the CHEST Trial (Cronbach α= 0.88) (Appendix D).

Patient average scores at baseline, one month and six months were compared as were the percentage change from baseline at one and six months.

3.3.2.4. **Questionnaire results from baseline, one month and six months**

Figure 10 shows that the patient average scores at baseline, one month and six months. Completion rates of questionnaires at the three time points was important in assessing feasibility. Eleven participants completed the baseline questionnaire whereas nine participants completed the one and 6 month questionnaires (see Appendix C for raw data).

![Patient Average Scores](image)

**Figure 10 Phase I patient average score at baseline, one month and 6 month scores.**

At one month, scores increased for Knowledge of Symptoms, Risk of Lung Disease, Intention to Consult, Self-efficacy, HADs (Hospital, Anxiety and Depression scores) and cancer worry. However, scores decreased for views on own health and HADs Total score.
After 6 months, all scores slightly decreased compared to 1 month (apart from Cancer Worry) but showed mixed improvement compared to baseline results. The following scales showed a higher score at 6 months compared to baseline: Risk of Lung Disease, Self-efficacy and Cancer Worry.

Of concern, is the increase in the Cancer Worry scale over 6 months. However, if we examine Appendix C, Table 6, it can be seen that one patient contributed to this increase (patient 11) and if we look at the individual patient bar graphs, patient 11 was the only patient to show a high increase in this score.

If the overall percentage change from baseline is plotted, this shows that all scores increased over one month apart from views on own health (which is only marginally decreased) and HADS total, which is encouraging because the trial tries to prevent an increase in adverse events such as anxiety and worry. As mentioned above the large increase in Cancer Worry at one and six months is slightly skewed due to one patient.

![% Change from Baseline Survey](image)

**Figure 11** Phase I percentage change from baseline at one and six months.

### 3.3.3. Feedback from follow-up interviews

Phase I follow up phone calls to determine the acceptability of the booklet, the questionnaires and information sheet were used. This was seen as a suitable approach to get initial feedback from the pilot trial. A final question as to why they wanted to
participate in the study was also asked. Follow up phone calls were made two weeks after the initial consultation.

Six patients were willing to have a follow up phone call to discuss the trial process. We were unable to get hold of three of the patients and two did not want to be interviewed. It was decided phone interviews would be a suitable approach for an initial assessment of the intervention.

3.3.3.1. Self-help Booklet

Overall all patients were satisfied with the manual. All patients understood the language used and could understand the booklet.

Two patients claimed it was “common sense.”

Other comments included it “was straightforward, easy to follow and perfectly clear...”

There were not any changes suggested or negative feedback regarding the manual.

3.3.3.2. Questionnaire design and length

The five patients enrolled in the pilot study thought the questionnaire length and size of the booklet was acceptable. All patients said it took about 25-30 minutes to complete and was not a long process or an inconvenience.

A small number of potential concerns were raised regarding the wording of the questions:

Two patients did refer to the questions being “repetitive” at times.

One patient referred to the questions being “confusing” and that “they could have been written simpler.” This was in particular reference to the confidence scales (questions 12-22, CHEST questionnaire, Appendix D). After an explanation of what the question was asking, this patient felt more confident answering this section of the questionnaire.

Whereas another patient commented that the questions “were common sense.....”

3.3.3.3. Information Sheet Feedback

All patients felt there was sufficient information in the information sheet and that it was clear to understand.
One patient said the information sheet “let them know what they were getting involved with...”

Another patient said “there was sufficient information for me to decide to be part of the study....”

None of the patients felt there was insufficient information provided or that they did not understand what the study involved.

3.3.3.4. Feedback on the monthly reminders

All patients thought the monthly reminders were a good idea. One patient remarked that they helped him remember what symptoms to look out for.

“If a cough or something is persistent and you know, and over three weeks or so, then you tend to worry about it, so I guess that’s fair enough. Otherwise, you just tend to forget these things......”

3.3.3.5. Reasons for participation in the study

There were varied reasons for participating in the study.

Health issues were reported by two patients. One patient said she was concerned about her mother dying of end stage COPD so she “wanted to be made aware of the early symptoms and be supported with that...”

Another patient said “she thought the study would help with my cough...you know, somebody would tell me something about my cough and how to get rid of it....”

Another patient felt “it was his civic duty...”

While another patient said “I was probably bored...”

One patient liked the idea of just going to his general practice to participate in a study. He would not have participated if the study if he had to travel to the University or one of the hospitals. This feedback was positive considering all the Phase II recruitment would be at General Practices.
3.3.3.6. Discussion

Many factors can affect the successful implementation and validity of intervention studies. A primary purpose of feasibility and pilot studies is to assess the potential for successful implementation of the proposed trial protocol and to reduce threats to the validity of these studies.

We wanted to address the feasibility and acceptability of the trial by testing the:

1. Process (CHEST Consultation and recruitment procedures).
2. Resources (Patient Information Sheet, CHEST handbook and questionnaire).
3. Management (Management of patient data and information collected by establishing a database for trial recruitment).
4. Scientific Basis of the planned Phase II RCT (Feasibility measurement which also captured respiratory consultation rates (the primary outcome measurement for Phase II) and assessment.

It was feasible to obtain information about respiratory consultation rates by reviewing the electronic medical records. An initial assessment of the primary outcome specified for the Phase II trial showed that out of the 11 patients exposed to the intervention, four consulted again with respiratory symptoms.

One of the objectives of the Phase I trial was to address the acceptability of the intervention and how patients reacted to the intervention. Feedback from the follow up phone calls allowed us to gauge initial opinion on this, specifically regarding some of the procedures. Overall most were satisfied with the procedure and felt they had sufficient information about the study from the Patient Information Sheet. All participants could understand the language used in the self-help manual and that it was clear and useful. Similarly, the questionnaire design and length were acceptable, taking approximately 25-30 minutes to complete. Many felt the Intervention itself was straightforward and easy to understand and did not express any concerns with process.

For the pilot trial, all management of patient data was in an excel spreadsheet. It was decided that while this was sufficient for this phase 1 trial, that a larger database would be
required for the phase II study such as Microsoft Access. Development of a larger database is described in Chapter 4, (Section 4.2.5).

Part of the process of assessing feasibility was to test the following:

1. The numbers eligible. As described above, 255 patients were extracted from the MD software of which 86 were eligible. From these 86, 13 returned expression of interest forms and after further screening, 11 were eligible and consented to the study. While the Canning Tool extracts an initial list of possible participants, it was discovered that further screening was necessary to determine when an ex-smoker stopped smoking and to establish the exact number of pack years. Often, the quality of the data from the GP medical records did not allow for accurate assessment of pack years. Further screening was necessary to determine those that were eligible for the CHEST Study (see Section 3.4.3.3-Development of the Expression of Interest Form).

2. The response rates. Thirteen participants initially responded from the 86 approached, which is a 15% response rate. This is slightly lower than the response rate from the Scottish Chest study of 19%. Our approach did not have any secondary follow up for those invited to the study, so it was decided that all eligible participants would be followed up with postcards two weeks after being initially invited into the study for the Phase II design to increase the Response Rate.

3. Retention and follow up rates. Of the 11 who were recruited into the pilot trial, 11 completed the baseline questionnaire, 9 completed the one month questionnaire and 9 completed the 6 month questionnaire. Therefore 9/11 were still completing follow-up after 6 months. One patient dropped out of the trial due to personal reasons and the other patient we were unable to make contact with to follow-up questionnaire completion. Six patients agreed to a follow-up phone interview, and 3 did not want to be interviewed. The remaining two patients were unable to be contacted for a follow-up interview.

4. Adherence rates to study procedures, intervention attendance and engagement. There was good adherence to the study procedures and all those invited to the consultation attended.
5. Data collection assessment. Part of the phase I trial was to determine if the patients understood the questions within the questionnaire. From the six patients interviewed with follow up phone calls, all seemed happy with questionnaire, design and size. We also wanted to know if the participants had enough time to complete the data procedures. Feedback from those interviewed suggest that the length of the questionnaire was not burdensome. In most cases, the questionnaire took approximately 25-30 minutes to complete which was not seen as an inconvenience. The intervention procedure took no longer than 30 minutes and this also was not seen as an inconvenience.

6. Adverse events. We were interested to know if any part of the intervention process caused distress to the participant. With the exception of one patient, results from the initial quantitative results show that the process is not causing any unnecessary distress. The reason for this patient’s distress was unrelated to the study.

An assessment of the overall feasibility outcomes suggested the CHEST trial could lead to a potentially feasible valid Phase II study and this led us to pursue the next stage.

3.4. Final material established for the CHEST Australia phase II trial

As a result of piloting the trial procedures, changes were made to the Patient Information Sheet, the Individual Consent Form, and new material was created such as the Expression of Interest Form (used to further clarify smoking pack years and smoking history). It was decided for the Phase II intervention that a spirometry test would be included in both arms of the trial, as this was considered a good “hook” for recruitment as well as acting as an attention control (see Chapter 4, Section 4.2.1). In addition, in order to reduce response burden and to prevent a Hawthorne effect, it was decided that questionnaires would be delivered at baseline, one month and 12 months and the 6 month questionnaire was withdrawn.

3.4.1. Modification to the research consultation script and Intervention following the phase I pilot trial

The Scottish Trial used a research consultation script to outline what was said and done in the Intervention (Appendix A). The script was modified for a researcher rather than a research nurse, and generally followed the process of taking baseline measurements, carrying out a spirometry test and going through the booklet for those in the intervention...
arm. The spirometry test was the only clinical test performed in the intervention, and therefore it was decided if a researcher was trained to correctly perform this test, this would enable a health researcher to deliver the intervention rather than a research nurse. Hiring independent research nurses solely for the study may have incurred more costs and using a research nurse from a practice may have used up valuable clinical time. The Australian trial also included a script for the control arm in order to maintain consistency of the messages in both arms.

Specifically the following changes were made to the Scottish Consultation script (Appendix D).

- Patients from the Australian Study bought their baseline questionnaire with them and the researcher checked that they answered all of the scores, also checking the MRC Dyspnoea score required for randomisation and the self-harm score from the HADs scale (if a patient did feel like harming themselves then their GP was notified). In addition the patient was asked if they had any questions regarding the questionnaire.

- The patients smoking pack years were confirmed.

- Within the personalised Action Plan, the patient is to go through a series of questions to ascertain what they would do in certain situations. In the Scottish trial, the patient was asked to write these down, whereas in the Australian Trial answers were discussed verbally. Feedback from the Scottish Trial suggested that it took too long to write down action plans, and verbal discussion was just as effective.

- The Australian trial also did not seek verbal permission from a close other for deciding which prompt to use. Rather, each participant was asked if they prefer postcard, text, an email or a phone call as a reminder.

- The question; ‘What if the receptionist at your practice offers you the practice nurse when you really want to see the doctor?’ was excluded as this was not relevant in the Australian setting.

- It was discovered through the course of the Phase I trial that the question; “What if you are not offered an appointment within 3 days?” was not so relevant to the Australian Population.
A script for the control arm was developed for the Phase II Australian Trial (see Appendix D). Specifically questions were asked around lung disease generally, if there was any family history, any exposure to Asbestos or industrial pollution.

A script for both arms was designed to end the Australian consultation, reminding them of upcoming questionnaires at 1 and 12 months, and if they have any respiratory consultations they will receive a shorter questionnaire in the mail. If any patient asked about smoking cessation advice they were referred to their GP and Quit line.

The Scottish Intervention concluded with a blood pressure test, followed by spirometry, whereas the Australian Intervention did not take blood pressure, only a spirometry test that was done early on in the consultation process.

### 3.4.2. Further development of the Patient Information Sheet

The Patient information sheet was simplified and amended into a more user friendly format. It was felt that there was too much information in the booklet and it needed to be more “obvious” as to what would happen if a patient participated.

The following changes were made and amendments were approved from UWA HREC (Appendix D).

The following sub-headings were added:

- How can I help? Why have I been invited? Do I have to take part? What happens if I choose to withdraw? Will I be paid to take part? What this study requires from you? Will my taking part in this study be kept confidential? And contact information was also made available.

It was important to describe initially how participation in the study would be useful, i.e. evaluation of a self-help manual and what participation would involve. Patient confidentiality was also a priority and if there is any payment to be involved in the study and if participation is voluntary or not.

There was also a brief blurb on the inside leaf with the heading “You can help improve lung disease outcomes.” which describes the aims of the CHEST study and a bit of background about the study. The outer leaf has photos of chief investigators with quotes encouraging seeking help earlier.
Key contact details and Human Ethics contact details (these were not included in the first PIS) were included for people who may have complaints or concerns about the way in which the study is being conducted. It is important to let people know that the study has been reviewed by an independent ethics committee to protect their safety, rights, wellbeing and dignity (Appendix D).

3.4.3. Development of new material

3.4.3.1. Development of the Expression of Interest Form- secondary screening questions

The Expression of Interest form was designed to deal with the limitations of data extraction. While the Canning Tool selected patients who met most of our criteria, more accurate information was required to determine if patients who had stopped smoking, had stopped within the last 15 years. Also, the extraction tool did not provide a Date of Birth. It was decided that an extra screening procedure was required, to ascertain exact dates for smoking cessation, periods of abstaining from smoking and birthdate to determine smoking pack years. Potentially eligible patients were invited to participate in the study by letter from their general practice. The general practice letter head was printed on top of the invitation letter. The invites not only included the patient information sheet but also the expression of interest form. The Expression of Interest form asked four screening questions aimed at assessing smoking pack years. They were:

1. Have you ever smoked?
2. How many cigarettes per day do you smoke/did you smoke?
3. How old were you when you started smoking?
4. If you no longer smoke, how old were you when you stopped?
5. What is your date of birth?

These screening questions provided more accurate information regarding the eligibility of patients and overcome limitations of electronic data on smoking in the medical record. Expression of Interest Form is located in Appendix D.
3.4.3.2. Development of prompts or monthly reminders

A range of monthly self-monitoring prompts were developed to appraise any current symptoms and were tailored to individual preferences. These included postcards, SMS, email reminders and fridge magnets. The prompts reminded the patient of the “It’s as easy as 123 slogan,” reinforcing that patients had to look out for number 1, take worrying respiratory symptoms to their GP and remember the 3 week rule, don’t wait longer than 3 weeks with some symptoms...

“It’s as easy as 1, 2, 3”. These three key actions are:

1. Look after number one and know the symptoms of lung disease.

2. It takes two to tango: the doctor can only help you if you see them when you have symptoms.

3. Remember the 3-week rule and see your doctor if you have symptoms for more than three weeks.

3.4.3.3. Development of the magnet/postcard

A magnet was used in conjunction with the intervention and acted as a reminder. As shown in Figure 12, the magnet just contained the logo and the slogan “it’s as easy as 123.”

Two postcards were developed. The first postcard, used for follow-up recruitment, was designed to attract the attention of a potential participant who had previously been invited into the study but had not sent in an Expression of Interest Form. Hence, the ‘did you receive our invite,” seemed like a good catch phrase to draw someone’s attention and get them interested enough to phone up to be recruited (Figure 12).

The second postcard was designed as a monthly prompt reminder. It was more detailed than the magnet, containing images and explanations of what the “1, 2, 3” slogan means. This was to be used in the monthly prompts served and served as reminders (Appendix D).
3.4.3.4. **General Practice Information Sheet**

In addition to the revised PIS, a general Practice information Sheet (Appendix D), based upon the PIS, was designed for General Practices who would be recruited into the study. Specifically, it informed General Practices about the purpose of the CHEST study, how patient confidentiality was handled, and how the general Practice is involved. Importantly, what staff members had to do was detailed in the brochure as well as payment for participation. Like the PIS, the GP Information Sheet provided key contact details on the back of the pamphlet and presented in the same manner with the CHEST logo and slogan on the front sheaf.

3.4.3.5. **Individual and Practice Consent Form**

Individual consent forms and Practice consent forms were revised for individuals and general practices participating in the trial (Appendix D).

3.4.3.6. **Development of Participant and Practice withdrawal consent forms**

Formal withdrawal forms for participants and general practices were also developed for the Phase II protocol (Appendix D).
Chapter 4. Quantitative Phase II Methods

This thesis applies the well-established Medical Research Council (MRC) methodological framework for the design and evaluation of complex interventions[51]. A complex Intervention consists of several components combined to produce a desired outcome. Evaluation of complex interventions requires the use of quantitative and qualitative evidence. While the phase I trial was carried out to determine feasibility and piloting procedures, the objectives of the Phase II study are to primarily test potential efficacy and determine the need for a phase III trial. Therefore, according to the MRC framework, this is an exploratory trial. A trial based on lung cancer outcomes would not be feasible given the size of a trial required and the amount of follow-up time to measure survival outcomes. Consultation rates in general practice for respiratory symptoms represent a relevant intermediate outcome along a causal pathway that ultimately results in earlier diagnosis of lung cancer. These are critical phases of research that need to be conducted prior to conducting a definitive trial[51].

Qualitative approaches can contribute in several ways to the development and evaluation of a complex intervention. The use of multiple, integrated approaches are particularly useful in the evaluation of the effects of health interventions as these involve social or behavioural processes that are difficult to explore or capture using quantitative methods alone. In this case, qualitative methods were used during the trial to determine whether the intervention was delivered as intended (see Chapters 5 and 7).

This trial represents a mixed methods approach using an embedded design. This is where the researcher combines the collection and analysis of both quantitative and qualitative data within a traditional quantitative research design or a qualitative research design. It is intended in this study that collection and analysis of the second data set (the qualitative data) shall occur during the implementation of the data collection and analysis procedures traditionally associated with the larger design. The purpose of the embedded design is to provide more than one data set, that is, a single data set alone is insufficient to determine the impact of the CHEST Intervention. In this study we are embedding the qualitative aspect of the study into the larger quantitative trial to examine the process of the intervention and gain more data to confirm the theoretical basis of the intervention.
4.1. Participants

4.1.1. Practice recruitment

Opportunistic practice recruitment was based on existing relationships and knowledge of research interested parties in Perth and Melbourne. In Perth, practices who had previously participated in research and had expressed an interest in participating in future research were approached. The developer of the Canning tool, also proved to be a useful resource for helping to recruit general practices in Perth. He had installed software at local practices and identified practices who used the software we required and identified practice managers we could approach. Nine out of the 11 practices in Perth were identified initially through his connections. In Melbourne, the first practice was recruited from the “ViCReN” database; the practice based research network associated with the University of Melbourne (www.gpunimelb.edu.au/vicren/)[116]. Word of mouth and contacting practices previously involved in other projects led to the recruitment of the other five practices. (see Appendix H for practices recruited into the study).

4.1.2. Participant recruitment

Participants were recruited from general practices in Perth, Western Australia and Melbourne, Victoria. Inclusion and exclusion criteria are specified in Chapter 3. As described in Chapter One, these inclusion criteria are similar to the US National Lung Cancer Screening Trial[21] and represent a population at increased risk of lung cancer, the only difference being that this trial recruited patients with 30 pack years. The number of pack years was less stringent for the CHEST trial to allow a greater pool of people to recruit from.

Smokers and ex-smokers were identified from practice computerised records using the modified Canning tool developed in the Phase I pilot research (Chapter 3). Potentially eligible patients were invited to participate in the study by letter with the relevant general practice letter head. If a patient was too sick to travel to the GP they were excluded. Transport was offered to those who were well but could not get to the GP on their own. The Intervention was only performed at the General Practice not in participant’s homes. The invitations included a patient information sheet, expression of interest (EOI) form and a consent form. As described in Chapter 3, the EOI screening questions provided more accurate information regarding the eligibility of patients and overcome any lack of
recording in a GP database. Non-responders were followed up after two weeks with reminder postcards.

4.1.3. **Procedure and randomisation**

Patients returning an expression of interest form were followed up by phone to confirm an appointment with a health researcher at their general practice. Randomisation, stratified by score on the MRC Dyspnoea Scale and general practice site, was performed centrally using the automated telephone randomisation services of the NHMRC Clinical Trials Centre at the University of Sydney. This was performed once the patient’s baseline MRC dyspnoea score was determined and informed consent had been obtained. Patients were randomised to either receive the intervention or usual care on a 1:1 ratio.

4.2. **The CHEST Intervention**

A detailed consultation script and training module developed for the Scottish trial had been successfully piloted and modified in the Australian phase I study (Chapter 3). A trained researcher (two from Perth and one from Melbourne were involved in the Intervention delivery) then guides the patient through the self-help manual (Appendix D) which is taken home by the participant. ‘If-then’ action plans are developed during the consultation which is linked to symptom checklists; ‘If-then’ coping plans are discussed to tackle barriers to consultation. A range of monthly self-monitoring prompts to appraise symptoms on a regular basis after the consultation were offered and tailored to individual preferences. These included SMS and e-mail reminders, postcards and fridge magnets. Participants also had spirometry conducted to mimic the control arm and act as a “hook” for patient recruitment as described previously.

4.2.1. **Control**

Participants randomised to the control arm attended a consultation where they performed a spirometry test and follow-up procedures in the trial were discussed. There was also a general discussion about lung health. This was aimed as an attention control to account for the non-specific elements of the CHEST consultation process and to increase overall engagement in the trial for control participants. Participants then received usual care at their general practice, including follow-up of abnormal spirometry.
4.2.2. **Sample size and power calculation**

Data from the Scottish trial were used to inform power calculations[49].

Assuming that the primary endpoint of consultations for respiratory symptoms follows a Poisson distribution, and that the expected average rate over 12 months in the study population will be 1.06 for placebo patients and 25% higher for intervention patients, a sample of 534 will provide at least 80% power to reject the null hypothesis of no difference between the groups at the two-sided 5% level of significance. The primary endpoint will be measured from medical record audit, therefore minimising attrition. Accounting for the same attrition rate observed in the Scottish trial, we required a total sample of 550 participants. We anticipated that around 1,800 patients would need to be invited to reach this target assuming a 30% uptake rate. Current smoking prevalence in Australia is 19% although this varies significantly by socio-economic status and age [Tobacco in Australia][117]. On this basis and based on the data from the Scottish Trial we assumed that 10% of a general practice population would meet our eligibility criteria. It was therefore determined we required a total practice population from which to invite participation in the trial of 18,330 (see Appendix E, Figure 1).

4.2.3. **Outcome measures**

The *primary outcome* of the Phase II trial was consultation rates for respiratory symptoms. Data on consultations in the year before the trial and for 12 months after the consultation were collected through audit of GP records. We applied the same predetermined definitions of consultation for respiratory symptoms as those used in the Scottish CHEST trial. These are based on symptoms from a previous study conducted by Smith *et al.* (2009)[9] (based on Cancer UK guidelines) which are also listed in the self-help manual as reasons to seek medical help including, a cough, a worsening cough, coughing up blood, dyspnoea, chest pain, wheeziness, weight loss, fatigue and shoulder pain. The same symptoms are listed by Cancer Australia as symptoms that could be indicative of Lung cancer.

Consultations for respiratory symptoms represent a pragmatic, measurable intermediate outcome along a causal pathway which links the intended action of the intervention with potential earlier diagnosis of lung cancer [31, 48]. Additional outcomes have been described in Chapter 3 but also included the following not assessed in the Phase I trial:
1. **Symptom appraisal and help-seeking intervals** was measured using the SYMPTOM instrument (lung cancer version), a self-completed questionnaire that obtains data on presenting symptoms and their duration prior to consultation[118] Searches of electronic GP records occurred monthly to identify consultations. If a consultation had occurred about a respiratory symptom in that timeframe, the participant was sent a SYMPTOM questionnaire to complete about symptoms relating to that consultation.

2. **Quality of life** was measured using the AQoL-8d[119] a validated self-completed, multi-attribute utility measure, based on Australian normative data, which can be used as part of the health economic evaluation of the intervention. This 35-item scale covers the following domains: independent living, happiness, mental health, coping, relationships, self-worth, pain and senses (Appendix D).

The Assessment of Quality of Life (AQoL) instruments are health-related multi-attribute utility (MAU) quality of life instruments. Initially they were designed for use in economic evaluation studies, cost utility analysis (CUA). However their use is broader and need not be limited to economic or health related work. To date, four AQoL instruments have been developed. MAU instruments are useful even in clinical trials where the focus of the study is well defined such as a program for improving vision. While there is a plethora of disease specific instruments the use of a broad based, multi attribute, instrument is often desirable as it has the potential to identify unexpected effects of a therapy. In particular a narrowly focused element instrument may fail to detect psycho-social changes which some MAU instruments were designed to measure (www.aqol.com.au)[120]. A particular advantage of a MAU is that it weights the various responses by the relative importance (preference weight or utility) to the public of each attribute which allows a meaningful summation of scores. Instruments such as the AQoL suite may serve multiple purposes.

4.2.4. **Measurement timing**

The participant-completed measures (1-7 above) were taken at baseline, 1 and 12 months, with the exception of the SYMPTOM instrument as already described. Health service utilisation data were collected at 12 months by general practice medical record audit and by accessing their Medicare and PBS data. These data were not collected for participants who formally withdrew from the trial. The health economic analysis will not be reported as this is outside the scope of this PhD.
4.2.5. **Participant data and study management**

All participants were allocated a unique identifying code. Questionnaire data were entered into a custom built Oracle database (on a secure server held at the University of Western Australia) to allow scoring of the measures in the questionnaire and enable patient tracking through the study.

The custom built Oracle database evolved from a Microsoft Access database. It was decided that this web based database was preferable due the high level of security (each user is given a certain level of security with one person overseeing both sites). Another advantage of the web-based system is that multiple users can use the database at one time and being an interstate trial, the system was required so information could be easily shared. A web based database could also be utilised in the future to allow participants to enter questionnaire data directly into a website rather than via the postal route.

The CHEST database allows a new patient to be created, all questionnaire data to be entered and generates a new report each time you log in, giving the most up to date information, including how many questionnaires are overdue at each time point, how many symptom questionnaires have been received and the number allocated to intervention and usual care, as well as the number of smokers versus non-smokers. All data entered in the database could be downloaded into Microsoft Excel to enable statistical analysis.

4.2.6. **Methodological rigour**

All other conditions between the two arms were equivalent. Individual patient randomisation is appropriate given that the intervention is at the patient level and was delivered by health researchers not involved in routine care of participants. This avoided potential contamination. As an exploratory complex intervention trial multiple process measures were chosen based on the theoretical model of the intervention (e.g. self-efficacy, knowledge) and the need to identify potential harms (anxiety and depression) as well as intermediate measures of benefit (consultation rates). The frequency of measurement of patient-reported outcomes was designed to obtain sufficient information about intervention efficacy balanced against the potential risk of a Hawthorne effect (where individuals behave differently due to their awareness of being observed). Reasons for attrition were recorded, and recruitment and dropout bias assessed. Intention to treat analyses was conducted. Outcomes assessed by self-report obviate the need for researcher blinding. For the extraction and analysis of health service utilisation data, research staff
were blinded to group assignment. In addition there were different staff members delivering the Intervention to those performing the quantitative analysis.

### 4.2.7. Statistical analyses

All randomised patients were eligible for inclusion in the analysis in accordance with the intention to treat analysis principle. The baseline characteristics of the two arms were analysed using descriptive statistics. Means, standard deviation, median, minimum and maximum were presented for continuous variables, whilst counts and percentages were presented for categorical variables. Consort diagrams were prepared on the numbers of patients randomised, reasons for withdrawal, rates of questionnaire data and primary outcome completeness.

The primary analysis was a comparison between the two groups on the rate of respiratory consultations (to Month 12) using a negative binomial model linear model for count data with general practice and MRC Dyspnoea Scale included as a factor. The analysis was repeated adjusting for additional baseline covariates (i.e. number of consultations in 12 months prior to randomisation, gender, comorbidities, baseline smoking status, baseline MRC Dyspnoea Score) as part of a sensitivity analysis. The proportion of participants that had at least one consultation for respiratory symptoms (to Month 12) were compared between groups in a secondary analysis using a logistic regression that accounts for general practice.

Comparisons between groups for total consultations were undertaken using the approach described for the primary analysis.

A mixed model for repeated measures was applied to the scale scores from patient reported outcomes (secondary outcomes) and included covariates for general practice, treatment allocation, time point, baseline, and a time-point-by-treatment-allocation interaction.

Time to first consultation from baseline was analysed using a Kaplan-Meier survival curve. For participants that do have consultations, a comparison between randomised groups of the interval from symptom appraisal to help-seeking was undertaken using a linear model that includes general practice and MRC Dyspnoea score as a factor.

All analysis was performed using Statistical Analysis Software (SAS).
“Did a complex intervention create a behaviour change in seeking medical help for patients at increased risk of lung cancer?”

This Phase II study explored the experiences of high-risk lung cancer patients who were exposed to a complex intervention ([consultation and self-help manual (CHEST Intervention)]) to determine the impact of the intervention. A sub-set of patients who received the intervention in the Phase II Randomised Controlled Trial (RCT), were purposively sampled for the qualitative aspect of the study.

Specifically, the objectives were to “unpack” how they felt about the intervention and compliment the quantitative study, by using interviews to go below the surface of the topic being discussed, explore what is being said in more detail and uncover new areas or ideas that were not anticipated. Specifically the objectives were to:

- Explore the experience of the patient consultations.
- Evaluate the resource – the self-help booklet- and determine the thoughts and opinions of the patient regarding this.
- Explore what the patient remembers about the consultation.
- Explore how patients appraise their lung symptoms and at what stage they seek help and determine if the intervention resulted in any behaviour change. Is it clear when a patient should go back for a follow up consultation?
- Explore how confident the patients are in consulting their GP.
- Identify any barriers to consultation.
- Explore why the patient participated in the study.
- Determine how the intervention could be improved.
5.1. **Research methodology**

This study represents a mixed methods approach using an embedded design whereby the qualitative study is embedded in the larger quantitative trial to describe participants’ experiences with the intervention. Semi-structured interviews were conducted, audiotaped and transcribed. Data collection followed a very simplified “phenomenological approach,” that is, it was attempted to explore the phenomenon of interest (the intervention) with a group of individuals. The underlying philosophical position can be described as “interpretivist with a pragmatist framework”[121]. That is, while we do not want to unpack new phenomena, we need to understand the theoretical framework that was already established in the original Scottish intervention in more depth and understand how it is applied to an Australian setting.

The qualitative study commenced after the first set of patients completed their 12 month questionnaires. In order to reduce researcher bias and avoid having any effect on the data gathered, participants were interviewed by researchers who had not conducted the intervention with the same patient.

5.2. **Data collection**

5.2.1. **Semi-structured interview process**

A face-to-face interview method was adopted for this qualitative study. A face-to-face interview is considered more advantageous than a phone interview as the researcher is able to assess and observe body language of the participants and also the surroundings which can be very revealing[122]. Also, an interviewee can easily terminate an interview early in a phone interview. A person can feel more comfortable in their home and be more open with their answers[122].

Semi-structured interviews are conducted on the basis of a loose structure consisting of open ended questions that define the area to be explored. The interviewer can then diverge in order to pursue an idea in more detail. This is different from a structured interview which is usually with a structured questionnaire or an in-depth interview which covers one or two issues in great detail and the questions are based on what the interviewee says. Patton (cited in Mays and Pope)[122] said that good questions should be open ended, neutral, sensitive and clear to the interviewee. He identified six types of questions that can be asked; those based on:
• Behaviour or experience.
• Opinion or belief.
• Feelings.
• Knowledge.
• Sensory experience.
• Demographic or background details.

He suggests starting with questions that the interviewee can answer easily and then proceeding to more difficult or sensitive topics. The less structured the interview is, the less the questions are determined and standardised before the interview occurs.

The key topics to cover for the semi-structured interview were:

• The CHEST handbook - ease of understanding and completion.
• Experiences with the consultation.
• Experiences with the monthly prompts.
• Experiences with the questionnaires and completion.
• Lung disease perceptions.
• Acceptability of the intervention.
• Overall perceived impact of the intervention.
• Motivations to make behavioural changes to consult in primary care as a result of the intervention.

The CHEST interviews were semi-structured and were informed on a topic guide based on relevant literature (see Appendix D). After piloting the initial interview guide with the first two patients and revising the subsequent data collected, it was amended mainly due to the length (19 questions) and the fact it resembled more of a questionnaire structure with closed and leading questions. The new version was shortened to seven questions that reflected what we directly wanted to know, and was used more as a guide, rather than
following a strict list of questions. This allowed the conversation to flow more openly and enabled exploration of more prominent and emerging themes (see Appendix F; Version 1 and 2).

Qualitative interviews require a lot of skill on the part of the interviewer. In order to monitor interviewing technique audio recordings of the interviews were critically appraised and followed Whyte’s “directiveness scale for analysing interviewing technique”[123].

Whyte devised a six point directiveness scale to help novice researchers analyse their own interviewing technique. These are:

1. Making encouraging noises.
2. Reflecting on remarks made by the informant.
3. Probing on the last remark by the informant.
4. Probing an idea preceding the last remark by the informant.
5. Probing an idea expressed earlier in the interview.

(Where 1=least directive and 6 = most directive)[123].

In order to maintain control of the interview Patton’s strategic advice of knowing what it is the interviewer wants to find out was used as a guide, asking the right questions to get the information required and giving appropriate verbal and non-verbal feedback. Being aware of any pitfalls in interviewing were identified by Field and Morse[124]. These include ensuring there are no disruptions from outside, ensuring there are no competing distractions such as children, stage fright, awkward questions, jumping from one subject to another and the temptation to counsel interviewees. For the CHEST study, detailed field notes were written after the interview to reflect on improvements that could have been made in the interview process or to note any distractions that may have occurred during the process.
5.2.2. **Recording the interviews**

Interviews were digitally recorded and transcribed verbatim by a professional transcription Service (Pacific Transcription Services, Queensland, Australia [www.pacifictranscription.com.au](http://www.pacifictranscription.com.au)). All participants signed consent forms agreeing to be audio-recorded. It was understood that some participants may take time to speak freely if they know they are being recorded. The recording device used was an (Olympus VN-712PC) which was tested prior to commencement of the interviews to ensure no technical disruptions and is suitable for recording interviews.

An interview protocol was followed which not only included the questions to be asked during an interview but also allocated space to record essential data such as time, date and place of the interview.

5.3. **Sample and recruitment**

5.3.1. **Sample strategy**

A sample size was not determined from the onset of this qualitative work. Instead purposive sampling was utilised to reflect the larger study group’s demographics to provide rich interview data. This approach enabled a wider selection of participants and also enabled selection of participants with access to important sources of knowledge. Sampling considered age, gender, location, smoking status, previous consultation rates, MRC Dyspnoea Score and SEIFA codes (see Table 7).

Patients who had completed their 12 month questionnaire, no later than one month afterwards, were recruited into the qualitative study. Thirteen patients were recruited from Perth and seven patients were recruited from Melbourne from October 2015 through to June 2016. Interviews were conducted until data saturation was reached around key themes (see Chapter 7).
A maximum variation of patients were selected from the CHEST database to get a wide selection of the population sample.

5.4. Population and setting

As previously described in Chapter 4 (Quantitative Methods).

5.5. Recruitment

For the quantitative study, smokers and ex-smokers were identified from general practice computerised records and invited to participate in the study by letter. The letter also contained a patient information sheet and consent form. The Participant Information Sheet and Consent Form that was read and signed by each participant at the baseline appointment (for the quantitative study) specified that in addition to involvement in the CHEST Intervention, a sub-set of patients would be invited to participate in a 30 minute interview. It was made clear to all participants this is not an obligatory aspect of participating in the main study, and that not all participants who consent to this aspect of the study will be approached. Those selected for recruitment in the qualitative study were contacted by phone by the CHEST Trial Co-ordinator Sonya Murray and Research Assistants Yvonne Kutzer and Emily Habgood. A qualitative consent from was explained to the participant at the start of the qualitative interview.

---

Table 7 Sampling stratification strategy

<table>
<thead>
<tr>
<th></th>
<th>Melbourne n=7</th>
<th>Perth n=13</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>M/F</td>
<td>M/F</td>
</tr>
<tr>
<td>Age</td>
<td>&gt;55 years</td>
<td>&gt;55 years</td>
</tr>
<tr>
<td>State</td>
<td>Victoria</td>
<td>Western Australia</td>
</tr>
<tr>
<td>Socioeconomic score</td>
<td>772-1096 (selected a range from lowest SEIFA score to highest for Victoria).</td>
<td>918-1088.5 (selected from lowest to highest SEIFA score for WA).</td>
</tr>
<tr>
<td>Smoking status</td>
<td>Current smoker/Former smoker</td>
<td>Current smoker/Former smoker</td>
</tr>
<tr>
<td>Previous Total 12 month consultation rates.</td>
<td>Selected a range from High &gt;20/ Moderate 10-20 and Low&lt;10. **</td>
<td>Selected a range from High &gt;20/ Moderate 10-20 and Low&lt;10. **</td>
</tr>
<tr>
<td>MRC dyspnoea score</td>
<td>1-3/4-5</td>
<td>1-3/4-5</td>
</tr>
</tbody>
</table>

*Four Economic indexes from Social/Economic Census Info. 1000 or above is classified at above average and below 1000 is seen as more disadvantaged (Source: Australian Bureau of Statistics).

**Based on previous Total consultation rates we selected people to interview from each category.
5.6. Data analysis

Various qualitative methodologies were employed to unpack the CHEST Intervention. Framework Analysis provided an interpretation of what was occurring in the CHEST setting and a constant comparison technique was used to link existing theory with new theories and develop themes. Thematic Analysis was used to identify overarching themes and group them accordingly. Thematic analysis therefore featured as a step within framework analysis. Each process will be discussed with the theory behind each qualitative technique, followed by how it was applied to the CHEST qualitative study.

5.7. Framework analysis

The CHEST framework was developed using “Framework analysis,” a technique developed in 1994 by Ritchie and Spencer[125]. Framework analysis is useful in research that has specific questions and a limited timeframe. Whilst framework analysis may generate theories, its prime purpose is to describe and interpret what is happening in a particular setting. In this type of research analysis, data is sifted, charted and sorted in accordance with key issues and themes using five steps:

- Familiarisation.
- Identifying a thematic framework.
- Indexing.
- Charting.
- Mapping and interpretation.

Within the context of this analysis, the theories underpinning the Scottish CHEST model (described in Chapter Two) and models relevant to the CHEST Intervention were considered. In particular, the Model of Pathways to Treatment described in Chapter One, was continually reflected upon to link existing findings to new findings.

Qualitative data analysis was undertaken as an ongoing iterative process. Soon after the commencement of the initial interviews, a process similar to a constant comparison technique was used. This technique is described by Glaser and Strauss (1967)[126] and involves identifying an event or object of interest, identifying features of this event and making decisions regarding initial collection of data based on one’s initial understanding of
that event. The literature relevant to the study was periodically referred to for guidance regarding key themes and their relationship with one another. This iterative process of rearranging core themes allowing a framework to be developed that will confirm and add to existing work in this area as well as offering novel aspects to this study.

Data were collected and analysed concurrently with systematic efforts made to check and refine emerging categories of data. Themes identified in an earlier interview were explored further and informed the areas of investigation in later interviews.

Interviews continued until theme saturation was reached in key areas.

5.8. Thematic analysis

The CHEST study transcripts were initially read and manually analysed with codes and major categories being established using a process called “Thematic Analysis.” Thematic Analysis is a method for identifying, analysing and reporting patterns (themes) within data. It minimally organises and describes data in (rich) detail and can sometimes go further and interpret various aspects of the research topic[127].

The phases of thematic analysis can be described by Braun and Clarke, 2006, and were applied to the CHEST study[128].

1. Familiarising oneself with the data. This involves transcribing data, reading, re-reading and noting down initial ideas.

2. Generating initial codes, coding interesting features of the data in a systematic fashion across the entire data set and collating data relevant to each code.

3. Searching for themes by collating codes into potential themes, gathering all data relevant to a particular theme.

4. Defining and naming themes. Ongoing analysis is carried out to refine the specifics of each theme and the overall story the analysis tells, generating clear definitions and names for each theme.

5. Producing a report. This is the final opportunity for analysis and involves selection of vivid, compelling extract examples, final analysis of selected extracts and relating back of the analysis to the research question and literature producing a scholarly report of the analysis.
Thematic analysis is not a linear process of moving from one phase to the next, instead it is more a recursive process where movement is back and forward as needed throughout the phases. Ely et al. (1997) also states “It is a process that develops over time and should not be rushed”[129]. This approach was applied when analysing the CHEST transcripts. Key words and themes that were considered similar were grouped together and assigned headings that encapsulate the underlying words and reflect a logical flow or relationships between ideas. The theories underpinning the intervention and the development of the Scottish Chest Intervention were continually reflected upon to interpret and explain any findings.

Data were collected and analysed concurrently with systematic efforts made to check and refine emerging categories of data. Themes identified in an earlier interview were explored further and informed the areas of investigation in later interviews. Interviews continued until theme saturation was reached in key areas.

Two independent researchers (Sonya Murray and Yvonne Kutzer from UWA) read the transcripts and coded accordingly. Regular meetings were held during and after the interview phase which enabled discussion of patient’s stories and agreement on recurrent themes and findings.

5.9. **NVivo analysis**

In the later stages of analysis, both manual and computer assisted methods of analysis were performed using data management software NVivo to facilitate data coding and retrieval.

NVivo is a qualitative data analysis (QDA) computer software package produced by QSR International. It has been designed for qualitative researchers working with very rich text-based and/or multimedia information, where deep levels of analysis on small or large volumes of data are required (QSR International Retrieved on 9-10-2015)[130]. NVivo is intended to help users organize and analyze non-numerical or unstructured data. The software allows users to classify, sort and arrange information; examine relationships in the data; and combine analysis with linking, shaping, searching and modeling.

The researcher can test theories, identify trends and cross-examine information in a multitude of ways using its search engine and query functions. They can make observations in the software and build a body of evidence to support their case or project.
5.10. Rigour

Various strategies were employed in this study to protect against bias and enhance the reliability of findings. This qualitative study addressed the following criteria in relation to rigour.

(i) Descriptive Rigour: This ensured the researchers were recording information accurately. It ensured that the researchers did not misinterpret, mis-transcribe or mis-remember words. The interviews were all audio-recorded and professionally transcribed. There was independent examination of transcriptions by two researchers to ensure descriptive rigour [121].

(ii) Methodological rigour includes how the data were collected and analysed. As described, the techniques of data collection have been well established and all forms of data analysis were transparent [121].

(iii) Interpretive rigour shows clearly how a researcher has moved from pages of raw interview data to interpretation. It must show transparency as to how the researcher came up with certain interpretations and it could be that someone else may interpret things differently. This study included a conceptual discussion of the results and linked existing theory or new theory to explain the relevance of findings and any deviant cases[121].

(iv) Theoretical rigour asks if the study integrates the research problem with the method it employs. For the purpose of this study, semi-structured interviews were the most suitable qualitative technique to answer our research question[121].

(v) Evaluative Rigour is the transparent description of ethical and political aspects of the conduct of research. It ensures that ethics and politics must be addressed procedurally. Human Research Ethics approval was sought from HREC at the University of Western Australia and The University of Melbourne. In addition, it was clearly stated who was interviewed, for how long, in what setting and what interview questions were asked[121].

In an attempt to increase the validity and reliability of this research, two independent researchers (Sonya Murray and Yvonne Kutzer from UWA) interviewed participants and reviewed the material independently prior to coding. This ensured a reduction in error and
provided adequate interpretative rigour to the data as well as credibility and trustworthiness[122].

This study enhanced and safeguarded validity by using the process of triangulation. This is where evidence is deliberately sought from a wide range of different independent sources and often by different means. In this study, the interview data were compared with the quantitative data and the qualitative results from the Scottish Trial.

Reflexivity is also a crucial step in addressing the validity of the qualitative findings[122]. In order to reduce researcher bias and avoid having any effect on the data gathered, participants were interviewed by researchers who had not conducted the intervention to the same patient. It must also be noted that the researchers performing the interviews had a vested interest in the findings of the trial and this potentially could led to a bias in the data collection and interpretation.

5.11. Ethical considerations

To initiate the qualitative interviews, an ethics amendment was required, due to the consent form from the quantitative study stating that “some participants may be followed up for a 30 minute phone call.” The protocol was changed to request a face to face interview and a new qualitative consent form was drafted which outlined the rights of the patient regarding recorded interviews. This amendment was approved by the UWA HREC and the University of Melbourne HREC in September 2015.

In order to consent, patients must have met all the inclusion criteria and none of the exclusion criteria as defined previously. All tape recordings were stored securely and will be destroyed after a period of five years.

All research followed the NHMRC principles of respect, justice, merit and beneficence. The usual ethical processes following informed consent and confidentiality were observed. Steps were put in place to address potential patient distress during and after the interview process. Primarily, this involved referral to their GP if a patient became overly anxious or distressed.
Chapter 6. Quantitative Results

6.1. Introduction

Analysis of the primary and secondary outcomes of the CHEST Australia Trial are described in this chapter using statistical analysis as described in Chapter 4. This chapter will also summarise the flow of participants into the trial and through the trial and present an analysis of the baseline characteristics of patients randomised into the trial to compare the control arm with those who received the intervention.

A discussion around methodological issues will also be described including:

- Practice Recruitment.
- Generalisability of the participant group.
- Response Rate.
- Attrition and tracking patients through the study.

Finally, a summary of key findings will be presented.

6.2. Practice Recruitment

Recruitment of participants through primary care practices was time-consuming, but not overly challenging as expected. Each practice required a specific agreement around the logistics of recruiting a patient and protecting patient’s confidentiality. The GP needed to be aware their patient was in a study, and be supportive of this, but there was no time commitment required by the GP that may have hindered the recruitment process. The practice manager was the main facilitator of the study and the key person to communicate with regarding room booking and patient follow-up.

In Perth, fourteen practices were approached and eleven practices were recruited, including three practices using Medical Director Software practices and eight practices using Best Practice software. In Melbourne eleven practices were approached and six practices were recruited, including three clinics using “Best Practice” software, one clinic using “Zedmed” software and three “Medical Director” Software based clinics (see Appendix H for practices recruited into the Phase II study).
A list of general practices, the software used, and the number of invites sent out, the response rate and subsequent recruitment rates are presented in Table 8. The “SEIFA” (Social and Economic Index Census Information) code for each suburb for Perth and Melbourne.

The SEIFA code is a suite of four indexes that have been created from social and economic census information. Each index ranks geographic areas across Australia in terms of their relative socio-economic advantage and disadvantage. The four indexes each summarise a slightly different aspect of the socio-economic conditions in an area.

The indexes can be used for a number of different purposes, including targeting areas for business and services, strategic planning and social and economic research. For each index, every geographic area in Australia is given a SEIFA score which measures how relatively ‘advantaged’ or ‘disadvantaged’ that area is compared with other areas in Australia.

The four indexes in SEIFA 2011 are:

- Index of Relative Socio-Economic Disadvantage (IRSD).
- Index of Relative Socio-Economic Advantage and Disadvantage (IRSAD).
- Index of Economic Resources (IER).
- Index of Education and Occupation (IEO).

The four indexes of SEIFA each capture a slightly different concept of socio-economic advantage and disadvantage. In summary, a score of 1000 or above is more socioeconomically advantaged than a score below 1000. From Table 8 it can be seen that a range of different socio-economic groups were covered in metropolitan Perth and Melbourne indicating good representation from these cities. In Perth, the clinic recruited with the lowest SEIFA code was Bentley, whereas the clinic recruited in Glengarry had the highest SEIFA code. In Melbourne, the lowest SEIFA code was in the suburb of Dianella (and the lowest socio-economic area in the entire study) whereas the highest SEIFA score was recorded in Deepdene in Melbourne.

Variation in recruitment for each practice was observed (Table 8) given different socioeconomic groups and populations were represented. Also, some practices were much larger and more established than others, resulting in differing recruitment numbers.
6.3. **Response rate**

Overall, 5281 invites were sent to potentially eligible participants from Perth and Melbourne (3307 to Perth and 1974 to Melbourne). This was from an estimated patient population of 222,864. The overall response rate was 18% (as well as 18% for both cities individually). This is comparable to the 20% response rate from the Scottish trial[50]. Of those that responded, 66% were eligible after further screening overall (79% in Perth and 54% in Melbourne). Of those eligible, 88% were recruited into the CHEST study (93% from Perth and 83% from Melbourne) (see Table 8).

6.4. **Generalisability**

Primary care is a notoriously difficult setting to recruit research patients from[131] but it is important to reflect on precisely what portion of the community this study group maybe representing. The mean age (65.7 years), gender (Female 44%) and smoking status (N=44%) of the non-responder group is similar to the study group (Table 10). However, a response bias was likely among the study group. From the baseline characteristics (Table 10), it can be seen that there was a definite selection bias towards ex-smokers who participated in the study. Sixty per cent of the 940 who responded were ex-smokers, compared to 36% of current smokers. This was higher than expected from those initially invited (51% ex-smokers and 47% smokers).

There was also a possible selection bias towards those who were retired. So while those 55 or older were invited into the study, the majority recruited were retired and fell into the 60-69 year category. Many felt they wanted to contribute to research and help the community by participating in a research study. Some were very aware of their past smoking behaviour and wanted to learn more about their health overall.

Obviously, those who were very sick were unable to participate in a study that required a visit to their GP, so the population most likely represented a “physically well” cohort, albeit at increased risk of lung cancer due to their smoking history.

6.5. **Study flowchart and feasibility**

Recruitment took place between 29 May 2013 to November 19, 2015. Of the 2501 smokers and 2666 ex-smokers initially approached, 940 (18%) responded overall. Of those, 287 were deemed not eligible, mainly due to having quit smoking greater than 15 years prior and having less than 20 pack years smoking. 623 were eligible and 72 were excluded.
mainly due to refusal to participate (42%). Reasons for refusal primarily included business, work, and dealing with other family members and their health. 551 were subsequently randomised (236 smokers and 315 ex-smokers) with excellent follow-up rates for the primary outcome data available for >95% of the cohort (see Figure 13).

Of the 551 randomised into the trial, 274 were in the Intervention group and 277 were in the usual care or control group. Of the 274 in the Intervention group, 170 (62%) were ex-smokers, and 104 (38%) were smokers. Of the 277 in the Usual care group, 131 (47%) were smokers and 146 (53%) were ex-smokers. The total number who were analysed for the primary outcome (respiratory consultations) in the Intervention group were 269 and 273 in the control group.

Follow-up took place between 29 June 2013 to November 19, 2016 with 269 participants in the Intervention completing the trial and 274 participants in the usual care group completing the trial.

Two hundred and sixty three (96%) completed the baseline questionnaire in the in the Intervention group, and 268 (97%) completed the baseline questionnaire in the usual care group. At one month, 236 (89%) completed their 1 month questionnaire in the Intervention group and 219 (79%) completed the 1 month questionnaire in the usual care group. At 12 months, 212 (72%) completed in the Intervention group and 204 (74%) in the usual care group (see Figure 14). Three patients were diagnosed with lung cancer during the 12 month follow-up period, two from the Intervention group and one from the usual care group.
<table>
<thead>
<tr>
<th>Software used</th>
<th>Practice</th>
<th>City</th>
<th>No. invited</th>
<th>Responded</th>
<th>Eligible</th>
<th>Recruited</th>
<th>Total Patient Population</th>
<th>Full time GPs</th>
<th>SEIFA **</th>
</tr>
</thead>
<tbody>
<tr>
<td>MD</td>
<td>Riverton</td>
<td>Perth</td>
<td>386</td>
<td>58</td>
<td>15%</td>
<td>41</td>
<td>71%</td>
<td>38</td>
<td>93%</td>
</tr>
<tr>
<td>MD</td>
<td>Glengarry</td>
<td>Perth</td>
<td>486</td>
<td>113</td>
<td>23%</td>
<td>51</td>
<td>45%</td>
<td>51</td>
<td>100%</td>
</tr>
<tr>
<td>MD</td>
<td>Champion Lakes</td>
<td>Perth</td>
<td>257</td>
<td>55</td>
<td>21%</td>
<td>50</td>
<td>91%</td>
<td>49</td>
<td>98%</td>
</tr>
<tr>
<td>BP</td>
<td>Landsdale</td>
<td>Perth</td>
<td>111</td>
<td>14</td>
<td>13%</td>
<td>13</td>
<td>93%</td>
<td>13</td>
<td>100%</td>
</tr>
<tr>
<td>BP</td>
<td>Granada</td>
<td>Perth</td>
<td>150</td>
<td>27</td>
<td>18%</td>
<td>26</td>
<td>96%</td>
<td>25</td>
<td>96%</td>
</tr>
<tr>
<td>BP</td>
<td>Bentley</td>
<td>Perth</td>
<td>300</td>
<td>44</td>
<td>15%</td>
<td>29</td>
<td>66%</td>
<td>29</td>
<td>100%</td>
</tr>
<tr>
<td>BP</td>
<td>East Fremantle</td>
<td>Perth</td>
<td>281</td>
<td>48</td>
<td>17%</td>
<td>36</td>
<td>75%</td>
<td>34</td>
<td>94%</td>
</tr>
<tr>
<td>BP</td>
<td>Illawarra</td>
<td>Perth</td>
<td>354</td>
<td>46</td>
<td>13%</td>
<td>40</td>
<td>87%</td>
<td>35</td>
<td>88%</td>
</tr>
<tr>
<td>BP</td>
<td>Leeming</td>
<td>Perth</td>
<td>178</td>
<td>37</td>
<td>21%</td>
<td>30</td>
<td>81%</td>
<td>27</td>
<td>90%</td>
</tr>
<tr>
<td>BP</td>
<td>Ellen Health</td>
<td>Perth</td>
<td>234</td>
<td>62</td>
<td>26%</td>
<td>42</td>
<td>68%</td>
<td>32</td>
<td>76%</td>
</tr>
<tr>
<td>BP</td>
<td>Kelmscott</td>
<td>Perth</td>
<td>570</td>
<td>93</td>
<td>16%</td>
<td>88</td>
<td>95%</td>
<td>73</td>
<td>83%</td>
</tr>
<tr>
<td><strong>PERTH TOTAL</strong></td>
<td></td>
<td></td>
<td>3307</td>
<td>597</td>
<td>18%</td>
<td>446</td>
<td>79%</td>
<td>406</td>
<td>93%</td>
</tr>
<tr>
<td>ZedMed</td>
<td>Coolaroo</td>
<td>Melbourne</td>
<td>654</td>
<td>85</td>
<td>13%</td>
<td>58</td>
<td>68%</td>
<td>42</td>
<td>72%</td>
</tr>
<tr>
<td>BP</td>
<td>Doctors on Broadway</td>
<td>Melbourne</td>
<td>132</td>
<td>13</td>
<td>10%</td>
<td>7</td>
<td>38%</td>
<td>3</td>
<td>60%</td>
</tr>
<tr>
<td>BP</td>
<td>Modern Medical</td>
<td>Melbourne</td>
<td>346</td>
<td>39</td>
<td>11%</td>
<td>28</td>
<td>72%</td>
<td>25</td>
<td>89%</td>
</tr>
<tr>
<td>BP</td>
<td>Deepdene</td>
<td>Melbourne</td>
<td>76</td>
<td>17</td>
<td>22%</td>
<td>11</td>
<td>65%</td>
<td>11</td>
<td>100%</td>
</tr>
<tr>
<td>MD</td>
<td>Thomas Street</td>
<td>Melbourne</td>
<td>234</td>
<td>62</td>
<td>26%</td>
<td>28</td>
<td>45%</td>
<td>27</td>
<td>96%</td>
</tr>
<tr>
<td>MD</td>
<td>Dianella</td>
<td>Melbourne</td>
<td>532</td>
<td>127</td>
<td>24%</td>
<td>45</td>
<td>35%</td>
<td>37</td>
<td>82%</td>
</tr>
<tr>
<td><strong>MELBOURNE TOTAL</strong></td>
<td></td>
<td></td>
<td>1974</td>
<td>343</td>
<td>18%</td>
<td>177</td>
<td>54%</td>
<td>145</td>
<td>83%</td>
</tr>
<tr>
<td><strong>OVERALL TOTAL</strong></td>
<td></td>
<td></td>
<td>5281</td>
<td>940</td>
<td>18%</td>
<td>623</td>
<td>66%</td>
<td>551</td>
<td>88%</td>
</tr>
</tbody>
</table>
Figure 13 Phase II consort flow diagram
6.6. **Subject disposition.**

Genuine withdrawals were recorded as those that did not want to continue in the study and who did not want their medical records checked. In the intervention arm, one patient withdrew their consent to check their medical records any further. For the control arm, no patients withdrew consent. Two people died while recruited into the trial and their data was measured until that time point.

Randomisation was stratified according to the Dyspnoea score (1-3) and (4-5) and general practice recruitment site. A comparison between the stratification factors for the Intervention and the Control are displayed in Table 9. Randomisation within each general practice is similar in each practice between the two arms. The majority of participants scored 1-3 on the MRC dyspnoea scale (94% in both groups). Only approximately 6% in each group had a MRC dyspnoea score of 4-5.
Table 9 Stratification factors

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Level</th>
<th>Intervention (N=274)</th>
<th>Control (N=277)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GP Site</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bentley Medical Practice</td>
<td>13 (4.7%)</td>
<td>16 (5.8%)</td>
<td></td>
</tr>
<tr>
<td>Champion Lakes Medical Centre</td>
<td>25 (9.1%)</td>
<td>24 (8.7%)</td>
<td></td>
</tr>
<tr>
<td>Coolaroo Clinic</td>
<td>23 (8.4%)</td>
<td>19 (6.9%)</td>
<td></td>
</tr>
<tr>
<td>Deepdene</td>
<td>6 (2.2%)</td>
<td>5 (1.8%)</td>
<td></td>
</tr>
<tr>
<td>Dianella</td>
<td>19 (6.9%)</td>
<td>18 (6.5%)</td>
<td></td>
</tr>
<tr>
<td>Doctors on Broadway</td>
<td>3 (1.1%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>East Fremantle MC</td>
<td>17 (6.2%)</td>
<td>17 (6.1%)</td>
<td></td>
</tr>
<tr>
<td>Ellen Health</td>
<td>15 (5.5%)</td>
<td>17 (6.1%)</td>
<td></td>
</tr>
<tr>
<td>Glengarry Medical Practice</td>
<td>25 (9.1%)</td>
<td>26 (9.4%)</td>
<td></td>
</tr>
<tr>
<td>Granada Medical Practice</td>
<td>12 (4.4%)</td>
<td>13 (4.7%)</td>
<td></td>
</tr>
<tr>
<td>Illawarra Medical Centre</td>
<td>17 (6.2%)</td>
<td>18 (6.5%)</td>
<td></td>
</tr>
<tr>
<td>Kelvale Medical Group</td>
<td>35 (12.8%)</td>
<td>38 (13.7%)</td>
<td></td>
</tr>
<tr>
<td>Landsdale</td>
<td>7 (2.6%)</td>
<td>6 (2.2%)</td>
<td></td>
</tr>
<tr>
<td>Leeming Doctors on Calley and South</td>
<td>13 (4.7%)</td>
<td>14 (5.1%)</td>
<td></td>
</tr>
<tr>
<td>Modern Medical</td>
<td>12 (4.4%)</td>
<td>13 (4.7%)</td>
<td></td>
</tr>
<tr>
<td>Riverton Medical Practice</td>
<td>18 (6.6%)</td>
<td>20 (7.2%)</td>
<td></td>
</tr>
<tr>
<td>Thomas Street</td>
<td>14 (5.1%)</td>
<td>13 (4.7%)</td>
<td></td>
</tr>
<tr>
<td>MRC Stratum</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-3</td>
<td>259 (94.5%)</td>
<td>260 (93.9%)</td>
<td></td>
</tr>
<tr>
<td>4-5</td>
<td>15 (5.5%)</td>
<td>17 (6.1%)</td>
<td></td>
</tr>
</tbody>
</table>

Table 10 describes the baseline characteristics of patients randomised into the trial. There were no clinically important differences between the intervention and usual care group identified.
Table 10 Baseline demographics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention (N=274)</th>
<th>Control (N=277)</th>
<th>Non responders (N=4341)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age: Mean (SD) [N]</strong></td>
<td>64.38 (9.8) [274]</td>
<td>64.07 (10.6) [277]</td>
<td>65.7 (10.1) [4341]</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F</td>
<td>117 (42.7%)</td>
<td>114 (41.2%)</td>
<td>1911 (44%)</td>
</tr>
<tr>
<td>M</td>
<td>157 (57.3%)</td>
<td>163 (58.8%)</td>
<td>2430 (56%)</td>
</tr>
<tr>
<td><strong>FEV1: Mean (SD) [N]</strong></td>
<td>80.9 (21.65) [273]</td>
<td>81.63 (20.51) [276]</td>
<td></td>
</tr>
<tr>
<td><strong>Smoking pack years: Mean (SD) [N]</strong></td>
<td>45.18 (23.84) [274]</td>
<td>45.99 (24.4) [277]</td>
<td></td>
</tr>
<tr>
<td><strong>Smoker</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>168 (61.3%)</td>
<td>148 (53.4%)</td>
<td>2257 (52%)</td>
</tr>
<tr>
<td>Y</td>
<td>106 (38.7%)</td>
<td>129 (46.6%)</td>
<td>2084 (48%)</td>
</tr>
<tr>
<td><strong>Respiratory consultations 12m to Baseline: Mean (SD) [N]</strong></td>
<td>0.86 (1.62) [269]</td>
<td>0.76 (1.25) [273]</td>
<td></td>
</tr>
<tr>
<td><strong>All consultations 12m to Baseline: Mean (SD) [N]</strong></td>
<td>9.06 (7.49) [270]</td>
<td>9.11 (7.7) [273]</td>
<td></td>
</tr>
<tr>
<td><strong>Accommodation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>10 (3.6%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Own your home</td>
<td>204 (74.5%)</td>
<td>212 (76.5%)</td>
<td></td>
</tr>
<tr>
<td>Rent your home</td>
<td>50 (18.2%)</td>
<td>33 (11.9%)</td>
<td></td>
</tr>
<tr>
<td>Other (please specify below)</td>
<td>20 (7.3%)</td>
<td>22 (7.9%)</td>
<td></td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>3 (1.1%)</td>
<td>8 (2.9%)</td>
<td></td>
</tr>
<tr>
<td>Year 11 or below</td>
<td>86 (31.4%)</td>
<td>89 (32.1%)</td>
<td></td>
</tr>
<tr>
<td>Year 12 or equivalent</td>
<td>40 (14.6%)</td>
<td>38 (13.7%)</td>
<td></td>
</tr>
<tr>
<td>Trade/Apprenticeship</td>
<td>29 (10.6%)</td>
<td>39 (14.1%)</td>
<td></td>
</tr>
<tr>
<td>Tertiary Certificate/Diploma</td>
<td>49 (17.9%)</td>
<td>57 (20.6%)</td>
<td></td>
</tr>
<tr>
<td>Undergraduate University Degree</td>
<td>24 (8.8%)</td>
<td>17 (6.1%)</td>
<td></td>
</tr>
<tr>
<td>Post Graduate University Degree</td>
<td>17 (6.2%)</td>
<td>12 (4.3%)</td>
<td></td>
</tr>
<tr>
<td>Other (please specify)</td>
<td>26 (9.5%)</td>
<td>17 (6.1%)</td>
<td></td>
</tr>
<tr>
<td><strong>Living arrangements</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>8 (2.9%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>On your own</td>
<td>70 (25.5%)</td>
<td>70 (25.3%)</td>
<td></td>
</tr>
<tr>
<td>With a partner/spouse</td>
<td>166 (60.6%)</td>
<td>166 (59.9%)</td>
<td></td>
</tr>
<tr>
<td>With other family</td>
<td>32 (11.7%)</td>
<td>28 (10.1%)</td>
<td></td>
</tr>
<tr>
<td>Other (please specify below)</td>
<td>6 (2.2%)</td>
<td>5 (1.8%)</td>
<td></td>
</tr>
<tr>
<td><strong>Occupation (more than one can apply)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retired</td>
<td>85 (31.0%)</td>
<td>98 (35.4%)</td>
<td></td>
</tr>
<tr>
<td>Caring for dependent relative</td>
<td>14 (5.1%)</td>
<td>16 (5.8%)</td>
<td></td>
</tr>
<tr>
<td>Voluntary worker</td>
<td>20 (7.3%)</td>
<td>14 (5.1%)</td>
<td></td>
</tr>
<tr>
<td>Unemployed</td>
<td>52 (19.0%)</td>
<td>63 (22.7%)</td>
<td></td>
</tr>
<tr>
<td>Student</td>
<td>8 (2.9%)</td>
<td>3 (1.1%)</td>
<td></td>
</tr>
<tr>
<td>Looking after home/family</td>
<td>43 (15.7%)</td>
<td>48 (17.3%)</td>
<td></td>
</tr>
<tr>
<td>Invalid/Disabled-Unable to work.</td>
<td>21 (7.7%)</td>
<td>22 (7.9%)</td>
<td></td>
</tr>
</tbody>
</table>
6.6.1. **Smoking history**

There were a higher percentage of ex-smokers compared to smokers in both groups, 62% ex-smokers and 38% current smokers in the Intervention group and 53% ex-smokers and 47% smokers in the control group. There was also a slightly higher percentage of ex-smokers recruited into the Intervention group compared to the control group (61.3% (intervention arm) versus 53.4 % (control arm)). The mean smoking pack years was similar between both groups (approximately 45 pack years each).

6.6.2. **Respiratory consultations 12 months to baseline.**

The mean number of consultations was recorded as slightly higher in the intervention group with a mean of 0.85 compared to 0.75 in the control group. Figure 15 shows the percentage of consultations 12 months pre-baseline for both treatment arms. Visually, it can be seen they are fairly similar between the arms with the highest percentage recorded for “0” consultations. Some higher consult figures are recorded (10-13) also.

![Distribution of Pre_12m_respiratory_consults](image)

*Figure 15 Respiratory consultations 12 months to baseline*

6.6.3. **All consultations 12m to baseline.**

The mean number of total consultations 12 months to baseline are similar for both treatment arms (mean is 8.92 for the Intervention group and 8.98 for the control group). Figure 16 displays all consultations for both treatment arms 12 months to baseline for both
treatment arms. The spread is from 0-58 consultations 12 months to baseline (suggesting one person consulted more than once per week).

![Graph showing distribution of pre-12m total consultations](image)

**Figure 16** All consultations 12 months to baseline

### 6.6.4. Co-morbidities

Table 11 describes the co-morbidities between the treatment arms. Overall, there was a reasonable balance of comorbidities between the treatment arms. Cardiovascular conditions were recorded as the highest co-morbidity overall and slightly higher in the control arm (41.5%) compared to the intervention arm (36.5%). Respiratory conditions were similar between groups (32.8% in the intervention and 32.1% in the control arm). Psychiatric co-morbidities were slightly higher in the intervention arm (16.1%) compared to the control arm (12.6%). Diabetes co-morbidities were recorded for 12.6% of patients in the control arm and 10.2% in the intervention arm. All other co-morbidities were similar between treatment arms (33% each).
Table 11 Comorbidities

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention (N=274)</th>
<th>Control (N=277)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular</td>
<td>100 (36.5%)</td>
<td>115 (41.5%)</td>
</tr>
<tr>
<td>Respiratory</td>
<td>90 (32.8%)</td>
<td>89 (32.1%)</td>
</tr>
<tr>
<td>Psychiatric</td>
<td>44 (16.1%)</td>
<td>41 (14.8%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>28 (10.2%)</td>
<td>35 (12.6%)</td>
</tr>
<tr>
<td>Other</td>
<td>92 (33.6%)</td>
<td>92 (33.2%)</td>
</tr>
</tbody>
</table>

6.7. Primary outcome analysis

The primary outcome for this trial is respiratory consultation rates following the intervention. Negative binomial analysis identified whether the number of respiratory and total consultations, 12 months prior and post the consultation represented a statistically significant association. Table 12 shows the mean respiratory consultation rates for both groups to month 12. This table also shows the number of post 12 month consultations separated from 0-5 consultations. The mean is higher (n) for respiratory consultations in the intervention arm to month 12 (0.67 mean average rate of consultations over 12 months) compared to the control arm (0.49 mean average rate of consultations over 12 months). The highest percentage of consultations are recorded as 0 for both groups (59.9% for the Intervention arm and 66.1% in the control arm). For 1 visit, 22.6% is recorded for the intervention group compared to 22% for the control group. For 2 visits a higher percentage is recorded in the intervention arm (9.1%) compared to (8.7%) in the control group. Likewise for 3 visits, a higher percentage of consultations is reported in the intervention arm (6.9%) compared to the control group (3.2%). Four or more visits were only reported in the intervention arm.

The distribution of respiratory consultations to month 12 for both treatment arms is shown graphically in Figure 17. The height of the bar represents the percentage of consultations and shows that more of the control patients had zero consultations but at the higher end of the consultation scale, the consultation rate was higher for the intervention group.
Table 12 Respiratory consultations to month 12

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Level</th>
<th>Intervention (N=274)</th>
<th>Control (N=277)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory consultations during 12m follow-up: Mean (SD) [N]</td>
<td></td>
<td>0.67 (1.01) [269]</td>
<td>0.47 (0.78) [273]</td>
</tr>
<tr>
<td>Post 12m respiratory consultations</td>
<td>0</td>
<td>163 (59.5%)</td>
<td>184 (66.4%)</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>58 (21.2%)</td>
<td>58 (20.9%)</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>27 (9.9%)</td>
<td>22 (7.9%)</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>17 (6.2%)</td>
<td>9 (3.2%)</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>3 (1.1%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>1 (0.4%)</td>
<td></td>
</tr>
</tbody>
</table>

Figure 17 Respiratory consultations to month 12

Table 13 shows adjusted Relative Rates and 95% CI and the p value (<0.1 which would represent a statistically significant different rate in consultations between the intervention and control) for respiratory consultations to month 12. The number of respiratory consultations 12 months after the intervention were statistically significant for the intervention group compared to the control group with a RR of 1.39 and a 95% CI of (1.07-1.81) and a p value of 0.0145. That is, we are seeing a 39% relative increase in the consultation rate for the intervention arm and this is statistically significant. These were
estimated from a negative binomial model with treatment group and GP site (p<.0001) as covariates, that is, treatment allocation arm and GP site were accounted for in this statistical model. (Table 13).

**Table 13 Primary analysis of respiratory consultation rate to month 12**

<table>
<thead>
<tr>
<th>Adjusted Rates (95% CI)</th>
<th>Relative Rate (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intervention</strong></td>
<td><strong>Control</strong></td>
</tr>
<tr>
<td>0.57 (0.46 to 0.70)</td>
<td>0.41 (0.32 to 0.52)</td>
</tr>
<tr>
<td>1.39 (1.07 to 1.81)</td>
<td>p=0.0145</td>
</tr>
</tbody>
</table>

Secondary analysis was repeated adjusting for additional baseline covariates (i.e. number of consultations in 12 months prior to randomisation, gender, comorbidities, baseline smoking status, baseline MRC Dyspnoea Score, FEV1, Pack Years, cardiovascular, respiratory or psychiatric comorbidity, diabetes and any other comorbidity) as part of a sensitivity analysis. Table 14 shows that if you remove GP site from the statistical model, the Relative Rate still remains statistically significant. Other covariates were also tested to see if there was any effect of the outcome. This type of sensitivity analysis shows that taking these other factors into account does not affect the treatment effect. That is, the treatment effect was still retained when taking into account, respiratory consultations 12 months to baseline or smoking status and all other covariates listed in Table 14. This suggests there is compelling evidence a true treatment effect is occurring.

The effect of clustering were estimated from the negative binomial model with treatment group and GP site (p<0.0001) as covariates and clustering was accommodated using the method of GEE (Generalised Estimating Equation). Fifteen married couples were recruited into the study and this was taken into account in this analysis. This shows that the number of married couples did not erode power on the treatment effect, that is, the number of married couples was so rare that it had no effect on the outcome. Table 15 shows that the effect of clustering on analysis did not affect the RR outcome and the comparison between groups still remained statistically significant (p=0.0136).
Table 14 Secondary analysis of respiratory consultation rate to month 12

<table>
<thead>
<tr>
<th>Covariates in Negative Binomial Model</th>
<th>Relative Rate (95% CI)</th>
<th>Adjusted for Covariate (95% CI)</th>
<th>P-Value† for Covariate Listed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment Group Only</td>
<td>1.42 (1.07 to 1.87) p=0.0136</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GP Site Plus the Following:</td>
<td></td>
<td>P-Value‡ for Covariate Listed</td>
<td></td>
</tr>
<tr>
<td>Respiratory consultations 12m to baseline</td>
<td>1.34 (1.03 to 1.73) p=0.0265</td>
<td>&lt;.0001</td>
<td></td>
</tr>
<tr>
<td>Pack Years</td>
<td>1.39 (1.07 to 1.81) p=0.0147</td>
<td>0.2618</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>1.39 (1.07 to 1.80) p=0.0151</td>
<td>0.0106</td>
<td></td>
</tr>
<tr>
<td>FEV1</td>
<td>1.36 (1.05 to 1.76) p=0.0192</td>
<td>&lt;.0001</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td>1.40 (1.07 to 1.82) p=0.0136</td>
<td>0.3475</td>
<td></td>
</tr>
<tr>
<td>Smoker</td>
<td>1.38 (1.06 to 1.81) p=0.0165</td>
<td>0.7331</td>
<td></td>
</tr>
<tr>
<td>MRC Dyspnoea (1-2 vs 3-4)</td>
<td>1.40 (1.07 to 1.82) p=0.013</td>
<td>0.0739</td>
<td></td>
</tr>
<tr>
<td>Cardiovascular comorbidity</td>
<td>1.36 (1.05 to 1.77) p=0.0217</td>
<td>0.0808</td>
<td></td>
</tr>
<tr>
<td>Respiratory comorbidity</td>
<td>1.37 (1.07 to 1.77) p=0.0131</td>
<td>&lt;.0001</td>
<td></td>
</tr>
<tr>
<td>Psychiatric comorbidity</td>
<td>1.39 (1.08 to 1.80) p=0.0118</td>
<td>0.9833</td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>1.39 (1.07 to 1.82) p=0.0137</td>
<td>0.4782</td>
<td></td>
</tr>
<tr>
<td>Other comorbidity</td>
<td>1.40 (1.08 to 1.83) p=0.0124</td>
<td>0.2378</td>
<td></td>
</tr>
</tbody>
</table>

Table 15 Effect of clustering on analysis of respiratory consultation rates to month 12

<table>
<thead>
<tr>
<th>Adjusted Rates (95% CI)</th>
<th>Relative Rate (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention</td>
<td>Control</td>
</tr>
<tr>
<td>0.57 (0.47 to 0.69)</td>
<td>0.41 (0.33 to 0.50)</td>
</tr>
</tbody>
</table>

Logistic Regression with treatment group and GP site (p<.0001) as covariates was performed with at least one respiratory consultation to Month 12. There was a high percentage of “zero-consulters” in both arms for respiratory symptoms to month 12 and this was compared with those who had at least 1 respiratory consult to 12 months. Table 16 shows that there was no significant difference between treatment arms when there was at least one respiratory consult to 12 months where treatment group and GP site was a covariate.
Table 16 At least one respiratory consultation to month 12

<table>
<thead>
<tr>
<th>At Least One Respiratory Consultations to Month 12</th>
<th>Intervention (N=274)</th>
<th>Control (N=277)</th>
<th>OR (95% CI)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Missing</td>
<td>5 (1.8%)</td>
<td>4 (1.4%)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>163 (59.5%)</td>
<td>184 (66.4%)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>106 (38.7%)</td>
<td>89 (32.1%)</td>
<td>1.32 (0.91 to 1.90) p=0.1408</td>
</tr>
</tbody>
</table>

The RR is adjusted for age, gender, MRC Dyspnoea Score, smoking status, smoking pack years, and FEV1. For each analysis clinic is a factor. Significant differences (p<0.1) are bolded.

6.8. Secondary outcome analysis

6.8.1. Total consultations to month 12

Comparisons between groups on any consultations were undertaken using the approach described for the primary outcome analysis. That is, a comparison between the two groups on the rate of all consultations (to Month 12) was conducted using a linear model for count data with general practice included as a factor. A negative binomial model was applied in this case.

The analysis were repeated adjusting for additional baseline covariates (i.e. number of consultations in 12 months prior to randomisation, gender, comorbidities, baseline smoking status, baseline MRC Dyspnoea Score) as part of a sensitivity analysis. The proportion of participants that have at least one consultation (to Month 12) were compared between groups in a secondary analysis using a logistic regression that accounts for general practice, or using a Cochran-Mantel-Haenszel test if the logistic regression fails to converge.

Figure 18 visually displays the total consultations during the 12 month follow-up. There is an initial spike at 0 total consultations and then a more normal distribution is displayed, but with no obvious visual pattern.
Table 17 shows the mean number of consultations to month 12 between the treatment arms, SD and number. It also shows the missing recorded consultations to month 12 and the number who had at least one consult to month 12. The percentage is even between both treatment arms 90.1% for the Intervention group and 89.5% for the control group. For those that did not have at least one consult to month 12, this is also similar between both treatment arms (7.7% for the Intervention group and 9.0% for the control group).

Table 17 All consultations to month 12

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Level</th>
<th>Intervention (N=274)</th>
<th>Control (N=277)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total consultations during 12m follow-up: Mean (SD) [N]</td>
<td>Missing</td>
<td>6 (2.2%)</td>
<td>4 (1.4%)</td>
</tr>
<tr>
<td>At least one consult to month 12</td>
<td>No</td>
<td>21 (7.7%)</td>
<td>25 (9.0%)</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>247 (90.1%)</td>
<td>248 (89.5%)</td>
</tr>
</tbody>
</table>

Table 18 shows that after adjusting for all possible confounders, a Relative Rate of 1.01 between treatment arms was shown not to be statistically significant (p=0.8863) for all consultations to month 12.
Table 18 Modelled rates of all consultations to month 12

<table>
<thead>
<tr>
<th></th>
<th>Adjusted Rate (95% CI)</th>
<th>Relative Rate (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intervention</strong></td>
<td>8.52 (7.63 to 9.52)</td>
<td>1.01 (0.88 to 1.16) p=0.8998</td>
</tr>
<tr>
<td><strong>Control</strong></td>
<td>8.45 (7.51 to 9.50)</td>
<td></td>
</tr>
</tbody>
</table>

6.8.2. **Patient reported outcomes to month 12**

A mixed model for repeated measures was applied to the scale scores from PROs obtained longitudinally and included covariates for general practice, treatment allocation, time point, baseline, and a time-point-by-treatment- allocation interaction. The analysis was repeated adjusting for additional baseline covariates if chance imbalances of a clinically significant magnitude arise between randomised groups. A GEE (Generalised Estimating Equation) approach was used to fit the repeated measure model in the event that the mixed model does not converge.

The PRO secondary variables include HADs Anxiety, HADS Depression, AQoL8D, Cancer worry scale, Perceived risk scale, self-efficacy, Knowledge of Symptoms, Intention to consult and Views on health. A mixed model repeated measures analysis will be reported for each PRO as well as a distribution graph showing the distribution of scores between the intervention and control.

6.8.3. **HADS Anxiety**

Table 19 shows that to month 1 and month 12 there were no statistically significant differences observed between treatment arms for the Anxiety score (p=0.3954 to month 1 and p=0.6083 to month 12). The p value generated from this analysis is robust for any differences from normality. This suggests that there is no evidence of any difference in anxiety scores between treatment arms at one and 12 months.

Figure 19 shows the distribution of anxiety scores to month 12 for the control and Intervention groups. Distribution of scores appears graphically similar between the groups.
Table 19 Anxiety

<table>
<thead>
<tr>
<th>Month</th>
<th>Randomised Group</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>Min</th>
<th>Max</th>
<th>LS Mean</th>
<th>LS Mean Difference</th>
<th>Lower 95%CL</th>
<th>Upper 95%CL</th>
<th>P-value for Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Control</td>
<td>268</td>
<td>5.6</td>
<td>4.1</td>
<td>0.0</td>
<td>21.0</td>
<td>.</td>
<td>.</td>
<td>.</td>
<td>.</td>
<td>.</td>
</tr>
<tr>
<td>0</td>
<td>Intervention</td>
<td>269</td>
<td>5.7</td>
<td>3.9</td>
<td>0.0</td>
<td>21.0</td>
<td>.</td>
<td>.</td>
<td>.</td>
<td>.</td>
<td>.</td>
</tr>
<tr>
<td>1</td>
<td>Control</td>
<td>223</td>
<td>5.3</td>
<td>4.2</td>
<td>0.0</td>
<td>18.0</td>
<td>5.5</td>
<td>-0.2</td>
<td>-0.7</td>
<td>0.3</td>
<td>0.3954</td>
</tr>
<tr>
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<td>Intervention</td>
<td>234</td>
<td>5.3</td>
<td>4.0</td>
<td>0.0</td>
<td>20.0</td>
<td>5.3</td>
<td>-0.1</td>
<td>-0.6</td>
<td>0.4</td>
<td>0.6083</td>
</tr>
<tr>
<td>12</td>
<td>Control</td>
<td>204</td>
<td>5.2</td>
<td>4.2</td>
<td>0.0</td>
<td>18.0</td>
<td>5.6</td>
<td>-0.1</td>
<td>-0.6</td>
<td>0.4</td>
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<tr>
<td>12</td>
<td>Intervention</td>
<td>212</td>
<td>5.3</td>
<td>4.1</td>
<td>0.0</td>
<td>19.0</td>
<td>5.4</td>
<td>-0.1</td>
<td>-0.6</td>
<td>0.4</td>
<td>0.6083</td>
</tr>
</tbody>
</table>

Figure 19 Anxiety

6.8.4. **HADS Depression**

Table 20 shows that to month 1 and month 12 there were no statistically significant differences observed between treatment arms for the Depression score (p=0.1557 to month 1 and p=0.3672 to month 12). The p value generated from this analysis is robust for any differences from normality. This suggests that there is no evidence of any difference in depression scores between treatment arms at one and 12 months.
Table 20 Depression Mixed Model Repeated Measures Analysis

<table>
<thead>
<tr>
<th>Month</th>
<th>Randomised Group</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>Min</th>
<th>Max</th>
<th>LS Mean</th>
<th>LS Mean Difference</th>
<th>Lower 95%CL</th>
<th>Upper 95%CL</th>
<th>P-value for Difference</th>
<th>P-value for Difference Rank Analysis</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Control</td>
<td>268</td>
<td>4.4</td>
<td>3.8</td>
<td>0.0</td>
<td>20.0</td>
<td>.</td>
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<td>.</td>
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<td>.</td>
</tr>
<tr>
<td></td>
<td>Intervention</td>
<td>269</td>
<td>4.1</td>
<td>3.4</td>
<td>0.0</td>
<td>19.0</td>
<td>.</td>
<td>.</td>
<td>.</td>
<td>.</td>
<td>.</td>
<td>.</td>
</tr>
<tr>
<td>1</td>
<td>Control</td>
<td>223</td>
<td>4.3</td>
<td>4.1</td>
<td>0.0</td>
<td>21.0</td>
<td>4.2</td>
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<td>.</td>
<td>-0.3</td>
<td>0.1657</td>
</tr>
<tr>
<td>1</td>
<td>Intervention</td>
<td>234</td>
<td>3.9</td>
<td>3.5</td>
<td>0.0</td>
<td>16.0</td>
<td>3.9</td>
<td>-0.7</td>
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<td>0.1557</td>
<td>0.3344</td>
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</tr>
<tr>
<td>12</td>
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<td>4.1</td>
<td>0.0</td>
<td>21.0</td>
<td>4.2</td>
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<td>.</td>
<td>-0.2</td>
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</tr>
<tr>
<td>12</td>
<td>Intervention</td>
<td>212</td>
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<td>3.5</td>
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<td>19.0</td>
<td>4.0</td>
<td>-0.7</td>
<td>0.2</td>
<td>0.3344</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 20 shows the distribution of depression scores to month 12 for the control and Intervention groups. Distribution of scores appears visually similar between treatment arms.

Figure 20 Distribution of depression
6.8.5. Quality of Life (AQoL-8D)

Table 21 shows that to month 1 and month 12 there were no statistically significant differences observed between treatment arms for the AQoL-8D score (p=0.2562 to month 1 and p=0.5111 to month 12). The p value generated from this analysis is robust for any differences from normality. This suggests that there is no evidence of any difference in AQoL-8D scores between treatment arms at one and 12 months.

<table>
<thead>
<tr>
<th>Month</th>
<th>Randomised Group</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>Min</th>
<th>Max</th>
<th>LS Mean</th>
<th>LS Mean Difference</th>
<th>Lower 95%CL</th>
<th>Upper 95%CL</th>
<th>P-value for Difference</th>
<th>Rank Analysis</th>
<th>P-value for Difference</th>
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<tbody>
<tr>
<td>0</td>
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<td>268</td>
<td>76.5</td>
<td>13.6</td>
<td>23.4</td>
<td>124.8</td>
<td>.</td>
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<td>.</td>
<td>.</td>
<td>.</td>
<td>.</td>
<td>.</td>
</tr>
<tr>
<td>0</td>
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<td>268</td>
<td>77.1</td>
<td>12.2</td>
<td>27.7</td>
<td>115.6</td>
<td>.</td>
<td>.</td>
<td>.</td>
<td>.</td>
<td>.</td>
<td>.</td>
<td>.</td>
</tr>
<tr>
<td>1</td>
<td>Control</td>
<td>221</td>
<td>77.5</td>
<td>15.9</td>
<td>11.4</td>
<td>124.8</td>
<td>78.1</td>
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<td>.</td>
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<tr>
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<td>Intervention</td>
<td>234</td>
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<td>14.2</td>
<td>31.2</td>
<td>124.8</td>
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<td>0.1915</td>
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<td>0.5923</td>
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</tr>
<tr>
<td>12</td>
<td>Intervention</td>
<td>213</td>
<td>79.1</td>
<td>15.1</td>
<td>27.0</td>
<td>124.8</td>
<td>78.8</td>
<td>0.7</td>
<td>-1.4</td>
<td>2.8</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 21 shows a visual representation of the distribution of AQoL-8D scores to month 12 for the control and Intervention groups. Distribution of scores appears visually similar between treatment arms.
6.8.6. Cancer Worry scale

Table 22 shows that to month 1 and month 12 there were no statistically significant differences observed between treatment arms for the Cancer Worry score (p=0.3381 to month 1 and p=0.2436 to month 12). The p value generated from this analysis is robust for any differences from normality. This suggests that there is no evidence of any difference in Cancer Worry scores between treatment arms at one and 12 months.

<table>
<thead>
<tr>
<th>Month</th>
<th>Randomised Group</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>Min</th>
<th>Max</th>
<th>LS Mean</th>
<th>LS Mean Difference</th>
<th>Lower 95%CL</th>
<th>Upper 95%CL</th>
<th>P-value for Difference</th>
<th>P-value for Rank Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
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<td>268</td>
<td>3.4</td>
<td>3.2</td>
<td>0.0</td>
<td>17.0</td>
<td>.</td>
<td>.</td>
<td>.</td>
<td>.</td>
<td>.</td>
<td>.</td>
</tr>
<tr>
<td>0</td>
<td>Intervention</td>
<td>269</td>
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<td>3.2</td>
<td>0.0</td>
<td>17.0</td>
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<td>.</td>
<td>.</td>
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<td>.</td>
</tr>
<tr>
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<td>Control</td>
<td>223</td>
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<td>0.0</td>
<td>16.0</td>
<td>3.7</td>
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<td>.</td>
<td>.</td>
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<td>.</td>
</tr>
<tr>
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<td>Intervention</td>
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<td>3.1</td>
<td>0.0</td>
<td>18.0</td>
<td>3.5</td>
<td>-0.2</td>
<td>-0.7</td>
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<td>0.0</td>
<td>16.0</td>
<td>3.5</td>
<td>.</td>
<td>.</td>
<td>.</td>
<td>.</td>
<td>.</td>
</tr>
<tr>
<td>12</td>
<td>Intervention</td>
<td>212</td>
<td>2.8</td>
<td>3.2</td>
<td>0.0</td>
<td>18.0</td>
<td>3.2</td>
<td>-0.3</td>
<td>-0.7</td>
<td>0.2</td>
<td>0.2436</td>
<td>0.1576</td>
</tr>
</tbody>
</table>

Figure 21 Distribution of Aqol8D scores
Figure 22 shows a visual representation of the distribution of Cancer Worry scores to month 12 for the control and Intervention groups. Distribution of scores appears visually similar between treatment arms.

![Distribution of Cancer Worry](image)

### 6.8.7. Perceived risk

Table 23 shows that to month 1 and month 12 there were no statistically significant differences observed between treatment arms for the Perceived Risk score (p=0.0728 to month 1 and p=0.6452 to month 12). The p value generated from this analysis is robust for any differences from normality. This suggests that there is no evidence of any difference in Perceived Risk scores between treatment arms at one and 12 months.

Figure 23 shows a visual representation of the distribution of Perceived Risk scores to month 12 for the control and Intervention groups. Distribution of scores appears visually similar between treatment arms.
### Table 23 Perceived risk scale

<table>
<thead>
<tr>
<th>Month</th>
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<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>Min</th>
<th>Max</th>
<th>LS Mean</th>
<th>LS Mean Difference</th>
<th>LS Mean Difference Lower 95%CL</th>
<th>LS Mean Difference Upper 95%CL</th>
<th>P-value for Difference</th>
<th>P-value for Difference Rank Analysis</th>
<th>P-value for Difference Rank Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Control</td>
<td>268</td>
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<td>1.9</td>
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<td>10.0</td>
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<td>.</td>
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<td>.</td>
</tr>
<tr>
<td>0</td>
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<td>269</td>
<td>6.9</td>
<td>1.7</td>
<td>0.0</td>
<td>10.0</td>
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</tr>
<tr>
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<td>Control</td>
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<td>2.0</td>
<td>0.0</td>
<td>10.0</td>
<td>6.8</td>
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<td>Intervention</td>
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<td>1.7</td>
<td>2.0</td>
<td>10.0</td>
<td>7.1</td>
<td>0.2</td>
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<td>1.9</td>
<td>0.0</td>
<td>10.0</td>
<td>6.8</td>
<td>.</td>
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<td>.</td>
<td>.</td>
</tr>
<tr>
<td>12</td>
<td>Intervention</td>
<td>212</td>
<td>6.7</td>
<td>1.9</td>
<td>0.0</td>
<td>10.0</td>
<td>6.8</td>
<td>0.1</td>
<td>-0.2</td>
<td>0.3</td>
<td>0.6452</td>
<td>0.4904</td>
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</tr>
</tbody>
</table>

![Distribution of Risk_LD](image)

**Figure 23 Distribution of perceived risk scores**

#### 6.8.8. Self-Efficacy for consulting without delay

Table 24 shows that to month 1 and month 12 there were no statistically significant differences observed between treatment arms for the self-efficacy score ($p=0.1583$ to month 1 and $p=0.1695$ to month 12). The $p$ value generated from this analysis is robust for any differences from normality. This suggests that there is no evidence of any difference in Self efficacy scores between treatment arms at one and 12 months.
Figure 24 shows a visual representation of the distribution of self-efficacy scores to month 12 for the control and Intervention groups. Distribution of scores appears visually similar between treatment arms.

6.8.9. Knowledge

Table 25 shows that to month 1 and month 12 there were no statistically significant differences observed between treatment arms for the Knowledge score (p=0.7769 to
month 1 and \( p=0.0.0509 \) to month 12). While the increase in knowledge does increase for the Intervention group to month 12, this just falls short of being statistically significant.

<table>
<thead>
<tr>
<th>Month</th>
<th>Randomised Group</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>Min</th>
<th>Max</th>
<th>LS Mean</th>
<th>LS Mean Difference</th>
<th>Lower 95%CL</th>
<th>Upper 95%CL</th>
<th>P-value for Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Control</td>
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<td>5.4</td>
<td>-8.0</td>
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<td>.</td>
</tr>
<tr>
<td>0</td>
<td>Intervention</td>
<td>269</td>
<td>8.7</td>
<td>5.9</td>
<td>-10.0</td>
<td>19.0</td>
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</tr>
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<td>Control</td>
<td>223</td>
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<td>5.4</td>
<td>-9.0</td>
<td>19.0</td>
<td>9.5</td>
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<td>21.0</td>
<td>9.6</td>
<td>0.1</td>
<td>-0.8</td>
<td>1.1</td>
<td>0.4583</td>
</tr>
<tr>
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<td>Control</td>
<td>204</td>
<td>8.8</td>
<td>5.9</td>
<td>-11.0</td>
<td>19.0</td>
<td>8.9</td>
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<td>.</td>
<td>.</td>
</tr>
<tr>
<td>12</td>
<td>Intervention</td>
<td>212</td>
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<td>6.1</td>
<td>-8.0</td>
<td>19.0</td>
<td>9.9</td>
<td>1.0</td>
<td>-0.0</td>
<td>2.0</td>
<td>0.0509</td>
</tr>
</tbody>
</table>

Graphically, it appears that the Intervention group have higher scores at the upper end of the scoring range (Figure 25).

![Distribution of knowledge scores](image-url)
6.8.10. **Intention to consult**

Table 26 shows that to month 1 and month 12 there were no statistically significant differences observed between treatment arms for the Intention to consult score (p=0.3151 to month 1 and p=0.1636 to month 12). A lower score suggests a shorter time to consult. In this case, there is no evidence of any difference in Intention to consult scores between treatment arms at one and 12 months.

<table>
<thead>
<tr>
<th>Month</th>
<th>Randomised Group</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>Min</th>
<th>Max</th>
<th>LS Mean</th>
<th>LS Mean Difference</th>
<th>Lower 95% CL</th>
<th>Upper 95% CL</th>
<th>P-value for Difference</th>
<th>P-value for Difference</th>
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</thead>
<tbody>
<tr>
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<td>Intervention</td>
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<td>11.5</td>
<td>21.0</td>
<td>105.0</td>
<td>70.8</td>
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<td>-3.5</td>
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<td>0.3151</td>
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<tr>
<td>12</td>
<td>Control</td>
<td>204</td>
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<td>15.1</td>
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<td>119.0</td>
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<td>.</td>
</tr>
<tr>
<td>12</td>
<td>Intervention</td>
<td>212</td>
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<td>13.7</td>
<td>18.0</td>
<td>116.0</td>
<td>70.3</td>
<td>-1.7</td>
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</tr>
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</table>

Figure 26 shows a visual representation of the distribution of Intention to Consult scores to month 12 for the control and Intervention groups. Distribution of scores appears visually similar between treatment arms.
6.8.11. Views on health

Table 27 shows that to month 1 and month 12 there were no statistically significant differences observed between treatment arms for the Views On Health score (p=0.6922 to month 1 and p=0.3017 to month 12). In this case, there is no evidence of any difference on “Views on Health” scores between treatment arms at one and 12 months.

Table 27 Views on health

<table>
<thead>
<tr>
<th>Month</th>
<th>Randomised Group</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>Min</th>
<th>Max</th>
<th>LS Mean</th>
<th>LS Mean Difference</th>
<th>Lower 95%CL</th>
<th>Upper 95%CL</th>
<th>P-value for Difference</th>
<th>P-value for Rank Analysis</th>
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</thead>
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<td>Control</td>
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</tr>
<tr>
<td>1</td>
<td>Control</td>
<td>223</td>
<td>48.0</td>
<td>12.0</td>
<td>0.0</td>
<td>89.0</td>
<td>47.3</td>
<td>.</td>
<td>.</td>
<td>.</td>
<td>0.6922</td>
<td>0.5405</td>
</tr>
<tr>
<td>1</td>
<td>Intervention</td>
<td>234</td>
<td>47.0</td>
<td>8.1</td>
<td>26.0</td>
<td>84.0</td>
<td>47.0</td>
<td>-0.3</td>
<td>-1.8</td>
<td>1.2</td>
<td>0.6922</td>
<td>0.5405</td>
</tr>
<tr>
<td>12</td>
<td>Control</td>
<td>204</td>
<td>48.0</td>
<td>10.7</td>
<td>0.0</td>
<td>78.0</td>
<td>47.6</td>
<td>.</td>
<td>.</td>
<td>.</td>
<td>0.3017</td>
<td>0.2945</td>
</tr>
<tr>
<td>12</td>
<td>Intervention</td>
<td>212</td>
<td>46.9</td>
<td>9.0</td>
<td>21.0</td>
<td>87.0</td>
<td>46.8</td>
<td>-0.8</td>
<td>-2.3</td>
<td>0.7</td>
<td>0.3017</td>
<td>0.2945</td>
</tr>
</tbody>
</table>

Figure 27 shows a visual representation of the distribution of Views on Health scores to month 12 for the control and Intervention groups. Those in the Intervention group appear to have scored higher overall for the mid-range scores.

![Distribution of Views_Health](image-url)
6.8.12. **Time to first consultation from baseline**

Time to first consultation from baseline was analysed using survival analysis methods, and in this case a Kaplan Meir curve was used for presentation. The applicability of survival analysis methods for recurrent events was investigated. For participants that do have consultations, a comparison between randomised groups of the interval from symptom appraisal to help-seeking was undertaken using a linear model that includes general practice as a factor. Other factors (e.g. MRC Dyspnoea Scale) was also accounted for in this analysis but only if there was evidence they were likely confounders.

Figure 28 shows the time to the first consultation for a respiratory event. It can be seen that the cumulative incidence is higher for the Intervention group compared to the control group indicating a shorter length of time to consult in the intervention group compared to the control group. That is the interval is shorter for the intervention group. This graph only accounts for the first event only.

While Figure 28 shows the extent to which the groups separate is due to a treatment effect, there is no outstanding or prominent pattern that has emerged revealing anything of significance. Table 28 shows that there is no statistically significant difference between groups.

![Figure 28 Cumulative incidence function showing time to first consultation for a respiratory symptom](image-url)
6.8.13. Symptom appraisal to help-seeking

Table 29 describes the delays in Days-Mean (SD) and the number who contributed to the mean delay interval. In the first line of Table 1 there are 108 who contributed to the intervention group and 95 who contributed to the control group. The mean delays interval (or time to consult from first respiratory symptom) was 66.43 days for the Intervention group and 75.66 days for the control group, showing that those from the intervention group consulted approximately 9 days sooner. The average interval for each subsequent appointment is then presented for those who presented more than once. The log mean interval is also presented in this table.

Table 28 Time to first consultation for a respiratory symptom.

<table>
<thead>
<tr>
<th>Test of Equality over Strata</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Test</td>
<td>Chi-Square</td>
<td>DF</td>
<td>Pr &gt;Chi-Square</td>
</tr>
<tr>
<td>Log-Rank</td>
<td>2.7387</td>
<td>1</td>
<td>0.0979</td>
</tr>
</tbody>
</table>

Table 29 Symptom appraisal to help-seeking interval

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention (N=274)</th>
<th>Control (N=277)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delay in Days: Mean (SD) [N]</td>
<td>66.43 (108.82) [108]</td>
<td>75.66 (101.96) [95]</td>
</tr>
<tr>
<td>Appointment 1: Mean (SD) [N]</td>
<td>61.77 (101.79) [77]</td>
<td>75.41 (102.06) [71]</td>
</tr>
<tr>
<td>Appointment 2: Mean (SD) [N]</td>
<td>71.22 (119.75) [23]</td>
<td>83.85 (111.74) [132]</td>
</tr>
<tr>
<td>Appointment 3: Mean (SD) [N]</td>
<td>68 (132.63) [7]</td>
<td>39.25 (37.85) [4]</td>
</tr>
<tr>
<td>Appointment 4: Mean (SD) [N]</td>
<td>304 (. ) [132]</td>
<td>. (. ) [132]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Log10 Delay in Days: Mean (SD) [N]</th>
<th>Back-transformed Mean</th>
<th>Back-transformed Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.32 (0.66) [108]</td>
<td>20.9</td>
<td>1.50 (0.6) [95]</td>
</tr>
<tr>
<td>Log10 Appointment 1: Mean (SD) [N]</td>
<td>1.32 (0.64) [77]</td>
<td>1.50 (0.6) [71]</td>
</tr>
<tr>
<td>Log10 Appointment 2: Mean (SD) [N]</td>
<td>1.35 (0.67) [23]</td>
<td>1.54 (0.63) [132]</td>
</tr>
<tr>
<td>Log10 Appointment 3: Mean (SD) [N]</td>
<td>1.13 (0.88) [7]</td>
<td>1.40 (0.5) [4]</td>
</tr>
<tr>
<td>Log10 Appointment 4: Mean (SD) [N]</td>
<td>2.48 (. ) [132]</td>
<td>. (. ) [132]</td>
</tr>
</tbody>
</table>
It must be noted that these results must be treated with a degree of caution as the interval is only known for those who consulted and returned the Delays questionnaire. There were those who had symptoms but did not return a questionnaire, however, there was a good response rate for returning the Delays questionnaire (88% RR for the Intervention group and 66% for the control group, 77% overall).

6.8.14. Delays with the first appointment

The delay to the first appointment using product limit survival estimates for those subjects at risk is presented in Figure 29. Table 30 shows that there is no evidence of a numerical statistically significant difference between treatment groups, even though the trend is in the right direction.

Table 30 Delay with first appointment

<table>
<thead>
<tr>
<th>Test of Equality over Strata</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Test</td>
<td>Chi-Square</td>
</tr>
<tr>
<td>Log-Rank</td>
<td>1.5923</td>
</tr>
</tbody>
</table>

Figure 29 Delay with first respiratory appointment
Table 31 presents Delay with combined appointments overall which resulted in a p value of 0.1469 using hazard ratio analysis, once again indicating no significant difference between treatment arms.

<table>
<thead>
<tr>
<th>Hazard Ratio</th>
<th>95% Hazard Ratio Confidence Limits</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.827</td>
<td>0.640</td>
<td>1.069</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.1469</td>
</tr>
</tbody>
</table>

### 6.8.15. Type of symptom reported and associated delay in days

Table 32 describes the type of symptom and associated delay in days for the CHEST Australia cohort. A new or worsening cough was the most frequently reported first symptom (n=94) followed by breathlessness (n=41) and chest and shoulder pain (n=20). From these top three symptoms recorded, chest and shoulder pain had the shortest patient delay (median=12 days) followed by cough (median= 21 days) and breathlessness (median=30 days). The longest patient delay overall was reported for fatigue (median=183 days).

Cough combined with breathlessness had a shorter help seeking interval compared to breathlessness alone (median=26 days), but only 10 patients reported this type of symptom.

<table>
<thead>
<tr>
<th>Observation</th>
<th>First Symptom</th>
<th>Frequency</th>
<th>min</th>
<th>p25</th>
<th>median</th>
<th>p75</th>
<th>max</th>
<th>mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Overall</td>
<td>212</td>
<td>1</td>
<td>7</td>
<td>21</td>
<td>72</td>
<td>365</td>
<td>71</td>
</tr>
<tr>
<td>2</td>
<td>Cough</td>
<td>94</td>
<td>1</td>
<td>7</td>
<td>21</td>
<td>60</td>
<td>365</td>
<td>66</td>
</tr>
<tr>
<td>3</td>
<td>breathlessness</td>
<td>41</td>
<td>3</td>
<td>14</td>
<td>30</td>
<td>172</td>
<td>365</td>
<td>99</td>
</tr>
<tr>
<td>4</td>
<td>chest/shoulder pain</td>
<td>20</td>
<td>3</td>
<td>4</td>
<td>12</td>
<td>58</td>
<td>310</td>
<td>56</td>
</tr>
<tr>
<td>5</td>
<td>cough/breathlessness</td>
<td>10</td>
<td>7</td>
<td>7</td>
<td>26</td>
<td>137</td>
<td>365</td>
<td>83</td>
</tr>
<tr>
<td>6</td>
<td>fatigue</td>
<td>7</td>
<td>3</td>
<td>3</td>
<td>183</td>
<td>300</td>
<td>365</td>
<td>151</td>
</tr>
</tbody>
</table>

*Log transformed data. All values are in days.
6.9. Summary of key findings from the quantitative analysis

6.9.1. Overall key message

Results from the statistical analysis have shown that the CHEST Intervention increased respiratory consultations by 39% in a population at increased risk of lung cancer. This effect was specific and did not affect overall total consultation rates. While those in the intervention group consulted 9 days sooner on average for a first respiratory consultation, compared to the control group, this was not clinically significant. The results also did not indicate any evidence of harm on any of the psycho-social scales (HADS, cancer worry, views on health or quality of life).

While the Intervention has had a demonstrated effect on respiratory consultations, it is unclear how. None of the process intermediate measures such as self-efficacy or intention to consult, knowledge of symptoms or perceived risk of lung cancer showed any significant difference between treatment arms. Knowledge of Symptoms of Lung Disease was very close to becoming statistically significant for the Intervention group compared to the control group at month 12 (p=0.0509) which could partially explain the primary outcome result, but there is still not strong enough evidence from any of these measures to pinpoint or explain how the intervention worked.

The definition of a respiratory outcome using the key symptoms described in Chapter 3 and derived from the Scottish trial were workable. If there was any discrepancy or confusion over whether a consultation was defined as a respiratory consult, this was discussed among the research group for clarification. For example, a flu vaccination was not defined as a respiratory consultation. In many cases there were multiple symptoms from the list in one consultation. In the majority of cases GPs were consistent in their recording of a respiratory symptom, compared to smoking status which was more difficult to decipher. Clarification was sought from the GP if it was hard to determine what was recorded in the medical records.

6.9.2. Practice recruitment

Eleven practices were recruited in Perth and 5 practices in Melbourne. Overall, 5281 invites were sent to potentially eligible participants from Perth and Melbourne (3307 to Perth and 1974 to Melbourne). This was from an estimated patient population of 222864 The overall response rate was 18% Of those that responded, 66% were eligible after further screening
overall (79% in Perth and 54% in Melbourne). Of those eligible, 88% were recruited into the CHEST study (93% from Perth and 83% from Melbourne). Establishing a rapport with the Practice manager was important during the recruitment phase.

6.9.3. Generalisability of the participant group

The demographic data showed a skewing towards ex-smokers to current smokers for both treatment arms, with a higher percentage of males than females recruited into the study, who lived with a spouse and had an education level of below Year 11 or equivalent. Most people were retired and owned their own home. The suburbs tested represented a range of socio-economic areas as coded by the SEIFA index.

6.9.4. Response rate in comparison to the Scottish study

The 551 patients recruited into the CHEST study reflected an 18% response rate sent to patients at 16 general practices in Perth and Melbourne (ranging from 10-26% range). This is similar to the Scottish trial where a 20% response rate was recorded.

6.9.5. Attrition and tracking

Of the 940 responders, 623 were eligible. The main reason for ineligibility was that most had ceased smoking greater than 15 years prior and had less than 20 pack years. From the 623 eligible. 60% of the 940 who responded were ex-smokers, compared to 36% of current smokers, indicating a selection bias towards ex-smokers. Problems were reported in Perth and Melbourne of patients who transferred to another GP clinic. This made it difficult to track and follow-up these patients. This was not a reported issue in the Scottish trial. However, those lost to follow-up for the primary outcome was low, with only 5 lost in the intervention arm and 4 lost in the control arm. Good response rates were recorded for the questionnaire data, although there was a slight drop off at month 1 and 12.

6.9.6. Preferred reminders for the Intervention group

Of the four types of reminders sent to those in the Intervention group (n=274), 148 (54%) preferred emails, followed by 89 (33%) preferring a short message service (SMS) and 35 (13%) selecting a postcard reminder. Only 2 (0.7%) selected the phone call reminder option.
Chapter 7. Qualitative Results

7.1. Response rate

Twenty participants were purposively selected and participated in a follow-up face to face interview. Appendix G, Table 1, describes each participant in terms of their age, gender, smoking status, socioeconomic score (SEIFA code) number of pack years, number of symptom questionnaires returned, previous 12 month consultation rate, MRC dyspnoea score and FEV1 predicted score.

Compared to the overall study group, our purposive sampling technique provided a sub-set of interviewees that represent the larger study group in most demographics (Table 33). It can be seen that a similar ratio of males and females, with ages ranging from 59 to 79 years were selected. The ratio of WA: VIC patients smoking pack years, FEV1 ratios and MRC dyspnoea scores and the percentage of home ownership were similar for both groups.

A slightly higher percentage of employed and retired participants were selected compared to the larger study group as well as a higher percentage of participants living on their own. While we attempted to select more current smokers for the study, this proved challenging given our time frames for sampling during the end of the 12 month follow-ups and finding smokers who were agreeable to a follow up interview.

Table 33 Qualitative Interview group versus overall study group demographics.

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n=274)</th>
<th>Control (n=277)</th>
<th>Qualitative Study (n=20)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>State</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Western Australia</td>
<td>197 (72%)</td>
<td>209 (75%)</td>
<td>13 (65%)</td>
</tr>
<tr>
<td>Victoria</td>
<td>77 (28%)</td>
<td>68 (25%)</td>
<td>7 (35%)</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>157 (57%)</td>
<td>163 (59%)</td>
<td>12 (60%)</td>
</tr>
<tr>
<td>Female</td>
<td>117 (43%)</td>
<td>114 (41%)</td>
<td>8 (40%)</td>
</tr>
<tr>
<td><strong>Age Group</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>55-59</td>
<td>64 (23%)</td>
<td>59 (21%)</td>
<td>5 (25%)</td>
</tr>
<tr>
<td>60-69</td>
<td>130 (47%)</td>
<td>147 (53%)</td>
<td>7 (35%)</td>
</tr>
<tr>
<td>70-79</td>
<td>67 (24%)</td>
<td>60 (22%)</td>
<td>8 (40%)</td>
</tr>
<tr>
<td>&gt;80</td>
<td>13 (5%)</td>
<td>11 (4%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td><strong>Smoking History</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current Smoker</td>
<td>104 (38%)</td>
<td>131 (47%)</td>
<td>5 (25%)</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>-----------</td>
<td>-----------</td>
<td>--------</td>
</tr>
<tr>
<td>Ex-Smoker</td>
<td>170 (62%)</td>
<td>146 (53%)</td>
<td>15 (75%)</td>
</tr>
<tr>
<td>Smoking Pack Years (Min</td>
<td>Mean</td>
<td>Max)</td>
<td>20</td>
</tr>
<tr>
<td>FEV1 Predicted (Min</td>
<td>Mean</td>
<td>Max)</td>
<td>0</td>
</tr>
<tr>
<td>MRC Dyspnoea Score</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-3</td>
<td>258 (94%)</td>
<td>260 (94%)</td>
<td>18 (90%)</td>
</tr>
<tr>
<td>4-5</td>
<td>16 (6%)</td>
<td>17 (6%)</td>
<td>2 (10%)</td>
</tr>
<tr>
<td>Existing Medical History</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>100 (37%)</td>
<td>115 (42%)</td>
<td>4 (20%)</td>
</tr>
<tr>
<td>Respiratory</td>
<td>90 (33%)</td>
<td>89 (32%)</td>
<td>4 (20%)</td>
</tr>
<tr>
<td>Psychiatric</td>
<td>44 (16%)</td>
<td>41 (15%)</td>
<td>2 (10%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>28 (10%)</td>
<td>35 (13%)</td>
<td>1(10%)</td>
</tr>
<tr>
<td>Lung Cancer (Diagnosed on trial)</td>
<td>2(0.7%)</td>
<td>1(0.04%)</td>
<td>1*(5%)</td>
</tr>
<tr>
<td>(Other)</td>
<td>92 (34%)</td>
<td>92 (33%)</td>
<td>5 (25%)</td>
</tr>
<tr>
<td>Employment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unemployed</td>
<td>38 (14%)</td>
<td>33 (12%)</td>
<td>1 (5%)</td>
</tr>
<tr>
<td>Employed</td>
<td>38 (14%)</td>
<td>31 (11%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Looking after home/family</td>
<td>16 (6%)</td>
<td>15 (5%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Caring for dependent relative</td>
<td>4 (1%)</td>
<td>1 (0%)</td>
<td>1(5%)</td>
</tr>
<tr>
<td>Voluntary worker</td>
<td>4 (1%)</td>
<td>4 (1%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Student</td>
<td>3 (1%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Retired</td>
<td>38 (14%)</td>
<td>57 (21%)</td>
<td>7 (35%)</td>
</tr>
<tr>
<td>Invalid/Disabled</td>
<td>13 (5%)</td>
<td>12 (4%)</td>
<td>3 (15%)</td>
</tr>
<tr>
<td>Other (please specify)</td>
<td>46 (17%)</td>
<td>43 (16%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Blank</td>
<td>10 (4%)</td>
<td>15 (5%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Highest Educational Qualification</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Year 11 or below</td>
<td>86 (31%)</td>
<td>89 (32%)</td>
<td>9 (45%)</td>
</tr>
<tr>
<td>Year 12 or equivalent</td>
<td>40 (15%)</td>
<td>38 (14%)</td>
<td>3 (15%)</td>
</tr>
<tr>
<td>Trade/Apprenticeship</td>
<td>29 (11%)</td>
<td>39 (14%)</td>
<td>1 (5%)</td>
</tr>
<tr>
<td>Tertiary Certificate/diploma</td>
<td>50 (18%)</td>
<td>56 (20%)</td>
<td>2 (10%)</td>
</tr>
<tr>
<td>Undergraduate university degree</td>
<td>23 (8%)</td>
<td>18 (6%)</td>
<td>2 (10%)</td>
</tr>
<tr>
<td>Post graduate university degree</td>
<td>17 (6%)</td>
<td>12 (4%)</td>
<td>2(10%)</td>
</tr>
<tr>
<td>Other</td>
<td>26 (9%)</td>
<td>17 (6%)</td>
<td>1 (5%)</td>
</tr>
<tr>
<td>None of these</td>
<td>3 (1%)</td>
<td>8 (3%)</td>
<td></td>
</tr>
<tr>
<td>Home Ownership</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Own your home</td>
<td>205 (75%)</td>
<td>211 (76%)</td>
<td>15(75%)</td>
</tr>
</tbody>
</table>
Rent your home | 50 (18%) | 33 (12%) | 4 (20%)
---|---|---|---
Other | 19 (7%) | 23 (8%) | 1 (5%)
Blank | 0 (0%) | 10 (4%) | 0 (0%)

**Living**

<table>
<thead>
<tr>
<th>Living</th>
<th>Rent your home</th>
<th>Rent your partner with children</th>
<th>Rent your home with your partner</th>
<th>Rent your home with others</th>
</tr>
</thead>
</table>
| On your own | 70 (26%) | 70 (25%) | 9 (45%)
| With a partner/spouse | 166 (61%) | 166 (60%) | 11 (55%)
| With other family | 32 (12%) | 28 (10%) | 0 (0%)
| Other | 6 (2%) | 5 (2%) | 0 (0%)
| Blank | 0 (0%) | 8 (3%) | 0 (0%)

*Patient 22029 developed lung cancer during the study period. A case study of this patient is described in Box 2.*

One patient (Patient 22029) was purposively selected in Perth who developed lung cancer during the study period. This patient was exposed to asbestos and farming chemicals while growing up as a child migrant in Australia. He suffered asthma as a child and had asbestos scarring on the lungs. He suffered asthma, breathlessness and two bouts of pneumonia prior to his lung cancer diagnosis. Worsening breathlessness and a worsening cough were observed at the start of 2015, but were not reported to the GP until nine months later. His lung cancer was diagnosed early as a Stage 3a, non-small cell carcinoma. It was found in the upper right lobe and biopsied. The tumour was described as T3N1, but due to this patient having emphysema and repeated bouts of pneumonia, he was deemed not eligible for aggressive chemotherapy and radiotherapy.

Box 2 describes the timeline of events that led to this patient’s diagnosis including the CHEST consultation.
7.2. Thematic analysis

This Phase II study explored the experiences of high-risk lung cancer patients who were exposed to a complex intervention [(consultation and self-help manual (CHEST Intervention)] to determine the impact of the intervention.

The key objectives of the Intervention were as follows; 1. Increase the salience and personal relevance of symptoms, 2. Improve knowledge of symptoms by introducing chest disease prototypes 3. Reinforce the benefits of early intervention in lung cancer and other chest disease 4. Sanction early consultation 5. Tackle barriers to consultation 6. Develop personalised action and coping plans.

An overall summary of the overarching themes and sub-themes from the CHEST study are described in Table 34.
Table 34 Summary of overarching themes and sub-themes from the CHEST qualitative study.

<table>
<thead>
<tr>
<th>Barriers to visiting the GP</th>
<th>Perceptions of the CHEST Intervention (The key objective addressed in parenthesis)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FEAR AND FATALISM</strong>&lt;sup&gt;**&lt;/sup&gt;</td>
<td><strong>SALIENCE</strong> <em>(Objective 1)</em></td>
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<td>Lung cancer was viewed in a fatalistic way and this drove an underlying fear of having to face a terminal disease and deal with the consequences. It was seen as easier to go into denial.</td>
<td>There is evidence the Intervention altered salience, or personal relevance of symptoms. Some already had a broader self-awareness of their health, due to past or present exposure or current health issues or family history. Those who were chronically ill they did not respond as well to the Intervention due to reasons such as; they already knew what to look out for, or they were already frequently visiting their GP or it was “too late” to be useful for them. This group already had salient symptoms and fewer barriers to help seeking.</td>
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<tr>
<td><strong>SYMPTOM NORMALISATION</strong>&lt;sup&gt;**&lt;/sup&gt;</td>
<td><strong>IMPROVE SYMPTOM AWARENESS</strong> <em>(Objective 2)</em></td>
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<td>Symptom normalisation was identified as a barrier to visiting the GP. Many attributed their cough or other symptoms to old age, or “what I normally have.” The phenomenon of cognitive dissonance was also observed in various ways. The concept of candidacy (the idea another person is a better candidate for getting cancer) optimistic bias (the idea that because it has not happened to others it will not happen to me) and rationalisation (innocuous reasons justifying behaviour) were evident and this contributed to a delay in consulting.</td>
<td>A list of symptoms led to a clearer understanding of what to look out for and when to take action. Supporting quotes indicate that it made people more aware of the signs to look out for and when to contact their GP.</td>
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<tr>
<td><strong>GUILT AND STIGMA</strong>&lt;sup&gt;**&lt;/sup&gt;</td>
<td><strong>PERCEPTIONS OF THE TOOLS OF THE INTERVENTION</strong></td>
</tr>
<tr>
<td>Many felt stigmatised and labelled as “an outcast” in society and by their own families because of their smoking and this was reinforced by the GP. Many ex-smokers said if they were currently smoking they may not have been so inclined to participate in the study <em>(Avoidance Coping).</em></td>
<td>Feedback from the self-help manual suggested that this tool is potentially addressing the objective of improving knowledge of symptoms for patients at increased risk of lung cancer <em>(Objective 2).</em> Feedback from the self-help manual The CHEST self-help manual was described as useful, logical and a good “reference guide” with valid information. Many liked the perceived control they had when referring to the booklet. The manual also reinforced the benefits of early intervention <em>(Objective 3).</em> Feedback from the monthly reminders There was evidence that the prompts and reminders had an impact on sanctioning early consultation <em>(Objective 4)</em> and this added weight on an intention to act <em>(Objective 6).</em></td>
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Reminders or prompts of wanted behaviour were carried out monthly which reminded participants to check their symptoms and visit the doctor if needed. Tailoring reminders to individual preferences was important in promoting self-efficacy.

Many preferred the positive messages, images and reminders from the CHEST Intervention such as the “123” logo and the fridge magnet.

<table>
<thead>
<tr>
<th>PREVIOUS EXPERIENCES OF VISITING THE GP.</th>
<th>TACKLING BARRIERS (Objective 5).</th>
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<tbody>
<tr>
<td>Lecturing and Reprimanding</td>
<td>There is evidence that the Intervention tackled barriers around lecturing and feelings of guilt and stigma.</td>
</tr>
<tr>
<td>Many patients were put off by lecturing or reprimanding to cease smoking by their GP as this reinforced a feeling of guilt. How the GP delivers this message is important in building trust.</td>
<td>The intervention was reported as a relaxed, non-threatening environment where patients at increased risk of lung cancer could openly talk about their smoking and lung health. The intervention did not judge patients or make them feel guilty for smoking or having previously smoked.</td>
</tr>
<tr>
<td>Perceived Mistrust</td>
<td>Some liked the “extra level of care” provided by the Intervention</td>
</tr>
<tr>
<td>Underlying mistrust of the GP related to various reasons such as perceptions of a missed or misdiagnosis, not understanding addiction and not taking symptoms seriously.</td>
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<tr>
<td>Miscommunication</td>
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<tr>
<td>Another concern expressed by some patients was the perception of miscommunication between the GP and patient. Some did not understand their diagnosis and would find further information on the internet to clarify their condition Some expressed that their GP could not relate or understand their addiction or simply they were not being listened too.</td>
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The major themes and associated sub-themes will be described below with supportive quotes from the transcripts.

7.2.1. **Barriers to visiting the GP**

7.2.1.1. **Fear and fatalism**

Many viewed lung cancer in a fatalistic way; it was seen as a condition that was invariably fatal and not curable. Other cancers were seen to be less fatalistic such as breast cancer, and as a result this fatalistic attitude led to fear. Many felt this fear of cancer, or a fear that if one has a disease that could be terminal, then important life decisions will have to be made. If one goes into a form of denial, you don’t have to address these issues and it appeared easier to go into a form of denial rather than face them.
“You try to block it off. You try and think, no, it's not me. But then again, you're also, on the other side of it, every little pain or wheeze you feel you think, oh no, oh no, this might be it; this might be the cigarette that gives me lung cancer. Yeah, it's a psychological battle really because you're addicted but you know the consequences also. So it's like you've got this head fight all the time” (7012, female, 59 years).

“No, because I didn't want to know, because I hadn't stopped and I knew I was continuing smoking. Whereas now, no, I have to face up to it; it's in the past, what damage have I done” (1400, male, 60 years).

Some participants felt they would leave visiting their GP to the last minute because of this fear.

“Because of the fear of, as I said, it's like when they have ads on TV of smokers and what damage it can do, flick it over, don't want to face it, don't want to face it. It's like an ostrich” (21012, female, 60 years).

This “Avoidance coping” mechanism was reiterated by this patient.

“It's hard to determine because some people like to stick their head in the sand, particularly if you're a smoker and you know you're doing something that's damaging your health. It's hard to look at yourself and say, okay, I'd better go to the doctors with this. I think you're more likely to hide it or ignore it”” (1400, male, 60 years).

This lady also expressed her hesitation in participating in anything to do with the lungs.

“Yeah. Because when you are a smoker, you're always hesitant about anything to do with the chest and the lungs, you know?” Because when you smoke, you know it's bad and I mean I can only just say me, but I know a lot of people that smoke, they don't want to have a chest x-ray because they're scared, basically. Of cancer or yeah what they find. Yeah I can remember always thinking that, mmm” (13007, female, 68 years).
7.2.1.2. **Symptom normalisation**

Symptom normalisation was also identified as a barrier to visiting the GP. Reasons for not visiting the GP were justified by innocuous explanations which seemed to be well justified. Many attributed their cough or other symptoms to old age, or what they normally have.

The following participant attributed his cough to old age.

“So I just felt that one two three check, that was the one that oh okay I am getting older you know. But is that just age or whatever? I believe it’s just age. Or my body you know you can't do as many push ups as you used to do, you can’t do as many sit ups, it’s just natural. I just believe 62 to me was a defining birthday that hang on you’re getting old now, you know. Yeah” (7017, male 71 years).

While this participant described his friend (who did eventually die of lung cancer) who apart from a cough was otherwise fine and put off going to visit the GP even though friends urged him to.

“But I mean he looked quite well. I mean he could walk and talk and [laughs] do normal things. He was physically active.

Facilitator: So he felt well...

Interviewee: Yeah.

Facilitator: ...what's the point of me going in?” (13001, male, 67 years).

Two chronically ill patients felt they already knew they had to see their GP urgently if they had a chest problem and they felt the intervention was useful to others but not themselves.

“other blokes who don’t want to go to the doctor and put off going, but not for me, I know I have a chronic lung condition and I know I have to get into my GP as soon as something is wrong” (8001, male, 69 years).

Similarly another lady felt she did not need the intervention or reminders, she already knew when to visit her GP.

“I'm always conscious of the fact about my chest because I'm - not that I'm paranoid about it, but I think because it's something that is so important to your
wellbeing and the cough I know it’s quite debilitating for me. So having had polyps removed from my voice box, having had situations with my throat and my chest, it’s really for me that’s been my biggest issue around this area. So I’m very conscious of that. I don’t need any reminders” (12003, female, 74 years).

7.2.1.3. Observed cognitive dissonance

The phenomenon of cognitive dissonance was repeatedly identified in many transcripts, where there was a dissonance between attitudes and behaviours. This was displayed in many ways through either an idea of candidacy (i.e. another family member is a better candidate for getting ill), optimistic bias (the idea that other people who have the same behaviour are not sick) or rationalisation of behaviour (justification and explanation of a type of behaviour) and this contributed to a delay in consulting.

For example some felt because they were only smoking a small amount of cigarettes per day, this meant they were not at risk of getting a serious lung condition.

“No, not really because I’m not really a heavy smoker. No I don’t smoke many cigarettes at all. I smoke something else, but…I should be fine in the long term…..” (14017, male 59 years).

Some believed that because their parents lived a long time and smoked, that the same would apply to them. This idea of “candidacy” or that another family member would have been a candidate for getting cancer was repeatedly expressed.

“…My parents lived to 103 and 102 and they died of old age. It doesn’t matter what I do, I’m invincible…..” (4002, male, 71 years).

“I still get a bit congested in the mornings, but that’s about it. Like I said, I-under no illusions that anything could happen down the track. Well I mean my parents smoked and both my parents at the moment are fine…” (14017, male, 59 years).

Another man claimed because he wasn’t a female, those anti-smoking ads did not apply to him. Once again, this idea of not being the ideal candidate to get cancer was expressed.

“But the ones (ads) that say you’re going to harm my baby if I ’m pregnant, don’t really affect me” (8001, male, 69 years).
One man described how he dealt with the stress of his father dying of a smoking related illness.

“Yeah, and the stupidity of all of that is that I hadn’t smoked for four years, and the night Dad passed away I started again……but the stupidity of it was that the smoking by and by caused Dad’s death and I decided to start smoking again, which was ridiculous. Smoked for about another 10 years before I ended up giving it away. Just stupid...” (14016, male, 56 years).

This lady explained that her issues had nothing to do with her lung health, and she rationalised it was an entirely different matter.

“Well, I don’t have chest symptoms, I have swallowing problems” (3018, female, 63 years).

7.2.1.4. Guilt and stigmatisation

Many felt they were constantly being told off when they visited their GP. Many felt guilty and outcast especially within society and even within their own families because of their smoking. This was reinforced when they visited their GP.

Many patients talked about the stigmatisation experienced within society.

“But I’m always being hassled as an evil person of society. I just feel as though we’re a very much persecuted minority now. I know - I don’t encourage it - I wouldn’t recommend it. But when you think of everything else they support, except for us. I just get - so yeah.....” (3013, male, 59 years).

“Just you’re an evil sinner and so that’s it....” (7019, female, 59 years).

“If you were having a cigarette out in the carpark, they’ll slam you. But they supply needle bins in the toilets. So it’s okay to shoot up, but if you’re having a cigarette out in the carpark, they’ll come after you....” (3013, male, 59 years).

“you are the outcast aren’t you? You can’t smoke inside, you can’t smoke anywhere. You’ve got to be out in the blooming paddock to have a smoke now, don’t you? Or outside of the building, three metres from the door. You’re an outcast,” (8002, female, 70 years).
“Because smokers are now like witches they used to burn at the stake...” (3018, male, 59 Years).

Other patients expressed guilt from their smoking especially when visiting the GP.

“You feel kind of guilty I suppose. You know he’s going to say are you still smoking or it’s the same, have you lost weight? That type of thing. You think oh gosh, you almost feel like a juvenile that you’re doing something wrong. You feel quite guilty” (3018, female, 63 years).

“Smokers don’t think they’re drug addicts. I never put myself with that, but you are. You are craving that drug. But anyway, the guilt is for the children, the guilt is because you might get sick and you might die and leave your children and it’s a legal drug, so people would just say, oh quit. Yeah, well if it was that easy, I would, but I’m addicted...” (8002, female, 70 years).

Some ex-smokers described that if they were still smoking, they would be less inclined to visit the GP and would have avoided going if possible. The once again emphasised that the stigma attached to smoking is a barrier.

“I think it would be hard to go through that booklet if you were a smoker. I’d be more - maybe it’s just me, because I can’t answer for anyone else, because if I put, oh I’ve had pain or anything like that, it’ll all go back to my smoking; it’s all related to smoking and I said, you feel bad when you smoke. I don’t know. Whereas now that I don’t smoke, I feel quite confident, yeah, no, I haven’t - if I had a pain, I would go, yes I had a pain. Whereas if I was smoking - it would all depend actually, if you had like one pain and if it went away, it’d be okay. Yeah, constant pain and you’re a smoker, yes, you would - I would say yes you would. But if it’s just an occasional pain, that’s what I think yeah” (7012, female, 59 years).

7.2.1.5. Previous experiences of visiting the GP

Lecturing and reprimanding

Past experiences of visiting the GP was identified as a key barrier to early help-seeking. Many patients were put off by perceptions of lecturing or reprimanding to cease smoking by their GP and they felt this reinforced a feeling of guilt. How the GP delivered this message was seen as important in building trust.
One patient said he would go into talk about his knee and the GP would lecture him to stop smoking.

“...because I’m a smoker and I’m used to being just lectured. It’s just when I got lectured all the time, I just stopped going to see them. I used to have past GPs - you go in there because you’ve got a crook knee, and they want to go, smoking’s thing nyah! So it just sort of puts a wall up to me. Like my late wife used to get upset because whenever an anti-smoking ad came on telly, I used to go outside and have a cigarette. That’s my attitude....” (3013, male, 59 years).

Another patient mentioned that he visited a locum and not his normal GP, and as soon as the consultation began she was pointing her finger ready to tell him off and his response was to walk away, because he did not want to be lectured about stopping smoking.

“They’d given me another doctor, and it’s a lady doctor because I told them I only want a lady doctor. When I went and I sat down, and the lady said to me, do you smoke? I said, yes. I said, I smoke. I said, what are you shaking your finger at me for? So I don't like that. I said, when I was little I was pushed, shoved and shaken. I got up and I walked out” (22029, male, 79 years).

Comments about being reprimanded constantly caused reluctance to visit the GP.

“.....and the more they lecture and annoy me about it, the more the fence goes up, if you know what I mean - which is wrong, I know....” (3013, male, 59 years).

“Well sometimes, like with the - if someone is at you all the time about something, like about my smoking and about my weight, you're not going to do it...” (8002, female, 70 years).

“But I got told off for smoking again. He looked really annoyed when I came through all those tests very healthy. I could tell it. He was annoyed. He was looking for something to...” (13007, female, 68 years).

Perceived mistrust

An underlying mistrust of the GP was perceived by some of the patients due to various reasons such as experiences of a missed diagnosis, not understanding addiction or not taking symptoms seriously.
The following lady explains her experience and perceptions of what she describes as a missed bowel cancer diagnosis.

“Well, I think she had a problem with her husband was sick at the time and she was only coming in at certain days and she probably wasn’t on the ball at that time. But I’ve been going to her for two or three months before saying something’s wrong. She did give me tests for an ultra - not a - she gave me certain tests, but she didn’t give me a colonoscopy or didn’t take a poo test, which he said that should have been the first thing she should have done. So, unfortunately my - with the bowel cancer, it perforated, so it got into the blood stream, so that's why I've got it all in different places...” (8002, female, 70 years old, missed bowel cancer diagnosis).

Her reaction to visiting the GP after this incident was.

“So, I feel - although I feel confident going to see them, I don’t know, I feel I just want to have another doctor’s surgery to go to. Yeah, I just - I don’t know what it is. I don’t feel comfortable anymore going there” (8002, female, 70 years old).

Similarly, this man described what he perceived as a misdiagnosis of his wife and this resulted in mistrust of the GP through miscommunication.

“Yeah, because I had a horror - my late wife was going to see her GP constantly about not felling well- and he kept saying, your asthma - upping the asthma medication - and giving her other things for asthma - and it ended up she actually had leukaemia - and that was six months down the track of going to her and I’m just saying, it's not asthma. The GP - she would be in and out in five minutes, more asthma medication - and it ended up she had leukaemia - and that really made me think twice about doctors generally. They’re like mechanics. You get good ones and bad ones” (3013, male, 59 years).

Perceived miscommunication

Mistrust derived from perceived experiences of miscommunication from the GP was also commonly described. Many would search the Internet to learn more about their consultation and any diagnosis because this was not clarified by the GP.

The following man described his thoughts when the GP told him he had emphysema, which he thought was mesothelioma.
“Once I understood what emphysema was about because the doctor just said I had emphysema, he didn’t say much about it. I Googled it and I found out that it wasn’t a death sentence that mesothelioma was -I was relieved” (7017, male, 71 years).

Part of communication is feeling like you are being listened by the other person. This lady describes her experience of feeling like she was not being listened too by her GP.

“That when you turn up you’re going to be listened too” (3018, female, 63 years).

Another participant talks about his thoughts following a GP visit where he thought he was diagnosed with a terminal illness and was relieved to find that COPD was manageable.

“No, it scared the shit out of me knowing that, having been diagnosed with COPD at that time and that’s when I got home and had a look on the internet and found out what it was and what the various prognoses were. Well I was relieved that I had a good reading on the spirometer test so that sort of eased it a fair bit but it still had me in anxiety for a couple of weeks wondering what was right and what was wrong on the internet” (8001, male, 69 years).

In some cases, many felt the GP needed to tell them exactly what symptoms to look out for rather than just lecturing them to stop smoking.

“Even if you go to the doctor and they say you should get off smoking and if you see these symptoms you should get back to me quickly. You never get that. It’s just you should stop. But they don’t tell you what you should look out for in case something does happen and you need to get to see me. So it has been extremely helpful to both of us. We sort of have both become aware of what’s happening. So I’m so glad that I did it (took part in the intervention)” (6002, female, 72 years).

7.2.2. Perceptions of the CHEST Intervention

The Intervention consultation was viewed as a relaxed, non-threatening environment where patients at increased risk of lung cancer could openly discuss their smoking and lung health. Many describe that the authoritarian relationship between the GP and patient did not exist and most felt they could open up and not feel they were being judged. Some even described what an “ideal GP” would be like.
“So I have gone and she is lovely. She’s a really good doctor, I feel. I go in there-and she’s done the tests and sort of harrumphed-but she doesn’t lecture me. But whenever you go there for anything, she seems to be giving you good attention. It’s not like some of the others were you’re in, out-no, I’m quite comfortable going to see her. I think she’s a good doctor” (3013, male, 59 years).

The overarching themes about how the Intervention was perceived and associated sub-themes are discussed below. The objectives being addressed in the original Scottish model are in parenthesis.

7.2.2.1. Salience

There was evidence that the intervention altered salience, or personal relevance of symptoms (Objective 1). Some patients expressed that the intervention bought symptoms to the forefront of their mind and they therefore addressed them more quickly. Some patients already had a broader self-awareness of their health, due to past or present exposure or current health issues or family history and this may have also triggered their participation in the study. In Perth, those who had been exposed to the mining industry were particularly aware of their lung health. A family history of cancer also reinforced the need to be vigilant in some. Some who were chronically ill did not respond as well to the intervention and gave reasons such as; they already knew what to look out for, they were already frequently visiting their GP or it was “too late” to be useful for them. Salience was not only reinforced by a list of symptoms to look out for, but also encouraging patients to listen to family and friends if they notice something is wrong.

“Yeah my wife said you better see someone about that cough, it has gone on too long, reading the booklet helped me see that too….“ (14005, male, 60 years).

Salience was also reinforced in the Intervention booklet with a case study of a patient who initially ignored symptoms but finally did see the doctor. Lung cancer was diagnosed and treatment began. Many recalled this case study after the intervention.

“I remember the story of the one who ignored the symptoms, I thought, that’s not going to be me……” (4002, male, 71 years).
Salience or personal relevance of symptoms was also reinforced by using the slogan “Look out for number 1, 2, Visit your GP if uncertain about some symptoms and don’t wait longer than 3 weeks with some symptoms.”

Many already had a broader self-awareness of one’s health particularly due to past or present exposure or current health issues or family history and this triggered participation.

**Self-awareness**

An overall self-awareness of one’s health led to many participating in the trial.

This lady talks about making the time to look after her health.

“I didn’t know whether I had the time but, then I thought, I have to make time for myself so - that’s part of everything, is us just having time. I do smoke, so that’s another plus for why I should do it” (7012, female, 59 years).

Reoccurring themes of looking after ones health featured in a lot of the interviews.

“You can go on in your life in this fairy land and think everything’s going to be okay, which I know it doesn’t, so I think it just opens you up to think about it more” (13007, female, 68 years).

“It just makes you a bit more aware of yourself and what’s actually happening with yourself, because people go through life and they don’t even know who they are, so when it comes to health problems they’re not even going to think about other things” (12003, female, 74 years).

This man believed that it is important to do something about any worrying symptoms.

“Look, I know guys myself that have ailments of one thing or another and they do nothing about it. In fact, I know two personal friends of mine who had ailments but, because they were men - I’m tough - they refused to go to the doctor and it finished up costing them their lives. I really believe they’d be alive today if they had have done something about it” (14005, male, 60 years).
**Previous exposure**

Some patients felt that previous exposure to either work conditions or home conditions could have been detrimental to their health and this had increased their awareness of lung health.

The following lady’s family had lived and worked at Wittenoom, a blue asbestos mining town in Western Australia that has been associated with multiple mesothelioma deaths. Her awareness of this previous exposure made her more inclined to participate in any chest related studies.

> “Then I’m an ex-Wittenoom mine worker and I just thought well if it’s about lungs, yeah we’re in. My husband is a smoker, so he thought it would be a good thing to do. So yeah, we signed it and sent it back straight away” (6002, female, 70 years, worked in asbestos mine).

> “Well I think it would be an advantage if somebody has worked in a place like I’ve done and because of my dad dying of mesothelioma. Smokers - if they were given the book with the information I would have thought that that would be fantastic” (6002, female, 70 years, worked in asbestos mine and father died of mesothelioma).

One participant’s family had exposure to asbestos through shipping.

> “My dad died of mesothelioma. Where he was working they couldn’t see that far in front of them and then they used to load the boats. My brother used to carry him out of the hole because he’d collapsed and he would work his shift” (6002, female, 70 years, worked in asbestos mine).

Some were not only worried about their own smoking but exposure to cigarette smoke by other family members (passive smoking).

> “But like in my family, my dad smoked, my mother never smoked, but my aunty and uncle, that era, but it was just an accepted thing. Even when I started smoking it was accepted. Oh well, buy your own ashtray. When I think of it now, if my children started smoking, I would be, oh. I am worried about this” (21012, female, 60 years).
Others were concerned at their previous smoking history and the long term effects on lung health.

“Of course it’s got to be fingers crossed. Life is that way. I’ve smoked a lot in my life so hey if that’s got to be, it’s got to be. But at least I’ve got a head start of knowing a bit about it. Yeah, so that’s why I did it” (7012, female, 59 years).

“Yeah to Sonya, I said I’m not under the delusion that nothing can happen, not after smoking for 38 years. I know that the damage is already done and I can’t reverse the damage. I’ve had chest x-rays done and that and my doctor says everything is okay. There’s no shadows or whatever that’s not mean to be there. I’m not under any delusions that anything could happen” (7019, female, 59 years).

**Current health issues**

For others, current health issues enforced them to participate.

“Yeah, but anything major I go and see him about because with emphysema well I’ve got it early so there’s no big drama. I’ll lose a bit of lung capacity......Oh, yeah, I’m wary of that so I’m more conscious of having lung problems. Because I’ve got a lung problem, if the lung problem is worse, so if there’s something there and I think that’s not right and it seems a bit dangerous I’ll go and make an appointment with the doctor straight away” (21003, male, 76 years).

After years of smoking the following lady already had some lung issues and is very conscious of being aware of her lung health.

“I’m always conscious of the fact about my chest because I’m - not that I’m paranoid about it, but I think because it’s something that is so important to your wellbeing and the cough I know it’s quite debilitating for me” (13007, female, 68 years).

**Family history**

Previous family health issues featured prominently as a reason to participate in the CHEST study. Many felt concerned at their families’ experiences of illness and were worried about their own heath. By participating they felt they were doing something positive for themselves.
“Then my sister died just before her sixtieth birthday with lung cancer” (7019, female, 59 years).

“I don't want to do it and that's why because that's talking about your chest and family history. It all melds in to me and I'd rather not go where Mum and Dad went” (3022, male, 64 years).

The following lady experienced her mother passing away from ovarian cancer and it encouraged her to not only stop smoking but also increase her awareness of her own lung health.

“I made a promise. My mother was a very - my mother was a heavy smoker, so was my dad. Both my parents smoked and my mother had kept on saying me - she actually died of ovarian cancer and she actually said to me please I want you to give it up. It was quite a stressful time when she was dying, but I promised myself that once she does pass on I am going to give that up and I did” (13007, female, 68 years).

**Knowledge that there is an association between lung cancer and smoking**

Many participants knew about the association between smoking and lung cancer, and that they felt compelled to participate because of this knowledge.

The following man referred to quitting smoking and participating in the study.

“I don’t know. It was time to stop. I mean the risks of lung cancer had been well and truly established” (13001, male, 61 years).

**Contributing to research**

A recurring sub theme was that many felt they would like to Help others and contribute to medical research in general.

“I was actually quite pleased to do that because I feel that it's important for people to be able to give some research towards some sort of research, because I think that's the way we get to learn more and more about people and how we can best help people and just expand. The more knowledge that I think that you can gain the better we can actually proceed with medical breakthroughs” (13007, female, 68 years).
“just thought it was interesting to - that that’s why I found it, because my doctor - I talked to - because my doctor spoke to me about it and I said to him yeah I don’t mind doing it because if it’s going to help somebody else well then I do it. That’s why I did it” (7019, female, 59 years).

“Well, I think anything that can help and any study that can improve someone’s health, maybe later on down the track through various studies, it’s worthwhile doing” (4002, male, 71 years).

Applicability of the Intervention to those with chronic illness

There was a less clear benefit of the intervention to those who were chronically ill with COPD or Lung cancer. This group of people were already frequently visiting their GP with salient symptoms.

The following patient developed lung cancer during the study and reasons he is already visiting his GP regularly.

Interviewee: “If it was just a cough and I wasn’t coughing up blood or anything - well, see, I’ve been going every two weeks or every week.”

Facilitator: So you’re going quite frequently already?

Interviewee: Yeah. But I don’t think I would wait much more than - well, I’ve usually got a script for antibiotics. So I would crack them before I - if it’s gluggy or colourful, you know, not blood, I would probably wait until I had had a course of antibiotics. Yeah, and you’re not going to pop off with a cough” (22029, male, 79 years).

This same patient felt it was too late for the Intervention to be useful for me.

“Well yeah, but it didn’t really worry me because sometimes I’ve got an attitude, and I say to myself, well you’ve got to go sometime, right? Then I used to think I’d be better off if I went, instead of suffering and living on my own” (22029, male, 79 years).

Another chronically ill patient with bowel cancer feels the intervention was not applicable to her because she had other priorities in her life.
“At this stage, because I’ve got other things happening, my focus has not really been on that. Had it not - if I’d not been in this situation, maybe it would have made the difference…” (8002, female, 70 years, diagnosed with bowel cancer).

“I think I read some of it and it was about if you notice various symptoms contact the doctor, but because I was already under the doctor and so much was happening in other areas with my health, I didn’t really have time to focus on that” (8001, male 69 years, diagnosed with COPD).

One man with COPD focused on preparing for death and making sure family arrangements were sorted, rather than checking for relevant symptoms.

“I want to make sure everything is in order for the next generation” (8001, male, 69 years).

7.2.2.2. Increase in symptom awareness

Most people felt that a list of symptoms provided in the CHEST self-help manual led to a clearer understanding of what to look out for and when to take action (Objective 2). In some cases, patients reported that the intervention made them think about how long they had experienced a symptom for and whether the symptom was getting worse. It also made some more aware of which symptoms were of importance.

During the interviews many of the patients recalled the 123 slogan.

“Basically I look after number one and that sort of thing. That’s what I mean by reading your body. I found it very basic, easy to understand and that sort of thing” (3018, female, 58 years).

“…Just the signs. Well, it makes you aware of what to do if you do get chest complaints and what some of the symptoms are that might lead to a possible heart attack, stroke, et cetera. It does make you more aware. It also explains a lot more than what I knew about lung disease” (4002, male, 71 years).

“Yeah, if I have something [I’d go] - if I have a persistent symptom of some sort I’m probably more likely to go more quickly than in the past” (12003, female, 73 years).

“It’s also making the reader more knowledgeable about lung complaints so that if he does get a problem he’ll see the doctor” (21003, male, 76 years).
“I suppose the major point is that you don’t wait too long [unclear]. If you’re bleeding or coughing up blood then you go straight away, otherwise wait a few weeks. If it persists, go to the doctor” (13001, male, 67 years).

“I think it makes you think, it makes you try to remember as well. Because sometimes if you've had that symptom even the month before, you’re thinking, going, hang on a minute, did I have that symptom or was it or not? Like a month ago or whatever.” (7017, male, 71 years).

This lady remarked that the symptoms for lung disease seem straightforward, whereas in other diseases this was not the case.

“Yeah. I'm just amazed - I don't know if you go through life being amazed; the number of auto-immune diseases and the scary part is they don’t have any great symptoms. At least here, the lung symptoms, you've got are pretty cut and dried symptoms” (12003, female, 73 years).

7.2.2.3. Perceptions of the components of the Intervention

Feedback on the self-help manual

Feedback from the self-help manual suggested that this tool is potentially addressing the objective of improving knowledge of symptoms (Objective 2). The CHEST self-help manual was seen as useful, logical and a good “reference guide” with the “correct” information. Many liked having control over when they could refer to the booklet.

Many found it simple and easy to understand.

“I think it's very good. It's very self-explanatory and I don't think that anyone would actually have a problem understanding it, so I think it's great. I just felt that overall I thought it was a very well-constructed book” (13007, female, 68 years).

“The booklet is also very good, in the fact that it's just got - it's laid out nice and simply, clearly - because I'm a tradie - I'm not an English lit professor - so it's laid out very simply and honestly to me” (3013, male 71 years).

“I liked the set out of it. It is clear. It is not over-jargonised. It's not overly wordy and difficult to follow. I think it's quite simple English, which for a simple man like me, it works. What did I see in there that I - just the reminders of what you should
do - and I think I'm like a lot of people - where I won't go to the doctor, if I don't think it's a real issue” (14014, male, 79 years).

“Well, it was all laid out really well, I mean, all in simple terms and making you aware of all the different steps” (13007, female, 67 years).

There was a perception of validity about the self-help manual and that it was a trusted source of information. Some people felt they could rely on the booklet, whereas when they looked up health information on the internet they were unsure of its validity.

“Yeah, it's a booklet I can always refer to and I will, if I'm not sure of anything, that's the bible” (4002, male, 71 years).

“I mean a lot of people say well you can get on the internet and Google everything and everything comes up. As my husband says, I would find an article and I'll read it and I'd say oh my God you should read this. He said yeah, but who wrote it? So a good reference...” (6002, female, 70 years).

The following man describes his dilemma of finding the correct information on the Internet.

“Well one thing I found looking at the internet so versus the book. The internet - I was looking for the prognosis if you get an illness like emphysema and with the internet you don't know what's old and what's new. What's - in other words what's true and what's false anymore because there's so much bloody pile of people that all have their bit to say about that one topic and it's not bloody always dated. So you don't know which one is. So if I want a prognosis of my health like with emphysema do I take the one that says you snuff it after four years or the one that says you have a normal lifestyle if you've only got stage one. So that was the confusion I was faced with” (21003, male, 76 years).

Many liked the fact that they could read the booklet when it suited them, as opposed to being exposed to anti-smoking adverts. They felt they had control as to when they were ready to read the booklet.

The following man is employed in the Navy and he took the book away with him.

“Did you do anything with the booklet after the consultation?

Interviewee: Other than read it? No.
Facilitator: On your own or?

Interviewee: On my own, yeah. Like I say I took it away with me, on board the ship. I thought I'll read that now, so that's what I did” (3022, male, 64 years).

One man described the fact he could pick up the booklet when he wanted, rather than being forced to watch something on TV.

“Yeah I could pick it up when I felt like reading it, it is not thrust upon you when you are watching TV...” (3013, male, 59 years).

One lady felt the booklet was common-sense and “logic.”

“Well, it was all laid out really well, I mean, all in simple terms and making you aware of all the different steps, et cetera. But, as we've spoken before, I’m a person who runs on logic and it's - a lot of this is just logic” (3018, female, 63 years).

This man claimed that the Intervention increased his knowledge.

“I just think that if I hadn't signed the form to go and do the test in the first place I wouldn’t be as knowledgeable or aware of my symptoms as I am now” (4002, male, 71 years).

The manual also reinforced the benefits of early intervention (Objective 3).

“So I read about the guy who left it too late in the booklet, I thought, nah, that’s not going to be me...” (3013, male, 59 years).

“The booklet really made me aware that it is useful for me to see the doctor early and not let things drag on“ (12003, female 68 years).

Feedback on the self-monitoring reminders

There was evidence that the prompts and reminders had an impact on sanctioning early consultation (Objective 4) and this added weight on an intention to act (Objective 6).

Patients were asked to choose prompts (either a SMS, postcard, email or phone call) which reminded them to check their symptoms. Many found the reminders useful, but there were mixed feedback on the types of reminders preferred.
“What did I see in there that I - just the reminders of what you should do - and I think I'm like a lot of people - where I won't go to the doctor, if I don't think it's a real issue, but this reminded me I should go...” (14016, male, 56 years).

This male found that the reminder was useful and not obtrusive in any way.

“Yes it (the intervention) changed my way of thinking. I am normally a “let's just wait and see” person. I found the email follow up once a month or whatever - I found that very good. It wasn't intrusive. It just sort of - that little jog of memory on the email - because I think I'm like most - I check my emails twice a day normally - morning and night. So when it came through, oh yep, okay, oh that, right - bang. That simple reminder without being in your face sort of thing” (21003, male, 76 years).

The prompts needed to be tailored to the patient's preference. Many preferred different modes of a reminder to be effective in promoting self-efficacy. The following person described their preference for postcards.

“I think it has got a role and I think the post cards are a great idea and I think it's made me aware, just the presence of it. I'm a great procrastinator at the best of times. I mean, the fact that I, you know, stick it, I'll do it next time. But I'm beginning to write things down. But no, it's - and I have seen surveys and research programs do very good things with friends. I mean, I've got the time and I think that's another thing, it's someone keeping tabs on you” (14014, male, 79 years).

However the following lady preferred the text messages.

“I had a business up until recently and I just think that texts are instantaneous; whereas I think we get a lot of rubbish coming through on our emails and quite often a lot of people - I don't, but if it's an email that I'm not sure of I often delete it, or it's quiz programs, it's all of that so you can't be bothered. So I think a text is something you don't delete, you actually read it first and then if you want to delete you delete it” (13007, female, 68 years).

For those who were chronically ill they did not find the reminders not so useful.

“I'm always conscious of the fact about my chest because I'm - not that I'm paranoid about it, but I think because it's something that is so important to your
wellbeing and the cough I know it’s quite debilitating for me. So having had polyps removed from my voice box, having had situations with my throat and my chest, it’s really for me that’s been my biggest issue around this area. So I’m very conscious of that. I don’t need any reminders” (13007, female, 68 years).

The following man with COPD claimed he would not wait to see a GP, he knew he should go in if he became sick.

“All the phone call and then the emails they reinforced the message, drummed it home, so I mean once you’ve got something like emphysema you don’t muck around anyway. You know you’ve got something serious and if it’s going to take - starts taking a turn for the worst go straight to the doctor anyway because you know it’s such a discomforting thing” (8001, male, 69 years).

Preference for positive images and messages

Positive messages were perceived as effective. Many preferred the positive images and reminders from the CHEST Intervention such as the 123 logo and the fridge magnet.

This man described what he remembers about the 123 rule.

“All basically I look after number one and that sort of thing. That’s what I mean by reading your body. I found it very basic, easy to understand and that sort of thing. Positive too” (3018, female, 63 years).

“The promotions that I found were always the positive ones. Those ones where you see someone dying or - that was my reaction to it was to turn it over immediately, because I didn’t want to see that, and then I’d always think gee, light up a cigarette because it was quite stressful. So, it had the opposite effect on me. I think if you’re trying to get someone’s attention you need to be positive. It needs to be a positive, like this study” (8002, female, 70 years).

This man describes how the fridge magnet reminded him to check his overall health and he responded to the positive comments in the booklet.

“But I thought - even like that page there - action plans - nothing to lose - the message in there is to go if you’ve got a reason. I know this is concerned about the chest, but I think I’ve found the use for it in just general health, for me. Even the
fridge magnet - if I'm cooking up my dinner and I see it there and so I might - health - it reminds me of health. So I think, oh okay, I won't put that extra chop in the frying pan. You know what I mean?” (3013, male, 59 years).

One lady described receiving a leaflet in the mailbox from “Smoke Enders.” The “Smokers wanted” campaign really appealed to her.

“So the smokers wanted was yes, I'm the wanted species [laughs] I'm not alienated anymore…..” (8002, female, 70 years).

7.2.2.4. Tackling barriers

There is evidence that the intervention tackled barriers (Objective 5) around lecturing and feelings of guilt and stigma associated with this. Many felt the Intervention was relaxed and people could “open-up” about their smoking and lung health in general in contrast to the experiences of a GP consultation. Many reported that they preferred not to feel “lectured at”.

This man liked that he was not lectured or judged and not made to feel guilty for his smoking behaviour in the CHEST consultation.

“So I found the consultation very good. It was relaxed. Sonia's a lovely person, just to be able to speak to, in her style as well, and I wasn't lectured, which is something I really liked” (21003, male, 76 years).

Whereas this man claimed he normally has trouble speaking to people, but he did not feel this way in the CHEST consultation.

“Because sometimes I get trouble talking to people. I keep quiet and don’t say anything. But there was something about her, I could talk to her all day. No, well I found I could talk to her because I can ask her questions. Because sometimes I won't ask anybody a question....” (22029, male, 79 years, diagnosed with lung cancer).

Overall comments about the consultation included.

“Relaxing - we had a laugh” (3013, male, 59 years).

“Everyone was pleasant and - no, I found it quite fine” (22029, male, 79 years).
“I found everybody pleasant and I found it all very flowing” (3018, female, 63 years).

“She just made us feel very comfortable” (21012, female 74 years).

Some people remarked that the spirometry test was informative and useful.

The following patient was asked how he found the lung function test.

“Yeah good. I can’t say it was easy because I mean that’s a long blow, but it wasn’t uncomfortable or anything like that. No, it was pretty easy. It was useful” (21003, male, 76 years).

“Oh, yeah, it was useful, I mean, mine was a little bit low, wasn’t it, I think [laughs]. I’ve always had shallow breathing…” (3018, female, 63 years).

**Overall usefulness in the GP setting**

Many commented that the intervention would be useful in the GP setting.

“So if the books were there and the forms were there I just think that would be another wonderful service that the doctor could give their patients. They know who smokes are and they know who’s got lung problems or whatever. Without the book we would never have known what we now know. I don’t know whose idea it was, but it was a good idea” (13007, female, 68 years).

The following lady felt the intervention could be applied to any cancers.

“I think it should be in general practice. I think anything, whether it be the chest, whether it be for breast, whether it be for any - ovarian, whatever, I think these things should be available in doctor’s surgeries. I think that if I was a patient, which I am, but if someone has a continual chest problem I think that these should be given to someone that has a chest problem. Just say look I think it would be a really good idea for you to have a read through this because you have continual chest problems. I think it would be great for you actually have a little read through this and perhaps get involved with that” (12003, female, 68 years).
One participant remarked that it would be useful for smokers like himself.

“Smokers - if they were given the book with the information I would have thought that that would be fantastic” (4002, male, 71 years).

This lady felt that the doctor-patient relationship held them back in getting an appointment and felt the intervention would promote more spontaneous consulting.

“I thought it was a good thing for the GP and I think probably that's the way to go because people still have the doctor attitude and if doctor said there’s not an appointment we don’t do it, whereas I think people have to be a bit more aware on their own...” (12003, female, 74 years).

7.3. Summary of key findings from thematic analysis

The qualitative CHEST study explored the patients’ experiences of a complex intervention to promote early consultation to determine the impact of the intervention on consulting behaviour and identify any barriers to consultation.

The following key areas of discussion emerged from the qualitative data which will be described in detail in Chapter 8 and the resulting publication is located in Appendix J.

- Barriers to seeking help identified in the CHEST Australia trial included; smoker stigmatisation, fatalism, symptom normalisation and the worry that GPs had a negative attitude towards smokers and that they were not taken seriously. An underlying perception of mistrust of the GP was also expressed in the Australian setting. This was due to reasons such as a perceived previous missed diagnosis or miscommunication. Previous experiences of visiting the GP which had focused on perceived reprimanding by the GP to quit smoking were commonly described as an important barrier to early consultation.

- Similar barriers to consultation were also described in the original Scottish CHEST Trial. Obtaining an appointment to visit a GP was identified as an important barrier for early consultation in the Scottish study, but this was not observed in Australia. All participants reported they felt confident they could get an appointment within 1-3 days. This could suggest that GP accessibility is not a barrier to consulting, at least not in metropolitan Perth or Melbourne.
• Perceptions reported by participants suggest that the Intervention tackled barriers around lecturing and feelings of guilt and stigma. The intervention was reported as a relaxed, non-threatening environment where patients at increased risk of lung cancer could openly talk about their smoking and lung health. The intervention did not make participants feel judged or feel guilty for smoking or having previously smoked, it therefore enabled more open and honest discussion.

• Patients reported a clearer understanding of what to look out for and when to take action after the intervention and felt the CHEST self-help manual was a valid and useful guide. The benefits of early consultation were understood.

• There was some initial evidence that the intervention altered salience, or personal relevance of symptoms and this potentially led to changing attitudes regarding visiting the GP. Some already had a broader self-awareness of their health, due to past or present exposure or current health issues or family history.

• Those who were chronically ill did not respond as well to the intervention, due to reasons such as they already knew what to look out for, or they were already frequently visiting their GP or it was “too late” to be useful for them. Potentially, this group already had salient symptoms and fewer barriers to help seeking. This is a newly identified group in the Australian study, compared to the original Scottish study.

• There is evidence that the prompts and reminders had an impact on early help seeking behaviour and this added weight on an individual’s intention to act. Tailoring reminders to individual preferences was important in promoting self-efficacy.

• These findings suggest that the CHEST Australia Intervention is achieving the desired objectives at the qualitative level. The quantitative analysis (Chapter 6) will be discussed further in light of the qualitative findings in the Discussion (Chapter 8).

7.4. Proposed framework

The Scottish CHEST Intervention took elements from several health psychology theories to underpin the intervention. As described in Chapter 2, the combination of the consultation and self-help manual aimed to increase salience of chest symptoms, increase personal
relevance of symptoms, reinforce benefit of early presentation and sanction early consultation. By combining this with tailored prompts, this led to the patient developing a personalised action plan and ultimately seeking help earlier.

The Australian CHEST Intervention framework was based upon the original Scottish theoretical CHEST model. The qualitative study was not a large component of the mixed methods research, but it enabled a deeper understanding of the proposed Scottish theoretical model and allowed the application of the model in an Australian setting.

Figure 30 describes the original Scottish model, but highlights unique differences relevant to the Australian setting as described above.
Chapter 8. Discussion and Conclusion

This chapter will start by briefly reviewing the key findings of this thesis before discussing the methodological issues and key outcomes of the quantitative and qualitative studies. It will conclude by relating the outcomes of this study to other published lung screening trials and provide a potential pathway for the use of the CHEST Intervention in primary care in the future.

8.1. Summary of key findings

The processes undertaken to develop key material for an Australian audience, were initially tested on a consumer group, followed by the Phase I 6 month pilot trial, ultimately resulting in modifications to the key material and study methodology for the Phase II trial.

A target sample size of 551 patients (intervention n = 274; usual care n = 277) were recruited from Perth and Melbourne for the Phase II trial. Statistical analysis showed a 39% statistically significant increase in respiratory consultations for the intervention arm compared to the usual care arm one year after the Intervention. Those in the intervention arm consulted 9 days sooner than those in the control arm, but this was not statistically or clinically significant. There was no statistically significant effect on total consultation rates 12 months post intervention (RR=1.01 (0.88-1.16) p=0.8998). There was no evidence of harm reported on the psychosocial scales, anxiety, depression, quality of life or cancer worry. There was also no difference on any process intermediate measures such as perceived risk of lung cancer, self-efficacy or intention to consult and knowledge of symptoms.

Qualitative data from the 20 in-depth interviews identified themes consistent with the theoretical basis of the CHEST Intervention. Barriers to consultation identified in the CHEST-Australia trial were: smoker stigmatisation, guilt, fatalism and symptom normalisation. Similar barriers were identified in the Scottish trial. A general perceived mistrust of GPs, based on previous negative experiences of visiting their GP in relation to their smoking was also identified. The intervention tackled barriers around lecturing and feelings of guilt and stigma related to smoking by being delivered in a non-judgemental environment where participants could openly talk about their smoking and lung health. Expected effects on salience and personal relevance of symptoms were identified. Participants reported a
clearer understanding of what to look out for and when to take action after the CHEST Intervention. There is evidence that the Intervention including the prompts and reminders had an impact on early help seeking behaviour and this added weight on an individual’s intention to act. Tailoring reminders to individual preferences was important in promoting self-efficacy. These findings suggested that the CHEST Australia Intervention is achieving the desired objectives at the qualitative level through the proposed theoretical mechanisms, however, the quantitative findings for the process intermediate measures, such as knowledge, self-efficacy and intention to consult, showed no differences between treatment arms.

8.2. **Quantitative study key outcomes**

8.2.1. **Primary outcome analysis**

Consultations for respiratory symptoms represents a pragmatic, measurable intermediate outcome along a causal pathway which links the intended action of the intervention with potential earlier diagnosis of lung cancer[49]. For individuals at risk of lung cancer, a theory based intervention in primary care significantly increased the number of respiratory consultations 12 months after delivery of the CHEST Intervention by 39%. These were estimated from a negative binomial model with treatment group and GP site (p<.0001) as covariates, that is treatment allocation arm and GP site were accounted for in this statistical model.

The adjusted ratio of consultation rates with new chest symptoms in the intervention versus control group was 1.19 (0.92 to 1.53) p= 0.18, for the Scottish Trial, however, this trial was never powered around respiratory consultations[49]. The CHEST-Australia consultation rates overall were lower than those reported in the Scottish trial. This is interesting because most of the current qualitative research suggests that access to a GP or making an appointment is not an issue in Australia compared to Scotland. Other evidence also suggests that an important barrier to consulting in the UK is “wasting the doctor’s time.” [133]. Ambient temperature has an effect on respiratory illness rates[134] and due to Scotland being colder, this could potentially explain higher respiratory consultation rates overall in the Scottish trial compared to Australia.

In the CHEST-Australia trial, higher respiratory consultations were observed in the winter months from May through to October, which is consistent with the respiratory influenza trends observed in Australia[135].
8.2.2. **Time to presentation**

While the CHEST Intervention resulted in an increase in respiratory consultations, participants did not consult significantly sooner. As described in Chapter 4, symptom and help-seeking intervals were measured using the SYMPTOM instrument to obtain data on presenting symptoms and their duration prior to consultation. General Linear Analysis showed that the Intervention group consulted 9 days sooner than the control group for a first respiratory consultation, but this was not statistically significant. The time to presentation was 66.91 days for the Intervention group and 76.0 days for the control group. While the trend is in the right direction, it would be hard to determine if 9 days would be clinically important. Relevant to this discussion is the study by Torring (2012) who examined the impact of the diagnostic interval, as a continuous variable, on mortality and found a U shaped association between diagnostic interval and mortality for colorectal, lung and prostate cancer. Mortality was shown to rise for intervals greater than the 60th percentile, which for lung cancer equated to a diagnostic interval of 60 days. Torring set a reference point of 4 weeks (28 days) as being defined as a “short” diagnostic time frame[12].

As discussed in Chapter 1, other studies have reported mean time to presentation intervals. Two studies of lung cancer patients from Western Australia found mean patient intervals of 47-80 days, ranges consistent with the range reported in the CHEST Australia trial[33, 136]. Campbell et al. (2001) interviewed 360 Scottish patients with lung cancer and found 50% had experienced symptoms for more than 14 weeks before presenting to a doctor with a median of 99 days and IQR of 31-381 days[137]. These findings should be compared with the reported lung cancer median volume doubling time of 98 days as reported by Henschke et al. (2012)[138] who reported lung cancer diagnosed at CT screening and their volume doubling times.

8.2.3. **Type of symptom**

Previous reviews of “patient delay” have shown that the nature of symptoms is an important predictor of help-seeking behaviour. Pain or bleeding has been shown to be associated with shorter intervals, whereas non-specific symptoms or those that do not interfere with daily activities are shown to present later[139]. The CHEST findings presented here are consistent with this. Fatigue resulted in a significantly longer time to
present compared to a new or worsening cough. Patients with fatigue had a median patient delay interval of 183 days versus those with a new or worsening cough of 21 days.

Similarly, research has shown that symptoms that are intermittent, perceived as mild or increased gradually over time were more likely to present later. Participants in other studies with more severe symptoms such as pain or haematuria recognised these straight away and knew action should be taken[136]. In the study by Emery et al. (2014), participants also knew that coughing up blood meant that they must take action quickly. In the questionnaire 90% of people responded with a “one day or less” answer to seeking help if they noticed blood in their cough. Whereas, observing weight loss took on average a considerably longer time to present to a healthcare provider.

Similar results were observed in the CHEST Australia Trial. With the absence of pain, or the presence of just a single symptom, this seemed to be perceived as a less severe illness. Fatigue alone was not seen as significant, but fatigue combined with a cough halved the patient delay interval (183 days to 93 days). Chest, combined with shoulder pain, took a median time of 11 days to seek help, suggesting that in the presence of a visible pain which hindered everyday activities, may have resulted in a shorter patient delay.

From the qualitative studies it was seen that often there were alternative explanations for symptoms, particularly, aging or “getting old.” Symptom normalisation was another common explanation, “I always have a cough” or “I am always tired.” This contributed to longer periods for appraising symptoms pre-Intervention. Fear of the diagnosis of cancer also led to later help-seeking pre- Intervention. Failure to recognise the seriousness of symptoms and misattributing them to other existing conditions or another more common cause have been described elsewhere[136].

Most lung cancer patients present with a range of symptoms to the GP in the months before diagnosis[140]. Symptoms such as cough and breathlessness are relatively common in the general population[141] whereas alarm symptoms for lung cancer have low positive predictive values[41]. Symptoms and signs from lung cancer can mimic other diseases such as COPD leading to a risk for delayed diagnosis[6]. Only a third of lung cancer patients actually present to GPs with an alarm symptom (such as prolonged coughing, haemoptysis or weight loss) which is the entrance criterion for the urgent referral route for lung cancer in the United Kingdom. The positive predictive values (PPVs) for such symptoms are, depending on age, between 1 and 4.5%[6].
Walter et al. (2015)[35] prospective cohort study aimed to identify symptom and patient factors that influence time to lung cancer diagnosis and stage at diagnosis. Data relating to symptoms were collected from patients upon referral with symptoms suspicious of lung cancer in two English regions. Primary care and hospital records for diagnostic routes and diagnoses were also examined. Among 963 participants, 15.9% were diagnosed with primary lung cancer. Half the cohort had an isolated first symptom (475, 49.3%); Haemoptysis, reported by 21.6% of cases, was the only initial symptom associated with cancer. Diagnostic intervals were shorter for cancer than non-cancer diagnoses (91 vs 124 days, P=0.037) and for late-stage than early-stage cancer (106 vs 168 days, P=0.02). Chest-shoulder pain was the only first symptom with a shorter diagnostic interval for cancer compared with non-cancer diagnoses (P=0.003). The authors concluded that programmes for expediting earlier diagnosis need to focus on multiple symptoms and their development.

The results from the cohort study by Walter et al. (2015) emphasises the challenge for earlier detection in primary care for patients with less specific symptoms. Symptoms other than haemoptysis in their study did not help differentiate lung cancer from other diagnoses. Also, they showed that identification of one type of symptom is not a strong indicator of lung cancer diagnosis. Rather the focus should potentially be on multi-symptom presentations now. The results from the CHEST Australia trial also show that while single symptom presentations were frequently reported by patients at high risk for lung cancer, multiple symptoms tended to result in a shorter help seeking interval, especially those associated with pain (Chapter 6, Table 32). This suggests that in the future, lung cancer awareness campaigns should potentially focus on more than single symptom presentations or the importance of the development of new symptoms.

8.2.4. Total consultation rates

The intervention did not have a significant effect on total consultations but seemed to have a specific, targeted effect on respiratory consultation rates only. Table 13 in Chapter 6 showed that after adjusting for all possible confounders, a Relative Rate of 1.01 between treatment arms was shown not to be statistically significant (p=0.8863) for all consultations to month 12. This result suggests that the Intervention was quite tailored in its approach and did not have an effect on consultation rates for other illnesses. This is in contrast to the findings of the Scottish trial, where overall consultation rates also increased.
This is the first powered randomised trial to test the effect of an intervention on respiratory consultation rates, in patients at increased risk of lung cancer. Patterns of general practice utilisation around diagnosis of lung cancer were recently reported by Gulbrandsen et al. 2016[6]. The study looked at the pre-diagnostic activity in general practice the year before lung cancer diagnosis. Danish registers were used to perform a population based matched cohort study including lung cancer patients. They compared lung cancer patients with different stage, and patients with and without chronic obstructive pulmonary disease (COPD). This study included lung cancer patients \((n = 34,017)\) and matched comparison subjects \((n = 340,170)\). During months 12 to 1 prior to diagnosis, 92.6% of lung cancer patients and 88.4% of comparison subjects had one or more contacts with general practice. 13.0% of lung cancer patients and 3.3% of comparison subjects had two or more X-rays. 20.8% of lung cancer patients and 8.5% of comparison subjects had two or more first-time antibiotic prescriptions. The incidence rate ratio for having a contact to general practice was similar for lung cancer patients with localized disease compared to those with metastatic disease. Lung cancer patients with COPD had more frequent contacts, lung functions tests, X-rays, and prescriptions than COPD patients without lung cancer, but not as pronounced as compared to patients without COPD. Results showed that there was a significant increase in healthcare seeking and diagnostic activity in the year prior to a lung cancer diagnosis, regardless of stage at diagnosis.

8.2.5. Theoretically-based Intermediate measures

8.2.5.1. Knowledge

A small, non-significant difference in knowledge scores \((p=0.0509)\) after 12 months between treatment arms was observed. In contrast, the Scottish trial found knowledge scores were significantly higher for the Intervention group compared to the control group at one month, but not after 6 months. Knowledge scores are an intermediate process measure that potentially indicate that the Intervention is achieving what it intended. In the CHEST trial, each patient was given a simple checklist of symptoms that need action. For example, symptoms that would require attention urgently included coughing up phlegm with signs of blood or chest pain. For other symptoms, the three week rule was applied whereby patients were told not to let specific symptoms such as a cough linger for longer than three weeks. While not statistically significant (but positive in the right direction) the combination of the quantitative and qualitative findings potentially show that by
introducing these prototypes or sets of symptoms this contributed to a patient’s knowledge of symptoms and ultimately reinforced at what stage they should visit their GP.

Increased knowledge of symptoms and awareness from other interventions for other cancers have also been shown in various randomised trials. Rimer et al. (2002) showed that tailored written information with a reinforcing newsletter at 12 months plus two telephone counselling sessions increased the proportion who gave the correct answer to a question about age-related risk by 12% compared with usual care 2 years after the written information is sent[142]. Less intensive interventions increased cancer awareness more modestly. An interactive computer programme increased the average melanoma knowledge score by 6% after 6 months[143] and a leaflet increased average oral cancer knowledge score by 4% after 8 weeks[144]. A leaflet about prostate cancer increased the proportion who knew that the effectiveness of treatment in early prostate cancer is unknown by 12% after 2 weeks, but the magnitude of this difference may be at least partly due to the short follow-up[145]. This trial found that the leaflet did not increase knowledge of the natural history of untreated early prostate cancer.

From Austoker’s systematic review, it was found that tailored print information was more effective than general information. Tailored information increased average cancer knowledge scores by about 11% compared with no information and 4% compared with general information after 3 weeks[146]. Tailored print information modified attitudes towards paying attention to and seeking help for symptoms only very modestly (1–2% change in average scores) compared with no information[146].

Community studies examining the effectiveness of the public education campaign in the United States and the effectiveness of the interactive multimedia kiosk in Sweden found no effect on knowledge[147, 148]. The studies of the educational programme for breast cancer in the United States and the UK health promotion initiative for testicular cancer found modest increases in knowledge, the first an increase in average breast cancer knowledge score of about 6% after 8 months[149, 150] and the second an increase in average testicular cancer knowledge score of 20% after 6 weeks[151].

In contrast to the papers just described, the qualitative paper by Crane et al. (2016) suggests that knowledge may not necessarily lead to earlier presentation. In this study 16 focus groups in NSW were used to explore lung cancer awareness of sentinel symptoms and risk factors and beliefs and attitudes. In exploring participants’ knowledge about lung
cancer several themes arose. All groups could identify some sentinel symptoms correctly but there was a great deal of uncertainty and most groups assessed that these symptoms were not necessarily a reason to suspect lung cancer. The majority of participants were able to identify smoking as a risk factor for lung cancer but despite awareness of cancer symptoms and risks, high-risk individuals have poor perceptions about their personal risk and the seriousness of sentinel symptoms and this combined with other factors does not lead to earlier presentation[152, 153].

The validity and reliability of knowledge outcome measures also needs to be considered. It may have been more useful to have used a list of symptoms specific for lung disease rather than measuring the knowledge structures based on a chest disease prototype approach. In addition the reliability and validity of the test needs to be addressed when assessing this outcome measure. Knowledge of lung cancer symptoms and risk factors in the UK were determined from the Lung Cancer Awareness Measure (Lung CAM), which showed good internal (Cronbach’s α = 0.88) and test-retest reliability (r=0.81, p<0.01) in the general population[36]. This may have been a more effective way of determining the effect of the CHEST Intervention on knowledge scores.

Overall, other studies have found modest positive effects on cancer knowledge or attitudes. The CHEST-Australia trial showed an increase in knowledge over a 12 month period, but this was not statistically significant.

8.2.5.2. Perceived risk and self-efficacy

Risk perception was measured using a five-point scale ranging from “very low” to “very high.” There was no evidence of a difference between groups for perceived risk at one or 12 months. Similar results were also reported for the Scottish Trial, where no evidence was reported at 1 or 6 months. Awareness of risk is important in this high risk population and this measure was used to assess the effectiveness of the intervention in driving early consultation behavior. It is possible that this cohort already recognised they were at increased risk and therefore the intervention did not enhance what they already knew. The scores were fairly high already in the intervention group (7.1/10) and after the intervention the mean score was 6.8 out of 10.

Bandura demonstrated that an individual’s behavior is strongly influenced by their confidence in their ability to perform it and when there are high levels of self-efficacy for early consultation, this usually indicates that intention will be translated into action[154]. A
small, non-significant change in self-efficacy was observed in the CHEST Australia Trial. Similar results were also reported from the Scottish trial where no evidence of a difference between groups in self-efficacy were reported.

8.2.5.3. Intention to consult

Self-reported consulted intentions were used to measure an individual’s intention to behave in a certain way. While not equivalent to behaviour, it does give a strong likelihood that a behaviour will be performed as described by Ajzen’s theory of planned behaviour. Although this has also been critiqued by others as described in Chapter 2, it is the best measure of expected behaviour to date. In the CHEST Australia trial, there was no evidence of any difference in “intention to consult” scores between treatment arms at one and 12 months. This is slightly disappointing given that the intervention group in the Scottish trial reported an intention to consult score statistically significantly sooner: 31 days (95% CI =7 to 54) earlier at one month and 25 days (95% CI =1.5 to 48) earlier at 6 months. Measuring behavioural intentions is difficult and there are few trials that have shown benefits to consulting intentions. In a randomised trial, which included some lung cancer among other cancer symptoms, De Nooijer et al. (2004) reported benefits to consulting intentions when assessing the effects of computer-tailored information and general information on determinants and intentions to engage in early detection behaviours. Six months after the intervention, there were still differences between the tailored information group and the control group in intentions toward help seeking[146].

Boxell et al. (2012) report a quantitative evaluation of an information leaflet to prompt help-seeking for gynaecological cancer symptoms. In this study, women (N = 484) completed questionnaires before and after reading the leaflet. The primary outcome was change in anticipated time to help-seeking for 12 symptoms. The number of symptoms for which women anticipated seeking help promptly increased (p < 0.001). In addition, changes in knowledge (OR 4.21, 95% CI 1.95-9.13) and perceived barriers (OR 4.60, 95% CI 1.91-11.04) were independently associated with increased help-seeking also. This intervention was shown to be effective in altering knowledge, beliefs and help-seeking intentions for gynaecological cancer symptoms, but only in the short term and the authors concluded that a proper randomised trial would need to be delivered in a primary care setting to determine true effectiveness[155].
Wagland et al. (2016) explored symptomology and help-seeking behaviours of primary care patients at ‘high-risk’ of lung cancer (≥50 years old, recent smoking history) to inform targeted interventions. This was a mixed method study with patients at eight general practitioner (GP) practices across southern England. The study incorporated a postal symptom questionnaire, clinical records, review of participant consultation behaviour 12 months pre- and post-questionnaire; and qualitative participant interviews (n = 38) with a purposive sample. Results showed that participant consulting behaviour significantly increased in the 3-month period following questionnaire completion compared with the previous 3-month period (p = .002), indicating questionnaires impacted upon consulting behaviour. Of nine symptoms associated with lung cancer, 53.4% (629/1172) of total respondents reported ≥1, and 35% (411/1172) reported ≥2. Most participants (77.3%, n = 686/908) had comorbid conditions; 47.8%, (n = 414/908) associated with chest and respiratory symptoms. They also identified a small percentage (6.7%) of primary care patients who, despite reporting potential symptoms of lung cancer in questionnaires, had not consulted a GP ≥12 months. They also found that symptomatic non-consulters were predominantly younger, employed, with higher multiple deprivation scores than their GP practice mean.

Wagland et al. (2016) state that even if experienced symptoms are not signs of lung cancer, they may be indicative of other comorbidities such as COPD, asthma or emphysema. Furthermore they claim that targeting these individuals within primary care with interventions designed to facilitate earlier diagnosis may prove effective and resource-efficient, and while the focus may be lung cancer, other comorbidities may also be discovered[133].

In summary, while there is quantitative evidence that the Intervention increased respiratory consultation rates, no significant differences have been identified in any of the process intermediate measures (knowledge, perceived risk, self-efficacy, and intention to consult) based on the theory behind the intervention. A possible reason for this could be the insensitivity of the measures. That is, while small changes were observed individually, these were not statistically significant, yet overall, there was still a significant impact on the primary outcome. This finding will be discussed in light of the qualitative findings in Section 8.3.
8.2.6. Assessment of adverse events. HADS, Cancer Worry measures and Views on Health

A key process in delivering the CHEST Intervention was identifying any potential harms. Any adverse events such as general anxiety and depression were measured using the HADS tool[115]. It was important to evaluate the effects of the intervention and to explore changes of, anxiety, worry and depression, particularly in a population who are not presenting to healthcare (even though they have an increased risk of lung cancer). As noted in the original design of the intervention, measures were implemented to reduce unnecessary worry and fear (such as avoiding specific discussions on lung cancer but rather broadly referring to chest disease). However, there was the potential that the Intervention could cause unnecessary distress, in this population, so it was important to evaluate these psychosocial measures.

Results from the CHEST trial showed no evidence of a difference between groups for anxiety or depression at 1 and 12 months. Similarly, the Scottish Trial also showed that HADS scores were not affected by the Intervention at one month and 6 month intervals[49].

There was also no evidence of a difference between groups for the cancer worry scale at 1 or 12 months. Once again this measure is encouraging for the CHEST trial as it shows the intervention did not result in any unnecessary worry. For the Scottish trial, cancer worry scores were not statistically different at 1 month but were found to be higher in the intervention group at 6 months. The authors state that the intervention caused a small increase in cancer worry but that this did not translate into anxiety or depression[49].

There was no evidence of a difference between groups on Views on Health scores. The scores remained constant over the 1 and 12 month timeframes suggesting no negative impact on perceived health.

8.2.7. Quality of Life questionnaire

In the CHEST study the Aqol-8D was used before and after the Intervention for use in the economic evaluation. As described previously, the AQol8D is a 35 item scale that covers eight domains, including independent living, happiness, mental health, coping, relationships, self-worth, pain and senses. The results from the CHEST trial did not show any significant differences between the treatment arms after the Intervention. It is plausible that the nature of the CHEST Intervention was unlikely to have any impact on the
main domains measured or detect any generic issues related to cancer. The AQoL program was undertaken to increase instrument sensitivity and have the ability to pick up nuanced differences in quality of life in areas such as mental health or health states with a major impact upon handicap (as distinct from impairment). More of an effect may have been detected with a cancer clinical trial that was testing a new drug treatment and was looking at comparing the trade-off between quality of life and survival.

8.3. Qualitative study key outcomes

8.3.1. Thematic outcomes

8.3.1.1. Barriers to consulting

This qualitative study allowed us to identify the barriers to consult for patients as an increased risk of lung cancer, and identify the features of a successful intervention to promote earlier consultation.

The key barriers we identified in this current study (poor communication, mistrust, stigma, fear and symptom normalisation) were also found in existing studies. Fear and denial were described in a qualitative lung cancer symptom study by Birt et al. (2014)[5] and Macleod et al. (2009) [139]. Birt et al. (2014) identified reasons given by interviewees in their qualitative study for delaying GP consultation included a fatalistic perception that their condition was ‘self-inflicted’, that they did not want to ‘burden’ GPs, and that they were unworthy of medical attention[5].

More recently, fear of bad news, feelings of stigma associated with smoking, and symptom normalisation were described as common barriers by Crane et al. (2016)[152] who identified a major barrier to help seeking were feelings of stigma associated with smoking in 16 qualitative smoking focus groups in NSW. A report by the London School of Economics, also indicated that stigmatising smoking led to an increase in resistance to quitting and caused smokers to become defensive and angry, with negative messages leading to a drop in self-esteem[132]. Similar terms for smokers from this study, were also identified by our research, such as “outcast or “bad person”.

Consistent with the qualitative study by Crane et al. (2016), symptom normalisation was common among those interviewed, many downplayed their risk of developing lung cancer and attributed their symptoms to other causes, or thought that because they had stopped
smoking, or were only smoking a few cigarettes per day, this minimised any risk to themselves.

Similar barriers to help seeking were identified in a qualitative study by Mazza et al. (2011)[156] which involved 18 focus groups in two areas of metropolitan Melbourne. This study aimed to identify barriers and enablers of preventative care in general practice from the perspective of community members, and to explore their sense of the effectiveness of that care. Barriers to these participants seeking help through their GPs included lack of knowledge particularly about what preventative care was relevant to them, consultations that focused primarily on acute-care concerns, time pressures and the cost of consultations. Whereas, trust, rapport and continuity of care were viewed as enablers for participants to engage in prevention with their GP. Participants saw preventative care as legitimate in general practice when it was associated with a test or a “concrete action.” This finding was also noted in the CHEST Intervention. Many participants liked having the spirometry test as a measure of something they could take away, it was described as useful, and viewed as “an extra level of care.”

Similar attitudes and beliefs about lung cancer were reported in a qualitative study by Scott et al. (2014)[152] among Chinese, Vietnamese and Arabic-speaking communities in Sydney, New South Wales (NSW). Fatalistic views towards lung cancer were apparent across all three culturally and linguistically diverse communities (CALD) communities. There were low levels of awareness of lung cancer signs and symptoms, with the exception of haemoptysis. Differences in help-seeking behaviour and levels of trust of general practitioners (GP) were apparent.

Barriers at the patient-general practice interface were described by Smith et al. (2012) when designing the original Scottish complex intervention[48]. Participants from focus groups reported that GPs had a very negative attitude towards smokers. Many participants expressed a need to be taken seriously by their GP, similar to the smoker stigmatisation theme identified in the CHEST Australia study. Smith et al. (2012) also discovered through their focus groups that smokers would be a high risk group to engage and recruit due to many being in denial, or believing smoking will not affect them. Similar avoidance coping mechanisms were described by many in the CHEST trial, ex-smokers in particular expressed that if they had been currently smoking they would most likely not have participated. Evidence shows that avoidance coping is a strategy used by smokers[157, 158] which may
reflect the lower numbers of smokers recruited into the overall CHEST Australia study (57% ex-smokers versus 43% smokers).

Obtaining an appointment to visit a GP was identified as an important barrier for early consultation in the Scottish study, but this was not observed in Perth or Melbourne practices, indicating that GP accessibility is not a barrier to consulting in metropolitan Australia. All participants reported they felt confident they could get an appointment within 1-3 days. In another UK based study, Wagland et al. (2016) explored help-seeking behaviours in primary care patients at “high-risk” of lung cancer (>50 years old, recent smoking history). Qualitative interviews showed three overarching differences between the views of consulting and non-consulting participants. These were 1. concern over wasting their own as well as GP time, 2. a high tolerance threshold for symptoms, and 3. a greater tendency to self-manage symptoms. These reasons for patient delay differ from those found in the CHEST Australia study, wasting the GPs time and one’s own time were not brought up as a common theme in the CHEST Australia interviews but appear to be prominent reasons for consulting delay in the UK (as also described by Birt 2014). In addition, reasons 2 and 3 described by Wagland were not prominent reasons for delay in seeking help in the CHEST Australia interviews. However, similar themes were feelings of guilt and a “fatalistic perception” that their condition was “self-inflicted” resulting in GP consultation delay.

An underlying perception of mistrust of the GP was expressed in the Australian setting, due to reasons such as a perceived previous missed diagnosis or miscommunication. Previous experiences of visiting the GP which had focused on perceived reprimanding by the GP to quit smoking were commonly described as an important barrier to early consultation.

To overcome this stigmatisation, the tactic employed by the CHEST Intervention was to make targeted patients feel they were getting special attention, rather than the usual stigmatisation hence, the slogan- “Special Attention for those who maybe at high risk of a lung disease...”. In Australia, many liked the extra attention given, as it was viewed as an extra level of care.

8.3.1.2. Perceptions of the CHEST Intervention

Perceptions reported by participants suggest that the intervention tackled barriers around lecturing and feelings of guilt and stigma. The intervention was reported as delivered in a relaxed, non-threatening environment where patients at increased risk of lung cancer could
openly talk about their smoking and lung health. The intervention did not make participants’ feel judged or feel guilty for smoking or having previously smoked, it therefore enabled more open and honest discussion. After the intervention, participants reported a clearer understanding of what symptom changes to look out for and when to take action and they felt that the CHEST self-help manual was a valid and useful guide. The benefits of early consultation appeared to have been understood. A potential implication existed whereby patients may not have been able to clearly recall the consultation 12 month prior, however, it soon appeared that all interviewed participants has a good recollection of the intervention.

There was concern that even if a patient was engaged and attended a consultation whether this was going to lead to a behaviour change. Apathy, optimistic bias and non-recognition of personal risk were identified as the main contributors to not achieving a positive behaviour change by Smith et al. (2012)[48]. This is where the idea of the self-monitoring prompts were introduced, as well as keeping the messages within the self-manual simple, emphasising symptoms are not just occurring because of old age, provision of support help lines, quotes from people telling similar stories and reinforcing the benefits of early diagnosis. This in turn led to the Intervention giving people the knowledge they need to recognise the correct symptoms. Reports from the Australian qualitative study indicate that many liked receiving the “correct information” in an easy to read document. The CHEST Information booklet was seen as useful, logical and a good “reference guide” and some reported that this was effective communication. Many liked having control over when they could refer to the booklet. The idea behind increasing patient knowledge was that this would lead to the development of illness prototypes, or ideas on what symptom-sets are associated with particular conditions. The feedback received was that the simple checklist of symptoms of what needs action and when, was very useful. Many reported a clearer understanding of what to look out for and when they should contact their GP. This evidence suggests that the intervention is performing as expected and achieving one of the key objectives proposed: improving knowledge. However, from the quantitative results there was no significant difference noted in Knowledge scores. As noted previously this could be due to the insensitivity of the measure and while the separate intermediate constructs were unable to detect a difference, there was still an overall effect detected.

There was also evidence that the prompts and reminders had an impact on early help seeking behaviour. Participants responded particularly well to positive messages and
images in the Australian CHEST Intervention. The community based lung cancer symptom awareness intervention published by Athey et al. in 2011[44] showed that the take home message of looking out for a “persistent cough” was successfully received. Similarly, the CHEST Intervention promoted a recall of the “123” message. These complimentary health messages were seen as beneficial to individuals at high risk of developing lung cancer, given the disparity between an individual’s knowledge and perceived risk.

Tailoring reminders to individual preferences was important in promoting self-efficacy in the CHEST Australia Trial. The majority of participants preferred an electronic form of reminder such as an email (54%) or an SMS (32%), whereas the postcard option was one of the least preferred options (13%) (Chapter Six, 6.8.6, p.136). This suggests that this population are technologically competent and it is therefore feasible that electronic media is an acceptable and cheap method for delivering lung healthcare-related information and resources in the future.

The “what if” exercise was very important in reinforcing when and how to seek help. After delivering the Intervention this was a very powerful way of ensuring each person knew what to do when they experienced different types of symptoms and when to recognise if a symptom required an urgent response or not. The reminders after the Intervention reinforced the message of checking symptoms on a regular basis and this led to the development of well-planned implementation intentions.

The Intervention also aimed to bring symptoms in the foreground of thinking, giving it a higher priority in one’s life. Through the CHEST Australia interviews, we identified a very salient group, who were very aware of their health particularly due to past or present exposure to smoke or asbestos or industrial pollution. This group also knew their family history put them at a greater risk. Birt et al. (2014) also reported a heightened concern about personal risk for lung cancer due not only to smoking but also to environmental exposure and this seemed to facilitate further help-seeking[5]. We also identified a group of people who tended to have a wait and see approach, and would only go to their GP if prompted.

Those with a chronic illness, or those who were diagnosed with lung cancer through the trial, did not respond as well to the Intervention. Many already felt they were visiting the GP frequently enough, or “it was too late” for them. Symptoms were low in their “system of relevance,” that is, they had more important priorities with their current situations. It
would have been interesting to have had more “negative cases “in response to the Intervention, especially from those who were not chronically ill. This may have been useful in identifying improvements to the Intervention.

It has been suggested that any future lung screening programs in Australia should incorporate a smoking cessation intervention as part of the approach as this is a valuable teaching opportunity (Brims, 2016)[159]. However, this qualitative research suggests that this could potentially hinder uptake to screening programmes and act as a possible barrier. Instead, incorporating an intervention such as the CHEST Intervention could be more effectively applied in conjunction with any future screening programmes.

Overall, taking the qualitative work and comparing with the quantitative results, we have more powerful data in the broader context. The quantitative results show that the Intervention has the potential to increase respiratory consulting behaviours, but time to presentation was not significantly different. Also, the projected effects on various intermediate process measures were unable to be detected. However, the qualitative results indicate that the Intervention is achieving the desired objectives through the proposed theoretical mechanisms. The focus appears to be less about previously reported nihilism now as reported in the Scottish and other UK trials, but more directed towards perceived attitudes towards the GP in the Australian setting. This could partially explain why the respiratory consultation rates were lower overall compared to the Scottish trial but they still consulted quite a lot in general. This could also explain why the cohort is not consulting sooner. This cohort obviously do feel stigmatised and feel less inclined or reluctant to consult, but the Intervention tackles this barrier and significantly alters consulting behaviours in this hard to reach population.
8.4. Lung Cancer screening

At the outset of the CHEST Australia study (in 2012) the results of lung cancer screening trials were just being considered. There was promising evidence from the 2011 US lung cancer screening trial[14], but uncertainties remained over the cost-effectiveness and feasibility of implementing a national lung cancer screening program in Australia. The development of useful biomarkers was still continuing and therefore, at the time, other approaches to timely diagnosis of lung cancer were required, particularly through prompt recognition and investigation of symptoms suggestive of the disease in those at higher risk. This section will provide the most up to date literature and current research about lung cancer screening in the international and local setting and will describe what type of role the CHEST Intervention may now have in relation to these findings, particularly in the Australian context.

8.4.1. The United States National Lung Screening Trial (NLST) (2011)

In 2011, new evidence was reported to support annual screening for people at high risk of lung cancer using low-dose computed tomography (LDCT). The National Lung Screening Trial (NLST) recruited individuals at high risk of lung cancer by identifying adults aged 55 to 80 years who had a smoking history of at least 30 pack-years and currently smoked or had quit within the past 15 years. This randomised controlled trial conducted in the United States, involved 53,454 current and former heavy smokers. The study, found a 20% reduction in mortality from lung cancer with annual screening with LDCT compared to those screened with chest radiography across three screening rounds, and a 6.7% reduction in all-cause mortality in the LDCT screened group (NLST, 2011)[14]. However, as a primary screening modality, there are issues involved with CT screening. It is expensive and leads to a significant percentage of false positives (>90% of nodules are found to be benign) and unnecessary invasive procedures.

In response to the results of the NLST, the U.S. Preventive Services Task Force (USPSTF) published a statement in December 2013, recommending annual screening for people at high risk of lung cancer using LDCT. The U.S. Preventive Services Task Force recommendation states that chest x-ray has not shown adequate sensitivity or specificity as a screening test[160].
8.4.2. Implementation of screening and identifying high-risk populations

Quaife et al. (2016) states that for any screening programme to be effective, it must achieve a positive benefit-harm ratio, which in turn depends upon attracting the high risk population. Increasing the risk profile of participants has potential to reduce avoidable invasive follow-up tests and the number needed to screen[161]. NLST participants categorised within the three highest quintiles of risk benefited from 88% of screen-prevented deaths[162].

However, as Quaife et al. (2016) further states, enrolment to screening offered within the trial context has been extremely low, ranging from 0.2–4.6 % of the total age-eligible population invited[163-166], and biased toward former smokers, rather than current smokers and towards higher socioeconomic status (SES) individuals[14, 167]. In the UK Lung Screening Trial (UKLS), the proportion of individuals with a high lung cancer risk score (using the Liverpool Lung Project model)[168] increased with socioeconomic deprivation, yet response rates and follow-up clinic attendance decreased. This suggests that despite their high risk, lower SES smokers are less likely to engage with an offer of screening, a pervasive problem observed across other screening programmes and healthcare services. It is essential that screening communication effectively engages this group if lung cancer screening is to be an equitable early detection strategy and attain adequate uptake[169].

Up until now, methods of recruitment into trials have been heterogeneous, including mass-mailing, media advertisements, community outreach and GP enrolment[14, 163, 170]. Some initially invited all individuals in the at-risk age group who were requested to complete risk assessment measures and engage in further correspondence to determine eligibility. Therefore, while it is known uptake is poorer among low SES smokers, it is difficult to ascertain the denominator of eligible individuals invited to screening needed to reliably calculate levels of uptake among high risk candidates. Furthermore, these individuals were invited to participate in a research trial evaluating the clinical effectiveness of LDCT screening; an invitation that is likely to be interpreted very differently from that for a lung cancer screening service. Interestingly, the authors conclude that no study has taken a targeted approach to the design of invitation and information materials for (and in consultation with) high risk and ‘hard-to-reach’ groups, nor attempted to test such a strategy in the real-world context of a demonstration pilot lung cancer screening service.
The proposed randomised trial by Quaife et al. (2016) will test whether targeted invitation materials are effective at improving engagement with an offer of lung cancer screening for high risk candidates in the UK. Two thousand patients aged 60–75 and recorded as a smoker within the last five years by their GP, will be identified from primary care records and individually randomised to receive either intervention invitation materials (which take a targeted, stepped and low burden approach to information provision prior to the appointment) or control invitation materials. The primary outcome is uptake of a nurse-led ‘lung health check’ hospital appointment, during which patients will be offered a spirometry test, an exhaled carbon monoxide (CO) reading, and an LDCT if eligible. Initial data on demographics (i.e. age, sex, ethnicity, deprivation score) and smoking status will be collected in primary care and analysed to explore differences between attenders and non-attenders with respect to invitation group. Those who attend the lung health check will have further data on smoking collected during their appointment (including pack-year history, nicotine dependence and confidence to quit). Secondary outcomes will include willingness to be screened, uptake of LDCT and measures of informed decision-making to ensure the latter is not compromised by either invitation strategy. If effective at improving informed uptake of screening and reducing bias in participation, this invitation strategy could be adopted by local screening pilots or a national programme[169].

### 8.4.3. **PLCO risk model**

Unlike other screening programs that select participants according only to risk factors of age and sex, eligibility for lung cancer screening is more complicated. It has been argued that the NLST selection criteria is not necessarily the most effective for identifying those who may benefit most from screening[171]. Using probabilistic multivariate lung cancer risk prediction models to select individuals for screening may improve overall efficiency and cost effectiveness, and are recommended by international organisations. The “PLCOM2012” lung cancer risk model was developed during the US Prostate, Lung, Colorectal, Ovarian Screening (PLCO) Trial, and has been validated in the NLST cohort. This model uses data on age, smoking status, duration and intensity, family history, body mass index (BMI), and comorbidities (including self-reported chronic obstructive pulmonary disease [COPD], chronic bronchitis and emphysema) to estimate an individual’s risk of developing lung cancer within 6 years. A PLCOM2012 lung cancer risk of greater than 1.5% has been proposed as an alternative lung cancer screening eligibility criterion[172].
An independent validation of the PLCO\textsubscript{m2012} risk prediction model in an Australian population has recently been reported by Cancer Council NSW\cite{173}. The risk was calculated by applying PLCO\textsubscript{m2012} to baseline data from 95,882 smokers over 45 years in the Sax Institute’s 45 and Up Study (2006-2009) with a total of 1035 lung cancer diagnoses in the cohort. In the 55-74 year age group (the age range likely to be targeted for screening), it correctly predicted nearly 70 per cent of all lung cancer diagnoses. The study claims that the model was better at predicting those individuals who would go on to develop lung cancer than the guidelines that are currently being used to identify high risk individuals in the US and Europe (NLST criteria)\cite{173}.

It is estimated that around 29% of people who have ever smoked may be eligible for screening according to the model, by the time they are 55 years old. However the authors still claim that there is still a need for more data and evidence, to confirm the effectiveness of screening those identified as high risk via the use of the tool. Currently, there is a joint Australian and Canadian trial underway that will further validate the model and optimise the trade-off between screening benefits and harms.

### 8.4.4. Early cancer detection test Lung Cancer Scotland (ECLS) study (2017)

Currently, a randomised trial conducted for the early detection of lung cancer using the “EarlyCDT\textsuperscript{®}-Lung test”, an autoantibody biomarker blood test is being carried out by Sullivan et al. (2017) in the UK\cite{18}. The primary research question is; Does using the EarlyCDT\textsuperscript{®}-Lung Test to identify those at high risk of lung cancer, followed by X-ray and computed tomography (CT) scanning, reduce the incidence of patients with late-stage lung cancer compared to standard practice?

EarlyCDT\textsuperscript{®}-Lung is a blood test that could stratify a screening population and enable the early detection of lung cancer in high-risk, asymptomatic patients. First announced in March 2012, the ECLS Study was established to determine if the use of EarlyCDT\textsuperscript{®}-Lung leads to earlier detection of lung cancer and can help to save lives in the long term. As part of the study, half of the patients (n=6000) pre-identified as high-risk (smokers and ex-smokers, aged 50-75 years and at least 20 years pack history (the same criteria as the CHEST study but less than the NLST study)) for lung cancer were followed up by usual care, and half (n=6000) were asked to take the EarlyCDT\textsuperscript{®}-Lung test. Those who received a positive result were effectively triaged into a much higher risk group and referred for X-ray and low dose computerized tomography (CT) scans. This higher-risk selection protocol
results in fewer low dose CT scans, but with the same mortality benefit of low dose CT scans already established in the U.S. National Lung Screening Trial (“NLST”).

The study has demonstrated a cancer detection rate (sensitivity) of 81% for EarlyCDT®-Lung in preliminary findings. While the control arm in the study has not been formally assessed, the positivity rate was as expected with a specificity of 91%[174]. The study will determine the clinical and cost effectiveness of EarlyCDT®-Lung Test for early lung cancer detection and assess its suitability for a large-scale, accredited screening service. The study will also assess the potential psychological and behavioural harms arising from false positive or false negative results. The final study results will be published after all patients have had two years of follow up CT scans and these are expected in 2019.

Other smaller LDCT screening trials are underway or completed in Europe and the United Kingdom. This includes the DANTE trial[170] the NELSON trial[166] and a Danish trial[175]. The results of these European trials will be pooled to increase the generalisability of the findings. It is anticipated that these data will be available in late 2017[176].

### 8.4.5. Issues involved with screening

There are various problems arising with population based lung screening including a high false positive rate of screening with the risk of harms from follow-up investigation; variability in follow up protocols for a positive test; uncertainty regarding the target population and screening interval; uncertainty regarding cost-effectiveness; and the issue of screening versus smoking cessation measures.

#### 8.4.5.1. High false positive rate

One of the primary potential harms of any screening modality is false-positive tests, along with the resultant diagnostic work and any follow-up complications. The overall false positive rate for the NLST was 96.4%, leading to a high rate of follow up investigation which could include potentially invasive procedures to confirm diagnosis. The rate of identification of positive findings, typically small pulmonary nodules, averaged 24.2%/year, the vast majority of which were false positives[14].

#### 8.4.5.2. Generalisability

While the NLST showed a reduction in lung cancer–specific mortality, there were issues relating to generalisability to the broader U.S. population. A review by Tanoue in 2014
outlined the main issues associated with the NLST trial. Firstly, the demographics of NLST participants were different from the estimated 8 million Americans who would meet NLST entry criteria. Overall, NLST participants were younger, healthier, more educated, and less likely to be current smokers[160]. These differences reflect the “healthy volunteer effect” in screening trials, in which there is a self-selection of better educated, health conscious persons with better access to medical care. Secondly, NLST participants were enrolled in urban, tertiary care hospitals with specialist lung cancer expertise, and access to specialists, therefore outcomes maybe better. Thirdly Tanoue states that although NLST allowed participants to choose their own site for evaluation of a screen-detected nodule, it is likely that many were managed at an NLST site. Eight-two percent of these sites were tertiary care centres and 76% had a National Cancer Institute designation; these settings typically have dedicated thoracic surgeons and perform high volumes of procedures, both of which are associated with better outcomes[160]. This may explain the superior surgical outcomes in NLST; surgical mortality in NLST subjects undergoing thoracic surgery was 1%, compared with the national average of 3–5%. Such differences emphasise the harm that could be incurred related to performing unnecessary procedures, or performing surgery in settings of limited experience. These are real challenges, because access to specialty expertise in the broader community is not consistent. Geographic differences in care delivery patterns are well described, and patients may not be able or may not desire to travel distances to obtain tertiary care. If the number of invasive procedures performed and the surgical mortality risk are higher in the broader community than in NLST, the same benefit of lung cancer screening may not occur[142].

8.4.5.3. Radiation exposure

CT imaging necessarily incurs radiation exposure, with radiation-related cancer being another source of potential harm. The radiation dose of LDCT is ten times higher than chest radiography. Bach *et al.* (2012)[177, 178] reported that using data from NLST, it is estimated that one cancer death per 2,500 people screened could be attributed to radiation exposure. Although this would be outweighed in the NLST population by benefit in lung cancer mortality reduction, the trade-off would be less advantageous for younger persons or those at lower risk for developing lung cancer.

Currently, technology to decrease radiation exposure related to CT scanning while preserving imaging quality is becoming available; clinical application in the near future should reduce radiation exposure incurred in screening settings[160].
8.4.5.4. Psychological distress

Psychological distress associated with a positive test result is another harmful effect of lung cancer screening. This is a particularly important issue given the high false positive rate of LDCT. Overall, 39.1% of participants in the NLST LDCT group had at least one positive screening test, with a false positive rate of 96.4% across the three rounds of screening[14]. When screening large numbers of individuals, participant reported health related quality of life (HRQoL) is an important consideration; even small decrements in HRQoL may have important implications when applied across large populations. NLST found participants with true positive scans had worse generic HRQoL outcomes at 1 and 6 months after the first screening scan, but those with false positive scans or significant incidental findings were similar to participants with Negative Scans at both time points[179].

In the NELSON trial of LDCT screening in Europe, Van Den Bergh et al. (2010) showed that participants with an indeterminate result (a positive screen with a recommended follow-up CT at 3 months) experienced increased lung cancer-specific distress in the short term[180].

It is thought the potential for over diagnosis should be considered with any screening test. This is the identification of a cancer that would have not have otherwise become clinically significant. Patients may undergo unnecessary diagnostic interventions and treatment and incur morbidity, health care cost and emotional burden for a finding that would have caused no limitation to duration of quality of life[181]. An examination of over diagnosis in NLST suggested that 1.38 cases of over diagnosis would be found in 320 participants needed to be screened to prevent one death[182].

Overall evidence suggests individuals undergoing screening are at risk of negative HRQoL effects. Those most at risk are individuals diagnosed with lung cancer and individuals with pre-existing higher levels of anxiety. Positive scans may cause temporary adverse effects on HRQoL[188].

8.4.5.5. Quality of Life

Data for health related quality of life was reported for the NELSON trial[166]. Before and after receiving lung cancer screening using LDCT scans, 600 participants in the NELSON trial completed the EQ-5D and the SF-12 to assess three dimensions of health related quality of life: overall, physical and mental. The EQ-5D uses a visual analogue (thermometer-style) scale to indicate general health status assigning 100 as the best score possible. The SF-12
also uses a scoring range from zero to 100, with better health indicated by higher scores. For overall quality of life the baseline (pre-screening) mean score was 79.3 (SD 13.7) and the post-screening mean score was 78.4 (SD 13.7). The computed MCS showed a significant decrease in the summary score (i.e., participants’ overall health related quality of life) over time [-0.90 (95% CI -1.59, -0.21)]. For the physical dimension of quality of life, the baseline mean score was 49.50 (SD 8.7) and the post intervention mean score was 50.0 (SD 8.2); both scores fall within the normal range. The computed MCS showed a significant improvement in the summary score (i.e., participants’ physical quality of life) over time [0.50 (95% CI 0.07, 0.93)]. Finally, for the mental dimension of quality of life, the baseline mean score was 51.9 (SD 10.3) and the post intervention mean score was 51.6 (SD 11.1); again, both scores fall within the normal range. The computed MCS showed no difference in the summary score (i.e., participants’ mental quality of life) over time [-0.30 (95% CI -8.84, 0.24)]

8.4.5.6. Cost

The costs of treating advanced lung cancer are greater than the costs of treating the early stage disease[159]. Furthermore, a consequence of rising pharmaceutical costs of cancer treatment is that early detection becomes more desirable both in direct mortality reduction and reduction of downstream treatment costs. Cost effectiveness of LDCT screening varies between studies and has been predominantly analysed in U.S. context. Researchers in Australia are currently investigating effectiveness and economic viability. However, an early analysis of the cost-effectiveness of LDCT screening in Australia found screening was likely to be expensive[183] The most feasible scenario under which CT screening for lung cancer could be cost-effective would be if very high-risk individuals are targeted and screening is either highly effective or CT screening costs fall substantially[171].

Issues relating to cost were summarised in a position statement by the Cancer Council in 2015[184]. LDCT screening as performed in the NLST was estimated to cost $81,000 (USD) per quality-adjusted life-year (QALY) gained. The equivalent incremental cost-effectiveness ratio (ICERs) was $52,000 (USD) per life year gained. However, the study noted modest changes in assumptions would significantly alter the figure and the ICER varied widely in the subgroup and sensitivity analysis[185]. An earlier U.S. study estimated that annual screening of current and former smokers aged 50-74 with a minimum 20-pack years of smoking cost $126,000(USD)-$169,000 (USD) per quality-adjusted life-year gained;
screening individuals with a minimum of 40 pack-years cost $110,000(USD)-$166,000(USD) per quality-adjusted life-year gained.

In Canada, annual screening of individuals with a 30 pack-year smoking history, aged between 55 and 74 years, saved 51,000 QALYs and had an incremental cost-effectiveness ratio of CaD$52,000 per QALY compared with no screening. Annual screening of individuals with a 20-pack year smoking history had an incremental cost-effectiveness ratio of CaD$62,000 per QALY, whereas screening individuals with a 40 pack-year smoking history resulted in an incremental cost-effectiveness ratio of CaD$43,000 per QALY. In comparison, a smoking cessation program improved the incremental cost-effectiveness ratio to CaD$24,000 per QALY[187].

In contrast, for Breast Screen Australia, the current policy of screening eligible women aged 40+ who participate, while specifically targeting women aged 50–69 years, yielded a cost-effectiveness estimate of $38,302 per life year gained (LYG) and $23,713 per LYG over a period of 20 and 40 years, respectively, so more cost-effective compared to lung cancer [Breast Screen Australia Evaluation].

The Cancer Council in Australia also reported that there is no evidence that smoking cessation is affected by LDCT meaning that it is not known whether smokers are falsely reassured by screening. However, as stated by McMahon et al. (2011)[186] screening potentially diverts scarce health dollars from tobacco control measures.

**8.4.6. What’s happening in Australia?**

In Australia, about 2.2 million people aged 55-75 years are current or former smokers, but the proportion of those eligible for lung cancer screening, using either the NLST or PLCOM2012 criteria, is unknown[117]. Estimating the proportion of people eligible for lung cancer screening will both aid policy makers when planning future capacity and assessing infrastructure requirements, and help estimate screening participation rates.

The “Population Based Screening Framework” provides guidance for decision makers when considering potential population based screening programs in Australia. The framework identifies the need for a strong evidence base on the safety, reproducibility and accuracy of screening tests and the efficacy of treatment. It also includes the requirement that screening programs offer more benefit than harm to the target population. Using these
criteria, the Framework states there is insufficient evidence at this stage to support the benefits of population-based screening for lung cancer using LDCT.

Based on the current evidence and the feedback from the framework, the Australian Cancer Councils latest position statement (published in 2015) states that “the Standing Committee on Screening does not support an Australian lung cancer screening program, either for the general population or for high risk populations. The Standing Committee on Screening will continue to evaluate and advise on emerging evidence on lung cancer screening.”[184] They further state that they await future local studies to clarify the efficacy, cost effectiveness and feasibility of implementing such screening program in an Australian setting and results from the existing screening trials with longer follow up time and pooled analysis of European screening trials to provide a sample size with adequate power to confirm the mortality reduction from LDCT.

Currently, there is minimal evidence on the benefits and harms of lung cancer screening within the Australian health care setting. The Queensland Lung Cancer Screening Study investigating the feasibility of LDCT screening in Australia has published initial findings showing that the magnitude of benefit and harm is consistent with the NLST trial. However, these findings were limited by the small sample size of the local study [188, 189]. The feasibility of lung cancer screening has also been demonstrated in the Western Australia based Asbestos Review Program[173]. Although, uncertainties remain over the best recruitment strategies, management of pulmonary nodules and the most cost-effective approach.

The key Issues requiring more clinical research to address gaps in the Australian context include firstly, the cost-effectiveness of population based CT screening in Australia and secondly, the best way to implement safe and effective population based CT screening in Australia. There must be a balanced approach to recruitment into a screening program in a way that maximizes uptake from eligible individuals, yet minimizes distress and or screening demand from lower-risk screening-ineligible individuals. Another key issue relevant to Australia is how access to screening with LDCT technology be provided to those living in rural and remote Australia[190].

The NHMRC in Australia have funded the ‘International Lung Screen Trial’ (ILST) designed to examine a number of these outstanding questions. Brims and colleagues in Western Australia are currently testing two different methods to identify and recruit patients at a
higher risk of developing lung cancer. This includes a general mail out from the electoral roll versus a more targeted approach of data extraction from the GP electronic medical records (using the CHEST extraction tool). The ILST is being undertaken in Victoria, Queensland and Western Australia with the aim to identify suitably high risk individuals for screening to determine lung cancer effectiveness.

In the interim, while these studies are underway, Cancer Council Australia state in their latest position statement, that primary prevention is the most important strategy for reducing the burden of lung cancer and that lung cancer screening is not an alternative to smoking cessation. Efforts should continue to focus on preventing smoking uptake, encouraging smoking cessation and minimising exposure to second hand tobacco smoke. It also states that general practitioners and health care providers play a vital role in managing people who have or may have lung cancer[184]

8.5. Implications for future research and practice using the CHEST Intervention.

8.5.1. Comparison to previous awareness campaigns

The Lung cancer ‘signs and symptoms’ campaigns discussed in Chapter 1 demonstrated the potential to improve the early diagnosis of the disease. However, all eight interventions identified were targeted specifically towards members of the general community and evaluation data for these interventions were limited and mainly based on observational data. These large scale community based campaigns were not only very broad in their approach but most likely expensive to run. However, there was limited cost effectiveness data available for any of the interventions.

The CHEST Intervention has addressed many of the limitations of the larger population based interventions and the existing smaller targeted studies too. It has used relevant theories to help identify relevant factors influencing behaviour, and developed strategies to change behaviours in a targeted high-risk group. Furthermore, the results from the CHEST-Australia randomised trial have shown that this tailored approach has had a specific effect on increasing respiratory consulting behaviour in a hard to reach population. The evidence provided and outcome measures are superior to the limited observational findings described by the previous symptom awareness studies. In addition, the CHEST Australia trial provides a cheaper more cost-effective approach, in comparison to the expensive, larger scale awareness campaigns.
There is also the possibility that this targeted symptom awareness approach used by the CHEST Intervention could also be successfully applied to other types of cancers. A good example would be for ovarian cancer. High-risk individuals such as those with a family history of the disease, or aged between 55-64 years, could be identified through electronic searches of the GP medical records and educated on what specific symptoms to look out for, such as bloating or pelvic pain. Melanoma could be another example, where high risk individuals such as those with family history, or fair skin and high sun exposure are identified in general practice and educated on early symptom warnings, such as observational changes in a mole.

### 8.5.2. Potential for a phase III trial

As described in Chapter 4, the objectives of the Phase II study were to establish acceptability of the intervention and to test the potential efficacy of the intervention powered on consultation rates to determine the need for a Phase III trial. According to the MRC framework for complex interventions, the Phase II trial is described as an “exploratory trial” a crucial stage prior to running a Phase III trial, where all the evidence to date is put to the test. The CHEST-Australia Phase II trial has shown that respiratory consultation rates can increase after delivery of the CHEST intervention but this has not resulted in significantly shorter times to consultation. The next logical step would be to potentially perform a larger Phase III trial powered on consultation rates and time to diagnosis in a cohort of people with lung cancer. However, the feasibility of this is questionable given that 3 out of 551 participants recruited to the CHEST Australia trial were diagnosed with lung cancer in the 12 month follow-up. Issues arise around the numbers needed to recruit for such a trial. Large screening trials are powered to detect differences in mortality so require very large numbers. Incidence data from the NLST trial shows that 941 lung cancers were detected in the control group (chest x-radiograph group) from 26 732 participants over 7 years and 190 lung cancers were detected after one year (0.7%). Therefore detecting 3 cases from 551 patients (0.5%) after one year in the CHEST trial is fairly comparable[14]. However, the NLST trial recruited over 54,000 participants[14]. A potential phase III CHEST trial would also require large numbers, but possibly not as many as a screening trial, because the outcome would be differences in time to diagnosis.

The question remains as to whether the results from the CHEST-Australia Trial have any real clinical significance. From Table 12, page 108, it can be seen that there were 41 more consultations over the course of a year in 274 patients. This increase in respiratory
consultations maybe enough in this high risk population to prompt earlier investigation of respiratory symptoms given the statistically significant effect, however it is recognised that it is a relatively small effect and may not be enough on its own. It is also important to reflect on the skewed recruitment of ex-smokers into the CHEST Trial. There is a real possibility that those recruited represented a “worried well” population, that is, they represented a group who were more interested in their health and therefore more likely to participate in such a study. Any future design would have to take this into consideration.

Given these challenges, it is probably not feasible to pursue a larger Phase III trial. However, the Intervention could still potentially have a place in the identification and recruitment of high risk populations identified in general practice and be useful for those who don’t meet current CT screening criteria.

8.5.3. Where does the CHEST Intervention fit in relation to current lung screening trials?

There is promising evidence from the US NLST study and other studies that LDCT screening potentially has an effect in reducing lung cancer mortality. The population recruited for the CHEST Australia study represented a population at slightly lower risk of lung cancer compared to the NLST study, because the NLST inclusion criteria was 30 pack years and the CHEST trial used 20 pack years. There is controversy concerning whether it is reasonable to offer screening by LDCT to individuals who do not meet NLST criteria, and in particular those who have not smoked at the intensity of the subjects of NLST but have additional lung cancer risk factors. When applying NLST findings to other groups who have lung cancer risk factors but who do not meet NLST enrolment criteria, it is important to remember that individuals with a lower risk of lung cancer than the average NLST participant are less likely to benefit and are probably at least as likely to be harmed[160]. Our results show that the CHEST Intervention had an effect on consulting behaviour in this population, but did not reduce the time to consult. The question remains if there are possibilities for its role in the future especially with the emergence of lung cancer screening in Australia.

Brims (2016) states that “the majority of outstanding questions for lung cancer screening are likely to be answered in the next few years. Australia needs to generate progress now towards a cohesive national approach and avoid procrastination. The challenge facing Australia is the translation of international results into sustainable, cost-effective clinical
practice, ensuring that the desired benefit outweighs the known harms”[159]. With this in mind, the CHEST Intervention could still have a place in the future.

One approach could be to use the CHEST Australia extraction tool to identify a population at high risk initially in general practice. The CHEST-Australia trial has proven that the extraction tool is capable of identifying an accurate targeted high risk population. If a patient meets the specified criteria required for screening, then they undergo a CT scan. If patients are not at high enough risk of lung cancer for CT screening, but are still long term smokers and have additional risk factors, then they could be exposed to the CHEST Intervention.

How this could be implemented in Australia is currently being addressed. As discussed, the CHEST extraction tool is currently being used in a lung cancer screening study by Brims and colleagues in Western Australia to identify and recruit patients at high risk of lung cancer. This is being compared to a more broad scale recruitment method using a general mail out from the electoral roll.

While the CHEST study has focused on reducing the patient interval and encouraging early consultation, it is important to also determine a pathway for GPs when a symptomatic patient who is at increased risk of lung cancer presents. Recently the randomised controlled study by Neal et al. in 2017 evaluated the feasibility of an intervention aimed at improving earlier stage diagnosis of lung cancer in symptomatic patients presenting to primary care by testing the immediate chest X-ray for patients at risk of lung cancer[191]. Patients over 60, with a smoking history, presenting with new chest symptoms, were eligible to be randomised to intervention (urgent chest X-ray) or usual care. The authors recruited 255 patients from 22 practices in the UK, Survey responses (89%), and the fidelity of the intervention (82% patients X-rayed within 3 weeks) were good. Three patients (1.2%) were diagnosed with lung cancer suggesting that this approach was feasible and could inform the design of a definitive, fully powered, UK-wide, phase III trial of lowering the threshold for urgent investigation of suspected lung cancer. Current diagnostic methods for the detection of lung cancer in Australia typically already involve a chest x-ray initially for symptomatic individuals, followed by chest computed tomography if there is an abnormal chest x-ray prior to biopsy. Studies such as this stress how important the role of primary care is in the early detection for lung (or any) type of cancer. It is essential that GP pathways are clearly defined for symptomatic, high risk cases in order to also reduce the diagnostic interval.
8.6. Conclusion

“Cancer is impacting Australia’s health more than any other group of diseases,” according to a report released by the Australian Institute of Health and Welfare (AIHW) in June 2017[192]. Lung cancer will continue to pose an enormous burden on the Australian health system and economy, causing more deaths per annum than breast, prostate, and ovarian cancers combined[2]. It is estimated that it will remain the most common cause of death from cancer in 2017[2]. These statements stress the importance of continual research in prevention and early detection studies.

The CHEST-Australia trial is the first Australian trial to test the effect of a behavioural intervention to reduce time to presentation with lung cancer symptoms. The CHEST-Australia intervention has shown to be effective in increasing respiratory consultation rates within 12 months of consultation, but not significantly reducing the time to consult in a targeted high risk population, indicating that this one-to one tailored interaction is proven to be effective. This trial adds weight to the limited existing research on interventions to reduce the time before consultation and could potentially be a low-cost and safe approach to early diagnosis of lung cancer.
Bibliography


64. Wyke, S., et al., *Consultation and illness behaviour in response to symptoms: a comparison of models from different disciplinary frameworks and suggestions for future research directions*. Social science & medicine, 2013. 86: p. 79-87.


Appendix A. Original Scottish Material

Appendix A contains the material used in the Scottish CHEST Intervention[48]. This includes:

1. The CHEST Questionnaire.
2. The CHEST handbook.
3. The Nurse script.
The Chest Study Questionnaire

All the information that you provide in this questionnaire is confidential.

You will not be identifiable from any of the answers that you give.

If you have any questions regarding this questionnaire please contact:

Sarah Smith Tel: (01224) 552497 or email: s.m.smith@abdn.ac.uk
What is the purpose of this questionnaire?
The purpose of this questionnaire is to find out some things about you and your health. We are also interested in why people do or do not consult their doctor and we would appreciate your responses to some questions about this.

What if I am not sure how to answer some questions?
Do the best that you can.

Should you have any difficulties with completing the questionnaire, or have any questions about the study please contact:

Sarah Smith Tel: (01224) 552497
Email: s.m.smith@abdn.ac.uk

How long will it take to complete?
It should take no longer than 20-30 minutes to complete.

Is the information confidential?
All the information that you give is extremely valuable to the study and is treated in the strictest confidence.

What should I do with my completed questionnaire?
After you have filled in the questionnaire please put it in the addressed FREEPOST envelope provided and post it back to us. NO POSTAGE STAMP IS REQUIRED

We would be very grateful if you could return your completed questionnaire as soon as possible.

Thank you.
Section A: WHAT DO YOU KNOW ABOUT LUNG DISEASE

We would like to begin by asking what you know about lung disease.

Listed below are different types of lung disease that share some common symptoms:

- Asthma
- COPD (which includes chronic bronchitis and emphysema)
- Lung cancer
- Pneumonia
- TB (tuberculosis)

1. Please tick any symptoms you believe are common symptoms of any of these lung diseases.

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Yes</th>
<th>No</th>
<th>Not sure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sore throat</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hoarseness</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cough</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rash</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain when breathing or coughing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wheezing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diarrhoea</td>
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<td></td>
<td></td>
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<tr>
<td>Breathlessness</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Loss of appetite</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Coughing up phlegm</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Itchy skin</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>A cough that gets worse</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>More tired than usual</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Indigestion</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Shoulder or rib pain</td>
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<td></td>
</tr>
<tr>
<td>Sneezing</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Fever</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Losing weight</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Coughing up phlegm/glut with signs of blood in it</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>More breathlessness than usual</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Risk of lung disease**

The next questions ask you to rate your own chances of getting lung disease. Please tick one box for each question. If you already have a form of lung disease, please rate your chances of getting another one.

2. How would you rate your chance of getting lung disease?

<table>
<thead>
<tr>
<th>Very low</th>
<th>Moderately low</th>
<th>Neither high nor low</th>
<th>Moderately high</th>
<th>Very high</th>
</tr>
</thead>
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<td></td>
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</tbody>
</table>

3. Compared to other people of your age and sex do you think your risk of suffering lung disease is:

<table>
<thead>
<tr>
<th>Much lower</th>
<th>Somewhat lower</th>
<th>About the same</th>
<th>Higher</th>
<th>Much higher</th>
</tr>
</thead>
<tbody>
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</table>
Section B: CONSULTING THE DOCTOR

The next four questions come in two parts; a and b. First, we want you to imagine what you would do in certain situations. Second, we want you to say how easy or difficult that would be for you.

1a. If you develop a new, persistent, dry cough, but you are otherwise well, then at what point would you make an appointment to see a doctor?

<table>
<thead>
<tr>
<th>I will make an appointment to see a doctor after I have a new, persistent, dry cough for:</th>
<th>Tick one box only</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 day or less</td>
<td></td>
</tr>
<tr>
<td>3 days</td>
<td></td>
</tr>
<tr>
<td>1 week</td>
<td></td>
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<td>2 weeks</td>
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<tr>
<td>3 weeks</td>
<td></td>
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<tr>
<td>1 month</td>
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<tr>
<td>2 months</td>
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<tr>
<td>3 months</td>
<td></td>
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<tr>
<td>6 months</td>
<td></td>
</tr>
<tr>
<td>Longer than 6 months</td>
<td></td>
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<tr>
<td>Never</td>
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</tbody>
</table>

1b. On a scale of one to seven please circle the number that best describes how easy or difficult it would be for you to make an appointment to see a doctor with a new, persistent, dry cough in the time you have ticked?

Easy 1 2 3 4 5 6 7 Difficult
2a. If you become newly short of breath in day to day activities, but you are otherwise well, then at what point would you make an appointment to see a doctor?

<table>
<thead>
<tr>
<th>I will make an appointment to see a doctor after I have been newly short of breath in day to day activities for:</th>
<th>Tick one box only</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 day or less</td>
<td></td>
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<tr>
<td>3 days</td>
<td></td>
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<tr>
<td>1 week</td>
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<td>2 weeks</td>
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<td>3 weeks</td>
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<td>1 month</td>
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<tr>
<td>2 months</td>
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<tr>
<td>3 months</td>
<td></td>
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<tr>
<td>6 months</td>
<td></td>
</tr>
<tr>
<td>Longer than 6 months</td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td></td>
</tr>
</tbody>
</table>

2b. On a scale of one to seven please circle the number that best describes how easy or difficult it would be for you to make an appointment to see a doctor if you become newly short of breath in day to day activities in the time you

Easy  1  2  3  4  5  6  7  Difficult
3a. If you cough up phlegm/glut with signs of blood, but you are otherwise well, then at what point would you make an appointment to see a doctor?

<table>
<thead>
<tr>
<th>I will make an appointment to see a doctor after I have been coughing up phlegm/glut with signs of blood for:</th>
<th>Tick one box only</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 day or less</td>
<td></td>
</tr>
<tr>
<td>3 days</td>
<td></td>
</tr>
<tr>
<td>1 week</td>
<td></td>
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<tr>
<td>2 weeks</td>
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<tr>
<td>3 weeks</td>
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<td>1 month</td>
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<td>2 months</td>
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<tr>
<td>3 months</td>
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<tr>
<td>6 months</td>
<td></td>
</tr>
<tr>
<td>Longer than 6 months</td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td></td>
</tr>
</tbody>
</table>

3b. On a scale of one to seven please circle the number that best describes how easy or difficult it would be for you to make an appointment to see a doctor with coughing up phlegm/glut with signs of blood in the time you have ticked?

Easy 1 2 3 4 5 6 7 Difficult
4a. If you notice you are losing weight, but you are otherwise well, then at what point would you make an appointment to see a doctor?

<table>
<thead>
<tr>
<th>I will make an appointment to see a doctor after I have been losing weight for:</th>
<th>Tick one box only</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 day or less</td>
<td></td>
</tr>
<tr>
<td>3 days</td>
<td></td>
</tr>
<tr>
<td>1 week</td>
<td></td>
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<tr>
<td>2 weeks</td>
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<tr>
<td>3 weeks</td>
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<td>1 month</td>
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<td>2 months</td>
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<tr>
<td>3 months</td>
<td></td>
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<tr>
<td>6 months</td>
<td></td>
</tr>
<tr>
<td>Longer than 6 months</td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td></td>
</tr>
</tbody>
</table>

4b. On a scale of one to seven please circle the number that best describes how easy or difficult it would be for you to make an appointment to see a doctor with losing weight in the time you have ticked?

Easy 1 2 3 4 5 6 7 Difficult
In the following questions we would like to know what you think about consulting your doctor with chest symptoms.

5. For me making an appointment to see a doctor if I were to experience any chest symptoms for a month would be:

(Please tick one box in each line)

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>A good thing</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>2</td>
<td>Difficult</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>3</td>
<td>Worthless</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>4</td>
<td>Harmful</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>5</td>
<td>Impossible</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>6</td>
<td>Awkward</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>
In these next questions please circle the number that best describes your opinion about consulting a doctor with chest symptoms.

<table>
<thead>
<tr>
<th>For example</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>If you ‘strongly agree’ you might circle 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If you ‘strongly disagree’ you might circle 7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If you ‘neither agree nor disagree’ you might circle 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6. The decision whether to see a doctor if I have chest symptoms for a month is beyond my control:

   Strongly agree 1 2 3 4 5 6 7 Strongly disagree

7. I intend to see a doctor if I have chest symptoms for a month:

   Strongly agree 1 2 3 4 5 6 7 Strongly disagree

8. I am confident I could see a doctor if I had chest symptoms for a month:

   Strongly agree 1 2 3 4 5 6 7 Strongly disagree

9. I will try to see a doctor if I have chest symptoms for a month:

   Strongly agree 1 2 3 4 5 6 7 Strongly disagree

10. Whether or not I see a doctor if I have chest symptoms for a month is up to me:

    Strongly agree 1 2 3 4 5 6 7 Strongly disagree

11. I plan to see a doctor if I have chest symptoms for a month:

    Strongly agree 1 2 3 4 5 6 7 Strongly disagree
We would now like to know how confident you are about making an appointment to see your doctor under certain circumstances. Please circle the number that best describes your level of confidence for each of the following questions.

How confident are you that you can make an appointment to see a doctor when

12. you can’t get an appointment with your usual doctor? Not at all confident 1 2 3 4 5 6 7 8 9 10 Totally confident
13. the health centre number is busy when you phone to make an appointment? Not at all confident 1 2 3 4 5 6 7 8 9 10 Totally confident
14. you have had a cough for one week? Not at all confident 1 2 3 4 5 6 7 8 9 10 Totally confident
15. taking the time away from work or other commitments is difficult? Not at all confident 1 2 3 4 5 6 7 8 9 10 Totally confident
16. you have already been to see a doctor. You got some medication, which has helped a bit, but you still feel unwell? Not at all confident 1 2 3 4 5 6 7 8 9 10 Totally confident
17. you have chest symptoms at the weekend or while away from home? Not at all confident 1 2 3 4 5 6 7 8 9 10 Totally confident
18. you have been short of breath for one month? Not at all confident 1 2 3 4 5 6 7 8 9 10 Totally confident
19. you think your symptoms are not serious enough? Not at all confident 1 2 3 4 5 6 7 8 9 10 Totally confident
20. you know your doctor will mention the dangers of smoking? Not at all confident 1 2 3 4 5 6 7 8 9 10 Totally confident
21. you have been wheezy for six months? Not at all confident 1 2 3 4 5 6 7 8 9 10 Totally confident
22. the receptionist at your health centre offers for you to see the practice nurse instead of the doctor? Not at all confident 1 2 3 4 5 6 7 8 9 10 Totally confident
Section C: YOUR HEALTH

We would like to ask your views about your health.

1. In general, would you say your health is:

   (circle one number)

   | Excellent | 1 |
   | Very good | 2 |
   | Good      | 3 |
   | Fair      | 4 |
   | Poor      | 5 |

This next section asks questions mainly about your chest and chest symptoms. Please tick YES or NO where possible.

1. **COUGH**

   2. Do you usually cough first thing in the morning during winter? Yes [ ] No [ ]

   3. Do you usually cough during the day or at night in the winter? Yes [ ] No [ ]

   If you said YES to question 2 or 3:

   4. Do you cough like this on most days for as much as three months of the year? Yes [ ] No [ ]

**COUGHING UP PHLEGM/GLUT**

5. Do you usually bring up phlegm/glut from your chest first thing in the morning in the winter? Yes [ ] No [ ]
6. Do you usually bring up any phlegm/glut from your chest during the day or at night in winter? Yes ☐ No ☐

If you said YES to question 5 or 6:

7. Do you bring up phlegm/glut like this on most days for as much as three months each year? Yes ☐ No ☐

PERIODS OF COUGH & PHLEGM/GLUT

8. In the past three years have you had a period of increased cough and phlegm/glut lasting for three weeks or more? Yes ☐ No ☐

If YES:

9. Have you had more than one such period? Yes ☐ No ☐

BREATHLESSNESS

The following statements refer to your breathing

10. I only get breathless with strenuous exercise. Yes ☐ No ☐

11. I get short of breath when hurrying on level ground or walking up a slight hill. Yes ☐ No ☐

12. I get short of breath walking with other people of my age on level ground. Yes ☐ No ☐

13. I stop for breath after walking 100 yards/metres or after a few minutes on level ground. Yes ☐ No ☐

14. I am too breathless to leave the house. Yes ☐ No ☐

WHEEZE

15. Have you had attacks of wheezing or whistling in your chest at any time in the last 12 months? Yes ☐ No ☐

16. Have you ever had attacks of shortness of breath with wheezing? Yes ☐ No ☐
If YES:

17. Is/was your breathing absolutely normal between attacks? Yes □ □ No □ □

18. Have you at any time in the last 12 months been woken at night by an attack of shortness of breath? Yes □ □ No □ □

CHEST ILLNESSES

19. During the last three years have you had any chest illness which has kept you from your usual activities for as much as a week? Yes □ □ No □ □

If YES:

20. Did you bring up more phlegm/glut than usual in any of these illnesses? Yes □ □ No □ □

21. Have you ever been admitted to hospital for chest problems in the last 12 months? Yes □ □ No □ □
We are interested in any previous illness you may have had and whether you developed these during the past twelve months.

22. Have you had, or been told that you have any of the following illnesses below? Please tick appropriate answer in each line.

<table>
<thead>
<tr>
<th>Illness</th>
<th>Yes, for the first time in the last twelve months</th>
<th>Yes, for the first time more than twelve months ago</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung diseases</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Asthma?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease?</td>
<td></td>
<td></td>
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<tr>
<td>Chronic bronchitis?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emphysema?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pleurisy?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pneumonia?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pulmonary tuberculosis?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any other lung disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If yes for any other lung disease please state what:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other illnesses</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Heart trouble?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kidney failure?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stomach ulcer/ acid reflux/ hiatus hernia?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rheumatic troubles or arthritis?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depression or nervous trouble?</td>
<td></td>
<td></td>
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<tr>
<td>Other mental health problems?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Question</td>
<td>Answer</td>
<td></td>
</tr>
<tr>
<td>----------</td>
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<td></td>
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<tr>
<td>High blood pressure?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stroke?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>An injury or operation affecting your chest?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any other serious long-term illness?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If **yes** for any other serious long term illness please specify what:

__________________________________________________________________
Section D:  **HOW YOU FEEL**

Please read each item and place a tick in the box beside the reply which comes closest to how you have been feeling **in the past week**. Don’t take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought-out response. **Please tick only one box in each section**

1. I feel tense or ‘wound up’:
   - Most of the time
   - A lot of the time
   - Time to time, Occasionally
   - Not at all

2. I feel as if I am slowed down:
   - Nearly all the time
   - Very often
   - Sometimes
   - Not at all

3. I still enjoy the things I used to enjoy:
   - Definitely as much
   - Not quite as much
   - Only a little
   - Hardly at all

4. I get a sort of frightened feeling like ‘butterflies’ in the stomach:
   - Not at all
   - Occasionally
   - Quite often
   - Very often

5. I get a sort of frightened feeling as if something awful is about to happen:
   - Very definitely and quite badly
   - Yes, but not too badly
   - A little, but it doesn’t worry me
   - Not at all

6. I have lost interest in my appearance:
   - Definitely
   - I don’t take so much care as I should
   - I may not take quite as much care
   - I take just as much care as ever

7. I can laugh and see the funny side of things:
   - As much as I always could
   - Not quite so much now
   - Definitely not so much now
   - Not at all

8. I feel restless as if I have to be on the move:
   - Very much indeed
   - Quite a lot
   - Not very much
   - Not at all

9. Worrying thoughts go through my mind:
   - A great deal of the time
   - A lot of the time
   - From time to time but not too often
   - Only occasionally

10. I look forward with enjoyment to things:
    - As much as ever I did
    - Rather less than I used to
    - Definitely less than I used to
    - Hardly at all

11. I feel cheerful:
    - Most of the time
    - Not often
    - Sometimes
    - Not at all

12. I get sudden feelings of panic:
    - Very often indeed
    - Quite often
    - Not very often
    - Not at all

13. I can sit at ease and feel relaxed:
    - Definitely
    - Usually
    - Not often
    - Not at all

14. I can enjoy a good book or radio or TV programme:
    - Often
    - Sometimes
    - Not often
    - Very seldom

Cancer, including lung cancer, is a topic that is regularly discussed on radio, television and in newspapers. You may also have seen posters or pamphlets at your health centre about breast and other cancers. We would like you to tell us about your thoughts or worries about lung cancer.

15. During the past month, how often have you thought about your own chances of developing lung cancer?

not at all or rarely  sometimes  often  almost all the time

16. During the past month, how often have thoughts about your chances of getting lung cancer affected your mood?

not at all or rarely  sometimes  often  almost all the time

17. During the past month, have thoughts about your chances of getting lung cancer affected your ability to perform your daily activities?

not at all or rarely  sometimes  often  almost all the time

18. How concerned are you about the possibility that you might get lung cancer someday?

not at all or rarely  sometimes  often  almost all the time

19. How often do you worry about developing lung cancer?

not at all or rarely  sometimes  often  almost all the time

20. How much of a problem is worrying about lung cancer to you?

not at all  somewhat  definitely is  severe problem
Section E: ABOUT YOU

This is the final section where we would like to know a little bit about you.

1. Do you live?
   - On your own
   - With a partner/spouse
   - With other family (Please say who)
   - Other (Please say who)

2. Which of these qualifications do you have?
   - School leaving certificate
   - At least one O-level/Standard Grade/GCSE
   - At least one Higher/A-level
   - GSVQ/SVQ
   - HNC/HND
   - Professional/technical qualification
   - Undergraduate university degree
   - Post graduate university degree
   - None of these
   - Other please state________________________

3. Can you be described by any of the following? (Please tick all that apply)
   - Retired
   - Caring for a dependent relative
   - Invalid/disabled
   - Voluntary worker
   - Unemployed
   - Student
   - Looking after home/family
   - Other
   - If other, please specify:
Accommodation

4. Do you:  (Please tick one box only)

- Own your home
- Rent your home
- Other (Please state.............................)

Thank you for helping us with this important research.

If you have any comments about any of the questions that we have asked, please add them here.

Thank you for completing this survey. Please return it using the reply-paid envelope provided (NO STAMP IS NEEDED).
Chest Symptoms That Call For Action

Be one step ahead

It’s as easy as

Special attention for people who may be at risk of lung disease
Chest symptoms that call for action

Liz Dawn, best known for her role as Vera Duckworth in Coronation Street, was diagnosed with emphysema in 2004.

She sends this message:

“I am in full support of this study. Anything that gets lung disease diagnosed more quickly is a good thing in my book. I wouldn’t be here now if it weren’t for the medication that I’m on. So I’m telling everyone, any symptoms go and get them sorted out…… now!!”

“Small cancers are much easier to cure, so don’t delay seeing your doctor with any warning symptoms.”

Dr Marianne Nicolson
Consultant Medical Oncologist
Aberdeen Royal Infirmary

“The biggest frustration with looking after people with lung disease is that many people (especially smokers) put up with worrying symptoms for too long. I would rather see a lot of people with worrying symptoms early, and be able to cure a lung disease such as lung cancer, rather than picking things up too late.”

Dr Graham Devereux
Consultant Respiratory Physician
Aberdeen Royal Infirmary
Why you should act on the symptoms of lung disease

Lung disease is on the rise in the UK. Acting quickly on the warning symptoms and signs of lung disease allows a diagnosis to be made and treatment to begin. The sooner lung disease is treated the better the outcome. Knowing what symptoms to look out for will put you one step ahead. Leaving lung disease untreated can mean a decreasing quality of life and, in the case of lung cancer, missing out on surgery that can cure. The doctors, practice nurses, and receptionists at your health centre are keen for you to make an appointment if you notice any warning symptoms.

Let your family, friends or carers read this handbook; there may be ways they can help.

Be one step ahead!

- Find out about your personal risk
- Find out about the warning symptoms of lung disease and what action to take
- Find out about the benefits of early diagnosis

It’s definitely worth your while
Who is more likely to develop lung disease?

If you can tick any of the boxes below you are more likely to develop lung disease and need to pay particular notice to symptoms

☐ Are or were a smoker
☐ Have a long history of passive smoking
☐ Have frequent chest infections
☐ Are 50 years or over
☐ Already have a lung disease
☐ Have a family history of lung disease
☐ Have been exposed to asbestos
☐ Have been exposed to industrial pollution

“These people are known as the ‘missing millions’ could you be one of them?”

“There are over 2 million people in the UK who have chronic lung disease and don’t know it.”
Myths about lung disease

People say: “Breathlessness comes with old age.”
The truth is: breathlessness is health related not age related.

People say: “Only people who are old and who have smoked get lung disease.”
The truth is: lung disease can affect young, old, male and female alike.

People say: “It’s just a smoker’s cough I’ve got.”
The truth is: if a smoker, an ex-smoker or non-smoker has a persistent cough it’s time to see a doctor. You don’t need to have smoked to get lung disease.

People say: “Lung cancer is not treatable.”
The truth is: lung cancer is treatable and, if it is caught early enough, it can be cured.

People say: “If you have COPD you won’t get better.”
The truth is: although COPD is a progressive disease, if treated early, its progression can be slowed with appropriate management and care.

(P COPD is a lung disease which includes chronic bronchitis and emphysema)

People say: “TB (tuberculosis) is not a common disease.”
The truth is: TB is on the increase especially in larger cities, but it is difficult to catch.

People say: “My parents smoked their whole lives and never got cancer so I won’t get cancer.”
The truth is: just because your parents didn’t get cancer doesn’t mean that you won’t get cancer.

The truth is: lung disease can be helped by treatment.
It’s as easy as 1 2 3

1 Look after number one
   Take control
   Listen to your body when it tells you something's not right.
   Know what symptoms of lung disease to look out for.

2 It takes two to tango
   Take action
   Bring symptoms to your doctor.
   Help your doctor to help you.

3 Remember the three week rule
   Don’t wait
   Don’t wait any longer than three weeks with symptoms.
   Phone for an appointment.

Some symptoms may need more immediate attention - see next page

Know the symptoms of lung disease
Symptoms that need attention now

Coughing up phlegm with signs of blood - if you are coughing up blood, the blood may be coming from your lungs but whatever the source of the blood you should get in touch with your doctor today.

Chest pain - chest pain can indicate a problem in the lung area but it could be heart related so you should get in touch with your doctor today. If you start to feel severe chest pain you should phone 999 (or 112 from a mobile phone).

Severe, sudden breathlessness - can be a sign of lung disease but could be heart related so you should get in touch with your doctor today.

For these other symptoms remember the three week rule

A cough - any cough that has lasted 3 weeks can be an important early symptom of lung disease regardless of whether you are a smoker, ex-smoker or have never smoked.

A worsening cough - if a cough changes, for example, become harsher or more persistent it needs checked out.

Breathlessness or worsening breathlessness - shortness of breath is not normal regardless of how old you are. Remember breathlessness is health related not age related.

Coughing up phlegm (sputum) - If you are coughing phlegm or sputum it needs checked out.

Shoulder or rib pain - a sharp pain or a dull ache in the shoulder or ribs can indicate a problem in the lung area. The pain/ache may be there all the time or only felt when breathing in or coughing.

Wheeze - noisy breathing or wheezing is a sign that something is blocking the airways of your lungs or making the airways too narrow.

Weight loss; loss of appetite; and severe, unusual tiredness - are also symptoms that can indicate an underlying problem, particularly if accompanied by any of the above symptoms.
It takes two to tango – so take action
Bring your symptoms to the doctor

Symptoms that need attention now

If you
Cough up phlegm with signs of blood in it
Have chest pains
Severe, sudden breathlessness

Then
Phone your surgery today to make an appointment.

Tell the receptionist
“I am part of the CHEST study. I have (whatever symptoms you have). Can I have an urgent appointment?”

For other symptoms remember the three week rule

If you have had any of the symptoms below for more than three weeks
A cough or a worsening cough
Breathlessness or worsening breathlessness
Coughing up phlegm
Shoulder or rib pain especially when breathing and coughing
Wheezing
Loss of weight
Loss of appetite
Severe, unusual tiredness

Then
Phone your surgery today to make an appointment.

Tell the receptionist
“I am part of the CHEST study. I have had (whatever symptoms you have) for more than three weeks. Can you arrange an appointment within 48 hours please?”

Help your doctor to help you
If you feel unwell when your health centre is closed call NHS 24 on 08454 24 24 24
Early diagnosis is the key to successful treatment

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Asthma</strong> - simple breathing tests may be done to confirm the diagnosis. Your doctor may give you medication that reduces asthma symptoms. If the medication works, this suggests that you may have asthma.</td>
<td>Most people with <strong>asthma can be treated very successfully</strong>. The treatment may mean medication that you inhale (breathe in from an inhaler or puffer) or pills.</td>
</tr>
<tr>
<td><strong>COPD</strong> (which includes chronic bronchitis and emphysema) - a simple breathing test called a spirometry can usually be done at your GP surgery. This will indicate whether your airways have narrowed. In some cases you may need more detailed tests and a referral to hospital.</td>
<td>A lot can be done to relieve the symptoms of <strong>COPD</strong> but there is no cure. If treated early, with appropriate management and care, <strong>its progression can be slowed</strong>. Stopping smoking also slows down the progression of the disease and reduces damage to the lungs.</td>
</tr>
<tr>
<td><strong>Lung cancer</strong> - most cases are first suspected through a chest X-ray. You may also have some blood taken for routine tests. Many people have a special X-ray called a CT scan. All the tests are simple, safe and painless and will help map out the extent of the tumour.</td>
<td>Lung cancer can be treated in a number of ways, including a combination of surgery, chemotherapy and radiotherapy. <strong>Surgery can cure lung cancer if it is caught early enough</strong>. Other treatments can stop it from spreading and relieve symptoms.</td>
</tr>
<tr>
<td><strong>Pneumonia</strong> - is usually diagnosed based on symptoms and physical examination. Diagnosing pneumonia can be difficult in some people, especially those who have other illnesses. Occasionally a chest x-ray or other tests may be needed to distinguish pneumonia from other illnesses.</td>
<td>Antibiotic treatment usually works well, and <strong>you can expect to fully recover</strong>. Symptoms settle over a few days if the treatment is working. You may feel tired for a week or so after the infection has cleared.</td>
</tr>
<tr>
<td><strong>TB</strong> - a chest x-ray will be taken which may suggest that TB is present. The diagnosis should be confirmed by obtaining phlegm for analysis. Only if the TB bacteria are found in the phlegm is a diagnosis proved. This may take a few weeks.</td>
<td><strong>TB can be cured completely</strong> in almost every case, but the full course of treatment must be taken otherwise the infection can return in a drug-resistant form.</td>
</tr>
</tbody>
</table>
Don’t wait with symptoms
Remember the three week rule

All these people with lung disease put off going to the doctor.

“Don’t really want to annoy the doctor with petty little things you know?”

“I just don’t like going to doctors that’s all.”

“It’s got to get really bad before I do something about it.”

“My friend had mentioned to me a few times about me being breathless and I just though, och it’s old age. I am 63 so I thought old age.”

“I just started to get a stiff shoulder blade and it went on for a while but I stuck it out because I do suffer from rheumatism.”

Don’t make their mistake. The sooner lung disease is diagnosed the better!

Remember

- If other people notice your symptoms, seriously think about what they’re saying and take action.
- Don’t just put symptoms down to other causes. It makes sense to have them checked out, even if you don’t like going to the doctor.
- Waiting until things get really bad could mean losing valuable treatment time. Your doctor would rather see you sooner than later.
Your personalised action plan

Looking after number one

Means there are things you can do, like checking for lung symptoms on a regular basis. A good time to do this, so that you remember, is on the 1st day of every month.

We could help you to remember.

What would be the best way of reminding you to check for symptoms?

- Text message to me  
- Postcard to  
- Stickers for me

What if on one of your regular checks you have symptoms from the symptom list on page seven?

If on one of my regular checks I have any symptoms from the list then I will………………………………………………………………………………………………
………………………………………………………………………………………………

What if you phone your health centre to make appointment and the number is busy?

If the health centre number is busy then I will………………………………………………………………………………………………
………………………………………………………………………………………………

What if you can’t get your usual doctor?

If I can’t get my usual doctor then I will………………………………………………………………………………………………
………………………………………………………………………………………………

What if taking the time to go and see a doctor is difficult?

If taking the time to see a doctor is difficult then I will………………………………………………………………………………………………
………………………………………………………………………………………………
Your personalised action plan

What if you have symptoms but don’t like going to the doctor?
If I have symptoms but don’t like going to the doctor then I will

What if after being to see a doctor your symptoms still don’t get better?
If after being to see a doctor my symptoms don’t get better then I will

What if you have symptoms at the weekend?
If I have symptoms at the weekend then I will

What if you have symptoms while on holiday?
If I have symptoms while on holiday then I will

What if the receptionist at your health centre offers you the practice nurse when you really want to see the doctor?
If the receptionist at my health centre offers me the practice nurse when I really want to see the doctor then I will

What if .................................................................
Then I will.................................................................
What will happen when I go to the doctor?

First, be assured that all the doctors at your health centre want you to bring any symptoms to them.

**Symptoms will be taken seriously**

Even if you have only one of the symptoms on page seven the doctors want to see you. They are there to help you.

Second, symptoms alone don’t usually give the full picture. To determine if you have a lung disease your doctor may:

- give you a physical examination
- check your medical history
- have some simple tests done

Any treatment or further investigations can then begin.

Third and most important, it’s worth having symptoms dealt with because treatments can make you feel better, improve your quality of life, and even extend your life!

“As a GP working to improve the lives of patients suffering from lung disease, I often meet patients who tell me they wished they had gone to the doctor earlier. Early diagnosis and help is of great importance and I would encourage people to use this excellent booklet to understand about symptoms and what they can do to help themselves.”

Dr Iain Small
Peterhead Health Centre

“As a GP I am all too aware of the consequences of a delayed diagnosis of lung disease for patients and their families. I urge patients to contact the surgery as soon as possible with any symptoms they are worried about. There is always a doctor available to speak to.”

Dr Peter Watson
Links Medical Practice
Frequently asked questions about lung disease

Q: What is lung disease?
A: Lung disease is any illness or disorder that stops the lungs working properly, this includes: ongoing diseases such as asthma, COPD (which includes chronic bronchitis and emphysema); infections such as TB and pneumonia; cancers such as lung cancer and the much less common asbestos cancer (mesothelioma).

Q: Is lung disease a common health problem?
A: Yes but many people don’t realise they have it and miss out on treatments that can make them feel better. So it makes sense to tell your doctor about any symptoms.

Q: Should I be worried about lung disease?
A: Yes, because lung disease is on the rise. More people in the UK die from lung disease than coronary heart disease. So don’t hang about with symptoms, get them checked out.

Q: Can it be treated?
A: Yes, most lung diseases are helped by treatment and some can be cured. If you have any symptoms from the list on page seven get them checked out, you’ve nothing to lose.

Q: Is lung disease always caused by smoking?
A: No, people who have never smoked get lung disease too.
Mike’s story

September 2003  “I never gave my health a thought at all”

October 2003  “The first thing I noticed was I started to get a wee cough and this cough kept annoying me.”

November 2003  “I thought it was just an ordinary cough, just bear with it sorta thing and it’ll go away itsel’, taking Lemsips, this type o’ thing.”

January 2004  “But the cough was with me, it was always with me, but as I say apart from that I felt reasonably okay, I had no pain or anything like this, nothing obvious at all.”

March 2004  “Then I started to feel a bit tired, I put it down to moving house but I still had the cough.”

May 2004  “Then I started to get this sort of hoarseyness”

July 2004  “I said ‘Och I better go an see about this cough’, so I went tae my local doctor.”

August 2004  “I was sent for an x-ray. They noticed a shadow on the lung. Then they sent me for more tests.”

September 2004  “Then they told me unfortunately it was lung cancer I had. So the treatment started after that.”

Whether someone is a smoker, an ex-smoker or has never smoked, a cough that lasts for more than three weeks needs checked out.
Yvonne’s message

Yvonne was diagnosed with lung cancer in 2006. She stopped smoking nearly a decade ago. Yvonne’s cancer was operable and she has undergone successful surgery to remove part of her lung. Yvonne feels there is a positive message to lung cancer and there is hope for people.

“I really am one of the lucky ones. I am alive and feeling well. It’s important to tell people that you can survive and extend your life if you catch the disease early enough.”
# Lung disease explained

<table>
<thead>
<tr>
<th>Disease</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Asthma</strong></td>
<td>Asthma is inflammation and tightness in the airways. The airways become narrow and sometimes produce more mucus than usual. This makes it difficult to breathe. Asthma often starts in childhood, but it can happen for the first time at any age – even in people in their 70s or 80s.</td>
</tr>
<tr>
<td><strong>COPD</strong></td>
<td>COPD is a disease that leads to gradual damage to the airways in the lungs causing them to become narrower and making it harder for air to get in and out of the lungs. COPD stands for Chronic Obstructive Pulmonary Disease and includes conditions such as chronic bronchitis and emphysema. The word 'chronic' means that the problem is long-term.</td>
</tr>
<tr>
<td><strong>Lung cancer</strong></td>
<td>Lung cancer is the uncontrolled growth of abnormal cells in the lung which forms a lump or tumour. Lung cancer develops in the tubes that carry air in and out of the lungs (your airways). It can grow within the lung, and it can spread outside the lung.</td>
</tr>
<tr>
<td><strong>Pneumonia</strong></td>
<td>Pneumonia is an infection which causes the air sacs in the lungs and the smaller bronchial tubes to become inflamed and fill with fluid. This makes it hard for the lungs to do their job.</td>
</tr>
<tr>
<td><strong>TB (Tuberculosis)</strong></td>
<td>TB (Tuberculosis) is an infection caused by a germ. It most commonly affects the lungs, and is caught from other people coughing and sneezing. The body's immune system usually destroys the germs once they are inhaled, but they may cause an illness weeks or even months later.</td>
</tr>
</tbody>
</table>
Support Helplines

- **British Lung Foundation** The British Lung Foundation offers advice and support for anyone affected by a lung condition.
  Helpline: 08458 50 50 20
  Website: www.lunguk.org

- **Breathe Easy** Breathe Easy is the British Lung Foundation support group network where people living with lung disease and their family, friends, and carers can come together and share experiences.
  Tel: 0141 248 0050
  Email: scotland@blf-uk.org

- **CancerHelp UK** is an information service for anyone that has a question about cancer. Lines are open Monday to Friday, between 9am and 5pm.
  Call their team of Specialist Nurses on 020 7061 8355
  Or their free Helpline: 0808 8004040
  Website: www.cancerhelp.org.uk

- **Asthma UK** The Asthma UK Advice line team of asthma nurse specialists will give you independent, confidential advice about asthma.
  Helpline: 08457 01 02 03
  Email: an asthma nurse specialist
  Website: www.asthma.org.uk
## More sources of information about lung disease

<table>
<thead>
<tr>
<th>Condition</th>
<th>Source</th>
<th>Contact Information</th>
</tr>
</thead>
</table>
| **COPD (Chronic bronchitis and emphysema)** | The British Thoracic Society [COPD](https://www.brit-thoracic.org.uk) information for the public. | Tel: 020 7831 8778  
Email: bts@brit-thoracic.org.uk  
Web: [www.brit-thoracic.org.uk](https://www.brit-thoracic.org.uk) |
| **TB (Tuberculosis)**            | Patient information booklet about TB from NICE (The National Institute for Health and Clinical Excellence). | Tel: 0870 1555 455  
Web: [www.nice.org.uk](https://www.nice.org.uk) |
| **Lung Cancer**                  | Patient information booklet about lung cancer from [SIGN](https://www.sign.ac.uk) (The Scottish Intercollegiate Guidelines Network). | Tel: 0131 718 5090  
Email: karen.graham2@nhs.net  
Web: [www.sign.ac.uk](https://www.sign.ac.uk) |
| **Asbestos cancer** (Mesothelioma) | UK Patient Information Guide: [Mesothelioma](https://www.cancerbackup.org.uk) from Cancerbackup the UK’s leading information charity. | Tel: 0808 800 1234  
Web: [www.cancerbackup.org.uk](https://www.cancerbackup.org.uk) |
If you do notice any symptoms it may be helpful to tick them on the list below. You can then remove this page and take it with you to the doctor.

<table>
<thead>
<tr>
<th>Tick and Take</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coughing up phlegm with signs of blood in it</td>
</tr>
<tr>
<td>Chest pains</td>
</tr>
<tr>
<td>Severe, sudden breathlessness</td>
</tr>
<tr>
<td>A cough or a worsening cough</td>
</tr>
<tr>
<td>Breathlessness or worsening breathlessness</td>
</tr>
<tr>
<td>Coughing up phlegm</td>
</tr>
<tr>
<td>Shoulder or rib pain especially when breathing and coughing</td>
</tr>
<tr>
<td>Wheezing</td>
</tr>
<tr>
<td>Loss of weight and appetite</td>
</tr>
<tr>
<td>Severe, unusual tiredness</td>
</tr>
</tbody>
</table>
OUR MESSAGE TO YOU

REMEMBER 1,2,3

1. Look after number one – know what symptoms to look out for
2. It takes two to tango – bring symptoms to your doctor
3. The three week rule – don’t wait with symptoms

KNOW YOUR ACTION PLAN

- When to check for symptoms
- What to do if you have symptoms
- When to make that appointment

YOU’VE NOTHING TO LOSE AND A LOT TO GAIN

- Treatment can help you feel better
- Treatment can help improve your quality of life
- Treatment can help extend your life

MAKE IT HAPPEN!
A.3. Scottish Research Nurse Consultation

Research Nurse Consultation

Draft Script, Version 2, August 2012

Digitally record

“Good morning/afternoon, thank you for coming today. We spoke on the phone my name is ________________, and I am a researcher for the study. We’re meeting today so that you can learn how you can look after your health better by knowing when to contact a doctor if you have any lung problems – people tend to wait too long because they are not sure when to come.”

We will have a look through some of this booklet together to make sure you know what you’re expected to do. “Do you feel happy with that?”

**IF NOT, TRY AND ADDRESS ANY CONCERNS, BUT ULTIMATELY DO WHAT THE PARTICIPANT IS HAPPY WITH. REMEMBER THE FOCUS IS ON THE PARTICIPANT LEARNING WHAT THEY HAVE TO DO WHEN THEY EXPERIENCE SYMPTOMS.**

**IF HAPPY**

**Front cover.** “The booklet is specifically designed to make sure that people know what they have to do if they ever notice any symptoms that might indicate a lung problem. It’s all about trying to put you one step ahead, a good position to be in if you ever develop any symptoms.”

**P1** There are doctors from the University of WA, Monash and Aberdeen that support the study as well as the doctors here at your health centre.

**P3. Why you should act on the symptoms of lung disease?**

“The sooner lung disease is diagnosed the better because getting treatment for lung disease can help a person to keep their quality of life, and in the case of a lung disease such as lung cancer, it can mean getting the chance of surgery that can cure. So really what we would like you to do is look after yourself by looking out for any symptoms of lung disease, and this booklet is here to help you do that. It really is as easy as 1,2,3 as the booklet says.”

**P4. Who is more likely to develop lung disease?**
“If you can tick any of the boxes you are more likely to develop lung disease so you need to pay particular notice to symptoms.”

P5 Myths about lung disease

“Is a good page to look through in your own time. For example people may think that as they get older they should expect to get breathless, but this is not true. Breathlessness is health related not age related.”

P6. It’s as easy as 1,2,3

READ PAGE FROM BOOKLET, AFTER ‘IT TAKES TWO TO TANGO’ SECTION SAY:

“Your doctor can only help you if you bring any worrying symptoms to them to be checked out. You’ve nothing to lose.”

THEN CONTINUE READING THE REST OF THE PAGE.

P7. Look after number one. Know the symptoms of lung disease. READ PAGE FROM BOOKLET

Start with: “These are all the symptoms that you need to look out for and have checked out by a doctor.”

After ‘symptoms that need attention now’ finish with: “They may arrange for you to speak to a doctor who will decide the best course of action.”

After ‘other symptoms’ finish with: “Don’t wait longer than three weeks. Make an appointment to see a doctor.

Then ask: “Do you have any of these symptoms at the moment?”

IF YES ADVISE MAKING APPOINTMENT AND TICK RELEVANT BOX IN THE TEST RESULTS SHEET.

P8. ‘It takes two to tango’

Start with: “Means that unless you bring your symptoms to the doctor he or she can’t help you. So act on any symptoms you notice.” Then read rest of the page.
P9. Early diagnosis is the key to successful treatment

*Start with:* “This page describes how each of these diseases are diagnosed and treated. If you notice”:

*Read only the positive message in bold from booklet*

e.g. “Asthma can be treated very successfully”

*Then:* “So much can be done for lung disease and the secret is early diagnosis, so it’s worthwhile looking out for symptoms and acting on them.”

P10. Remember the three week rule. Don’t wait with symptoms. *JUST READ THROUGH PAGE.*

P11-12. Your personalised action plan
READ PAGE FROM BOOKLET UP UNTIL THE START OF QUESTIONS.

(We need verbal permission if they want a text message, postcard, or stickers.)

“And supposing its not very easy to get an appointment – what will you do in the following situations. We will discuss these situations now and leave them for you to fill in when you get home. We can also help you think of ways to overcome any difficulties you may foresee.

Complete all questions

Suggestions to overcome difficulties if the participant is unsure

Q. What if on one of your regular checks you have symptoms from the symptom list on page eight?

A Then I will follow the instructions in the booklet

Q. What if you phone the health centre and the number is busy?

A. Then I will keep trying until I get through (or if practice is near pop along in person/use ring back)

Q. What if you can’t get your usual doctor?

A. Then I will ask to see any doctor because waiting for an appointment with my usual doctor could mean losing valuable treatment time

Q. What if taking the time to go and see a doctor is difficult?

A. Then I will make the time/ WORK organise time-off with work/HOME COMMITMENTS organise someone to be at home while I get to the doctor

Q. What if you have symptoms but don’t like going to the doctor?
A. Then I will go anyway because it’s better to be safe than sorry and I know I don’t need to worry about wasting the doctor’s time.

Q. What after being to see a doctor your symptoms still don’t get better?

A. Then I will arrange another appointment.

Q. What if you have symptoms at the weekend or while on holiday?

A. If at weekend phone- after hours GP/JHC. If on holiday I will seek immediate medical help for chest pain, coughing up blood, severe, sudden breathlessness and if I have any other symptoms for more than 3 weeks I will arrange an appointment as soon as you return or get someone at home to arrange one for me.

Q. What if you are not offered an appointment within 3 days?

A. Then I will let the receptionist know I am part of the CHEST trial and I am really worried about my symptoms and that I need to see a doctor within 3 days

“We’ll quickly run through the rest of the booklet and I’ll leave you to read it more fully in your own time.”

P13. What will happen when I go to the doctor

“This is to let you know that symptoms will be taken seriously by your doctor. Doctors in this practice are supportive of this study.”

P14. Answers FAQ’s about lung disease

P15-16 Give accounts of other peoples experience of lung disease and are worth reading
P17 Lung disease explained

“Gives a fuller explanation of each lung disease that we discussed earlier on.”

P18-19 Give details of helplines and other sources of information about lung disease.

P20-24 A helpful list to take to the doctor

“If you do notice any symptoms you can tick them on this list, remove this page and take it with you to the doctor. This can be a help to you both and there are more lists if you need them.”

“So – to recap – the important thing to remember is your action plan – on pages 11 and 12.

I hope you find the booklet interesting when you have time to look through it more fully. You might want to discuss it or go through it with someone else – your wife/husband or a friend? Do you have any questions that you would like to ask?”

Answer any questions – remember the emphasis is on ensuring that they know what they have to do.

“If you have any questions about what we’ve discussed or about the booklet when you’ve had more time to read it – you can contact Jon Emery, Sonya Murray whose details you’ll find on the green information sheet that was sent to you in the post”.

Advise any participant to make an appointment with a doctor on their way out if they have HBP, or signs of COPD, or any symptoms from the symptom checklist.

Thank you again for coming. Don’t forget - you can look after your health better by ensuring you come to the doctor at the right time - it’s as easy as 1,2,3 – know what to look out for - just check page 7 – and be prepared to take action by making an appointment with your doctor.

If any participant asks for smoking cessation advice they need to see the doctor and Quitline.

ADDIT: verbal consent to accessing notes confidentially to see if they have presented for chest related symptoms & focus on lung cancer during intervention
Appendix B.  

**Exclusion criteria for GP Medical Software**

As specified in Chapter 3 (Section 3.3.1.3) the exclusion criteria for the CHEST trial were severe psychiatric or cognitive disorder or a previous diagnosis of lung cancer. Additional terms for exclusion used for the three different general practice software programmes, Medical Director, Best Practice and Zedmed are described below.
### B.1. Medical Director 3

#### SEVERE PSYCHIATRIC ILLNESS

<table>
<thead>
<tr>
<th>Medical Condition</th>
<th>Medical Condition</th>
<th>Medical Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcoholic encephalopathy</td>
<td>Encephalopathy - hepatic</td>
<td>Olfactory hallucination</td>
</tr>
<tr>
<td>Alzheimer’s Disease</td>
<td>Encephalopathy - Wernicke’s</td>
<td>Paranoid schizophrenia</td>
</tr>
<tr>
<td>Auditory hallucination</td>
<td>Encephalopathy - Liver Failure</td>
<td>Pick’s disease</td>
</tr>
<tr>
<td>Borderline schizophrenia</td>
<td>Fetal belief</td>
<td>Pseudo-dementia</td>
</tr>
<tr>
<td>Brain Injury</td>
<td>Fragile X Syndrome</td>
<td>Psychosis</td>
</tr>
<tr>
<td>Brain Trauma</td>
<td>Hallucination</td>
<td>Psychosis - Drug Induced</td>
</tr>
<tr>
<td>Brief reactive schizophrenia</td>
<td>Hallucination - auditory</td>
<td>Psychosis - Korsakoff’s</td>
</tr>
<tr>
<td>Catatonic schizophrenia</td>
<td>Hallucination - olfactory</td>
<td>Psychotic disorders</td>
</tr>
<tr>
<td>Cerebral Injury</td>
<td>Hallucination - visual</td>
<td>Schizoaffective disorder</td>
</tr>
<tr>
<td>Chronic Schizophrenia</td>
<td>Hallucinogen abuse</td>
<td>Schizophrenia</td>
</tr>
<tr>
<td>Cognition - abnormally low</td>
<td>Head injury</td>
<td>Schizophrenia - borderline</td>
</tr>
<tr>
<td>Concussion</td>
<td>Head Trauma</td>
<td>Schizophrenia - brief</td>
</tr>
<tr>
<td>Delusions</td>
<td>Hearing voices</td>
<td>Schizophrenia - catatonic</td>
</tr>
<tr>
<td>Demented state</td>
<td>Hepatic Pre-coma</td>
<td>Schizophrenia - chronic</td>
</tr>
<tr>
<td>Dementia</td>
<td>Injury - Brain</td>
<td>Schizophrenia - paranoid</td>
</tr>
<tr>
<td>Dementia - Lewy-Body</td>
<td>Liver Failure - Encephalopathy</td>
<td>Schizophreniform disorder</td>
</tr>
<tr>
<td>Dementia - Multi-infarct</td>
<td>Korsakoff’s dementia</td>
<td>Trauma - head</td>
</tr>
<tr>
<td>Dementia - Pick</td>
<td>Korsakoff’s psychosis</td>
<td>Trisomy 13</td>
</tr>
<tr>
<td>Dementia - Pseudo</td>
<td>Korsakoff’s psychosis</td>
<td>Trisomy 18</td>
</tr>
<tr>
<td>Dementia - Vascular</td>
<td>Mental subnormal</td>
<td>Trisomy 21</td>
</tr>
<tr>
<td>Down syndrome</td>
<td>Mentation - Subnormal</td>
<td>Vascular dementia</td>
</tr>
<tr>
<td>Drug induced Psychosis</td>
<td>Mentation retarded</td>
<td>Visual hallucination</td>
</tr>
<tr>
<td>Encephalopathy</td>
<td>Multi-infarct dementia</td>
<td></td>
</tr>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

254 | Page
B.2. Best Practice

SEVERE PSYCHIATRIC ILLNESS

<table>
<thead>
<tr>
<th>Alcoholics encephalopathy</th>
<th>Encephalopathy</th>
<th>Pick's disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alzheimer's disease</td>
<td>Encephalopathy, hepatic</td>
<td>Psychosis</td>
</tr>
<tr>
<td>Auditory hallucinations</td>
<td>Encephalopathy, Wernicke's</td>
<td>Psychosis, drug induced</td>
</tr>
<tr>
<td>Borderline schizophrenia</td>
<td>False belief</td>
<td>Psychosis, Korsakoff's</td>
</tr>
<tr>
<td>Brain injury</td>
<td>Fragile X Syndrome</td>
<td>Psychotic disorder</td>
</tr>
<tr>
<td>Brain trauma</td>
<td>Hallucinations</td>
<td>Psychotic disorder, brief</td>
</tr>
<tr>
<td>Brief psychotic disorder</td>
<td>Hallucinations, auditory</td>
<td>Schizoaffective disorder</td>
</tr>
<tr>
<td>Brief reactive schizophrenia</td>
<td>Hallucinations, olfactory</td>
<td>Schizophrenia</td>
</tr>
<tr>
<td>Catatonic schizophrenia</td>
<td>Hallucinations, visual</td>
<td>Schizophrenia, borderline</td>
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LUNG CANCER

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### B.3. ZedMed Tool

#### SEVERE PSYCHIATRIC ILLNESS

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#### LUNG CANCER

- Carcinoma of the lung
- Mesothelioma
- Malignant neoplasm of the lung
- Carcinoma of the bronchus
- Malignant neoplasm of the bronchus
Appendix C.  Phase 1 results

Appendix C contains the raw data for the 11 patients recruited into the Phase I trial.

The first three tables show the patient average score at baseline, one month and six months for each of the nine outcome measures. Individual bar graphs showing the change in scores at each time point are also displayed for each patient.
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<th>Intention To Consult</th>
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<td></td>
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<td>-13.39%</td>
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<tr>
<td>% Change from Baseline</td>
<td></td>
<td>-9.78%</td>
<td>1.31%</td>
<td>-3.84%</td>
<td>3.58%</td>
<td>-5.72%</td>
<td>-18.25%</td>
<td>-21.48%</td>
<td>-25.31%</td>
<td>55.56%</td>
</tr>
</tbody>
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Patient 1

Knowledge Of Symptoms  Risk of Lung Disease  Intention To Consult  Self Efficacy  Views On Own Health  HADS Anxiety  HADS Depression  HADS Total  Cancer Worry

Patient 2

Knowledge Of Symptoms  Risk of Lung Disease  Intention To Consult  Self Efficacy  Views On Own Health  HADS Anxiety  HADS Depression  HADS Total  Cancer Worry
Appendix D contains all the CHEST-Australia material designed for the Phase II trial in Perth and Melbourne.
**Who are we?**

"The biggest frustration with looking after people with lung disease is that many people (especially smokers) put up with worrying symptoms for too long. We would rather see a lot of people with worrying symptoms early, and be able to cure a lung disease such as lung cancer, rather than picking things up too late."

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**Further information and contact details**

Please feel free to contact Sonya Murray or Jon Emery if you have any question.

Sonya Murray, Trial Coordinator - CHEST Australia
School of Primary, Aboriginal and Rural Health
University of Western Australia
N Block, QAL Medical Centre, Nedlands, WA 6009
Tel: 08 9346 7237

Professor Jon Emery
Clinical Professor of General Practice, University of Western Australia.
Herman Professor of Primary Care Cancer Research,
University of Melbourne.
General Practice and Primary Care Academic Centre,
205 Bentley Street, Carlton, VIC 3053.
Tel: 03 9238 0018.

Who has reviewed the study? All research in the University is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. A copy of the approved Research Ethics Committee Approval number R4/4/1698.

What if there is a problem? If you have any complaints or concerns about the way in which the study is being conducted, you can contact the Chairperson of the Research Ethics Committee via 08 9327 1121.

**Chest Symptoms That Call For Action**

"It's as easy as 1 2 3 CHEST Australia".

**Thank you for taking the time to read this information sheet**

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**PARTICIPANT INFORMATION BROCHURE**

We would like to invite you to take part in a research study. Before you decide if you would like to take part it is important for you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Discuss it with relatives and friends, and your GP if you wish. Ask us if there is anything that is not clear or if you would like more information (contact details at the end). Take time to decide whether or not you wish to take part.

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**Thank you for taking the time to read this information sheet**

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**If you are happy to take part in the study please read and fill in the enclosed Expression of Interest form and return it in the reply paid envelope.**

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**Special attention for people who may be at risk of lung disease**

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**Who has reviewed the study?**

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**What if there is a problem?**

If you have any complaints or concerns about the way in which the study is being conducted, you can contact the Chairperson of the Research Ethics Committee via 08 9327 1121.

**What this study requires from you**

Once you have agreed to take part and signed consent form, you will be randomly allocated to one of two groups of the study. Randomisation means that you are put into a group by chance, like the toss of a coin. A statistician at the University of Western Australia will randomise you. Neither you nor your doctor can choose the group you will be in.

You will be invited to attend a 25-30 minute appointment at your general practice to discuss lung health and have a "spirometry test" to measure lung health.

You may also receive our self-help booklet.

Completing a questionnaire at three different time points in the study:

**Why have I been invited?**

People's views are important when planning health care services. We are looking for 550 volunteers to take part in the study who are aged 55 or over, who smoke or who have previously smoked.

**Do I have to take part?**

No, taking part is voluntary. If you would prefer not to take part, you do not have to give a reason.

**Will I be paid to take part?**

We cannot pay you to take part. However, we will refund all reasonable travel expenses you pay because of taking part.

**How can I help?**

We have designed a self-help booklet on lung disease which aims to encourage early consultation with symptoms that require investigation.

We now need to know if this booklet would be helpful and we would like people to test their lung function at the University.

Participation involves:

- Attending a 25-30 minute appointment at your general practice to discuss lung health and have a "spirometry test" to measure lung health.
- You may also receive our self-help booklet.
- Completing a questionnaire at three different time points in the study.

**What is the purpose of the CHEST study?**

The CHEST study aims to encourage people with symptoms of lung disease to consult their doctor earlier.

Approximately 14% of all deaths each year in Australia are as a result of lung disease, however many people are unaware of what symptoms to look out for.

Symptoms of lung disease, including lung cancer, are often put down to other causes, or not considered serious enough to seek medical help. This can mean the disease is not diagnosed until it has reached an advanced stage.

We know that treatments for lung disease are more effective if started at an early stage.

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**Do I have to take part?**

No, taking part is voluntary. If you would prefer not to take part, you do not have to give a reason. The care you receive will not be affected.

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We cannot pay you to take part. However, we will refund all reasonable travel expenses you pay because of taking part.

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D.2. Phase 2 GP Information Sheet

Who are we?

Associate Professor
David Barnes

“"The biggest frustration with looking after people with lung disease is that many people (especially smokers) just up with worrying symptoms for too long. We would rather see a lot of people with worrying symptoms early, and be able to cure a long disease such as lung cancer, rather than picking things up too late.”

Professor Jon Emery

Further information and contact details

We thank you for your help and interest.
Please feel free to contact Sonya Murray or Jon Emery if you have any questions.

Sonya Murray
Trial Coordinator - CHEST Australia
School of Primary, Aboriginal and Rural Health
University of Western Australia
N Block, DER Medical Centre, Nedlands, WA 6009
Tel: 08 9346 7237

Professor Jon Emery
Clinical Professor of General Practice, University of Western Australia.
Harman Professor of Primary Care Research, University of Melbourne,
Director, University of Melbourne Clinical Trials Group
Professor of General Practice and Primary Care Academic Centre
200 Berkeley Street, Carlton, Vic 3053,
Tel: 03 9335 8018

If you are happy for your practice to participate in the CHEST study, please contact Sonya Murray (contact details above).

Special attention for people who may be at risk of lung disease

General Practice INFORMATION BROCHURE

What is the Project?

Project Title
CHEST Australia: reducing time to consult with patients of lung cancer
Purpose
This randomised controlled trial tests a novel intervention in general practice aimed at improving early consultation by people at higher risk of lung cancer.
Who is the lead researcher?
Professor Jon Emery, Jon is currently the Clinical Professor of General Practice, University of Western Australia, the Herman Professor of Primary Care Cancer Research, University of Melbourne and the Chairperson of the Research Ethics Committee.
What is the purpose of the research study?
Approximately 12% of all deaths each year in Australia are a result of lung diseases. Symptoms of lung disease, including lung cancer, are often put down to other causes, or not considered serious enough to seek medical help. This can mean the disease is not diagnosed until it is far advanced and often beyond cure. We believe that by offering a simple self-help information booklet, we can extend early consultation with symptom and require investigation. We now need to assess whether the booklet would be helpful and we would like people living in the Perth and Melbourne Metro areas to assist us with this.
How will consent and confidentiality be handled?
All information which is collected about a patient during the course of the research will be kept strictly confidential, and any information about the patients which leaves the surgery will have name and address removed so that the patient cannot be identified. All information stored at the practice will be kept securely and destroyed after a period of five years.
Information needs to be obtained from our practice?

Is the GP involved?

Yes. We will pay practice $800-$1000 to participate depending on practice size and number of potentially eligible patients. This is to cover any administrative or time costs associated with supporting the study.

What does the GP have to do?

Every month we ask if the Practice Manager can check to see if any patients we have seen have consulted again about anything respiratory related. All patients will have signed consent forms to allow this to occur. The medical receptionists just need to be aware the research is there on a certain day during the recruitment time frame (usually 2-4 months).

Will the General Practice be paid to participate?

Yes. We will pay each practice $800-$1000 to participate depending on practice size and number of potentially eligible patients. This is to cover any administrative or time costs associated with supporting the study.

How long will the researcher be at the practice for?

This will depend on the availability of the rooms and the number of patients eligible in your practice. Usually, for a mid-size practice, recruitment will take from 2-4 months.

What does the GP have to do?

We require support from the GP for the study. We will also inform the GP of the patients’ symptoms and we are advised by the ethics committee to let the GP know if a patient obtains a score indicative of possible clinical anxiety or depression on the basis of their score on the Hospital Anxiety and Depression Questionnaire (HADs).

What do the Practice Manager or other staff members have to do?

Every month we ask if the Practice Manager can check to see if any patients we have seen have consulted again about anything respiratory related. All patients will have signed consent forms to allow this to occur. The medical receptionists just need to be aware the research is there on a certain day during the recruitment time frame (usually 2-4 months).

Is the GP involved?

Yes. We will pay practice $800-$1000 to participate depending on practice size and number of potentially eligible patients. This is to cover any administrative or time costs associated with supporting the study.

Who is organising and funding the research?

The project is being organised by the School of Primary, Aboriginal, and Rural Health Care (SPEAR) at the University of Western Australia. The General Practice Academic Centre at University of Melbourne, and the Academic General Practice Department, University of Aberdeen, Scotland, United Kingdom receives funding from the National Health and Medical Research Council (NHMRC) for four years.

Who has reviewed the study?

This study has been reviewed and given approval by the University of Western Australia Research Ethics Committee (Approval number 04/470/3.1). If you have any comments or concerns about the way in which the study is being conducted, you may contact the Chairperson of the Research Ethics Committee (Rev J 3271621).

Additional Information

What is the purpose of the research study?

We have designed a self-help booklet to assist us with symptoms of lung disease. Symptoms of lung disease, including lung cancer, are often put down to other causes, or not considered serious enough to seek medical help. This can mean the disease is not diagnosed until it is far advanced and often beyond cure. We believe that by offering a simple self-help information booklet, we can extend early consultation with symptom and require investigation. We now need to assess whether the booklet would be helpful and we would like people living in the Perth and Melbourne Metro areas to assist us with this.

What happens at one of the patient consultations?

Patient participation involves:
- Attending a 20-30 minute appointment at your general practice to discuss lung health and agree on a "symptom alert" to measure lung function. We will do this on 2 occasions to check on your progress. The "symptom alert" will be given a code so that we can check on your progress. The "symptom alert" will be given a code so that we can check on your progress.
- Completing a consent form to allow us to check if the patient consults again with respiratory symptoms over the next 12 months.
- Possibility to receive our self-help booklet and reminders to monitor their symptoms (intervention group).
- Completing a questionnaire at three different time points in the study.
- Help us to identify which patients are eligible for our trial. We have designed a self-help booklet (see above) which identifies eligible patients who are at high risk of lung cancer. The practice will test out 5 minutes with the support of your Practice Manager. Eligible patients are long-term smokers with at least 20 pack years, aged 55 and over, including ex-smokers and smokers if their cessation date was less than 15 years ago. Participants are eligible in your practice. Usually, for a mid-size practice, recruitment will take from 2-4 months.

What are the exclusion criteria?

Exclusion criteria will be severe psychiatric or cognitive disorder or previous diagnosis of lung cancer.

General Practice Involve

Who is the lead researcher?

Professor Jon Emery, Jon is currently the Clinical Professor of General Practice, University of Western Australia, the Herman Professor of Primary Care Cancer Research, University of Melbourne and the Chairperson of the Research Ethics Committee.

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D.3. Research Consultation Script

Introduction

“Good morning/afternoon, thank you for coming in today. We spoke on the phone my name is [Researcher], and I am a researcher from the University of Melbourne/Western Australia. We’re meeting today so that you can learn how you can look after your health better by knowing when to contact a doctor if you have any lung problems – people tend to wait too long because they are not sure when to come.”

Do you have the questionnaire with you? – Have a look through (check they have answered all of the questions; check their breathlessness score and self-harming question).

Today, first I will get you to read through and sign some forms (point to forms on the table), while I make a short phone call to see which group you are in, then we will do a spirometry test to check your lung function and then talk about lung health.

Which GP do you see here at the clinic?

So just to confirm your information here (looking at the expression of interest form), you roughly smoke(ed) x amount of cigarettes per day?

You started when you were about x old?

Why did you start smoking?

And you stopped about the age of x? Was that for any particular reason?

And you were born on the xx/xx/xxxx?

Great, now I have two forms here for you to read, they are the consent forms for the study – if you could just read through these and sign them if you are happy with all the information there and while you are doing that I will just make this quick phone call. Ask them to put their Medicare card number onto the form.

Feel free to ask me any questions.

Call up and randomise the patient. Check through forms and ask if they would like a copy of the consent forms. Once happy continue.
Spirometry

Conduct the **spirometry test**.

Ask for weight and height measurements if known – otherwise measure

Add information into the already set up spirometry program.

Get them to sit facing the computer while you stand next to them. Ask them if they have ever done a spirometry test before

Before you start explain: **You need to take a big deep breath in and then blow out as hard and as quickly as you can.**

**We will do the test three times. Try not to bite or stick your tongue out or cough while taking the test.**

Ask them to place the peg over their nose and start when they are ready.

Once completed explain that you are not a health professional and therefore cannot officially give you your results, but a copy will be provided to your GP, if you are interested you should ask your GP next time you see them. Have a quick look and see if above or below 60%, if above explain that 60 is the cut off and anything above that is good. It indicates that there is nothing obstructing your air flow. Your GP will explain further.

**Intervention booklet:**

We will have a look through some of this booklet together to make sure you know what you’re expected to do. “Do you feel happy with that?

**IF NOT, TRY AND ADDRESS ANY CONCERNS, BUT ULTIMATELY DO WHAT THE PARTICIPANT IS HAPPY WITH. REMEMBER THE FOCUS IS ON THE PARTICIPANT LEARNING WHAT THEY HAVE TO DO WHEN THEY EXPERIENCE SYMPTOMS.**

**IF HAPPY – continue...**

Front cover. “The booklet is specifically designed to make sure that people know what they have to do if they ever notice any symptoms that might indicate a lung problem. It’s all about trying to put you one step ahead, a good position to be in if you ever develop any symptoms.”
P1. There are doctors from the University of Melbourne, WA, Monash and Aberdeen that support the study as well as the doctors here at your health centre.

P3. Why you should act on the symptoms of lung disease?

“The sooner lung disease is diagnosed the better because getting treatment for lung disease can help a person to keep their quality of life, and in the case of a lung disease such as lung cancer, it can mean getting the chance of surgery that can cure. So really what we would like you to do is look after yourself by looking out for any symptoms of lung disease, and this booklet is here to help you do that. It really is as easy as 1, 2, 3 as the booklet says.”

P4. Who is more likely to develop lung disease?

“If you can tick any of the boxes you are more likely to develop lung disease so you need to pay particular notice to symptoms.”

P5. Myths about lung disease

“This is a good page to look through in your own time. For example people may think that as they get older they should expect to get breathless, but this is not true. Breathlessness is health related not age related.”

P6. It’s as easy as 1, 2, 3

READ PAGE FROM BOOKLET, AFTER ‘IT TAKES TWO TO TANGO’ SECTION SAY:

“Your doctor can only help you if you bring any worrying symptoms to them to be checked out. You’ve nothing to lose.”

THEN CONTINUE READING THE REST OF THE PAGE.

P7. Look after number one. Know the symptoms of lung disease. READ PAGE FROM BOOKLET

Start with: “These are all the symptoms that you need to look out for and have checked out by a doctor.”

After ‘symptoms that need attention now’ finish with: “They may arrange for you to speak to a doctor who will decide the best course of action.”
After ‘other symptoms’ finish with: “Don’t wait longer than three weeks. Make an appointment to see a doctor.

Then ask: “Do you have any of these symptoms at the moment?”

IF YES ADVISE MAKING APPOINTMENT AND TICK RELEVANT BOX IN THE TEST RESULTS SHEET.

P8. ‘It takes two to tango’

Start with: “Means that unless you bring your symptoms to the doctor he or she can’t help you. So act on any symptoms you notice.” Then read rest of the page.

P9. Early diagnosis is the key to successful treatment

Start with: “This page describes how each of these diseases are diagnosed and treated. If you notice”:

Read only the positive message in bold from booklet

e.g. “Asthma can be treated very successfully”

Then: “So much can be done for lung disease and the secret is early diagnosis, so it’s worthwhile looking out for symptoms and acting on them.”

P10. Remember the three week rule. Don’t wait with symptoms. JUST READ THROUGH PAGE.

P11 – 12. Your personalised action plan

READ PAGE FROM BOOKLET UP UNTIL THE START OF QUESTIONS.

(We need verbal permission if they want a text message, postcard, or stickers.)

“And supposing it’s not very easy to get an appointment – what will you do in the following situations. We will discuss these situations now and leave them for you to fill in when you get home. We can also help you think of ways to overcome any difficulties you may foresee.” Complete all questions

Suggestions to overcome difficulties if the participant is unsure:
Q. What if on one of your regular checks you have symptoms from the symptom list on page eight?
A. Then I will follow the instructions in the booklet

Q. What if you phone the health centre and the number is busy?
A. Then I will keep trying until I get through (or if practice is near pop along in person/use ring back)

Q. What if you can’t get your usual doctor?
A. Then I will ask to see any doctor because waiting for an appointment with my usual doctor could mean losing valuable treatment time

Q. What if taking the time to go and see a doctor is difficult?
A. Then I will make the time/WORK organise time-off with work/HOME COMMITMENTS organise someone to be at home while I get to the doctor

Q. What if you have symptoms but don’t like going to the doctor?
A. Then I will go anyway because it’s better to be safe than sorry and I know I don’t need to worry about wasting the doctor’s time.

Q. What after being to see a doctor your symptoms still don’t get better?
A. Then I will arrange another appointment.

Q. What if you have symptoms at the weekend or while on holiday?
A. If at weekend phone after hours GP/JHC. If on holiday I will seek immediate medical help for chest pain, coughing up blood, severe, sudden breathlessness and if I have any other symptoms for more than 3 weeks I will arrange an appointment as soon as you return or get someone at home to arrange one for me.

Q. What if you are not offered an appointment within 3 days?
A. Then I will let the receptionist know I am part of the CHEST trial and I am really worried about my symptoms and that I need to see a doctor within 3 days
“We’ll quickly run through the rest of the booklet and I’ll leave you to read it more fully in your own time.”

P13. What will happen when I go to the doctor?

“This is to let you know that symptoms will be taken seriously by your doctor. Doctors in this practice are supportive of this study.”

P14. Answers FAQ’s about lung disease

P15-16 Give accounts of other peoples experience of lung disease and are worth reading

P17 Lung disease explained

“Gives a fuller explanation of each lung disease that we discussed earlier on”

P18-19 Give details of help lines and other sources of information about lung disease.

P20-24 A helpful list to take to the doctor

“If you do notice any symptoms you can tick them on this list, remove this page and take it with you to the doctor. This can be a help to you both and there are more lists if you need them.”

“So – to recap – the important thing to remember is your action plan – on pages 11 and 12.

I hope you find the booklet interesting when you have time to look through it more fully. You might want to discuss it or go through it with someone else – your wife/husband or a friend? Do you have any questions that you would like to ask?”

Answer any questions – remember the emphasis is on ensuring that they know what they have to do

“If you have any questions about what we’ve discussed or about the booklet when you’ve had more time to read it – you can contact me (Emily Habgood) whose details you’ll find on the green information sheet that was sent to you in the post”

Advise any participant to make an appointment with a doctor on their way out if they have HBP, or signs of COPD, or any symptoms from the symptom checklist.
Thank you again for coming. Don’t forget - you can look after your health better by ensuring you come to the doctor at the right time - it’s as easy as 1,2,3 – know what to look out for - just check page 7 – and be prepared to take action by making an appointment with your doctor.

Control Arm:

Ask them about lung disease and work out how much they know.

Ask them if they have any family history of lung disease in their family.

Ask them if they have been exposed to asbestos.

Thank them for coming and explain about the following:

Both Arms:

- Remind them that there are two other questionnaires one in a month’s time and the last one in 12 months time.
- Ask for verbal consent to access their notes confidentially to see if they have presented for chest related symptoms.
- Explain that if they do consult about a respiratory symptom that they will receive a very brief questionnaire in the mail to complete.
- If any participant asks for smoking cessation advice – refer to doctor and Quit Line
CHEST-Australia Protocol

CHEST-Australia:
Reducing time to consult with symptoms of lung cancer

Phase II Trial - Study Protocol

Version: 1

Trial Co-ordinating Site:
School of Primary, Aboriginal and Rural Health
University of Western Australia

UWA HREC number: RA/4/1/6018
Trial ID: ACTRN12613000393752

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- Dr. Andrew Martin, University of Sydney
- Dr. Fiona Walter, University of Cambridge
- Dr. Stephen Goodall, University of Technology Sydney
- Dr. Neil Campbell, University of Aberdeen
- Prof Danielle Mazza, Monash University
- Prof David Barnes, University of Sydney
- Ms Sonya Murray, PhD Candidate, University of Western Australia
## 1. List of Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>AQoL</td>
<td>Assessment of Quality of Life</td>
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<td>CI</td>
<td>Chief Investigator</td>
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<td>COPD</td>
<td>Chronic Obstructive Pulmonary Disease</td>
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<td>GP</td>
<td>General Practitioner</td>
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<td>HADS</td>
<td>Hospital Anxiety and Depression Scale</td>
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<td>HREC</td>
<td>Human Research Ethics Committee</td>
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<td>MRC</td>
<td>Medical Research Council</td>
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<td>NHMRC</td>
<td>National Health and Medical Research Council</td>
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<td>PC4</td>
<td>Primary Care Collaborative Cancer Clinical Trials Group</td>
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<td>PBS</td>
<td>Pharmaceutical Benefits Scheme</td>
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<td>PM</td>
<td>Practice Manager</td>
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<td>RCT</td>
<td>Randomised Control Trial</td>
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<td>SES</td>
<td>Socioeconomic Status</td>
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<td>SMS</td>
<td>Short Message Service</td>
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<td>UoM</td>
<td>University of Melbourne</td>
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<td>USB</td>
<td>Universal Serial Bus</td>
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<td>UWA</td>
<td>University of Western Australia</td>
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<td>VicReN</td>
<td>Victorian Primary Care Practice-Based Research Network</td>
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# 2. Protocol Synopsis

<table>
<thead>
<tr>
<th>Title</th>
<th>CHEST-Australia: reducing time to consult in primary care with symptoms of lung cancer</th>
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<tbody>
<tr>
<td>Short Title</td>
<td>CHEST-Australia</td>
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<tr>
<td>Funding</td>
<td>NHMRC</td>
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<tr>
<td>Chief Investigator</td>
<td>Professor Jon Emery</td>
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<tr>
<td>Research Purpose</td>
<td>This randomised control trial tests a novel intervention in general practice aimed at promoting earlier consulting by people at higher risk of lung cancer.</td>
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| Aims | 1. To optimise the CHEST intervention, used previously in the Scottish CHEST Trial, for an Australian population.  
2. To measure the effect of the intervention on consultation rates and time to consultation for chest symptoms associated with lung cancer.  
3. To estimate resource use and quality of life impacts to inform future cost-effectiveness studies.  
4. To inform selection of clinical outcome measures, power calculations and final design of a future large, international phase III trial for which separate funding would be sought. |
| Study Design | Phase II, multisite RCT |
| Population and Setting | Patients with a high risk for lung disease will be recruited from general practices in Perth, WA and Melbourne, VIC. |
| Sample Size | A total of 550 participants will be recruited. Assuming a 30% uptake of the study, 1,800 patients will be approached. |
| Inclusion Criteria | - ≥ 20 pack years  
- ≥ 55 years of age  
- < 15 years smoking cessation date  
- Ability to read and write for informed consent |
| Exclusion Criteria | - Severe psychiatric or cognitive disorder  
- Previous diagnosis of lung cancer |
| Randomisation | Patients will be randomised 1:1 to either control (usual care) or intervention arm. Randomisation will be stratified by general practice and MRC Dyspnoea Scale score using the central automated telephone randomisation services of the NHMRC Clinical Trials Centre at the University of Sydney. |
| The Intervention | A consultation and provision of a Self-Help Manual called 'Chest Symptoms that Call for Action' and reminders to self-monitor symptoms. |
| Duration of Individuals Participation | Participation in the study will involve no more than 12 months. Patient reported outcomes will be collected at baseline, 1 month and 12 months post consultation. |
| Data Collection | Patients will complete the following measures at baseline, one month and 12 months post consultation:  
- Demographics and clinical variables |
| **Study Duration** | It is anticipated that the study will be completed 3 years post HREC approval |

3. **Funding**

Prof Jon Emery received an NHMRC grant (1064121) funding round commencing in 2014 of $880,425.
## 4. List of Collaborators

<table>
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<tr>
<th>Investigator</th>
<th>University</th>
<th>State/Country</th>
<th>Role</th>
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<tbody>
<tr>
<td>Prof Jon Emery</td>
<td>University of Melbourne/University of</td>
<td>VIC/WA</td>
<td>Management and oversight of project.</td>
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<td></td>
<td>Western Australia</td>
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<tr>
<td>Dr. Peter Murchie</td>
<td>University of Aberdeen</td>
<td>Scotland</td>
<td>Advising on the design and implementation of the study.</td>
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<tr>
<td>Dr. Andrew Martin</td>
<td>University of Sydney</td>
<td>NSW</td>
<td>Conducting and advising on the statistical analysis and data collection.</td>
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<tr>
<td>Dr. Fiona Walter</td>
<td>University of Cambridge</td>
<td>United Kingdom</td>
<td>Advising on the design and implementation of the study.</td>
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<tr>
<td>Dr. Stephen Goodall</td>
<td>University of Technology Sydney</td>
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<td>Conducting and advising on the health economic analysis aspect of the study.</td>
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<tr>
<td>Dr. Neil Campbell</td>
<td>University of Aberdeen</td>
<td>Scotland</td>
<td>Advising on the design and implementation of the study.</td>
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<td>Prof Danielle Mazza</td>
<td>Monash University</td>
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<td>Prof David Barnes</td>
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<td>Respiratory Physician advising on the design and implementation of the study.</td>
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<tr>
<td>Ms Sonya Murray</td>
<td>University of Western Australia</td>
<td>WA</td>
<td>PhD Candidate conducting the research.</td>
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*Principal investigator:*
Professor Jon Emery  
Clinical Professor of General Practice, University of Western Australia  
Herman Professor of Primary Care Cancer Research, University of Melbourne

*Site Co-ordinators:*

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<tr>
<th>Location</th>
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<th>University/Department</th>
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<tr>
<td>Perth, Western Australia</td>
<td>Ms Sonya Murray</td>
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<td></td>
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<td>Melbourne, Victoria</td>
<td>Ms Emily Habgood</td>
<td>Department of General Practice</td>
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<td>University of Melbourne</td>
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5. Study Schema

- Approach and recruit General Practices
- Run data extraction to identify potential participants
- Invite potential participants to the study and confirm eligibility

Eligible
- Contact and invite to a consultation. Mail out consultation information and baseline questionnaire
- Baseline data collected
- At recorded consultation explain study and obtain informed consent
- Randomise via phone

Intervention arm
- Spirometry
- Self-help manual
- Follow-up
- Follow up 1 data collected at 1 month post consultation

Control arm
- Spirometry
- Follow up
- Monthly reminders about respiratory symptoms throughout 12 months
- GP records checked monthly for consults about CHEST symptoms & 'Delays' Questionnaire completed
- Follow up 2 data collected at 12 months post consultation

Not Eligible
- Thank for interest

Audit of GP records, previous year to consultation and year of trial as well as Medicare and PBS data collected
- **6. Aims and Hypotheses**

  - **6.1 Purpose**
  This randomised control trial tests a novel intervention (comprising of a primary-care consultation, self-help manual, and self-monitoring reminders) in general practice aimed at promoting earlier consulting by people at higher risk of lung cancer.

  - **6.2 Aims**
    1. To optimise the CHEST intervention, used previously in the Scottish CHEST Trial, for an Australian population.
    2. To measure the effect of the intervention on consultation rates and time to consultation for chest symptoms associated with lung cancer.
    3. To estimate resource use and quality of life impacts to inform future cost-effectiveness studies.
    4. To inform selection of clinical outcome measures, power calculations and final design of a future large, international phase III trial for which separate funding would be sought.

  - **6.3 Hypotheses**
    1. The CHEST intervention will increase consultation rates for chest symptoms in people at higher risk of lung cancer.
    2. The CHEST intervention will be acceptable and will reduce symptom appraisal and help-seeking intervals in people at higher risk of lung cancer.
    3. The CHEST intervention will not cause significant distress or cancer worry in people at higher risk of lung cancer.

  - **6.4 Outcomes**

    **Primary Outcome**
    The primary outcome of this trial will be consultation rates (with the GP) for respiratory symptoms identified through audit of the general practice medical record.

    **Secondary Outcomes**
    - Self-efficacy for consulting without delay. This is a 10-item scale summed to score 10-100, within the self-completed questionnaire given at baseline, one month and 12 months.

    - Symptom Appraisal and help-seeking intervals. This will be measured using the DELAYS instrument (lung cancer version), a self-completed questionnaire that obtains data on presenting symptoms and their duration prior to consultation. We will monitor every month during the trial the consultations of trial participants through electronic searches of the GP records. If a consultation has occurred about a respiratory symptom in that timeframe, the participant will be sent a DELAYS questionnaire to complete about symptoms relating to that consultation.
7. Background and Rationale

Lung cancer is the fourth most commonly diagnosed non-cutaneous cancer in Australia and causes more deaths than any other cancer (1). This reflects its relatively high incidence, which is still rising in women, and its low survival: only 36% people survive beyond one year and 13% beyond five years (1). Five-year survival rates are closely related to stage at diagnosis (7, 8) suggesting that earlier, timely diagnosis could be a critical factor in improving lung cancer outcomes.

7.1 ‘Diagnostic delay’ in cancer

There is extensive literature spanning several decades on the concept of ‘diagnostic delay’ in cancer (9, 10). This recognises that patient pathways to presentation to healthcare and initial management in primary care are key determinants of cancer patient outcomes (11, 12). Much of the research on cancer diagnostic delay has suffered from lack of a theoretical model and precise definitions of key time points along the diagnostic pathway. CIs Walter and Emery and colleagues have recently published a systematic review of cancer diagnostic studies which applied the Andersen Model of Total Patient Delay (13, 14). On the basis of their review they have modified this theoretical framework, producing The Model of Pathways to Treatment (Figure 1).

Figure 1. Model of Pathways to Treatment (14)

The model proposes four key intervals:

1. The Appraisal Interval. Our review found that the nature of the symptoms was the most important factor determining the duration of the Appraisal Interval. Misattribution of symptoms either to a previous benign or concurrent condition or non-recognition of the seriousness of symptoms contribute to longer Appraisal Intervals (15).

2. The Help-Seeking Interval. Various factors may contribute to this interval including patient factors such as competing events (e.g. holidays), and emotional ones such as fear. This
includes fear of the consultation and examination, or of the diagnosis and treatment (16). Access to primary care and sanctioning help-seeking by family or friends, so that patients do not perceive themselves as wasting the doctor’s time, are also important factors (16).

3. The Diagnostic Interval. Depending on the healthcare setting this may involve a series of healthcare visits, referrals and investigations and often represents a complex process. System factors including the role of primary care as a gatekeeper and access to investigations and specialist care are key factors determining this interval (14).

4. The Pre-Treatment Interval. The time from formal cancer diagnosis to initiation of treatment is also strongly influenced by several healthcare system factors such as access to staging investigations and specialised treatments.

- **7.2 Symptom appraisal and help-seeking in lung cancer**
  Several studies have explored symptom appraisal and help-seeking in people recently diagnosed with lung cancer. Two studies of lung cancer patients from Western Australia (including one conducted by Cls Emery and Walter) have found that normalisation of respiratory symptoms is very common with mean patient delays to seek help of 47 and 80 days respectively (17, 18). Cl Campbell et al interviewed 360 Scottish patients with lung cancer; of these 50% had experienced symptoms for more than 14 weeks before presenting to a doctor (median 99 days; IQR 31-381 days) (19). Of these 360 patients, only four reported no symptoms and the median number of symptoms at presentation was four. The duration of these patient delays should be compared with reported lung cancer median volume doubling times of 98 days (20). Thus, a patient who presented 28 days earlier would have a 20% smaller tumour. Factors associated with longer symptom appraisal and help-seeking included living alone, a history of COPD and longer pack years of smoking. In contrast, haemoptysis, new onset of shortness of breath and cough were associated with earlier consulting. Another English study had similar findings: most patients recalled having symptoms for many months before seeking help but these symptoms were not recognised as serious, were attributed to everyday causes and therefore not acted upon (21, 22). There was reluctance to seek help amongst some people, partly because they were unsure whether their symptoms were normal and, for some, because of the stigma associated with smoking. Important recent evidence shows that patients do not discuss all their symptoms of lung cancer when they do visit their GP, suggesting patients need to be empowered to recognise the significance of symptoms and report them to healthcare providers (23).

- **7.3 The diagnostic interval affects lung cancer outcomes**
The key issue is whether earlier diagnosis affects lung cancer outcomes. A recent Danish cohort study examined the impact of diagnostic interval, as a continuous variable, on mortality and found a U-shaped association between diagnostic interval and mortality for colorectal, lung, and prostate cancer (Figure 2) (24, 25). Mortality begins to rise for intervals greater than the 60th percentile, which for lung cancer equated to a diagnostic interval of 60 days. Some lung cancers present with relatively short intervals and late stage disease reflecting the left-side of the U-distribution. Others, however, have longer diagnostic intervals which, if diagnosed earlier, would be associated with better outcomes. These differences probably reflect variation in tumour location and tumour biology. Previous studies of patient delay and effect on lung cancer stage have shown significantly longer symptom duration for stage III and IV disease compared with earlier stage disease (26). Others have failed to replicate these findings (27), probably due to one of two methodological problems: 1. Failure to treat the diagnostic interval as a continuous variable or 2. Measuring patient delay using medical record audit rather than patient interview, which is known to underestimate patient delay (28).
Further evidence for the potential to improve lung cancer outcomes by earlier diagnosis comes from the recently reported US National Lung Cancer Screening Trial, which found a 20% relative reduction in lung cancer mortality from annual low-dose computed tomography (29). However, the uncertain cost-effectiveness and feasibility of implementing a national lung cancer screening program in Australia means that other approaches to timely diagnosis of lung cancer are still needed. While the search for useful biomarkers of lung cancer continues (30), an alternative strategy is to attempt to diagnose lung cancer earlier through prompt recognition and investigation of symptoms suggestive of the disease, particularly in those at higher risk. This is the basis for community symptom awareness campaigns such as those recently developed by Cancer Australia (31) and in the UK as part of the National Awareness and Early Diagnosis Initiative (32). A systematic review of interventions to promote cancer awareness suggests that community campaigns and interventions delivered to individuals can increase cancer awareness and may prompt earlier presentation to healthcare (33). However, there were no trials identified by the systematic review, which was published prior to the CHEST Trial in Scotland, on lung cancer awareness.

### 7.4 The CHEST Trial

This study is based on a recently published trial in Scotland, funded by Cancer Research UK, led by CIs Campbell and Murchie (The CHEST Trial) (3, 4). They developed and tested a theoretically-based intervention which comprised a primary-care nurse consultation to discuss and implement a self-help manual, followed by self-monitoring reminders. The key objectives of the intervention were as follows, with the relevant underlying theories in parentheses:

1. Increase the salience and personal relevance of symptoms (Illness Action Model (34)).
2. Improve knowledge of symptoms by introducing chest disease prototypes (Illness Prototypes and Illness Action Model (34, 35)).
3. Reinforce the benefits of early intervention in lung cancer and other chest disease (Theory of Planned Behaviour (36, 37)).
4. Sanction early consultation (Zola’s triggers (38)).
5. Tackle barriers to consultation (Theory of Planned Behaviour (36, 37)).
6. Develop personalised action and coping plans (Social Cognitive Theory and Implementation Intentions (39, 40)).

Intervention components 1 and 2 aim to reduce the Symptom Appraisal Interval, while components 3-6 aim to reduce the Help-Seeking Interval. The initial model of the intervention was refined following a series of focus groups with consumers and general practice teams. Based on this feedback the intervention was designed specifically without any mention of smoking cessation, which was seen as a barrier to engagement.
Furthermore, the focus was on chest disease broadly, including the early detection of lung cancer, chronic obstructive pulmonary disease (COPD), and other chronic respiratory conditions. This was to reduce potential effects of fear and nihilism surrounding lung cancer (41). Figure 3 presents a summary of the intervention.

Two hundred and twelve people at increased risk of lung cancer were recruited into the Scottish trial, of which 206 completed the trial after one year of follow-up (102 intervention, 104 control). The total consultation rate was significantly higher in the intervention group (adjusted consultation ratio 1.15, 95% CI 1.04-1.27 p=0.005) with a median number of consultations in the year after intervention of 8 (IQR 4-11). The adjusted consultation ratio for new chest symptoms also increased but this did not reach statistical significance (ratio 1.19, 95% CI 0.92-1.53). There were non-significant increases in chest x-ray requests and referrals to respiratory.

The Scottish trial therefore provides important preliminary evidence for the potential efficacy of the intervention in altering symptom appraisal and help-seeking behaviour. It represents the first ever trial to test this type of an intervention and measure its impact on health care consultations. However, stronger evidence is required before this research can inform practice and policy. In particular, evidence is required on the generalisability of the intervention in other populations and the effect on clinical outcomes as well as consulting behaviours.

Figure 3. Intervention summary.

7.5 Rationale
This study will test the CHEST intervention in an Australian population, and provide additional data on the efficacy of the intervention. Unlike the Scottish trial, which had no data to inform power calculations, this Australian trial will be powered to detect a significant effect on consultation rates in general practice for respiratory symptoms. This represents the most relevant intermediate outcome along a causal pathway that ultimately results in earlier diagnosis of lung cancer. Figure 4 shows the causal pathway and the potential outcome measures along this pathway. We will collect data on additional measures along this pathway (emboldened in Figure 4) to inform a future phase III trial which would be powered to detect important clinical and health service outcomes.
7.6 Completed pilot study in Australia
During 2012 an initial pilot study was completed in Perth, WA to adapt the CHEST intervention for an Australian population. We have conducted a focus group with consumers with chronic respiratory disease to review the CHEST self-help manual and provide feedback on the overall intervention. We have obtained additional feedback on the acceptability of the intervention and trial design from the Joint Consumer Advisory Group of Primary Care Collaborative Cancer Clinical Trials Group (PC4) and the Psycho-oncology Group (PoCoG). We have developed and tested electronic data extraction software by adapting the Canning tool to identify potentially eligible participants from general practice records. We recruited 11 participants from one practice to pilot the CHEST consultation, self-monitoring prompts, and the outcome measures and follow-up procedures. This work resulted in modifications to the language used in the consultation and self-help manual and has demonstrated initial feasibility and acceptability.
8. Research Methods

8.1 Design
Randomised control trials are considered to be the best way of assessing the efficacy of an intervention. This phase II trial is a multisite randomised control trial (RCT), which will apply the well-established MRC methodological framework for the design and evaluation of complex interventions (5, 6). This phase II trial is expected to run for three years, and involve recruitment of up to 550 participants at high risk for lung disease across two Australian states (Western Australia and Victoria).

8.2 Participants
Approximately 1,800 patients will be approached, assuming a 30% uptake of the study. A target sample size of 550 participants to be recruited over a two year period. Participants will be recruited from general practices in Perth, WA and Melbourne, VIC. Potential participants will be identified by running an electronic data extraction tool, which extracts patients who fit the eligibility criteria. The patient’s eligibility is further confirmed by asking them to complete an expression of interest form with more specific screening questions. The inclusion and exclusion criteria are as follows:

Inclusion Criteria:
- ≥ 20 pack years
- ≥ 55 years of age
- < 15 years smoking cessation date and previous history of ≥ 20 pack years
- Ability to read and write for informed consent

Exclusion Criteria:
- Severe psychiatric or cognitive disorder
- Previous diagnosis of lung cancer

8.3 Study Setting
Participants are to be recruited through large general practices throughout two Australian cities (Melbourne, VIC and Perth, WA). Approximately 5-6 general practices per state will be recruited or until the recruitment target of 550 participants is reached.

8.4 Recruitment and Consent Procedure

General practice recruitment:
In Perth, general practices are recruited by sending out a letter to the Practice Manager, which contains a General Practice Information Brochure and Participant Information Sheet. A follow-up phone call is conducted 7 days after the letter is sent.

In Melbourne, general practices are identified using Victorian Primary Care Practice-Based Research Network’s (VicReN) database. They are identified on the basis of their location (within 15km of CBD), size of practice (large five or more GPs), use of electronic files (Medical Director or Best Practice software) and slightly lower SES (for increased number of smokers). General practices are approached initially from VicReN to either the GP or PM at an identified general practice. A letter inviting them to the study and the general practice information sheet (brochure) are emailed to the clinic. If the general practice expresses interest, a visit to the clinic by the PI (Prof Jon Emery) and the researcher to talk to staff involved.

Once general practice is onboard, the specially designed smoking tool software developed for the study (based on the Canning Tool) is run on the general practice’s software (either
MD or Best Practice) and identifies potentially eligible participants based on the eligibility criteria.

**Patient recruitment:**
A list of potentially eligible patients is generated by the smoking software, which are saved on either the researchers password protected computer or USB. A mail merge with the names and addresses is completed with the general practice letterhead (without the general practice phone numbers) and posted in a blank envelope. The pack includes:
- The letter from the practice inviting them to take part,
- Participant information sheet (brochure),
- An expression of interest form (with questions to confirm eligibility),
- Replied paid envelope (addressed to the university).
If no response is received after two or three weeks, a reminder postcard is mailed out to these potential participants.
An expression of interest form is returned in the reply paid envelope by the patient, their eligibility is determined using a website (http://smokingpackyears.com/calculate) to calculate 20 pack years (equivalent of smoking a pack a day for 20 years).
If the potential participant is eligible, they are contacted by telephone and invited to attend an appointment at the general practice. An appointment time is agreed upon, and a letter explaining the appointment and agreed appointment time as well as the baseline questionnaire, are sent to the potential participant. The potential participant is asked to bring the completed baseline questionnaire to the appointment, which takes approximately 20 – 30 minutes to complete.
All appointment times are previously agreed upon by the general practice depending on consulting room availability. The PM and reception staff are informed about all appointments and room use.
If the potential participant is not eligible, a brief letter is mailed to them thanking them for their interest.
At the consultation, the researcher will go through the study information sheet with the potential participant and ask them to sign the study consent form and the Medicare & PBS consent form.
Participants who do not attend the consultation will be contacted and the consultation will be re-booked.

**8.5 Randomisation**
Consenting participants will be randomised 1:1, to either usual care (control arm) or to the intervention arm. Randomisation is performed using a centralised independent tele-randomisation system managed by the National Health and Medical Research Council (NHMRC) Clinical Trials Centre based at the University of Sydney. Stratifying variables for randomisation are general practice and MRC Dyspnoea Score.

**8.6 Intervention**
The Self-Help Manual, entitled ‘Chest Symptoms that Call for Action’, is based around a simple action plan logo “It’s as easy as 1, 2, 3”. These three key actions are:
1. Look after number one and know the symptoms of lung disease.
2. It takes two to tango: the doctor can only help you if you see them when you have symptoms.
3. Remember the 3-week rule and see your doctor if you have symptoms for more than three weeks.
A detailed consultation script and training module developed for the Scottish trial has been successfully piloted in the Australian phase I study. The trained researcher guides the patient through the self-help manual, which is taken home by the participant. ‘If-then’ action plans are developed during the consultation, which are linked to symptom checklists; ‘If-then’
coping plans are discussed to tackle barriers to consultation. A range of self-monitoring prompts to appraise symptoms on a regular basis after the consultation will be offered and tailored to individual preferences. These will include a choice of e-mail reminders, SMS, postcards or phone calls. All those in the intervention group receive a fridge magnet.

- **8.7 Intervention consultation**

Participants randomised to the intervention arm will have their height, weight and spirometry (using the ‘Easy on-PC) measured at the consultation. The results of the spirometry test will be provided to the GP at the end of the consultation. The researcher will go through the script and work through the self-help manual with the participant. The participant will be asked to choose a method for which they will be reminds monthly to think about symptoms (via SMS, e-mail, postcards or phone calls). The follow up procedures for the trial will be explained (when they will receive questionnaires, how long they have to complete them, how they can receive help answering questions etc.). Each intervention participant is given a fridge magnet at the end of the consultation.

- **8.8 Control consultation**

Participants randomised to the control arm will have height, weight and spirometry (using the ‘Easy on-PC) measured at the consultation. The results of the spirometry test will be provided to the GP at the end of the consultation. A general discussion about lung health is conducted as well as the follow-up procedures in the trial (when they will receive questionnaires, how long they have to complete them, how they can receive help answering questions etc.). Participants will then receive usual care at their general practice including follow-up of any abnormal spirometry results.

- **8.9 Follow up**

One month post consultation, a letter reminding them of the study, a questionnaire and reply paid envelope addressed to the University, are mailed out to the participants in both arms of the study. The questionnaire is the same as the baseline questionnaire and takes approximately 20-30 minutes to complete.

Twelve months post consultation, a letter reminding them of the study, a questionnaire and reply paid envelope addressed to the university, are mailed out to the participants in both arms of the study. The questionnaire is the same as the baseline questionnaire and takes approximately 20-30mins to complete.

If a questionnaire has not been returned after 2-3 weeks, the participant is called and reminded about the questionnaire and asked if they have any questions or need any assistance. If the questionnaire still hasn’t been returned after 1 month, it is recorded as lost to follow up/missing.

When questionnaires are returned, HADS is scored and if the participant scored 10 or above on the anxiety scale or 8 or above on the depression scale or if the participant ticked the self-harming box in the AQoL, a letter is sent to notify the GP.

Every month the participant’s records at the general practice are checked to see if a participant has consulted a GP about a respiratory symptom. Either, the PM at the general practice will check the records or the researcher will visit the clinic to check through the participant’s records, it depends on the general practices preference.

If a participant has consulted a GP about a respiratory symptom, a questionnaire called the DELAYS questionnaire (different from the time point questionnaires) is sent out to the participant. A letter explaining why they are receiving this additional questionnaire, the DELAYS questionnaire and a reply paid envelope addressed to the university is sent to the participant.

After the participant has completed the trial, data on consultations for the 12 months during the trial as well as the previous 12 months to the trial are collected through an audit of the
GP records on each participant in both arms of the study. The Medicare and PBS records will also be requested.

- **8.10 Measures (Patient Reported Outcomes)**

*Demographics and clinical variables*
Age, gender, marital status, postcode, highest education level, occupation, MRC Dyspnoea Scale (43) and lung function at baseline only.

*Self-efficacy for consulting without delay*
A 10-item self-completed scale summed to score 10-100, developed for the Scottish CHEST Trial which showed good internal reliability (Cronbach α =0.85).

*Knowledge of symptoms of lung disease*
A 21-item self-completed checklist of possible symptoms expressed as a percentage correctly selected as associated with chest disease.

*Hospital anxiety and depression scale (HADS) (45)*
This 14-item self-completed scale has been widely used to measure distress and has been extensively validated and shown to perform well in a wide range of populations (mean Cronbach α = 0.82; sensitivity and specificity 0.80).

*Cancer-worry scale*
A 6-item self-completed scale, adapted from the breast cancer worry scale (46), which showed good internal reliability in the Scottish CHEST Trial (Cronbach α= 0.88).

*Quality of life*
Measured using the AQoL-8d (42), a validated self-completed, multi-attribute utility measure which can be used as part of the health economic evaluation of the intervention. This 35-item scale covers the following domains: independent living, happiness, mental health, coping, relationships, self-worth, pain and senses.

*Symptom appraisal and help-seeking intervals*
This will be measured using the SYMPTOM instrument (lung cancer version), a self-completed questionnaire that obtains data on presenting symptoms and their duration prior to consultation (44).
We will monitor every month during the trial the consultations of trial participants through electronic searches of the GP records. If a consultation has occurred about a respiratory symptom in that timeframe, the participant will be sent a SYMPTOM questionnaire to complete about symptoms relating to that consultation.

- **8.11 Measures (Non - Patient Reported Outcomes)**

*Heath service utilisation*
In addition to the primary measure of consultation rates for respiratory symptoms, we will measure total general practice consultation rates, chest x-ray requests and referrals to respiratory physicians, captured through audit of general practice records. We will consent participants to access their Medicare and PBS claims through the Department of Human Services. This will provide more complete data relating to visits to other general practices (and investigations and referrals arising from these), as well as prescribing data.
This will be identified through GP medical records and by flagging participants with the WA and Victorian Cancer Registries.

**Trial feasibility and acceptability**

As a phase II trial we will obtain data on patient recruitment and attrition, and response rates to outcome measures to inform decisions about a future phase III trial.

- **8.12 Audio Recordings**

Both control and intervention consultations will be recorded. The first ten consultation will be recorded and then every tenth from then on for quality assurance. Participants will be asked before the consultation starts if they are happy for the consultation to be recorded. They have the right to refuse.

- **8.13 Reimbursement**

General practices will be reimbursed between $500 - $1,500 depending on the practice size and number of eligible patients. This money is to cover any administrative or time costs associated with supporting the study.

- **8.14 Withdrawals and Protocol Deviations**

Participants are able to withdraw from the study at any time. If a participant does decide to withdraw, emphasise that it will not in any way affect their care or their relationship with the general practice. This should also be mentioned when explain the consent forms. Participants are also able to request removal of all their information/data collected during their participation in the study. If a participant would like to do this they are required to sign the withdrawal of participation form.

Deviations from the study protocol will be recorded by the research staff. Deviations include but are not restricted to the following:

- Control participant given the self-help booklet instead of usual care
- Questionnaire not completed
- Questionnaire not completed in normal time period
- Any other occasion whereby the above detailed instructions are not able to be adhered to for any reason

All deviations should be recorded. The information will be used to inform a future phase III trial.
10. Data Management

10.1 Participant Data
All participants will be given a unique identifying code. The consent form will have both the participants name and code so they will be stored separately from the surveys in separate locked filing cabinets. If a participant wishes to withdraw their data from the project, the researchers will be able to link their ID code from their consent form. Forms and surveys will be stored in locked filing cabinets in a secure building, and data will be stored on a password protected computer at the universities. Only the researchers on the study will have access to any data. Information will be aggregated in any publication to protect individuals from being identified.

10.2 Study Management
All information about the trial will be managed using a purpose built Microsoft Access database. This will be used to track participants through the study and score the measure in the questionnaires as they are returned.

10.3 Sample Size and Power Calculation
Sample size and power calculation. We have used data from the Scottish trial to inform our power calculations. Assuming that the primary endpoint of consultations for respiratory symptoms follows a Poisson distribution, and that the expected average rate over 12 months in the study population will be 1.06 for placebo patients and 25% higher for intervention patients, a sample of 534 will provide at least 80% power to reject the null hypothesis of no difference between the groups at the two-sided 5% level of significance. The primary endpoint will be measured from medical record audit, thus minimising attrition. Accounting for the same attrition rate observed in the Scottish trial, we require a total sample of 550 participants. We anticipate that around 1,800 patients will need to be invited to reach this target given a 30% uptake rate. Current smoking prevalence in Australia is 19% although this varies significantly by socio-economic status and age (47). On this basis and data from the Scottish Trial we assume that 10% of a general practice population would meet our eligibility criteria. We therefore require a total practice population from which to invite participation in the trial of 18,330. We estimate therefore that we will need to recruit 6-8 general practices depending on practice size and demographics.

10.4 Data Analysis
All randomised patients will be considered eligible for inclusion in the analysis in accordance with the intention to treat analysis principle. Appropriate methods for dealing with missing endpoint data will be detailed in the statistical analysis plan and be informed by a blinded review of the data. The baseline characteristics of the two arms will be described using summary statistics. Possible consent bias will be assessed by comparing demographic and clinical variables of participants against those who declined participation, and possible differential attrition will be assessed by comparing baseline characteristics of those who withdraw or die against those who remain in the study. These comparisons will be performed using a two sample t-test (or non-parametric equivalent) for continuous variables and chi-square test for categorical variables. The primary analysis will be a comparison between the two groups on the consultation rate for respiratory symptoms using a Poisson regression model with the randomisation stratification factors (i.e. general practice and MRC score) included as covariates. Comparisons between groups on continuous secondary endpoints will be undertaken using a linear model that includes the randomisation stratification factors as covariates along with the baseline value where applicable. Comparisons between groups
on categorical secondary endpoints will be performed using logistic regression with the randomisation stratification factors as covariates. The analyses performed on the primary and secondary endpoints will be repeated adjusting for additional baseline covariates as part of a sensitivity analysis. Point estimates of the treatment effect will be presented with two-sided 95% confidence intervals and two-sided p-values. Unadjusted p-values from secondary analyses will be interpreted in proper context and be clearly labelled.

The health economic analysis will estimate the cost of CHEST minus any cost-savings due to avoided healthcare utilisation through early diagnosis. Benefits will be extrapolated using modelling techniques that will incorporate data from the trial along with evidence from the published literature (CI Goodall).
12. References


31. Audio-visual resources on lung cancer stigma and symptoms. Canberra: Cancer Australia; 2012;


CONSENT FORM FOR PARTICIPANT TO GIVE INFORMED CONSENT TO TAKE PART IN A RESEARCH PROJECT.

UWA HREC Project Number: RA/4/1/6018

Research Project Title: CHEST Australia- Phase II Trial.

Researcher(s): Professor Jon Emery, Professor Danielle Mazza, Dr. Neil Campbell, Dr. Peter Murchie, Assoc.Professor David Barnes, Dr. Andrew Martin, Dr. Fiona Walter, Dr. Stephen Goodall, Ms. Sonya Murray.

I (participant name) Voluntarily consent to take part in the above research:

- I believe I understand the purpose, extent and possible effects of my involvement in this project which is being undertaken for research purposes.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I give permission to allow researchers in this study to check my GP medical records in order to check any respiratory consultations I may make.
- I understand that my participation is voluntary and I am free to withdraw my participation and/or my data supplied to the researchers at any stage.
- I understand that my participation will involve consultation with a member of the research team including a test of my lung function.
- I understand that the consultation may be audio-recorded and transcribed. I accept that there are arrangements in place to ensure the confidentiality of the data I provide.
- I understand that the researcher has agreed not to reveal results of any information involving me, subject to legal requirements.
- I am giving permission for researchers to access my Medicare and PBS claim data for outcome analysis.
- If information about the project is published or presented in any public form, I understand that the researcher will not reveal my identity.
- It has been explained that I will be randomly assigned to one of two different groups in the study and that my involvement in this project may not be of any direct benefit to me.
- I understand that if I refuse to consent, or if I withdraw from the project at any time without explanation, this will not affect my on-going medical care.
- I understand that if I refuse to consent, or if I withdraw from the project at any time without explanation, this will not affect my relationship with The University of Western Australia or associated institutions.
- I understand that this project follows the guidelines of the National Statement on Ethical Conduct in Research Involving Humans (2007).
- I understand that this project has been approved by the University of Western Australia Ethics Committee.
- I understand that I will receive a copy of this Participant Information Statement and that my signed consent form will be retained by researchers.
Signature ___________________________ Date ____________

Mobile Number ________________________ DOB _____ / _____ / ______

Address: __________________________________________________________

I have explained the project to the participant who has signed above, and believe that they understand the purpose, extent and possible effects of their involvement in this project.

Researchers
Signature ___________________________ Date ____________
D.6.  EOI Non Eligible Responder Letter

<Date>

<Title> <Non eligible patient name>
<Address>

Dear <Title> <Non eligible patient name>,

Thank you for expressing interest in the CHEST-Australia Trial. We appreciate the time and effort you spent to reply.

For this study, we were only looking for long term, heavy smokers. This means we cannot take you on as a participant as you do not fit our study requirements. Participating in research is a great way to contribute and help improve health services. We strongly encourage you to participate in research projects in the future.

If you have any further questions, please do not hesitate to contact <Researcher name> on (XX) XXXX XXXX.

Thank you for your time.

Yours sincerely,

Professor Jon Emery
Chief Investigator on the CHEST-Australia Trial
Herman Professor of Primary Care Cancer Research,
University of Melbourne
Clinical Professor of General Practice,
University of Western Australia
D.7. Fridge magnet and postcard

**Chest Symptoms That Call For Action**

*It’s as easy as*

1 2 3

**CHEST Australia**

Take control

Take action

---

**Fridge magnet**

*It’s as easy as 1 2 3*

1

**Look after number one**

Take control

2

**It takes two to tango**

Take action

3

**Remember the three week rule**

Don’t wait

---

**Reminder Postcard**
Dear Doctors /Practice Manager,

Invitation to participate in the CHEST Australia study.

The Departments of General Practice at UWA and Melbourne University are leading the CHEST Australia study aimed at identifying earlier, people with symptoms of serious lung disease including lung cancer.

We wish to invite your practice to participate in the trial. Please find enclosed a GP Information Brochure about the trial which summarises what involvement in the trial would mean for your practice and patients.

We would be pleased to visit your practice to discuss the trial further and hope that you are interested in participating.

Yours sincerely

Prof Jon Emery
Professor of General Practice, UWA
Professor of Primary Care Cancer Research
Melbourne University

Sonya Murray
CHEST-Australia trial coordinator
University of Western Australia

Practice Address
The University of Western Australia
35 Stirling Highway,
Crawley, WA 6009.

Date
By signing this agreement, you as the practice representative wish to WITHDRAW the practice’s consent to participate in the research study in the project named above and understand that such withdrawal WILL NOT jeopardise my relationship with the University of Melbourne or any study affiliated universities.

General Practice Name: ______________________________
Practice Representative’s Full Name: ______________________________
Position: ______________________________
Signature: ______________________________
Date: ...../...../20.....
Chest Symptoms That Call For Action

Be one step ahead

It’s as easy as

1 2 3

CHEST Australia

Special attention for people who may be at risk of lung disease
• Chest symptoms that call for action

“Small cancers are much easier to cure, so don’t delay seeing your doctor with any warning symptoms.”

Professor Jon Emery
Professor General Practice.
University of Western Australia.

“The biggest frustration with looking after people with lung disease is that many people (especially smokers) put up with worrying symptoms for too long. We would rather see a lot of people with worrying symptoms early, and be able to cure a lung disease such as lung cancer, rather than picking things up too late.”

Associate Professor David Barnes
Respiratory Physician
University of Sydney.
Why you should act on the symptoms of lung disease

About 14% of deaths in Australia are due to lung disease. Acting quickly on the warning symptoms and signs of lung disease allows a diagnosis to be made and treatment to begin. The sooner lung disease is treated the better the outcome. Knowing what symptoms to look out for will put you one step ahead. Leaving lung disease untreated can mean a decreasing quality of life and, in the case of lung cancer, missing out on surgery that can cure. The doctors, practice nurses, and receptionists at your GP Practice are keen for you to make an appointment if you notice any warning symptoms.

Let your family, friends or carer’s read this handbook; there may be ways they can help.

Be one step ahead
Find out about your personal risk
Find out about the warning symptoms of lung disease and what action to take
Find out about the benefits of early diagnosis

It’s definitely worth your while
Who is more likely to develop lung disease?

If you can tick any of the boxes below you are more likely to develop lung disease and need to pay particular notice to symptoms:

- Are or were a smoker
- Have a long history of passive smoking
- Have frequent chest infections
- Are 50 years or over
- Already have a lung disease
- Have a family history of lung disease
- Have been exposed to asbestos
- Have been exposed to industrial pollution

“There are over 2 million people in Australia who have chronic lung disease”

“These people are known as the ‘missing millions.’”
Myths about lung disease

People say: “Breathlessness comes with old age.”
The truth is: breathlessness is health related not age related.

People say: “Only people who are old and who have smoked get lung disease.”
The truth is: lung disease can affect young, old, male and female alike.

People say: “It’s just a smoker’s cough I’ve got.”
The truth is: if a smoker, an ex-smoker or non-smoker has a persistent cough it’s time to see a doctor. You don’t need to have smoked to get lung disease.

People say: “Lung cancer is not treatable.”
The truth is: lung cancer is treatable and, if it is caught early enough, it can be cured.

People say: “If you have COPD you won’t get better.”
The truth is: although COPD is a progressive disease, if treated early, its progression can be slowed with appropriate management and care. (COPD is a lung disease which includes chronic bronchitis and emphysema)

People say: “TB (tuberculosis) is not a common disease.”
The truth is: TB is on the increase especially in larger cities, but it is difficult to catch.

People say: “My parents smoked their whole lives and never got cancer so I won’t get cancer.”
The truth is: just because your parents didn’t get cancer doesn’t mean that you won’t get cancer.

The truth is: lung disease can be helped by treatment.
1  
**Look after number one**

*Take control*

Listen to your body when it tells you something's not right.  
Know what symptoms of lung disease to look out for.

2  
**It takes two to tango**

*Take action*

Bring symptoms to your doctor.  
Help your doctor to help you.

3  
**Remember the three week rule**

*Don’t wait*

Don’t wait any longer than three weeks with symptoms.  
Phone for an appointment.

*Some symptoms may need more immediate attention - see next page*
• **Look after number one –**
  **Know the symptoms of lung diseases**

• **Symptoms that need attention now**
  Coughing up phlegm with signs of blood – if you are coughing up blood, the blood may be coming from your lungs but whatever the source of the blood **you should get in touch with your doctor today.**

  Chest pain – chest pain can indicate a problem in the lung area but it could be heart related so **you should get in touch with your doctor today.** If you start to feel severe chest pain you should phone 000.

  Severe, sudden breathlessness – can be a sign of lung disease but could be heart related so **you should get in touch with your doctor today.**

• **For these other symptoms remember the three week rule**
  A cough – any cough that has lasted 3 weeks can be an important early symptom of lung disease regardless of whether you are a smoker, ex-smoker or have never smoked.

  A worsening cough – if a cough changes, for example, becomes harsher or more persistent it needs to be checked out.

  Breathlessness or worsening breathlessness – shortness of breath is not normal regardless of how old you are. Remember, breathlessness is health related not age related.

  Coughing up phlegm (sputum) – If you are coughing phlegm or sputum it needs to be checked out.

  Shoulder or rib pain – a sharp pain or a dull ache in the shoulder or ribs can indicate a problem in the lung area. The pain/ache may be there all the time or only felt when breathing in or coughing.

  Wheezing – noisy breathing or wheezing is a sign that something is blocking the airways of your lungs or making the airways too narrow.

  Weight loss; loss of appetite; and severe, unusual tiredness – are also symptoms that can indicate an underlying problem, particularly if accompanied by any of the above symptoms.
It takes two to tango –
Bring your symptoms to the doctor

Symptoms that need attention now

If you

Cough up phlegm with signs of blood in it
Have chest pains
Severe, sudden breathlessness

Then

Phone your surgery today to make an appointment.

Tell the receptionist

“I am part of the CHEST study. I have (whatever symptoms you have). Can I have an urgent appointment?

For other symptoms remember the three week rule

If you have had any of the symptoms below for more than three weeks

A cough or a worsening cough
Breathlessness or worsening breathlessness
Coughing up phlegm
Shoulder or rib pain especially when breathing and coughing
Wheezing
Loss of weight
Loss of appetite
Severe, unusual tiredness

Then

Phone your surgery today to make an appointment.

Tell the receptionist

“I am part of the CHEST study. I have had (whatever symptoms you have) for more than three weeks. Can you arrange an appointment within 48 hours please?”

Help your doctor to help you

If you feel unwell when your GPs Medical Centre is closed call After Hours GP 3056 Albany Highway (9391 2285). Your nearest hospital is the Fiona Stanley Hospital.
**Early diagnosis is the key to successful treatment**

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Asthma</strong> - simple breathing tests may be done to confirm the diagnosis. Your doctor may give you medication that reduces asthma symptoms. If the medication works, this suggests that you may have asthma.</td>
<td>Most people with asthma can be treated very successfully. The treatment may mean medication that you inhale (breathe in from an inhaler or puffer) or pills.</td>
</tr>
<tr>
<td><strong>COPD</strong> (which includes chronic bronchitis and emphysema) - a simple breathing test called a spirometry can usually be done at your GP surgery. This will indicate whether your airways have narrowed. In some cases you may need more detailed tests and a referral to hospital.</td>
<td>A lot can be done to relieve the symptoms of COPD but there is no cure. If treated early, with appropriate management and care, its progression can be slowed. Stopping smoking also slows down the progression of the disease and reduces damage to the lungs.</td>
</tr>
<tr>
<td><strong>Lung cancer</strong> - most cases are first suspected through a chest X-ray. You may also have some blood taken for routine tests. Many people have a special X-ray called a CT scan. All the tests are simple, safe and painless and will help map out the extent of the tumour.</td>
<td>Lung cancer can be treated in a number of ways, including a combination of surgery, chemotherapy and radiotherapy. Surgery can cure lung cancer if it is caught early enough. Other treatments can stop it from spreading and relieve symptoms.</td>
</tr>
<tr>
<td><strong>Pneumonia</strong> - is usually diagnosed based on symptoms and physical examination. Diagnosing pneumonia can be difficult in some people, especially those who have other illnesses. Occasionally a chest x-ray or other tests may be needed to distinguish pneumonia from other illnesses.</td>
<td>Antibiotic treatment usually works well, and you can expect to fully recover. Symptoms settle over a few days if the treatment is working. You may feel tired for a week or so after the infection has cleared.</td>
</tr>
<tr>
<td><strong>TB</strong> - a chest x-ray will be taken which may suggest that TB is present. The diagnosis should be confirmed by obtaining phlegm for analysis. Only if the TB bacteria are found in the phlegm is a diagnosis proved. This may take a few weeks.</td>
<td>TB can be cured completely in almost every case, but the full course of treatment must be taken otherwise the infection can return in a drug-resistant form.</td>
</tr>
</tbody>
</table>
• **Don’t wait with symptoms**  
**Remember the three week rule**

All these people with lung disease put off going to the doctor.

---

“Don’t make their mistake. The sooner lung disease is diagnosed the better!”

**Remember**

- **If other people notice your symptoms, seriously think about what they’re saying and take action.**
- **Don’t just put symptoms down to other causes.** It makes sense to have them checked out, even if you don’t like going to the doctor.
- **Waiting until things get really bad could mean losing valuable treatment time.** Your doctor would rather see you sooner than later.
• Your personalised action plan

Looking after number one

Means there are things you can do, like checking for lung symptoms on a regular basis. A good time to do this, so that you remember, is on the 1st day of every month.

We could help you to remember.

What would be the best way of reminding you to check for symptoms?

- [ ] Text message to me
- [ ] Fridge magnet to me
- [ ] Postcard to me
- [ ] Email to me
- [ ] Sticky notes for me

What if on one of your regular checks you have symptoms from the symptom list on page seven?

If on one of my regular checks I have any symptoms from the list then I will………………………………………………………………………………………………
…………………………………..

What if you phone your GP to make appointment and the number is busy?

If the GP number is busy then I will………………………………………………………………………………………………
…………………………………………………………………………

What if you can’t get your usual doctor?

If I can’t get my usual doctor then I will………………………………………………………………………………………………
…………………………………………………………………………

What if taking the time to go and see a doctor is difficult?

If taking the time to see a doctor is difficult then I will………………………………………………………………………………………………
…………………………………………………………………………
• Your personalised action plan

What if you have symptoms but don’t like going to the doctor?

If I have symptoms but don’t like going to the doctor then I will
……………………………………………………………………………………………………………………
………………………….

What if after being to see a doctor your symptoms still don’t get better?

If after being to see a doctor my symptoms don’t get better then I will………………………………
……………………………………………………………………………………………………………………
………………………….

What if you have symptoms at the weekend?

If I have symptoms at the weekend then I will
……………………………………………………………………………………………………………………
……………………………………………………………………………………………………………………

What if you have symptoms while on holiday?

If I have symptoms while on holiday then I will
……………………………………………………………………………………………………………………
……………………………………………………………………………………………………………………

What if you cannot get an appointment within 3 days?

If I am not offered an appointment within 3 days then I will…………………………………………
……………………………………………………………………………………………………………………
……………………………………………………………………………………………………………………

What if
……………………………………………………………………………………………………………………

Then I will……………………………………………………………………………………………………………….
……………………………………………………………………………………………………………………..
What will happen when I go to the doctor?

First, be assured that all the doctors at your general practice want you to bring any symptoms to them. 

**Symptoms will be taken seriously**

Even if you have only one of the symptoms on page seven the doctors want to see you. They are there to help you.

Second, symptoms alone don’t usually give the full picture. To determine if you have a lung disease your doctor may:

- give you a physical examination
- check your medical history
- have some simple tests done

Any treatment or further investigations can then begin.

Third and most important, it’s worth having symptoms dealt with because treatments can make you feel better, improve your quality of life, and even extend your life!

“As a GP working to improve the lives of patients suffering from lung disease, I often meet patients who tell me they wished they had gone to the doctor earlier. Early diagnosis and help is of great importance and I would encourage people to use this excellent booklet to understand about symptoms and what they can do to help themselves.”

“As a GP I am all too aware of the consequences of a delayed diagnosis of lung disease for patients and their families. I urge patients to contact the surgery as soon as possible with any symptoms they are worried about. There is always a doctor available to speak to.”

Dr Peter Watson
Links Medical Practice
Frequently asked questions about lung disease

Q: What is lung disease?
A: Lung disease is any illness or disorder that stops the lungs working properly, this includes: ongoing diseases such as asthma, COPD (which includes chronic bronchitis and emphysema); infections such as TB and pneumonia; cancers such as lung cancer and the much less common asbestos cancer (mesothelioma).

Q: Is lung disease a common health problem?
A: Yes but many people don’t realise they have it and miss out on treatments that can make them feel better. So it makes sense to tell your doctor about any symptoms.

Q: Should I be worried about lung disease?
A: Yes, because lung disease is on the rise. More people in the UK die from lung disease than coronary heart disease. So don’t hang about with symptoms, get them checked out.

Q: Can it be treated?
A: Yes, most lung diseases are helped by treatment and some can be cured. If you have any symptoms from the list on page seven get them checked out, you’ve nothing to lose.

Q: Is lung disease always caused by smoking?
A: No, people who have never smoked get lung disease too.

“I had never heard of COPD before. I started to suffer from chest pains and shortness of breath but like many people I kept putting off going to the doctor.”

“I was diagnosed with COPD in 2005. I was so shocked. I thought I was just too young for this to happen to me. What a wake-up call.”

“I didnae have the wheeze during the day, it was only when I lay down at night time, so I

“Everybody’s surprised, even the doctor, when I said...”
Mike’s story

September 2003  “I never gave my health a thought at all”

October 2003  “The first thing I noticed was I started to get a wee cough and this cough kept annoying me.”

November 2003  “I thought it was just an ordinary cough, just bear with it sorta thing and it'll go away itsel', taking Lemsips, this type o' thing.”

January 2004  “But the cough was with me, it was always with me, but as I say apart from that I felt reasonably okay, I had no pain or anything like this, nothing obvious at all.”

March 2004  “Then I started to feel a bit tired, I put it down to moving house but I still had the cough.”

May 2004  “Then I started to get this sort of hoarseyness”

July 2004  “I said ‘Och I better go an see about this cough’, so I went tae my local doctor.”

August 2004  “I was sent for an x-ray. They noticed a shadow on the lung. Then they sent me for more tests.”

September 2004  “Then they told me unfortunately it was lung cancer I had. So the treatment started after that.”

Whether someone is a smoker, an ex-smoker or has never smoked, a cough that lasts for more than three weeks needs to be checked out.
Yvonne’s message

Yvonne was diagnosed with lung cancer in 2006. She stopped smoking nearly a decade ago. Yvonne’s cancer was operable and she has undergone successful surgery to remove part of her lung. Yvonne feels there is a positive message to lung cancer and there is hope for people.

“I really am one of the lucky ones. I am alive and feeling well. It’s important to tell people that you can survive and extend your life if you catch the disease early enough.”
Lung disease explained

<table>
<thead>
<tr>
<th>Disease</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Asthma</strong></td>
<td>Asthma is inflammation and tightness in the airways. The airways become narrow and sometimes produce more mucus than usual. This makes it difficult to breathe. Asthma often starts in childhood, but it can happen for the first time at any age – even in people in their 70s or 80s.</td>
</tr>
<tr>
<td><strong>COPD</strong></td>
<td>COPD is a disease that leads to gradual damage to the airways in the lungs causing them to become narrower and making it harder for air to get in and out of the lungs. COPD stands for Chronic Obstructive Pulmonary Disease and includes conditions such as chronic bronchitis and emphysema. The word 'chronic' means that the problem is long-term.</td>
</tr>
<tr>
<td><strong>Lung cancer</strong></td>
<td>Lung cancer Is the uncontrolled growth of abnormal cells in the lung which forms a lump or tumour. Lung cancer develops in the tubes that carry air in and out of the lungs (your airways). It can grow within the lung, and it can spread outside the lung.</td>
</tr>
<tr>
<td><strong>Pneumonia</strong></td>
<td>Pneumonia is an infection which causes the air sacs in the lungs and the smaller bronchial tubes to become inflamed and fill with fluid. This makes it hard for the lungs to do their job.</td>
</tr>
<tr>
<td><strong>TB (Tuberculosis)</strong></td>
<td>TB (Tuberculosis) is an infection caused by a germ. It most commonly affects the lungs, and is caught from other people coughing and sneezing. The body's immune system usually destroys the germs once they are inhaled, but they may cause an illness weeks or even months later.</td>
</tr>
</tbody>
</table>
Support Helplines

The Australian Lung Foundation offers advice and support for anyone affected by a lung condition.

Helpline: 1800 654 301
Website: www.lungfoundation.com.au

The Cancer Council of Australia.

Cancer Council Helpline is a free, confidential telephone information and support service run by Cancer Councils in each state and territory. Specially trained staff are available to answer your questions about cancer and offer emotional or practical support.

Helpline: 13 11 20
Website: www.cancer.org.au/home.htm

The Asthma Foundations from every state and territory work together to help people with asthma and linked conditions to breathe better. We provide information, education, training, advocacy and promote research.

To find out more about asthma contact your local Asthma Foundation:

Helpline: 1800 645 130

Local websites: Asthma Foundations across Australia have local websites with information about their services for the community. Visit www.asthmaaustralia.org.au to access each state's websites.
### Helpful list to take to the doctor

If you do notice any symptoms it may be helpful to tick them on the list below. You can then remove this page and take it with you to the doctor.

<table>
<thead>
<tr>
<th>Tick and Take</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coughing up phlegm with signs of blood in it</td>
</tr>
<tr>
<td>Chest pains</td>
</tr>
<tr>
<td>Severe, sudden breathlessness</td>
</tr>
<tr>
<td>A cough or a worsening cough</td>
</tr>
<tr>
<td>Breathlessness or worsening breathlessness</td>
</tr>
<tr>
<td>Coughing up phlegm</td>
</tr>
<tr>
<td>Shoulder or rib pain especially when breathing and coughing</td>
</tr>
<tr>
<td>Wheezing</td>
</tr>
<tr>
<td>Loss of weight and appetite</td>
</tr>
<tr>
<td>Severe, unusual tiredness</td>
</tr>
</tbody>
</table>
OUR MESSAGE TO YOU

REMEMBER 1,2,3

1. Look after number one – know what symptoms to look out for
2. It takes two to tango – bring symptoms to your doctor
3. The three week rule – don’t wait with symptoms

KNOW YOUR ACTION PLAN

- When to check for symptoms
- What to do if you have symptoms
- When to make that appointment

YOU’VE NOTHING TO LOSE AND A LOT TO GAIN

- Treatment can help you feel better
- Treatment can help improve your quality of life
- Treatment can help extend your life

MAKE IT HAPPEN!
All the information that you provide in this questionnaire is confidential.

You will not be identifiable from any of the answers that you give.

If you have any questions regarding this questionnaire please contact:

Sonya Murray  Tel: (08) 9346 7237 (or email: Sonya.Murray@uwa.edu.au)
What is the purpose of this questionnaire?

The purpose of this questionnaire is to find out some things about you and your health. We are also interested in why people do or do not consult their doctor and we would appreciate your responses to some questions about this.

What if I am not sure how to answer some questions?

Do the best that you can.

Should you have any difficulties with completing the questionnaire, or have any questions about the study please contact:

Sonya Murray  Tel: (08) 9346 7237 (or email:

Sonya.Murray@uwa.edu.au)

How long will it take to complete?

It should take no longer than 20-30 minutes to complete.

Is the information confidential?

All the information that you give is extremely valuable to the study and is treated in the strictest confidence.

What should I do with my completed questionnaire?

After you have filled in the questionnaire please put it in the addressed FREEPOST envelope provided and post it back to us. NO POSTAGE STAMP IS REQUIRED.

We would be very grateful if you could return your completed questionnaire as soon as possible.

Thank you.
Section A: **WHAT DO YOU KNOW ABOUT LUNG DISEASE**

We would like to begin by asking what you know about lung disease.

Listed below are different types of lung disease that share some **common** symptoms:

- Asthma
- COPD (which includes chronic bronchitis and emphysema)
- Lung cancer
- Pneumonia
- TB (tuberculosis)

1. Please tick any symptoms you believe are **common** symptoms of any of these lung diseases.

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Yes</th>
<th>No</th>
<th>Not sure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sore throat</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hoarseness</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cough</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rash</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain when breathing or coughing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wheezing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diarrhoea</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breathlessness</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Loss of appetite</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coughing up phlegm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Itchy skin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A cough that gets worse</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>More tired than usual</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indigestion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shoulder or rib pain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sneezing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fever</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Losing weight</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coughing up phlegm/glut with signs of blood in it</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>More breathlessness than usual</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Risk of lung disease**

The next questions ask you to rate your own chances of getting lung disease. Please tick one box for each question. If you already have a form of lung disease, please rate your chances of getting another one.

2. How would you rate your chance of getting lung disease?

<table>
<thead>
<tr>
<th>Very low</th>
<th>Moderately low</th>
<th>Neither high nor low</th>
<th>Moderately high</th>
<th>Very high</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. Compared to other people of your age and sex do you think your risk of suffering lung disease is:

<table>
<thead>
<tr>
<th>Much lower</th>
<th>Somewhat lower</th>
<th>About the same</th>
<th>Higher</th>
<th>Much higher</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
Section B: CONSULTING THE DOCTOR

The next four questions come in two parts; a and b. First, we want you to imagine what you would do in certain situations. Second, we want you to say how easy or difficult that would be for you.

1a. If you develop a new, persistent, dry cough, but you are otherwise well, then at what point would you make an appointment to see a doctor?

I will make an appointment to see a doctor after I have a new, persistent, dry cough for:

<table>
<thead>
<tr>
<th>Duration</th>
<th>Tick one box only</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 day or less</td>
<td></td>
</tr>
<tr>
<td>3 days</td>
<td></td>
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<tr>
<td>1 week</td>
<td></td>
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<td>2 weeks</td>
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<tr>
<td>3 weeks</td>
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<td>1 month</td>
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<td>2 months</td>
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<tr>
<td>3 months</td>
<td></td>
</tr>
<tr>
<td>6 months</td>
<td></td>
</tr>
<tr>
<td>Longer than 6 months</td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td></td>
</tr>
</tbody>
</table>

1b. On a scale of one to seven please circle the number that best describes how easy or difficult it would be for you to make an appointment to see a doctor with a new, persistent, dry cough in the time you have ticked?

Easy 1 2 3 4 5 6 7 Difficult
2a. If you become newly short of breath in day to day activities, but you are otherwise well, then at what point would you make an appointment to see a doctor?

<table>
<thead>
<tr>
<th>I will make an appointment to see a doctor after I have been newly short of breath in day to day activities for:</th>
<th>Tick one box only</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 day or less</td>
<td></td>
</tr>
<tr>
<td>3 days</td>
<td></td>
</tr>
<tr>
<td>1 week</td>
<td></td>
</tr>
<tr>
<td>2 weeks</td>
<td></td>
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<tr>
<td>3 weeks</td>
<td></td>
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<tr>
<td>1 month</td>
<td></td>
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<tr>
<td>2 months</td>
<td></td>
</tr>
<tr>
<td>3 months</td>
<td></td>
</tr>
<tr>
<td>6 months</td>
<td></td>
</tr>
<tr>
<td>Longer than 6 months</td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td></td>
</tr>
</tbody>
</table>

2b. On a scale of one to seven please circle the number that best describes how easy or difficult it would be for you to make an appointment to see a doctor if you become newly short of breath in day to day activities in the time you

Easy 1 2 3 4 5 6 7  Difficult
3a. If you cough up phlegm/glut with signs of blood, but you are otherwise well, then at what point would you make an appointment to see a doctor?

<table>
<thead>
<tr>
<th>I will make an appointment to see a doctor after I have been coughing up phlegm/glut with signs of blood for:</th>
<th>Tick one box only</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 day or less</td>
<td></td>
</tr>
<tr>
<td>3 days</td>
<td></td>
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<tr>
<td>1 week</td>
<td></td>
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<td>2 weeks</td>
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<td>3 weeks</td>
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<td>1 month</td>
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<td>2 months</td>
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<tr>
<td>3 months</td>
<td></td>
</tr>
<tr>
<td>6 months</td>
<td></td>
</tr>
<tr>
<td>Longer than 6 months</td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td></td>
</tr>
</tbody>
</table>

3b. On a scale of one to seven please circle the number that best describes how easy or difficult it would be for you to make an appointment to see a doctor with coughing up phlegm/glut with signs of blood in the time you have ticked?

Easy     1     2     3     4     5     6     7    Difficult
4a. If you notice you are losing weight, but you are otherwise well, then at what point would you make an appointment to see a doctor?

<table>
<thead>
<tr>
<th>I will make an appointment to see a doctor after I have been losing weight for:</th>
<th>Tick one box only</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 day or less</td>
<td></td>
</tr>
<tr>
<td>3 days</td>
<td></td>
</tr>
<tr>
<td>1 week</td>
<td></td>
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<tr>
<td>2 weeks</td>
<td></td>
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<tr>
<td>3 weeks</td>
<td></td>
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<tr>
<td>1 month</td>
<td></td>
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<tr>
<td>2 months</td>
<td></td>
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<tr>
<td>3 months</td>
<td></td>
</tr>
<tr>
<td>6 months</td>
<td></td>
</tr>
<tr>
<td>Longer than 6 months</td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td></td>
</tr>
</tbody>
</table>

4b. On a scale of one to seven please circle the number that best describes how easy or difficult it would be for you to make an appointment to see a doctor with losing weight in the time you have ticked?

Easy     1     2     3     4     5     6     7 Difficult
In the following questions we would like to know what you think about consulting your doctor with chest symptoms.

5. For me making an appointment to see a doctor if I were to experience any chest symptoms for a month would be:

(Please tick one box in each line)

<p>| | | | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>A good thing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Difficult</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Worthless</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Harmful</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Impossible</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Awkward</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
In these next questions please circle the number that best describes your opinion about consulting a doctor with chest symptoms.

<table>
<thead>
<tr>
<th>Question</th>
<th>Strongly agree 1</th>
<th>Strongly agree 2</th>
<th>Strongly agree 3</th>
<th>Strongly agree 4</th>
<th>Strongly agree 5</th>
<th>Strongly agree 6</th>
<th>Strongly agree 7</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.</td>
<td>The decision whether to see a doctor if I have chest symptoms for a month is beyond my control:</td>
<td>Strongly agree 1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>7.</td>
<td>I intend to see a doctor if I have chest symptoms for a month:</td>
<td>Strongly agree 1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>8.</td>
<td>I am confident I could see a doctor if I had chest symptoms for a month:</td>
<td>Strongly agree 1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>9.</td>
<td>I will try to see a doctor if I have chest symptoms for a month:</td>
<td>Strongly agree 1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>10.</td>
<td>Whether or not I see a doctor if I have chest symptoms for a month is up to me:</td>
<td>Strongly agree 1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>11.</td>
<td>I plan to see a doctor if I have chest symptoms for a month:</td>
<td>Strongly agree 1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
</tbody>
</table>
We would now like to know how confident you are about making an appointment to see your doctor under certain circumstances. Please circle the number that best describes your level of confidence for each of the following questions.

How confident are you that you can make an appointment to see a doctor when

12. you can’t get an appointment with your usual doctor? Not at all confident Not at all confident
13. the health centre number is busy when you phone to make an appointment? Not at all confident Not at all confident
14. you have had a cough for one week? Not at all confident Not at all confident
15. taking the time away from work or other commitments is difficult? Not at all confident Not at all confident
16. you have already been to see a doctor. You got some medication, which has helped a bit, but you still feel unwell? Not at all confident Not at all confident
17. you have chest symptoms at the weekend or while away from home? Not at all confident Not at all confident
18. you have been short of breath for one month? Not at all confident Not at all confident
19. you think your symptoms are not serious enough? Not at all confident Not at all confident
20. you know your doctor will mention the dangers of smoking? Not at all confident Not at all confident
21. you have been wheezy for six months? Not at all confident Not at all confident
22. the receptionist at your health centre offers for you to see the practice nurse instead of the doctor? Not at all confident Not at all confident
Section C: YOUR HEALTH

We would like to ask your views about your health.

1. In general, would you say your health is:

   (circle one number)

<table>
<thead>
<tr>
<th>Health Level</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excellent</td>
<td>1</td>
</tr>
<tr>
<td>Very good</td>
<td>2</td>
</tr>
<tr>
<td>Good</td>
<td>3</td>
</tr>
<tr>
<td>Fair</td>
<td>4</td>
</tr>
<tr>
<td>Poor</td>
<td>5</td>
</tr>
</tbody>
</table>

This next section asks questions mainly about your chest and chest symptoms. Please tick YES or NO where possible.

COUGH

2. Do you usually cough first thing in the morning during winter?  Yes [ ] No [ ]

3. Do you usually cough during the day or at night in the winter?  Yes [ ] No [ ]

If you said YES to question 2 or 3:

4. Do you cough like this on most days for as much as three months of the year?  Yes [ ] No [ ]
COUGHING UP PHLEGM/GLUT

5. Do you usually bring up phlegm/glut from your chest first thing in the morning in the winter? Yes □ No □

6. Do you usually bring up any phlegm/glut from your chest during the day or at night in winter? Yes □ No □

If you said YES to question 5 or 6:

7. Do you bring up phlegm/glut like this on most days for as much as three months each year? Yes □ No □

PERIODS OF COUGH & PHLEGM/GLUT

8. In the past three years have you had a period of increased cough and phlegm/glut lasting for three weeks or more? Yes □ No □

If YES:

9. Have you had more than one such period? Yes □ No □

BREATHLESSNESS

The following statements refer to your breathing

10. I only get breathless with strenuous exercise. Yes □ No □

11. I get short of breath when hurrying on level ground or walking up a slight hill. Yes □ No □

12. I get short of breath walking with other people of my age on level ground. Yes □ No □

13. I stop for breath after walking 100 yards/metres or after a few minutes on level ground. Yes □ No □
14. I am too breathless to leave the house.  
   Yes            No

**WHEEZE**

15. Have you had attacks of wheezing or whistling in your chest at any time in the last 12 months?
   Yes            No

16. Have you ever had attacks of shortness of breath with wheezing?
   Yes            No

**If YES:**

17. Is/was your breathing absolutely normal between attacks?
   Yes            No

18. Have you at any time in the last 12 months been woken at night by an attack of shortness of breath?
   Yes            No

**CHEST ILLNESSES**

19. During the last three years have you had any chest illness which has kept you from your usual activities for as much as a week?
   Yes            No

**If YES:**

20. Did you bring up more phlegm/glut than usual in any of these illnesses?
   Yes            No

21. Have you ever been admitted to hospital for chest problems in the last 12 months?
   Yes            No
We are interested in any previous illness you may have had and whether you developed these during the past twelve months.

22. Have you had, or been told that you have any of the following illnesses below?

Please tick appropriate answer in each line.

<table>
<thead>
<tr>
<th>Lung diseases</th>
<th>Yes, for the first time in the last twelve months</th>
<th>Yes, for the first time more than twelve months ago</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asthma?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease?</td>
<td></td>
<td></td>
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<tr>
<td>Chronic bronchitis?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emphysema?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pleurisy?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pneumonia?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pulmonary tuberculosis?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any other lung disease</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If yes for any other lung disease please state what:

<table>
<thead>
<tr>
<th>Other illnesses</th>
<th>Yes, for the first time in the last twelve months</th>
<th>Yes, for the first time more than twelve months ago</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart trouble?</td>
<td></td>
<td></td>
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<tr>
<td>Kidney failure?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stomach ulcer/ acid reflux/ hiatus hernia?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rheumatic troubles or arthritis?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depression or nervous trouble?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other mental health problems?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Question</td>
<td>Answer</td>
<td></td>
</tr>
<tr>
<td>----------------------------------------------------</td>
<td>--------</td>
<td></td>
</tr>
<tr>
<td>High blood pressure?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stroke?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>An injury or operation affecting your chest?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any other serious long-term illness?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If **yes** for any other serious long term illness please specify what:

__________________________________________________________________
Section D:  HOW YOU FEEL

Please read each item and place a tick in the box beside the reply which comes closest to how you have been feeling in the past week. Don’t take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought-out response. Please tick only one box in each section.

1. I feel tense or ‘wound up’:
   - Most of the time
   - A lot of the time
   - Time to time, Occasionally
   - Not at all

2. I feel as if I am slowed down:
   - Nearly all the time
   - Very often
   - Sometimes
   - Not at all

3. I still enjoy the things I used to enjoy:
   - Definitely as much
   - Not quite as much
   - Only a little
   - Hardly at all

4. I get a sort of frightened feeling like ‘butterflies’ in the stomach:
   - Not at all
   - Occasionally
   - Quite often
   - Very often

5. I get a sort of frightened feeling as if something awful is about to happen:
   - Very definitely and quite badly
   - Yes, but not too badly
   - A little, but it doesn’t worry me
   - Not at all

6. I have lost interest in my appearance:
   - Very definitely and quite badly
   - Definitely
   - Yes, but not too badly
   - I don’t take so much care as I should

7. I can laugh and see the funny side of things:
   - As much as I always could
   - Not quite so much now
   - Definitely not so much now
   - Not at all

8. I feel restless as if I have to be on the move:
   - As much as I always could
   - Very much indeed
   - Not quite so much now
   - Quite a lot
   - Definitely not so much now
   - Not very much
   - Not at all

9. Worrying thoughts go through my mind:
   - A great deal of the time
   - A lot of the time
   - From time to time but not too often
   - Only occasionally

10. I look forward with enjoyment to things:
    - As much as ever I did
    - Rather less than I used to
    - Definitely less than I used to
    - Hardly at all

11. I feel cheerful:
    - Not at all
    - Not often
    - Sometimes
    - Most of the time

12. I get sudden feelings of panic:
    - Very often indeed
    - Quite often
    - Not very often
    - Not at all

13. I can sit at ease and feel relaxed:
    - Definitely
    - Usually
    - Not often
    - Not at all

14. I can enjoy a good book or radio or TV programme:
    - Often
    - Sometimes
    - Not often
    - Very seldom

Cancer, including lung cancer, is a topic that is regularly discussed on radio, television and in newspapers. You may also have seen posters or pamphlets at your health centre about breast and other cancers. We would like you to tell us about your thoughts or worries about lung cancer.

15. During the past month, how often have you thought about your own chances of developing lung cancer?

not at all or rarely  sometimes  often  almost all the time

16. During the past month, how often have thoughts about your chances of getting lung cancer affected your mood?

not at all or rarely  sometimes  often  almost all the time

17. During the past month, have thoughts about your chances of getting lung cancer affected your ability to perform your daily activities?

not at all or rarely  sometimes  often  almost all the time

18. How concerned are you about the possibility that you might get lung cancer someday?

not at all or rarely  sometimes  often  almost all the time

19. How often do you worry about developing lung cancer?

not at all or rarely  sometimes  often  almost all the time

20. How much of a problem is worrying about lung cancer to you?

not at all  somewhat  definitely is  severe problem
AQOL-8D
Tick the box that best describes your situation as it has been over the past week
Centre for Health Economics, Monash University

Q1 Thinking about how much energy you have to do the things you want to do: I am
☐ always full of energy
☐ usually full of energy
☐ occasionally energetic
☐ usually tired and lacking energy
☐ always tired and lacking energy

Q2 How often do you feel socially excluded or left out?
☐ never
☐ rarely
☐ sometimes
☐ often
☐ always

Q3 Thinking about how easy or difficult it is for you to get around by yourself outside your house (e.g., shopping, visiting):
☐ getting around is enjoyable and easy
☐ I have no difficulty getting around outside my house
☐ a little difficulty
☐ moderate difficulty
☐ a lot of difficulty
☐ I cannot get around unless somebody is there to help me

Q4 Thinking about your health and your role in your community (that is to say neighbourhood, sporting, work, church or cultural groups):
☐ my role in the community is unaffected by my health
☐ there are some parts of my community role I cannot carry out
☐ there are many parts of my community role I cannot carry out
☐ I cannot carry out any part of my community role

Q5 How often do you feel sad
☐ never
☐ rarely
☐ some of the time
☐ usually
☐ nearly all the time

Q6 Thinking about how often you experience serious pain: I experience
☐ very rarely
☐ less than once a week
☐ three to four times a week
☐ most of the time
Q7 How much confidence do you have in yourself?
- Complete confidence
- A lot
- A moderate amount
- A little
- None at all

Q8 When you think about whether you are calm and tranquil or agitated: I am
- always calm and tranquil
- usually calm and tranquil
- sometimes calm and tranquil, sometimes agitated
- usually agitated
- always agitated

Q9 Thinking about your health and your relationship with your family:
- my role in the family is unaffected by my health
- there are some parts of my family role I cannot carry out
- there are many parts of my family role I cannot carry out
- I cannot carry out any part of my family role

Q10 Your close relationships (family and friends) are:
- very satisfying
- satisfying
- neither satisfying nor dissatisfying
- dissatisfying
- unpleasant
- very unpleasant

Q11 When you communicate with others, e.g. by talking, listening, writing or signing:
- I have no trouble speaking to them or understanding what they are saying
- I have some difficulty being understood by people who do not know me. I have no trouble understanding what others are saying to me
- I am understood only by people who know me well. I have great trouble understanding what others are saying to me.
- I cannot adequately communicate with others

Tick the box that best describes your situation as it has been over the past week

Q12 How often do you have trouble sleeping?
- never
- almost never
- sometimes
- often
- all the time

Q13 How often do you feel worthless?
- never
- almost never
Q14 How often do you feel angry?
- never
- almost never
- sometimes
- often
- all the time

Q15 Thinking about your mobility, including using any aids or equipment such as wheelchairs, frames, sticks:
- I am very mobile
- I have no difficulty with mobility
- I have some difficulty with mobility (for example, going uphill)
- I have difficulty with mobility. I can go short distances only.
- I have a lot of difficulty with mobility. I need someone to help me.
- I am bedridden

Q16 Do you ever feel like hurting yourself?
- never
- rarely
- sometimes
- often
- all the time

Q17 How enthusiastic do you feel?
- extremely
- very
- somewhat
- not much
- not at all

Q18 And still thinking about the last seven days, how often did you feel worried?
- never
- occasionally
- sometimes
- often
- all the time

Q19 Thinking about washing yourself, toileting, dressing, eating or looking after your appearance:
- these tasks are very easy for me
- I have no real difficulty in carrying out these tasks
- I find some of these tasks difficult, but I manage to do them on my own
- many of these tasks are difficult, and I need help to do them

344 | Page
I cannot do these tasks by myself at all

Q20 How often do you feel happy
☐ all the time
☐ mostly
☐ sometimes
☐ almost never
☐ never

Q21 How much do you feel you can cope with life’s problems?
☐ completely
☐ mostly
☐ partly
☐ very little
☐ not at all

Q22 How much pain or discomfort do you experience:
☐ none at all
☐ I have moderate pain
☐ I suffer from severe pain
☐ I suffer unbearable pain

Q23 How much do you enjoy your close relationships (family and friends)?
☐ immensely
☐ a lot
☐ a little
☐ not much
☐ I hate it

Tick the box that best describes your situation as it has been over the past week

Q24 How often does pain interfere with your usual activities?
☐ never
☐ rarely
☐ sometimes
☐ often
☐ always

Q25 How often do you feel pleasure?
☐ always
☐ usually
☐ sometimes
☐ almost never
☐ never

Q26 How much of a burden do you feel you are to other people?
☐ Not at all
☐ A little
A moderate amount
A lot
totally

Q27 How content are you with your life?
      extremely
      mainly
      moderately
      slightly
      not at all

Q28 Thinking about your vision (using your glasses or contact lenses if needed):
      I have excellent sight
      I see normally
      I have some difficulty focusing on things, or I do not see them sharply. E.g. small print, a newspaper or seeing objects in the distance.
      I have a lot of difficulty seeing things. My vision is blurred. I can see just enough to get by with.
      I only see general shapes. I need a guide to move around.
      I am completely blind

Q29 How often do you feel in control of your life?
      always
      mostly
      sometimes
      only occasionally
      never

Q30 How much help do you need with jobs around the house (e.g. preparing food, cleaning the house or gardening):
      I can do all these tasks very quickly and efficiently without any help
      I can do these tasks relatively easily without help
      I can do these tasks only very slowly without help
      I cannot do most of these tasks unless I have help
      I can do none of these tasks by myself

Q31 How often do you feel socially isolated?
      never
      rarely
      sometimes
      often
      always

Q32 Thinking about your hearing (using your hearing aid if needed):
      I have excellent hearing
      I hear normally
      I have some difficulty hearing or I do not hear clearly. I have trouble hearing softly-spoken people or when there is background noise.
I have difficulty hearing things clearly. Often I do not understand what is said. I usually do not take part in conversations because I cannot hear what is said.

I hear very little indeed. I cannot fully understand loud voices speaking directly to me.

I am completely deaf

Q33 How often do you feel depressed?

- never
- almost never
- sometimes
- often
- very often
- all the time

Q34 Your close and intimate relationships (including any sexual relationships) make you:

- very happy
- generally happy
- neither happy nor unhappy
- generally unhappy
- very unhappy

Q35 How often did you feel in despair over the last seven days?

- never
- occasionally
- sometimes
- often
- all the time
Section E: ABOUT YOU

This is the final section where we would like to know a little bit about you.

2. What is your age?.........................

3. Are you Male □ Female □

4. Do you live? □ On your own
   □ With a partner/spouse
   □ With other family (Please say who)
   □ Other (Please say who)

5. What is your postcode? .....................

6. What is your highest level of education?
   □ Year 11 or below
   □ Year 12 or equivalent
   □ Trade/Apprenticeship
   □ Tertiary Certificate/diploma
   □ Undergraduate university degree
   □ Post graduate university degree
   □ None of these
   □ Other please state............................................................

7. Can you be described by any of the following? (Please tick all that apply)
   □ Retired  □ Working for a dependent relative
   □ Invalid/disabled □ Unemployed
   □ Voluntary worker □ Student
   □ Looking after home/family  □ Other


Accommodation

8. Do you: (Please tick one box only)

☐ Own your home                 ☐ Other please state………………………………
☐ Rent your home

If you have any comments about any of the questions that we have asked, please add them here.

Thank you for completing this survey. Please return it using the reply-paid envelope provided (NO STAMP IS NEEDED).
PARTICIPANT CONSENT FORM

Consent to release of Medicare and/or Pharmaceutical Benefits Scheme (PBS) claims information for the purposes of the CHEST TRIAL. Reducing time to consult with symptoms of lung disease.

Important Information

Complete this form to request the release of personal Medicare claims information and/or PBS claims information to the CHEST TRIAL. Reducing time to consult with symptoms of lung disease.

Any changes to this form must be initialled by the signatory. Incomplete forms may result in the study not being provided with my information.

By signing this form, I acknowledge that I have been provided with information about this study. I have been given an opportunity to ask questions and have been fully informed about this study.

PARTICIPANT DETAILS

1. Mr □ Mrs □ Miss □ Ms □ Other □

Family name: ____________________ First given name: ____________________

Other given name(s): ____________________

Date of birth: DD/MM/YYYY

2. Medicare card number: ____________________

3. Permanent address:

________________________________________________________

Postal address (if different to above):

________________________________________________________

AUTHORISATION
4. I authorise Medicare Australia to provide my:

- Medicare claims history OR
- PBS claims history OR
- Medicare & PBS claims history

for the period* DD/MM/YYYY to: DD/MM/YYYY to the [Chest Australia] study.

*Note: This period cannot exceed 4 ½ years

DECLARATION

I declare that the information on this form is true and correct.

5. Signed: ___________________________ (participant’s signature) OR

6. Signed by ___________________________ (full name) on behalf of participant

________________________ (signature)

☐ Parent (where the participant is under the age of 18)

☐ Legal guardian* (where the participant is under the age of 18)

☐ Power of attorney*

☐ Guardianship order* * Please attach supporting evidence

Power of attorney – A power of attorney is a document that appoints a person to act on behalf of another person who grants that power. In particular, an enduring power of attorney allows the appointed person to act on behalf of another person even when that person has become mentally incapacitated. The powers under a power of attorney may be unlimited or limited to specific acts.

Guardianship order – A Guardianship order is an order made by a Guardianship Board/Tribunal that appoints a guardian to make decisions for another person. A Guardianship order may be expressed broadly or limited to particular aspects of the care of another person.
A sample of the information that may be included in your Medicare claims history:

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<tr>
<th>Date of service</th>
<th>Date of Processing</th>
<th>Item number</th>
<th>Item description</th>
<th>Provider charge</th>
<th>Schedule Fee</th>
<th>Benefit paid</th>
<th>Patient out of pocket</th>
<th>Bill type</th>
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<td>$34.30</td>
<td>$34.30</td>
<td>$4.00</td>
<td>Cash</td>
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<tr>
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<td>23/06/09</td>
<td>11700</td>
<td>ECG</td>
<td>$29.50</td>
<td>$29.50</td>
<td>$29.50</td>
<td></td>
<td>Bulk Bill</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Scrambled ordering Provider number*</th>
<th>Scrambled rendering Provider number*</th>
<th>Date of referral</th>
<th>Rendering Provider postcode</th>
<th>Ordering Provider postcode</th>
<th>Hospital indicator</th>
<th>Provider derived major speciality</th>
<th>Item category</th>
</tr>
</thead>
<tbody>
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<td></td>
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<tr>
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<td>999999A</td>
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<td>2300</td>
<td>2302</td>
<td>N</td>
<td>Cardiologist</td>
<td>2</td>
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</tbody>
</table>

* Scrambled Provider number refers to a unique scrambled provider number identifying the doctor who provided/referred the service. Generally, each individual provider number will be scrambled and the identity of that provider will not be disclosed.

A sample of the information that may be included in your PBS claims history:

<table>
<thead>
<tr>
<th>Date of supply</th>
<th>Date of prescribing</th>
<th>PBS item code</th>
<th>Item description</th>
<th>Patient category</th>
<th>Patient contributio n</th>
<th>Net Benefit</th>
<th>Scrambled Prescriber number*</th>
<th>Pharmacy postcod e</th>
<th>Form Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/03/09</td>
<td>01/03/09</td>
<td>031 33X</td>
<td>Oxazepam Tablet 30 mg</td>
<td>Concession al Ordinary</td>
<td>$5.30</td>
<td>$25.55</td>
<td>99999999</td>
<td>2560</td>
<td>Original</td>
</tr>
<tr>
<td>ATC Code</td>
<td>ATC Name</td>
<td>Prescriber derived major speciality</td>
<td></td>
<td></td>
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<td></td>
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</tr>
<tr>
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<td>General Practitioner</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>N05 B A 01</td>
<td>Diazepam</td>
<td>Psychiatrist</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Scrambled Prescriber number refers to a unique scrambled prescriber number identifying the doctor who prescribed the prescription. Generally, each individual prescriber number will be scrambled and the identity of that prescriber will not be disclosed.
I hereby wish to WITHDRAW my consent to participate in the research study named above and understand that such withdrawal WILL NOT jeopardise my relationship with the General Practice or the University of Melbourne and affiliated universities.

Name: ________________________________

Signature: ______________________________

Date: ....../...../20.....
Expression of Interest Form

Please return this form in the prepaid envelope provided if you are interested in participating in the CHEST Trial.

Yes I (print name)_______________________ am interested in participating in the CHEST Trial.

Date _____ / _____ / ______.

Please select the best way to contact you:

Phone: (08)__________________________

Mobile Phone _________________________

Email _______________________________

Address __________________________________________

_________________________________________________________________________

We need to ask questions regarding your smoking history to see if you are suitable for our study.

1. Have you ever smoked? Yes □ No □

2. How many cigarettes per day do you smoke/did you smoke?

3. How old were you when you started smoking?

4. If you no longer smoke, how old were you when you stopped?

5. Your Date of Birth _____ / _____ / _____
Appendix E. Trial overview

Identification of eligible patients

Inclusion
- Long term smokers (≤20 pack years)
- ≥ 55 years
- Ex-smokers if cessation date was < 15 years ago.
- Ability to read and write English.
- Able to give informed consent.

Exclusion criteria
- Severe psychiatric or cognitive disorder
- Previous diagnosis of lung cancer
- Unable to write or read English.

Objectives of intervention
- Increased salience of chest symptoms
- Increased personal relevance of symptoms
- Reinforced benefits of early presentation
- Sanctioning of early consultation
- Explicit identification of barriers

Mail out to invitees
N=1833

Recruitment of consenters in clinic
N=550
Baseline questionnaires.

Randomised patients
Randomisation by automated phone service.

Intervention
N=275
Research Consultation and Self-help Manual
- Manual is taken home by patient
- “If then” action plans developed through consultation linked to symptom check lists.
- “If then” coping plans tackle barriers to consultation
- Self-monitoring prompts e.g.: SMS messages, fridge magnets, cigarette pack holders.
- Spirometry

Usual Care
N=275
- Lung check
- Spirometry
- Opportunistic smoking cessation advice

Follow up 1
1 month after intervention treatment
Measures: Participant-completed measures including HADs, Knowledge of symptoms of lung disease, Cancer worry scale, Self-efficacy for consulting without delay.

Follow up 2
N=534
12 months after intervention
Measures: Participant-completed measures including HADs, Knowledge of symptoms of lung disease, Cancer worry scale, Self-efficacy for consulting without delay.

Appendix F contains two versions of the qualitative participant interview guide. Version One was amended mainly due to the length (19 questions) and the fact it resembled more of a questionnaire structure with closed and leading questions. Version Two was shortened to seven questions that reflected what we directly wanted to know, and was used more as a guide, rather than following a strict list of questions.
F.1. Qualitative Participant Topic Guide One

Before we begin this interview I want to make sure that you understand your rights in relation to this interview:

- Have you signed a consent form?
- Do you understand you can stop this interview at any stage?
- Do I have permission to make a confidential recording of this interview?
- Can I use your first name when I talk to you?

“In this interview we would like to ask you for your thoughts and opinions on our study on “It’s as easy as 123.” For example what you liked about it, and what you think we could do differently to improve it. We hope to use this resource in a GP practice in the long term- so getting your opinions would be very valuable.

I’ll begin by asking:

Icebreaker

1. What did you think when you received the invitation to the study?

Trying to determine what triggered them to take part. (For example...)

- Concerns about getting a lung condition?
- Concern’s about asbestos exposure?
- Concerns about family history of lung disease
- Want to contribute to research?
- Free lung function test

What were your experiences of the consultation?

“I hope you remember having your meeting with me.....”

2. How did you find the consultation you had with Sonya, Yvonne or Emily?

- What did you like about it? Eg.Worries about lung health, concerns about lung health could be more openly discussed in this environment. Spirometry test: prompt: what did you think about having a lung function test.
- Was there anything you did not like about the consultation?

Explore thoughts and perceptions of the self-help booklet:
3. Do you remember we gave you the self-help booklet?”
   - What did you think about the booklet?
   - What did you like about it?
     - *Language, design, communication, content.......*
   - What could we do to make it better?

“Glad to hear you liked the booklet.....or Sorry to hear you did not like the booklet but....

4. What benefits do you think there are from using the self-help booklet?
   - *Clarify what symptoms to look for?*
   - *Remind you to visit your GP?*
   - *Clarify when to visit your GP?*
   - *Gives important information such as the afterhours GP number?*

5. What are the negative aspects of using a self-help booklet on lung disease?
   - *Time consuming to refer to a booklet?*
   - *Too obvious – I already know all the information in it...*
   - *I kept losing it?*

6. So, have you had any chest symptoms lately?
   - Have you actually referred to the self-help booklet for any of your respiratory symptoms in the past year?

7. Have you shown the booklet to anyone in the past year? Do they have an influence on whether or how you use it?

**Symptom recognition**

“Because this is a lung study, we want to know more about your visits to your GP about CHEST symptoms.....”

8. Have you visited your GP lately with any respiratory symptoms after taking part in the study?

Yes/No
• If Yes: -Could you describe your symptom/s. (duration).

9. How long did you wait before visiting your GP? (Delay in seeking help?).

10. What made you go and visit your GP about your symptoms? (Motivation in seeking help?)

Symptom recognition/Knowledge of symptoms.

11. After taking part in this study, do you believe you could recognise symptoms and signs of lung disease?

• Yes/No

• Do you think having the self-help booklet would have made this easier?

Reduce delay in consultation/benefits of early diagnosis

12. “Do you remember what the main things are you had to do if you have symptoms of lung disease?”

13. How has the booklet made this easier? Can you tell me more.....

14. What are the main things you think you have taken away from the booklet?

Confidence to visit GP: (We need to unpack confidence).

15. Are you confident after taking part in the study to visit your GP if you experience any symptoms of lung disease?

Yes/No

• Yes- Do you think the self-help booklet made a difference to your confidence?

• No-What makes you think you aren’t confident too do this?

Leads into...Barriers to consultation: (follows on from NO point above)

16. What might keep you from consulting your doctor....

-work, time, illness, mobility, access, family commitments, cost, stigma/embarrassment, not wanting to bother the doctor.....

Action Plan-Management of Symptoms:

17. “Can you tell me about your plan about consulting your doctor if you
experience any symptoms of lung disease?

- Yes; can you tell me more about your plan of consulting? Do you think the self-help booklet helped you establish a plan?
- No- can you tell me why not?

Overall feedback:

18. Do you think you will continue using the booklet after the study is over?

- What might keep you from using the self-help booklet?

19. In what ways do you think the study as a whole could have been better?

Is there anything more you would like to add?.......”

“Thank you very much for your time today. Your thoughts and opinions are really important to us and help us evaluate whether this resource is going to be useful in the long term in General Practice...”
F.2. Qualitative Participant Topic Guide Two

Introduction

“Before we begin this interview I want to make sure that you understand your rights in relation to this interview:

- Have you signed a consent form?
- Do you understand you can stop this interview at any stage?
- Do I have permission to make a confidential recording of this interview?
- Can I use your first name when I talk to you?

In this interview we would like to ask you for your thoughts and opinions on our study on “It’s as easy as 123.” For example what you liked about it, and what you think we could do differently to improve it. We hope to use this resource in a GP practice in the long term- so getting your opinions would be very valuable.”

Main interview discussion

1. “What did you think when you received the invitation to the study?”

- Concerns about getting a lung condition?
- Concern’s about asbestos exposure?
- Concerns about family history of lung disease.
- Want to contribute to research?
- Free lung function test?

2. Experience of the consultation.

“How did you find the consultation you had?”

- What did you like about it? Eg. Worries about lung health, concerns about lung health could be more openly discussed in this environment. Spirometry test: prompt: what did you think about having a lung function test.
- Was there anything you did not like about the consultation?

3. Explore thoughts and opinions on the self-help manual and reminders.

“Do you remember we gave you the self-help manual?”

- What did you think about the booklet?
- Useful, not useful?
- How did you use the booklet?
• Did you use it on your own or with someone else?
• Were the monthly reminders useful?

4. **Symptom Recognition.**

   “Because this is a lung study, we want to know more about your visits to your GP with chest symptoms”

5. “**Have you visited your GP lately with any respiratory symptoms after taking part in the study?**

If Yes: -Could you describe your symptom/s. (duration).

How long did you wait before visiting your GP?

What made you go and visit your GP about your symptoms? (Could lead into how you feel when the GP talks to you about smoking cessation here)

6. **What do you remember about the signs of lung disease?**

What are the main things you took away from the consultation/self-help manual?

7. **Unpacking Confidence**

   “Do you think the self-help booklet/consultation made a difference in whether you may see your GP in the future? “

Prompt: How confident do you feel about seeing your GP with lung symptoms?

If no: what might keep you from visiting your GP?

8. “**Is there anything more you would like to add**”

•

**Closing**

“Thank you very much for your time today. Your thoughts and opinions are really important to us and help us evaluate whether this resource is going to be useful in the long term in General Practice”
Table 1 describes each participant in terms of their age, gender, smoking status, socioeconomic score (SEIFA code), number of pack years, number of symptom questionnaires returned, previous 12 month consultation rate, MRC dyspnoea score and FEV1 predicted score for the qualitative study.
<table>
<thead>
<tr>
<th>Patient</th>
<th>Gender</th>
<th>Age</th>
<th>State</th>
<th>SEIFA Code</th>
<th>Clinic</th>
<th>Smoking Status</th>
<th>Pack Years</th>
<th>Delays</th>
<th>Prev Total 12 month consults</th>
<th>MRC Dyspnoea</th>
<th>FEVI pred.</th>
<th>Employment</th>
<th>Education Level</th>
<th>Home ownership</th>
<th>Live alone</th>
<th>Audio Length(min)</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>3018</td>
<td>F</td>
<td>63</td>
<td>WA</td>
<td>941.7</td>
<td>Granada</td>
<td>NS</td>
<td>21</td>
<td>0</td>
<td>7 (Low)</td>
<td>1.3</td>
<td>74</td>
<td>Carer/Employed</td>
<td>&lt;YR 11</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes 20</td>
<td>Looks after daughter with MND. Both parents smoked.</td>
</tr>
<tr>
<td>4002</td>
<td>M</td>
<td>71</td>
<td>WA</td>
<td>1075.7</td>
<td>Landsdale</td>
<td>S</td>
<td>34</td>
<td>0</td>
<td>0 (Low)</td>
<td>1.3</td>
<td>98</td>
<td>Retired</td>
<td>YR 12</td>
<td>Yes</td>
<td>With spouse</td>
<td>16</td>
<td>Lives with family, health conscious but still smokes.</td>
</tr>
<tr>
<td>3013</td>
<td>M</td>
<td>59</td>
<td>WA</td>
<td>941.7</td>
<td>Granada</td>
<td>NS</td>
<td>79</td>
<td>0</td>
<td>4 (Low)</td>
<td>1.3</td>
<td>91</td>
<td>Part time employed</td>
<td>Trade / Apprenticeship</td>
<td>Yes</td>
<td>Yes</td>
<td>36</td>
<td>Tradie/actor. Lives in country. Previous asbestos exposure.</td>
</tr>
<tr>
<td>3022</td>
<td>M</td>
<td>64</td>
<td>WA</td>
<td>941.7</td>
<td>Granada</td>
<td>NS</td>
<td>63</td>
<td>1</td>
<td>6 (Low)</td>
<td>1.3</td>
<td>107</td>
<td>Retired</td>
<td>YR 12</td>
<td>No</td>
<td>With spouse</td>
<td>23</td>
<td>Both parents died of emphysema, works in oil/gas, originally merchant seaman, grew up with asbestos, worked on old steamships that used asbestos, worked in refinery and was subjected to industrial pollutants</td>
</tr>
<tr>
<td>6002</td>
<td>F</td>
<td>70</td>
<td>WA</td>
<td>1011.1</td>
<td>Ballajura</td>
<td>S</td>
<td>21</td>
<td>0</td>
<td>11 (Moderate)</td>
<td>1.3</td>
<td>88</td>
<td>Unemployed</td>
<td>&lt;YR 11</td>
<td>Yes</td>
<td>With spouse</td>
<td>22</td>
<td>Ex Wittanoom blue asbestos mine (office). Only one surviving of her cohort. Worked there from age 17. Dad died of asbestos related disease. Brother works on ships and in mining, not diagnosed.</td>
</tr>
<tr>
<td>7012</td>
<td>F</td>
<td>59</td>
<td>WA</td>
<td>918</td>
<td>Bentley</td>
<td>NS</td>
<td>38</td>
<td>1</td>
<td>7 (Low)</td>
<td>1.3</td>
<td>105</td>
<td>full time employed</td>
<td>&lt;YR 11</td>
<td>Yes</td>
<td>With spouse</td>
<td>37</td>
<td>Full time worker. Lives with partner.</td>
</tr>
<tr>
<td>8001</td>
<td>M</td>
<td>69</td>
<td>WA</td>
<td>1088.5</td>
<td>East Fremantle</td>
<td>NS</td>
<td>27</td>
<td>3</td>
<td>16 (Moderate)</td>
<td>1.3</td>
<td>50</td>
<td>Retired</td>
<td>Undergraduate Uni</td>
<td>Yes</td>
<td>Yes</td>
<td>32</td>
<td>Already diagnosed with COPD. Wheezy during consilt. both parents smoked, gave up in late 40s, had breathlessness before. had pneumonia before. Inhaled asbestos/building materials during building demolition (isolated incident).</td>
</tr>
<tr>
<td>7017</td>
<td>M</td>
<td>71</td>
<td>WA</td>
<td>918</td>
<td>Bentley</td>
<td>NS</td>
<td>44</td>
<td>1</td>
<td>19 (Moderate)</td>
<td>1.3</td>
<td>95</td>
<td>Retired</td>
<td>Trade cert</td>
<td>Yes</td>
<td>With spouse</td>
<td>37</td>
<td>Diagnosed with COPD. Stage 1 emphysema. Dad had lung cancer. Worked in the Latrobe valley coal dust and power stations. Asbestos exposure Lorne Vic. Lagging from pipes.</td>
</tr>
<tr>
<td>8002</td>
<td>F</td>
<td>70</td>
<td>WA</td>
<td>1088.5</td>
<td>East Fremantle</td>
<td>NS</td>
<td>34</td>
<td>0</td>
<td>4 (Low)</td>
<td>1.3</td>
<td>68</td>
<td>Retired</td>
<td>Tertiary cert</td>
<td>Yes</td>
<td>Yes</td>
<td>37</td>
<td>Diagnosed with bowel cancer. Lives alone.</td>
</tr>
<tr>
<td>7019</td>
<td>F</td>
<td>59</td>
<td>WA</td>
<td>918</td>
<td>Bentley</td>
<td>NS</td>
<td>43</td>
<td>0</td>
<td>22 (High)</td>
<td>1.3</td>
<td>71</td>
<td>Invalid</td>
<td>&lt;YR 11</td>
<td>No</td>
<td>Yes</td>
<td>65</td>
<td>Heavy chest infections and asthma. Pleurisy when smoking.</td>
</tr>
<tr>
<td>22029</td>
<td>M</td>
<td>79</td>
<td>WA</td>
<td>1008.8</td>
<td>Ellen Health</td>
<td>S</td>
<td>28</td>
<td>1</td>
<td>22 (High)</td>
<td>4.5</td>
<td>28</td>
<td>Invalid</td>
<td>&lt;YR 11</td>
<td>No</td>
<td>Yes</td>
<td>47</td>
<td>Diagnosed with lung cancer during study.</td>
</tr>
<tr>
<td>13001</td>
<td>M</td>
<td>67</td>
<td>VIC</td>
<td>1091</td>
<td>Thomas Street</td>
<td>NS</td>
<td>113</td>
<td>0</td>
<td>6 (Low)</td>
<td>1.3</td>
<td>95</td>
<td>Employed</td>
<td>Undergraduate Uni</td>
<td>Yes</td>
<td>Yes</td>
<td>17</td>
<td>Quit smoking 10 years ago. Lives alone.</td>
</tr>
<tr>
<td>13007</td>
<td>F</td>
<td>68</td>
<td>VIC</td>
<td>1091</td>
<td>Thomas Street</td>
<td>NS</td>
<td>32</td>
<td>2</td>
<td>30 (Hgh)</td>
<td>1.3</td>
<td>97</td>
<td>Self-employed</td>
<td>YR 12</td>
<td>Yes</td>
<td>With spouse</td>
<td>52</td>
<td>Pneumonia twice in the last year.</td>
</tr>
<tr>
<td>12003</td>
<td>F</td>
<td>74</td>
<td>VIC</td>
<td>1096</td>
<td>Deeplene</td>
<td>S</td>
<td>27</td>
<td>1</td>
<td>19 (Moderate)</td>
<td>4.5</td>
<td>40</td>
<td>Invalid</td>
<td>Postgrad</td>
<td>Yes</td>
<td>Yes</td>
<td>43</td>
<td>Lives alone, has multiple health issues.</td>
</tr>
<tr>
<td>14014</td>
<td>M</td>
<td>79</td>
<td>VIC</td>
<td>1052</td>
<td>Caroline Springs</td>
<td>NS</td>
<td>56</td>
<td>0</td>
<td>21 (High)</td>
<td>1.3</td>
<td>78</td>
<td>Retired</td>
<td>&lt;YR 11</td>
<td>Yes</td>
<td>With spouse</td>
<td>54</td>
<td>High depression. Lives with partner and owns own house.</td>
</tr>
<tr>
<td>14005</td>
<td>M</td>
<td>60</td>
<td>VIC</td>
<td>1052</td>
<td>Caroline Springs</td>
<td>NS</td>
<td>25</td>
<td>1</td>
<td>11 (Moderate)</td>
<td>1.3</td>
<td>74</td>
<td>full time employed</td>
<td>Postgraduate Uni</td>
<td>Yes</td>
<td>With spouse</td>
<td>41</td>
<td>Academic Lecturer at University. Lives with partner and owns own house. Quit 14 years ago.</td>
</tr>
<tr>
<td>14017</td>
<td>M</td>
<td>59</td>
<td>VIC</td>
<td>1052</td>
<td>Caroline Springs</td>
<td>S</td>
<td>20</td>
<td>0</td>
<td>4 (Low)</td>
<td>1.3</td>
<td>103</td>
<td>Invalid</td>
<td>&lt;YR 11</td>
<td>No</td>
<td>Yes</td>
<td>24</td>
<td>Lives on own in caravan Park. Smokes &quot;other&quot; substances.</td>
</tr>
<tr>
<td>14016</td>
<td>M</td>
<td>56</td>
<td>VIC</td>
<td>1052</td>
<td>Caroline Springs</td>
<td>NS</td>
<td>45</td>
<td>1</td>
<td>7 (Low)</td>
<td>1.3</td>
<td>98</td>
<td>full time employed</td>
<td>&lt;YR 11</td>
<td>Yes</td>
<td>With spouse</td>
<td>22</td>
<td>Full time employment, transferred to Perth after the study finished in Melbourne.</td>
</tr>
<tr>
<td>21003</td>
<td>M</td>
<td>76</td>
<td>WA</td>
<td>996.1</td>
<td>Champion Lakes</td>
<td>NS</td>
<td>100</td>
<td>3</td>
<td>6 (Low)</td>
<td>1.3</td>
<td>54</td>
<td>Retired/Invalid</td>
<td>Grammar School UK</td>
<td>Yes</td>
<td>With spouse</td>
<td>29</td>
<td>Has emphysema, asthma, diabetes and has had pneumonia. Breathless a lot.</td>
</tr>
<tr>
<td>21012</td>
<td>F</td>
<td>60</td>
<td>WA</td>
<td>996.1</td>
<td>Champion Lakes</td>
<td>NS</td>
<td>74</td>
<td>2</td>
<td>11 (Moderate)</td>
<td>1.3</td>
<td>102</td>
<td>Full time employment</td>
<td>YR 8</td>
<td>Buying</td>
<td>With spouse</td>
<td>36</td>
<td>Smoking in family. Restarts when stressed. Lives with husband and owns house.</td>
</tr>
</tbody>
</table>
Appendix H.  Practices recruited into the CHEST-Australia Study

The following General Practices were recruited into the CHEST-Australia Trial in Perth, Western Australia and Melbourne, Victoria.

**Perth, Western Australia.**
- Riverton Medical Centre, Riverton, Perth.
- Glengarry Medical Group, Duncraig, Perth.
- Granada Medical Practice, Maddington, Perth.
- Bentley Medical Centre, St James, Perth.
- Landsdale Medical Centre, Landsdale, Perth.
- Illawarra Medical Centre, Ballajura, Perth.
- East Fremantle Medical Centre, East Fremantle, Perth.
- Leeming Doctors on Calley and South, Leeming, Perth.
- Ellen Health Medical Practice, Fremantle, Perth.
- Champion Lakes Medical Centre, Camillo, Perth.
- Kelvale Medical Group, Kelmscott, Perth.

**Melbourne, Victoria.**
- Doctors on Broadway, Reservoir, Melbourne.
- Coolaroo Medical Clinic, Coolaroo, Melbourne.
- Modern Medical Clinic, Caroline Springs, Melbourne.
- Deepdene Surgery, Deepdene, Melbourne.
- Thomas Street family Medical Clinic, Brighton East, Melbourne.
- Dianella Family Medical Centre, Dianella, Melbourne.
Appendix I. Related presentation and awards

I.1. Conference Presentations


2015. Australian Clinical Trials Association annual meeting, Sydney, New South Wales. Poster presentation: “PROTOCOL FOR THE CHEST AUSTRALIA TRIAL: A PHASE II RANDOMISED CONTROLLED TRIAL OF AN INTERVENTION TO REDUCE TIME TO CONSULT WITH SYMPTOMS OF LUNG CANCER.”


I.2. Awards

2012. Awarded a University of Western Australia Australian Postgraduate Award.

2012. Awarded a School of Primary, Rural and Aboriginal Health care (SPARHC grant). The University of Western Australia.
Appendix J. Publications

The work presented in this thesis resulted in two international journal articles.


BMJ Open Protocol for the CHEST Australia Trial: a phase II randomised controlled trial of an intervention to reduce time-to-consult with symptoms of lung cancer

Sonya R Murray,1,2 Peter Munchie,1 Neil Campbell,1 Fiona M Walter,1,2,3 Danielle Mazza,4 Emily Habgood,3 Yvonne Kutzer,3 Andrew Martin,4 Stephen Gould,1 David J Barnes,5,6 Jon D Emery1,2,3,4

ABSTRACT

Introduction: Lung cancer is the most common cancer worldwide, with 1.3 million new cases diagnosed every year. It has one of the lowest survival outcomes of any cancer because over two-thirds of patients are diagnosed when curative treatment is not possible. International research has focused on screening and community interventions to promote earlier presentation to a healthcare provider to improve early lung cancer detection. This paper describes the protocol for a phase II, multi-centre, randomised controlled trial, for patients at increased risk of lung cancer in the primary care setting, to facilitate early presentation with symptoms of lung cancer.

Methods/analysis: The intervention is based on a previous Scottish CHEST Trial that comprised of a primary-care nurse consultation to discuss and implement a self-help manual, followed by self-monitoring reminders to improve symptom appraisal and encourage help-seeking in patients at increased risk of lung cancer. We aim to recruit 550 patients from two Australian states, Western Australia and Victoria. Patients will be randomised to the Intervention (a health consultation involving a self-help manual, monthly prompts and spirometry) or Control (spirometry followed by usual care). Eligible participants are long-term smokers with at least 20 pack years, aged 50 and over, including ex-smokers if their cessation date was less than 15 years ago. The primary outcome is consultation rate for respiratory symptoms.

Ethics and dissemination: Ethical approval has been obtained from The University of Western Australia’s Human Research Ethics Committee (RA/4/1/6018) and The University of Melbourne Human Research Committee (14-41-43). A summary of the results will be disseminated to participants and we plan to publish the main trial outcomes in a single paper. Further publications are anticipated after further data analysis. Findings will be presented at national and international conferences from late 2016.

Trial registration number: Australian New Zealand Clinical Trial Registry ACTRN 12613000383752.

Strengths and limitations of this study

- The CHEST-Australia Trial represents the first trial in Australia to test this type of intervention and measure its impact on health care consultations.
- The trial builds on preliminary evidence from the Scottish CHEST Trial, which showed promising results for altering symptom appraisal and help-seeking behaviour.
- Information from this trial will enable planning of a larger phase III international trial to further assess the impact of the CHEST intervention on clinical outcomes.

INTRODUCTION

Lung cancer is the commonest cancer worldwide,1 in Australia, there were 11 280 new cases and 8099 deaths due to lung cancer in 2010, making it the leading cause of cancer death.2 Lung cancer ranks second for men and fourth for women when considering all causes of death. This reflects its relatively high incidence (58 per 100 000 for males and 31 per 100 000 for females), which is still rising in women, and its low relative survival, only 7.8% of males and 9.5% of females survive beyond 5 years.3,4

There is extensive literature spanning several decades on the concept of “diagnostic delay” in cancer.5 This recognises that patient pathways to presentation to health care and initial management in primary care are key determinants of cancer patient outcomes.6,7 Much of the research on cancer diagnostic delay has suffered from lack of a theorectical model and precise definitions of key time points along the diagnostic pathway. Walter et al8 published a systematic review of cancer diagnostic studies that applied the Andersen Model of Total Patient Delay.9 On
the basis of their review, they have modified this theoretical framework, producing The Model of Pathways to Treatment (figure 1).

The model proposes four key intervals:

1. The Appraisal Interval. The review found that the nature of the symptoms was the most important factor determining the duration of the Appraisal Interval. Misattribution of symptoms either to a previous benign or concurrent condition or non-recognition of the seriousness of symptoms contribute to longer Appraisal Intervals.

2. The Help-Seeking Interval. Various factors may contribute to this interval including patient factors such as competing events (e.g., holidays), and emotional ones such as fear. This includes fear of the consultation and examination, or of the diagnosis and treatment. Access to primary care and sanctioning help-seeking by family or friends, so that patients do not perceive themselves as wasting the doctor’s time, are also important factors.

3. The Diagnostic Interval. Depending on the healthcare setting, this may involve a series of healthcare visits, referrals and investigations, and often represents a complex process. System factors including the role of primary care as a gatekeeper, and access to investigations and specialist care, are key factors determining this interval.

4. The Pre-Treatment Interval. The time from formal cancer diagnosis to initiation of treatment is also strongly influenced by several healthcare system factors such as access to staging investigations and specialised treatments.

Several studies have explored symptom appraisal and help-seeking in people recently diagnosed with lung cancer. Two studies of lung cancer patients from Western Australia have found that normalisation of respiratory symptoms is very common with mean patient delays to seek help of 47–80 days, respectively. Campbell and colleagues interviewed 580 Scottish patients with lung cancer; of these, 50% had experienced symptoms for more than 14 weeks before presenting to a doctor (median 90 days; IQR 31–381 days). The duration of these patient delays should be compared with reported lung cancer median volume doubling times of 98 days. Factors associated with longer symptom appraisal and help-seeking included living alone, a history of chronic obstructive pulmonary disease (COPD) and longer pack years of smoking. In contrast, haemoptysis, new onset of shortness of breath and cough were associated with earlier consulting.

Another English study had similar findings: most patients recalled having symptoms for many months before seeking help, but these symptoms were not recognised as serious, were attributed to everyday causes, and therefore not acted on. There was reluctance to seek help among some people, partly because they were unsure whether their symptoms were normal and, for some, because of the stigma associated with smoking.

Furthermore, patients may not discuss all their symptoms of lung cancer when they do visit their general practitioner (GP), suggesting patients need to be empowered to recognise the significance of symptoms and report them to healthcare providers. Patients may also need clear guidance on reasons to revisit their GP if their symptoms persist, an important safety-netting function of general practice.

Further evidence for the potential to improve lung cancer outcomes by earlier diagnosis comes from the US

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Figure 1 Model of pathways to treatment.
National Lung Cancer Screening Trial, which found a 20% relative reduction in lung cancer mortality from annual low-dose CT. However, the uncertain cost-effectiveness and feasibility of implementing national lung cancer screening programmes means that other approaches to timely diagnosis of lung cancer are still needed. The search for useful biomarkers of lung cancer shows promise, but is still at the validation stage, suggesting an alternative strategy is to attempt to diagnose lung cancer earlier through prompt recognition and investigation of symptoms suggestive of the disease, particularly in those at higher risk.

Public awareness campaigns for educating patients on symptom awareness have shown promise, but many have limited reporting outcomes. Lung cancer ‘signs and symptoms’ intervention studies such as ‘Show us your lungs’ (Australia),23 ‘Be clear on Cancer (UK),24 ‘I’ll tackle it soon’ (UK),25 aimed to raise awareness of the signs and symptoms of lung cancer, and promote help seeking behaviour. The ‘I’ll tackle it soon’ study showed that a combined public awareness campaign and GP education programme led to increased chest X-ray referrals by 20% and lung cancer diagnoses by 27%.26

While patient level interventions show promise in increasing cancer awareness,27 there has been limited research on interventions delivered to individuals at increased risk of lung cancer aimed at promoting earlier presentation to healthcare. The Chest Trial in Scotland was the first to show preliminary evidence that this approach could alter consulting patterns in this population.28 29 In this trial, a theoretically-based intervention, which comprised of a primary-care nurse consultation to discuss and implement a self-help manual, was tested, followed by self-monitoring reminders. The key objectives of the intervention were as follows, with the relevant underlying theories in parentheses: (1) Increase the salience and personal relevance of symptoms (Illness Action Model and Illness prototypes30 31). (2) Improve knowledge of symptoms by introducing chest disease prototypes (Illness Action Model and Illness prototypes30 31). (3) Reinforce the benefits of early intervention in lung cancer and other chest disease (Theory of Planned Behaviour32 33). (4) Promote easy consultation (Zola’s triggers34 35). (5) Tackle barriers to consultation (Theory of Planned Behaviour36 37). (6) Develop personalised action and coping plans (Social Cognitive Theory and Implementation Intentions).38 39 Intervention components 1 and 2 aim to reduce the Symptom Appraisal Interval, while components 3-6 aim to reduce the Help-Seeking Interval. Based on consumer feedback the intervention was designed specifically without any mention of smoking cessation, which was seen as a barrier to engagement. Furthermore, the focus was on chest disease broadly, including the early detection of lung cancer, COPD and other chronic respiratory conditions. This was to reduce potential effects of fear and nihilism surrounding lung cancer.26 Figure 2 presents a summary of the intervention.

Figure 2 Intervention summary.

Two hundred and twelve people at increased risk of lung cancer were recruited into the Scottish CHEST Trial, of whom 206 completed the trial after 1 year of follow-up (102 intervention, 104 control). The total consultation rate was significantly higher in the intervention group (adjusted consultation ratio 1.15, 95% CI 1.04 to 1.27 p=0.005) with a median number of consultations in the year after intervention of 8 (IQR 4-11). The adjusted consultation ratio for new chest symptoms also increased but this did not reach statistical significance (ratio 1.19, 95% CI 0.92 to 1.53). Participants in the intervention group intended to consult sooner with symptoms. There were non-significant increases in chest X-ray requests and referrals to respiratory medicine in the intervention group.27

The Scottish CHEST Trial therefore provides important preliminary evidence for the potential efficacy of the intervention in altering symptom appraisal and help-seeking behaviour. However, stronger evidence is required before this research can inform practice and policy. In particular, evidence is required on the generalisability of the intervention in other populations and the effect on clinical outcomes as well as consulting behaviours.

Preliminary phase I research in Australia with consumer focus groups was conducted to review the CHEST self-help manual and provide feedback on the overall intervention. In addition, the intervention was piloted on 11 participants recruited from a general practice in Perth, Western Australia. This work resulted in modifications to the language used in the consultation and self-help manual, and led to the development of the CHEST Australia Trial: a phase II, multisite, randomised controlled trial that aims to test the modified CHEST Intervention in an Australian population and measure...
the effect of the intervention on consultation rates for chest symptoms.

METHODS AND ANALYSIS

The phase II trial is a multisite randomised controlled trial. Those who meet the eligibility criteria and who consent to participate are randomised 1:1 to either usual care (control arm) or to the intervention (figure 3). Randomisation is being performed using a centralised independent tele-randomisation system managed by the NHMRC Clinical Trials Centre, based at the University of Sydney. Stratifying variables for randomisation are MRC dyspnoea score (scores 1–3 and 4–5) and general practice recruitment site.

Population and setting

Participants are being recruited from general practices in Perth (Western Australia) and Melbourne (Victoria). Recruitment began in May 2013 and aims to be completed in mid-2015.

Inclusion criteria

Eligible participants are long-term smokers with at least 20 pack years, aged 55 and over, including ex-smokers if their cessation date was less than 15 years ago. This represents a population at increased risk of lung cancer. Participants are able to read and write English, and to give informed consent.

Exclusion criteria

Exclusion criteria are severe psychiatric or cognitive disorder or previous diagnosis of lung cancer.

Participant and recruitment procedures

Smokers and ex-smokers are identified from practice computerised records using a specific version of...
electronic data extraction software, the ‘Canning tool’ (http://www.canningtool.com.au), developed for this trial. Potentially eligible patients are invited to participate in the study by letter from their general practice. The invitations include a patient information sheet, ‘expression of interest form’ and a consent form. The expression of interest form asks four screening questions aimed at assessing smoking pack years. These screening questions provide more accurate information regarding the eligibility of patients and overcome limitations of electronic data on smoking in the medical record. Nonresponders are followed up after 2 weeks with a reminder postcard. Eligible patients returning an expression of interest form are followed up by phone to make an appointment with a health researcher at their general practice. Randomisation is performed after completion of baseline data and informed consent has been obtained.

**Intervention**

The Self-Help Manual, entitled ‘Chest Symptoms that Call for Action’, is based around a simple action plan logo, ‘It’s as easy as 1, 2, 3’. These three key actions are:

1. Look after number one and know the symptoms of lung disease.
2. It takes two to tango: doctors can only help you if you see them when you have symptoms.
3. Remember the 3-week rule and see your doctor if you have symptoms for more than 3 weeks.

Participants randomised to the intervention arm have their height, weight and spirometry (using an ‘Easy on PC’, Niche Medical) measured at the consultation. The results of the spirometry test are sent to the GP at the end of the consultation. The trained researcher then guides the patient through the self-help manual, which is taken home by the participant. ‘If/then’ action plans are developed during the consultation which is linked to symptom checklists ‘If/then’ coping plans are discussed to tackle barriers to consultation. A range of monthly self-monitoring prompts to appraise any current symptoms are tailored to individual preferences. These include: SMS and email reminders, postcards, phone calls and fridge magnets. To ensure trial fidelity, intervention consultations are recorded for quality assurance.

**Control group**

Participants randomised to the control arm attend a consultation where they perform a spirometry test, and followup procedures in the trial are discussed. There is also a general discussion about lung health. This is aimed as an attention control and to increase overall engagement in the trial for control participants. Participants then receive usual care at their general practice, including follow-up of abnormal spirometry.

**Outcomes and measures**

The primary outcome of this trial is consultation rates for respiratory symptoms. Data on consultations in the year before the trial and for 12 months after the consultation will be collected through audit of GP records. Additional outcomes include:

1. **Demographics and clinical variables.** Age, gender, marital status, postcode, highest education level, occupation, MRC Dyspnoea Scale and lung function at baseline only.
2. **Self-efficacy for consulting without delay.** A 10-item self-completed scale summed to score 10–100, developed for the Scottish CHEST Trial, which showed good internal reliability (Cronbach α=0.85).
3. **Knowledge of symptoms of lung disease.** A 21-item self-completed checklist of possible symptoms expressed as a percentage correctly selected as associated with chest disease.
4. **Symptom appraisal and help-seeking intent.** This will be measured using the SYMPTOM instrument (lung cancer version), a self-completed questionnaire that obtains data on presenting symptoms and their duration prior to consultation. This will be measured monthly during the trial through electronic searches of the GP records. If a consultation has occurred about a respiratory symptom in that timeframe, the participant is sent a SYMPTOM questionnaire to complete about symptoms relating to that consultation.
5. **Hospital anxiety and depression scale (HADS).** This 14-item self-completed scale has been widely used to measure distress, and has been extensively validated and shown to perform well in a wide range of populations (mean Cronbach α=0.82; sensitivity and specificity 0.80).
6. **Cancer-worry scale.** A 6-item self-completed scale, adapted from the breast cancer worry scale, which showed good internal reliability in the CHEST Trial (Cronbach α=0.88).
7. **Quality of life will be measured using the Apol-8d, a validated self-completed, multi-attribute utility measure that can be used as part of the health economic evaluation of the intervention. This 34-item scale covers the following domains: independent living, happiness, mental health, coping, relationships, self-worth, pain and senses.
8. **Health service utilisation.** In addition to the primary measure of consultation rates for respiratory symptoms, data relating to total general practice consultation rates, chest X-ray requests and referrals to respiratory physicians, will also be captured through audit of general practice records. Participants consent to access to their Medicare claims data (including pharmaceutical benefits scheme (PBS) and Medicare benefits schedule (MBS)) through the Department of Human Services. This will provide more complete data relating to visits to other general practices (and investigations and referrals arising from these) as well as prescribing data.
9. **Lung cancer incidence.** This will be identified through GP medical records, and by flagging participants with the WA and Victorian Cancer Registries.


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10. Trial feasibility and acceptability. As a phase II trial we will also obtain data on patient recruitment and attrition, and response rates to outcome measures, to inform decisions about a future phase III trial.

Measurement timing
The participant-completed measures (1–7 above) are taken at baseline, 1 and 12 months, with the exception of the SYMPTOM instrument, as already described. Health service utilisation data will be collected at 12 months by general practice medical record audit and accessing Medicare and PBS data. This data will not be collected for participants who formally withdraw from the trial.

Participant data and study management
All participants are allocated a unique identifying code. Questionnaire data are entered into a custom built Oracle database (on a secure server held at the University of Western Australia) to allow scoring of the measures in the questionnaire and enable participant tracking through the study.

Sample size and power calculation
Data from the Scottish trial was used to inform power calculations. Assuming that the primary end point of consultations for respiratory symptoms follows a Poisson distribution, and that the expected average rate over 12 months in the study population will be 1.06 for control patients and 2.5% higher for intervention patients, a sample of 334 will provide at least 89% power to reject the null hypothesis of no difference between the groups at the two-sided 5% level of significance. The primary end point will be measured from the medical record audit, thus minimising attrition. Accounting for the same attrition rate observed in the Scottish trial, we require a total sample of 550 participants.

Analyses
All randomised patients will be considered eligible for inclusion in the analysis in accordance with the intention-to-treat analysis principle. Appropriate methods for dealing with missing end point data will be addressed and informed by a blinded review of the data. The baseline characteristics of the two arms will be described using summary statistics. Possible consent bias will be assessed by comparing demographic and clinical variables of participants against those who declined participation, and possible differential attrition will be assessed by comparing baseline characteristics of those who withdraw or die against those who remain in the study. These comparisons will be performed using a two sample t test (or non-parametric equivalent) for continuous variables and $\chi^2$ test for categorical variables. The primary analysis will be a comparison between the two groups on consultations rate for respiratory symptoms using a Poisson regression model, with general practice included as a factor. Comparisons between groups on continuous secondary end points will be undertaken using a linear model that includes general practice as a factor and the baseline value as a covariate (where applicable). Comparisons between groups on categorical secondary end points will be performed using logistic regression with general practice fitted as a factor. The analyses performed on the primary and secondary end points will be repeated adjusting for additional baseline covariates (eg, number of consultations in 12 months prior to randomisation, gender, comorbidities, smoking status, MRC Dyspnoea Score) as part of a sensitivity analysis. Point estimates of the treatment effect will be presented with two-sided 95% CIs and two-sided p values. Unadjusted p values from secondary analyses are interpreted in proper context and will be clearly labelled.

The health economic analysis estimates the cost of CHEST minus any cost-savings due to avoided healthcare utilisation through early diagnosis. Benefits will be extrapolated from the primary end points and via the AQLQ-8D quality of life questionnaire. Results will be presented in terms of the incremental cost-effectiveness ratio. Many of these model parameters will not be powered for statistical significance. Therefore, mean estimates of resource utilisation will be used and CIs are generated by bootstrapping the data. Uncertainty will be explored using probabilistic sensitivity analysis.

The CHEST-Australia Trial represents the first trial in Australia to test this type of intervention and measure its impact on healthcare consultations. Information from this trial will enable planning of a larger phase III international trial to further assess the impact of the CHEST Intervention on clinical outcomes.

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Contributors All authors assisted with the development of the protocol, study design and refinement of study materials. SRM assisted in development of the protocol and designed the Australian study materials. SRM implemented the trial, and oversaw the protocol and collection of data in Perth. FM oversaw...
the collection of data in Melbourne, SRM and JLC led the writing of the manuscript. All authors will contribute to implementation of the protocol and acquisition of data. All authors have been involved in critical evaluation of the manuscript. All authors have read and approved the final version.

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Ethics approval: Ethical approval has been obtained from The University of Western Australia Human Research Ethics Committee (RA/4/1/2514) and The University of Melbourne Human Research Committee (14/1443). There is no formal Data Monitoring Committee for this trial as it was felt unnecessary for this type of intervention. Data management procedures are reported to HRWC. Interim analysis, stopping guidelines and protocol amendments are reported to HRWC. Any significant changes are reported to the ARB/CTU. Requests for the final dataset should be addressed to the corresponding author.

Pre-submission and peer review: Not commissioned; peer reviewed for ethical and funding approval prior to submission.

Data sharing statement: A summary of the results will be disseminated to the study participants. We plan to publish the main trial outcomes in a single paper. Further publications are anticipated after extracting the data in more detail relating to implementation of this complex intervention. Findings will be presented at national and international conferences from late 2018.

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Protocol for the CHEST Australia Trial: a phase II randomised controlled trial of an intervention to reduce time-to-consult with symptoms of lung cancer

Sonya R Murray, Peter Murchie, Neil Campbell, Fiona M Walter, Danielle Mazza, Emily Habgood, Yvonne Kutzer, Andrew Martin, Stephen Goodall, David J Barnes and Jon D Emery

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Qualitative Research

Reducing barriers to consulting a General Practitioner in patients at increased risk of lung cancer: a qualitative evaluation of the CHEST Australia intervention

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Abstract

Background. Lung cancer has one of the lowest survival outcomes of any cancer because over two-thirds of patients are diagnosed when curative treatment is no longer possible, partly due to later presentation with symptoms to a healthcare provider.

Objective. To explore the theoretical underpinning of the Scottish CHEST intervention in participants randomized to the intervention group within the CHEST Australia trial.

Methods. A purposive maximum variation sample of participants who received the intervention in the CHEST trial in Perth, Western Australia (N = 13) and Melbourne, Victoria, (N = 7) were interviewed. Patients were asked about their experience of the CHEST consultation, their recall of the main messages, their symptom appraisal and issues relating to help seeking when they develop symptoms. Thematic analysis was conducted to draw common themes between the participants.

Results. We identified themes consistent with the theoretical basis of the CHEST intervention. Barriers to consultation identified in the CHEST Australia trial participants were smoker stigmatization, guilt, fatalism and symptom normalization. We identified a general perceived mistrust of GPs based on previous negative experiences of visiting their GP in relation to their smoking. The intervention tackled barriers around lecturing and feelings of guilt and stigma related to smoking. We identified expected effects on salience and personal relevance of symptoms. Participants reported a clearer understanding of what to look out for and when to take action after the CHEST intervention.

Conclusions. These findings suggest that the CHEST Australia intervention is achieving the desired objectives at the qualitative level through the proposed theoretical mechanisms.

Key words. Early consultation, intervention, lung cancer and consultation, primary health care, qualitative.
Introduction

Lung cancer is the most common cancer worldwide (1). In Australia, there were 10,936 new cases in 2012 and 8216 deaths in 2013 (2). In 2017, it is estimated that 12,634 new cases of lung cancer will be diagnosed in Australia (7094 males and 5540 females). In 2013, lung cancer accounted for the highest number of cancer deaths in Australia and is estimated to remain the most common cause of death from cancer in 2017 (2). This reflects its relatively high incidence (55 per 100,000 for males and 33 per 100,000 for females in 2013) and its low relative survival, only 16% survive beyond 5 years (2).

There is extensive literature spanning several decades on the concept of 'diagnostic delay' in cancer (1-4). This recognizes that patient pathways to presentation to healthcare and initial management in primary care are important determinants of cancer patient outcomes. The Aarhus statement for improving design and reporting of research on early cancer diagnosis distinguishes between the appraisal interval or the time taken by the patient to interpret bodily changes and the help seeking interval, which describes the time taken to consult a clinician (5). Long intervals between patient detection of symptoms and presentation in primary care are documented in literature on lung cancer (6,7). This can come down to reasons such as normalising symptoms or fear and lack of knowledge of cancer.

The CHEST Australia trial delivered an intervention to individuals at increased risk of lung cancer aimed at promoting earlier presentation to primary healthcare. The intervention was based on the CHEST trial in Scotland, the first to show preliminary evidence that this approach could alter consulting patterns with potentially serious respiratory symptoms in this population (8). In this trial, a theoretically based intervention was tested which combined a primary-care nurse consultation to discuss and implement a self-help manual, followed by self-monitoring reminders to improve symptom appraisal and encourage help seeking in patients at increased risk of lung cancer.

The key objectives of the CHEST intervention were to (i) increase the salience and personal relevance of symptoms, (ii) improve knowledge of symptoms by introducing chest disease and illness prototypes, (iii) reinforce the benefits of early intervention in lung cancer and other chest disease, (iv) tackle barriers to consultation, (v) promote self-efficacy by developing personal action and coping plans, and (vi) sanction early consultation (9).

While population level interventions do show promise in increasing cancer awareness (10), there has been limited research on interventions delivered to individuals at increased risk of lung cancer and promotion of help seeking behaviour. The CHEST Australia trial is testing a locally adapted version of the CHEST intervention aimed at patients at increased risk of lung cancer (11). A small subset of participants from the trial were invited for an interview to explore the experiences of those randomised to receive the CHEST intervention. The aim of this qualitative substudy was to confirm the theoretical underpinning of the CHEST intervention and identify any barriers to early consultation.

Methods

Recruitment and sampling

For the CHEST Australia trial, smokers and ex-smokers were identified from general practice computerised records and invited to participate in the study by letter. Trial participants provided additional consent to be invited into the qualitative substudy by phone. Informed consent for the qualitative substudy was obtained prior to the commencement of each interview. Informed consent ensured that each participant consented to audio recordings and a verbal reminder that participants could withdraw without providing a reason at any stage.

We chose to conduct face-to-face interviews rather than phone interviews to enable the researcher to observe body language and nonverbal cues. We also felt that the participants would feel more comfortable in their own home and be more open with their answers. A purposive sampling strategy reflecting the larger study group's demographics was utilised to provide rich interview data and ensure representativeness (Table 1). Sampling for maximum variation was conducted according to age, gender, location and smoking status. Participants were recruited within a month of completing the 12-month exit questionnaire in the trial. Interviews were conducted until data saturation was reached around key themes.

Data generation

Data collection was carried out by two researchers (SM and YK) between October 2015 and June 2016. Individual qualitative interviews were conducted using a semi-structured topic guide. The topic guide was used to initiate discussion and included questions on the participant's experience of the CHEST consultation and self-help manual, their reasons for participation in the study, their recall of the main messages, their thoughts on prompts used in the trial, their symptom appraisal and issues relating to help seeking when they developed symptoms (Topic guide for participant interviews—Supplementary Material).

Interviews were audio-recorded and transcribed verbatim using Pacific Transcription Services (www.pacifictranscription.com.au).

Data analysis

Thematic analysis initially involved thorough reading of each transcript to generate early codes. Coding was carried out independently by two members of the research team and discussed at project meetings. NVivo software version 10 (QSR International) was used to organise and code data. After all the data were initially coded, overarching themes were generated by combining different codes. Themes were then reviewed and refined and linkages between themes were established and used to develop an interpretative model presented in Figure 1. Key representative quotes from the data to support each theme were identified (Tables 2 and 3).

Results

Twenty people participated in this study, 13 participants were recruited from Perth, Western Australia and seven from Melbourne, Victoria (representing the larger study group distribution). Eight participants were female, five were current smokers and ages ranged from 54 to 79 years (see Table 1). Interview lengths ranged between 16 and 65 minutes and the average duration was 35 minutes. Analysis resulted in a number of distinct themes. Quotations to support each overarching theme and subtheme are described in Table 2.

Barriers to visiting the GP

When examining how the CHEST intervention had been received by participants, we identified many barriers to help seeking. Figure 1 describes the original CHEST intervention model and objectives and highlights differences from an Australian perspective. While fear and fatalism, symptom normalisation, guilt and stigma were common barriers identified, in Australia making an appointment for a consultation was not a perceived barrier.
Reducing barriers to consulting a GP in patients at increased risk of lung cancer

Table 1. Baseline characteristics of participants (N = 206) who participated in the CHEST Australia qualitative study.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Number (%)</th>
<th>M (SD)</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>12 (60)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>8 (40)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td>67 (7.14)</td>
<td>56–79</td>
</tr>
<tr>
<td>Western Australia</td>
<td>13 (65)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Victoria</td>
<td>7 (35)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current smoking status</td>
<td></td>
<td>14 (70)</td>
<td></td>
</tr>
<tr>
<td>Never smoker</td>
<td>6 (30)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Past years (median, IQR)</td>
<td>36 (26.8)</td>
<td>20–113</td>
<td></td>
</tr>
<tr>
<td>Number of delays</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>9 (45)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>7 (35)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>2 (10)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Precise total 12-month controls</td>
<td>12 (8)</td>
<td>0–30</td>
<td></td>
</tr>
<tr>
<td>Low (&lt; 20)</td>
<td>20 (100)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate (20–40)</td>
<td>6 (30)</td>
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<td>High ( &gt; 40)</td>
<td>4 (20)</td>
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<tr>
<td>MRC dyspnea score*</td>
<td></td>
<td>18 (90)</td>
<td></td>
</tr>
<tr>
<td>1 to 3</td>
<td>18 (90)</td>
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<tr>
<td>4 to 5</td>
<td>2 (10)</td>
<td></td>
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<tr>
<td>FEV1 predicted score* (median, IQR)</td>
<td>80 (9) (23)</td>
<td>28–107</td>
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<td>Education level</td>
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<tr>
<td>&lt; Year 11</td>
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<tr>
<td>Year 12 or equivalent</td>
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<td></td>
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<tr>
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<tr>
<td>TAFE/vocational training</td>
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<tr>
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<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>5 (25)</td>
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<tr>
<td>Lives alone</td>
<td>9 (45)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lives with spouse</td>
<td>11 (55)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Previous medical comorbidity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>COPD</td>
<td>2 (10)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Empysema</td>
<td>1 (5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asthma</td>
<td>1 (5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lung cancer</td>
<td>1 (5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cancer (other)</td>
<td>1 (5)</td>
<td></td>
<td></td>
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</tbody>
</table>

COPD, chronic obstructive pulmonary disease; FFV1, forced expiratory volume; MRC, medical research council; TAFE, technical and further education.

A questionnaire that obtains data on presenting symptoms and the time interval from the noticing the symptom to presentation to a healthcare provider.

*Medical Research Council Dyspnea Scale for grading the degree of a patient’s breathing difficulty related to activity graded from 0–5.

FFV1 is the volume of air that can be forcibly blown out in one second, after full inspiration using a spirometer to measure lung function.

This patient was diagnosed with lung cancer while enrolled within the 12-month CHEST Australia trial.

Fear and fatalism

Many had a fatalistic attitude toward lung cancer and this resulted in an underlying fear of diagnosis. Many expressed their fear of the

unknown or having to face a terminal disease and dealing with the consequences of this. It was viewed as easier to go into denial and not have to address these issues. Some participants felt they would leave visiting their GP to the last minute because of this fear (Table 2).

Symptom normalization

Reasons for not visiting the GP were justified by innocuous explanations which seemed to be well considered. Many attributed their cough or other symptoms to "old age" or "what I normally have" (Table 2). Growing older was used to account for a number of symptoms such as coughing, wheeziness and shortness of breath. Those who were current smokers attributed their ongoing cough as being due to smoking, but because there was no obvious difference from what they normally had, they did not recognize this symptom as being important.

The phenomenon of cognitive dissonance was also observed in various ways and this contributed to a delay in consulting. Commonly there was a dissonance reported between attitudes and behavior such as responding to a stressful situation by smoking or rationalizing that because only a few cigarettes were smoked per day this limited the chances of getting lung cancer. Some even rationalized that they did not have a lung condition at all. Some participants validated their explanations by the experiences of family members such as explaining that because their parents had smoked for a long time and did not succumb to lung cancer, then the same would apply to them.

Guilt and stigma

Many felt stigmatized and labeled as an "ex-smoker" in society and by their own families because of their smoking and this was reinforced when they visited the GP. A form of "avoidance coping" was observed as many ex-smokers said if they were currently smoking they may not have been so inclined to participate in the study (Table 2).

Previous experiences of visiting the GP

Past experiences of visiting the GP was identified as a key barrier to early help seeking. Many patients were put off by perceptions of being confronted or reprimanded to cease smoking by their GP and they felt this enforced a feeling of guilt. How the GP delivered this message was seen as important in building trust (Table 2). An underlying perceived mismanagement of the GP related to various reasons such as experiences of a perceived missed diagnosis and misdiagnosis contributed to consulting delay. Another common expression by some patients was the perception of miscommunication between the GP and patient. Some did not understand their current chest diagnosis and would find further information on the internet to clarify their condition (Table 2). Some expressed that their GP could not relate or understand their addiction or simply they were not being listened too (Table 2).

Perceptions of the chest intervention

Feedback from the intervention demonstrated that the theoretically based objectives were potentially being achieved.

Salience

There was evidence that the intervention altered salience or personal relevance of symptoms. Some patients expressed that the intervention heightened symptoms to the forefront of their mind and they therefore addressed them more quickly. Some patients already had a broader self-awareness of their health, due to past or present exposure or current health issues or family history and this may have also
triggered their participation in the study. In Perth, those who had been exposed to the mining industry were particularly aware of their lung health. A family history of cancer also reinforced the need to be vigilant in some. Some who were chronically ill did not respond as well to the intervention and gave reasons such as they already knew what to look out for, they were already frequently visiting their GP or it was "too late" to be useful for them (Table 3).

Increase in symptom awareness
Most people felt that a list of symptoms provided in the CHEST self-help manual led to a clearer understanding of what to look out for and when to take action. In some cases, patients reported that the intervention made them think about how long they had experienced a symptom for and whether the symptom was getting worse. It also made some more aware of which symptoms were of importance.

Perceptions of the components of the intervention
Feedback from the self-help manual
Feedback from the self-help manual indicated that it helped increase some participants’ knowledge of relevant symptoms. The CHEST self-help manual was described as useful, logical and a good "reference guide" with valid information. In some cases, there was reassurance that the manual provided the “correct” information. The benefits of early consultation were reinforced in the manual using stories and timelines of diagnosed lung cancer patients and some reported this was effective communication. Many liked the practical control they had when referring to the manual that they could look at it on their terms (Table 3).

Feedback from the self-monitoring reminders
There was evidence that the prompts and reminders had an impact on symptom early consultation and that they added weight to an intention to act and promote self-efficacy or confidence make an appointment. Reminders or groups (in the form of email, SMS or postcard(s) of wanted behavior were carried out monthly reminding participants to check their symptoms and visit the doctor if needed. Encouraging reminders to individual preferences was also important in promoting self-efficacy. Many preferred the positive messages, images and reminders from the CHEST intervention such as the 123 logo and the fridge magnet (Table 3).

Tackling barriers
There was evidence that the intervention tackled barriers around GP receptiveness and feelings of guilt and stigma related to smoking. The intervention was viewed as "relaxed" and delivered in a non-threatening environment where patients at increased risk of lung cancer could openly talk about their smoking and lung health. The intervention was felt not to judge patients or make them feel guilty for smoking or having previously smoked. Many reported that they preferred not to feel "lectured at". Some liked the "extra level of care" such as having a spirometry test that was provided in the consultation (Table 3).

Conclusions
This study explored the experiences of Australian patients at higher risk of lung cancer who received the CHEST intervention. From these qualitative findings it appears that the intervention is performing as predicted by its theoretical underpinnings, with some novel findings in the Australian setting (see Figure 1).

The intervention was reported as delivered in a relaxed, non-threatening environment where patients at increased risk of lung cancer could openly talk about their smoking and lung health. The intervention did not make participants feel judged or feel guilty for smoking or having previously smoked, it therefore enabled more open and honest discussion. After the intervention, participants reported a clearer understanding of what symptoms changes to look out for and when to take action and they felt that the CHEST self-help manual was a valid and useful guide. The benefits of early consultation appeared to have been understood.

There was some initial evidence that the intervention altered patient’s personal relevance of symptoms and this potentially led to changing attitudes regarding visiting the GP. Some already had a broader self-awareness of their health, due to past or present exposure or current health issues or family history. Interestingly, those who were chronically ill did not respond as well to the intervention perhaps because they already had salient symptoms and fewer barriers to help seeking.
Table 2. Summary of barriers to visiting the GP from 20 participants who participated in the CHEST Australia qualitative study

<table>
<thead>
<tr>
<th>Fear and Fatigue</th>
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<tbody>
<tr>
<td>Lung cancer was viewed in a frightening way and this drove an underlying feeling of fear for some.</td>
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</table>
| "You try to block it off. You try and think, no, it's not me. But then again, you're also, on the other side of it, every little pain or where you feel you think, oh no, this might be it, this might be the cancer that's going to kill me."
| (1400, male, 68 years) |
| "Yeah, because when you are a smoker, you're always hesitant about anything to do with the chest and the lungs, you know? Because when you smoke, you know it's bad and I mean I can only say my, but I know a lot of people that smoke, they don't want to have a chest x-ray because they're scared, basically. Of cancer or yeah what they find. Yeah I can remember always thinking that, you know."
| (15061, female, 68 years) |
| Somatic normalization was particularly attributed to smoking and/or what participants perceived they should or shouldn't do. |
| "Many attributed these symptoms to old age or 'what I normally have'." |
| "But that just doesn't sit well and I think it's just not true. Or my body you know you can't do as many push ups as you used to do, you can't do as many sit ups, it's just normal."
| (1701, male, 71 years) |
| "But I mean he looked quite well. I mean he could walk and talk and that's normal thing. He was physically active, he just always coughed, he was always like that..."
| (1401, male, 67 years) |
| Consistent fear that this may be associated with lifestyle and behaviors. |
| "I'm not really a heavy smoker. So I don't smoke many cigarettes at all. I smoke something else, but... I should be fine in the long term..."
| (14019, male, 59 years) |
| One man described how he dealt with the stress of his father doing a smoking-related illness. |
| "Yeah, and the stupidity of all of this is that I didn't smoke for four years, and the night Dad passed away I started again, but the stupidity of it is that the smoking by me and caused Dad's death."
| (14005, male, 56 years) |
| Whereas others recognized that they didn't have a long condition. |
| "Well, I don't have chest symptoms, I have swallowing problems." |
| (14018, female, 65 years) |
| Some believed that because their parents lived a long time and smoked, that the same would apply to them. This idea of 'candour' or that another family member was a better candidate for getting cancer was repeatedly expressed. |
| "I still get a bit confused in the mornings, but that's about it. Like I said, I'm under the illusion that anything could happen down the track. Well I mean my parents smoked and both my parents are fine..."
| (14017, male, 59 years) |
| "...My parents lived to 103 and 102 and they died of old age. It doesn't matter what I do, I'm thinking..."
| (4002, male, 71 years) |
| Cautious and sceptical. |
| Feelings of guilt and stigmatization were commonly reported. |
| "I'm always being labelled as an evil person of society. I just feel as though we're a very much persecuted minority now..." |
| (13013, male, 59 years) |
| "Because smokers are now like when they used to be on the stageto..."
| (13014, male, 59 years) |
| "You feel kind of guilty, I suppose. You know he's going to say are you still smoking or it's the same, have you lost weight? That type of thing. You think oh gosh, you always feel like you're like a juvenile that you're doing something wrong." |
| (13002, female, 70 years) |
| Previous experiences of visiting the GP. |
| Past experiences of GP consultations was identified as a key barrier to early help seeking. |
| Learning and reprimanding. |
| "...Because I'm a smoker and I'm used to being lectured. It's just when I got lectured all the time, I just stopped going to see them. I needed to have past GPs - you go in there because you've got a cough now, and they want to go, something's wrong!"
| (13015, male, 59 years) |
| "They'd give me another doctor. When I went and I sat down, and the lady said to me, do you smoke? I said, yes. I said, I smoke, what are you shaking your finger at me for? So I don't think that, I just stop and I walked out!"
| (23209, male, 79 years) |
| Perceived Inconvenience. |
| "So, I feel - although I feel confident going to see them, I don't know, I feel just want to have another doctor's surgery to go to. Yeah, I just... I don't know what it is, I don't feel comfortable anymore going there."
| (18002, female, 70 years old, smoker bowel cancer diagnosis) |
| "Yeah, because I had aumor - my late wife was going to see her GP constantly about - and he kept saying, your asthmatherapy asthmameditation and giving her for other things for asthma - and it ended up she actually had leukemia..."
| (13018, male, 59 years) |
| Perceived Miscommunication. |
| "Once I understood what embolism was about because the doctor just told me..." |
| (15063, male, 59 years) |
| "I goggled it and I found out that it wasn't a death sentence that necrotizing was... I was relieved." |
| (7017, male, 71 years, did not understand diagnosis) |
| "No, it wasn't really knowing that, having been diagnosed with COPD at that time and that's when I got barned and had a look at the internet and found out what it was and what the various symptoms were."
| (18001, male, 69 years) |

Each theme is discussed with supporting quotes.

There was also evidence that the prompts and reminders had an impact on early help seeking behavior. Participants responded particularly well to positive messages and images in the Australian CHEST intervention. Tailoring reminders to individual preferences was important in promoting self-efficacy. Barriers to seeking help identified in the CHEST Australia trial included, smoker stigmatization, fear, symptom normalization and the worry that GPs had a negative attitude toward smokers and that they were not taken seriously. An underlying perception of mistrust of the GP was also expressed in the Australian setting. This was due to reasons such as perceived previous misdiagnosis or miscommunication. Previous experiences of visiting the GP which had focused on received reprimanding by the GP to quit smoking were commonly described as an important barrier to early consultation. Similar barriers to consultation were also described in the original Scottish CHiLST trial. Obtaining an appointment to visit a GP.
Table 3. Summary of perceptions of the CHEST intervention from 20 participants who participated in the CHEST Australia trial

<table>
<thead>
<tr>
<th>Salience</th>
<th>Objective 2 (improving knowledge of symptoms)</th>
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<tbody>
<tr>
<td>A sense of eliciting greater salience (Objective 1) on personal relevance of symptoms was perceived.</td>
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<tr>
<td>&quot;Yeah my wife said you better see someone about that cough, it has gone on too long, reading the booklet helped me see that now...&quot; (4005, male, 60 years).</td>
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<tr>
<td>&quot;Lo, I know you yourself that have ailments of one thing or another and they do nothing about it. In fact, I know two personal friends of mine who had ailments but, because they were men - I mean - they refused to go to the doctor and it finished up costing them their lives. I really believe they'd be alive today if they'd have done something about it.&quot; (4005, male, 60 years).</td>
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<tr>
<td>&quot;So I think it meant I highlighted the need to go onto these sorts of things, for the reasoning - with coughing, and some other potential symptoms of lung disease and so on. It just probably brought it to the front of my mind, though I guess, if it needed a bit of a prod.&quot; (4005, male, 60 years).</td>
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<tr>
<td>&quot;I used to keep some of it and it was like if you notice various symptoms contact the doctor, but because I was already under the doctor and so much was happening in other areas with my health, I didn’t really have time to focus on that.&quot; (4005, female, 69 years, diagnosed with COPD).</td>
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<table>
<thead>
<tr>
<th>Improve symptom awareness</th>
<th>Objective 2 (improving knowledge of symptoms)</th>
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<tbody>
<tr>
<td>A clearer understanding of what symptoms (Objective 2) to look out for and when to seek help from the GP was recalled by many after the intervention.</td>
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<tr>
<td>&quot;I just get the signs, Well, it makes you aware of what to do if you do get chest symptoms and what some of the symptoms are that might lead to a lung disease. It does make you more aware. It also explains a lot more than what I know about lung disease.&quot; (4002, male, 71 years).</td>
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<tr>
<td>&quot;It makes you think, it makes you want to remember it. Because sometimes if you haven’t had that symptom even the month before, you’re thinking, oh, hang on, a minute, did I have that symptom or was it now or was it like a month ago or whatever? (4017, male, 71 years).&quot;</td>
<td></td>
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<tr>
<td>&quot;So if the books were there (in the GP surgery) and the forms were there I just think that would be another wonderful service that the doctors could give their patients. They know who smokes and they know what’s gone wrong with their patients. Without the book we would never have known what we now know. I don’t know whose idea it was, but it was a good idea.&quot; (4007, female, 68 years).</td>
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<tr>
<td>&quot;I think it should be in general practice. I think anything, whether it be the chest, whether it be for breast, whether it be for every - any - asthma, whatever, i think these things should be available in doctors’ surgeries.&quot; (4005, female, 68 years).</td>
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<table>
<thead>
<tr>
<th>Perceptions of the components of the intervention</th>
<th>Objective 2 (improving knowledge of symptoms)</th>
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<tbody>
<tr>
<td>Feedback from the self-help manual suggested that the booklet is potentially addressing the objective of improving knowledge of symptoms (Objective 2) Feedback on the self-help manual</td>
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<tr>
<td>The self-help manual was described as a valid and useful reference.</td>
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<tr>
<td>&quot;The booklet is very good, in the face that it’s just got - it’s laid out nice and simply, clearly - because I’m a trade - I’m not an English Lit professor - so if it’s laid out very simply and honestly to me.&quot; (4013, male, 71 years).</td>
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<tr>
<td>&quot;I liked the set out of it. It’s clear. It’s not over-jargonised. It’s not overly wordy and difficult to follow. I think it’s quite simple English, which for a simple man like me, it works...&quot; (4014, male, 79 years).</td>
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<tr>
<td>&quot;Well the thing I was looking at the internet versus the book. The internet - I was looking for the progress of if you get an illness like emphysema and with the internet you don’t know what’s old and what’s now. What’s in other words what’s true and what’s false anymore...&quot; (4002, female, 70 years).</td>
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<tr>
<td>&quot;Could I pick it up when I felt like reading it, it is not thrown upon you like when you are watching TV and I learn stuff...&quot; (4012, female, 69 years).</td>
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<tr>
<td>Feedback on the self-monitoring reminders</td>
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<tr>
<td>There was evidence that the prompts and reminders had an impact on monitoring lung symptoms (Objective 4) and this added weight on an intention to act (Objective 6).</td>
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<tr>
<td>&quot;With the intervention changed my way of thinking, I am normally a bit just want and use person, I found the email follow up once a month or whenever - I found that very good. I wasn’t warned. It was just sort of: that little jog of memory or the email - because I think, I’m like most - I check my emails twice a day normally - morning and night. So when it came through, oh yes, okay, oh right - bang, I’ll see the doctor.&quot; (4003, male, 76 years).</td>
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<tr>
<td>&quot;What did you see there that I put the reminders of what you should do - and I think I’m like a lot of people - where I don’t go to the doctor, if I don’t think it’s a real issue, but this reminded me I should go...&quot; (4014, male, 56 years).</td>
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<tr>
<td>&quot;I remember the 123 rule very clearly now, I know what to do if I have certain symptoms...&quot; (4014, female, 63 years).</td>
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<tr>
<td>&quot;I had a business up until recently and I just think that texts are instantaneous whereas I think we get a lot of rubbish coming through our emails and quite often a lot of people - I don’t, but it’s an email that I’m not sure if I always delete it, or if I save, so this is all of that so you can’t be bothered. So I think it’s something you don’t delete, you actually read it first and then if you want to delete you delete it.&quot; (4007, female, 68 years).</td>
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Positive messages were perceived as effective. 

The promotions that I found were always the positive ones. Those ones where you see someone dying or - that was my reaction to it was to turn it over immediately, because I didn’t want to see that, and then I’d always think gosh, light a cigarette because it was quite stressful. So, it had the opposite effect on me. I think if you’re trying to get someone’s attention you need to be positive. It needs to be a positive, like this study." (4002, female, 70 years).
was identified as an important barrier for early consultation in the Scottish study (3), but this was not observed in Australia. All participants reported they felt confident they could get an appointment within 1–3 days. This could suggest that GP accessibility is not a barrier to consulting, at least in metropolitan Perth or Melbourne.

Other studies have also identified similar barriers to consulting. Fear and denial were described in a qualitative lung screening study by Birt et al. (7) and Mackay et al. (12). More recently, fear of bad news, feelings of stigma associated with smoking and symptom normalization were described as common barriers by Crane et al. (13).

It has been suggested that any future lung screening programs in Australia should incorporate a smoking cessation intervention as part of the approach so this is a valuable teaching opportunity (14). However, this research suggests that this could potentially hinder uptake to screening programs and act as a possible barrier. Instead, incorporating an intervention such as the CHEST intervention could be more effectively applied in conjunction with any future screening programs.

In summary, we found evidence that the intervention was achieving the theoretically predicted effects by reducing barriers to consulting, increasing salience of symptoms and self-efficacy to consult. The results of the CHEST Australia trial and the effect on consultation rates for chest symptoms will be reported in 2017.

Acknowledgements

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Declarations

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References


