STUDY PROTOCOL

General practice focussed strategies to increase participation in lung cancer screening – a systematic review protocol [version 1; peer review: awaiting peer review]

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Abstract

Background

Lung cancer is the leading cause of cancer-related mortality worldwide. Despite this, the uptake of lung cancer screening (LCS) using low-dose CT is substantially low in comparison to established cancer screening programmes. Additionally, those at higher risk of the disease are the least likely to participate in screening, including current smokers and those experiencing socioeconomic deprivation. General practice (which may be referred to as primary care or family medicine depending on location) plays a vital role in screening through the identification of eligible individuals, overcoming participation barriers, and facilitating shared decision-making. Given the low rates of participation, it is important to understand which, if any, strategies from general practice could improve the effectiveness of a national programme.

Objectives

To assess and quantify the effects of strategies implemented in general practice to increase participation in LCS.

Method

A systematic review and meta-analysis, where possible, will be conducted following PRISMA reporting guidelines. Searches of PubMed, Embase, CINAHL, Cochrane Library, Web of Science, ClinicalTrials.gov, and the WHO International Clinical Trials Registry Platform will be conducted. All randomised trials, non-randomised studies, and quantitative descriptive studies that report recruitment strategies based in general practice and LCS outcomes will be eligible. Screening and data extraction will be conducted independently by two reviewers. The risk of bias and overall certainty of findings will be assessed using the MMAT and GRADE tools, respectively. The Template for Intervention Description and Replication (TIDieR) checklist will be used for data extraction and the Behavioural Change Techniques (BCT) Taxonomy for data analysis of the components of interventions.

Conclusion

This review will provide data on the most effective general practice-based recruitment strategies aimed at improving LCS participation. Understanding the most effective and equitable strategies is important in the development of successful LCS and ensuring individuals at the greatest risk can participate.

Keywords
Participant recruitment, recruitment interventions, participant selection, recruitment strategies, lung cancer, screening, systematic review.

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Introduction

Lung cancer

Lung cancer is the leading cause of cancer-related mortality worldwide (Fitzmaurice *et al.*, 2019). Despite being the third most common cancer after breast and prostate cancer, lung cancer accounts for 21% of cancer mortality in the UK, with around 34,800 deaths annually (Cancer Research UK, 2023). While smoking cessation is the most effective preventative strategy, the early detection of lung cancer is effective in improving outcomes, with an increase in one-year survival of almost 70% when diagnosed at Stage I, in comparison to Stage IV, the most advanced stage of the disease (ONS, 2019). However, most cases are diagnosed at Stage III and Stage IV, at which point the likelihood of receiving curative treatment is significantly reduced (ONS, 2019). Given this, effective lung cancer screening (LCS) is widely recognised to be crucial in ensuring more people are diagnosed earlier when the disease is more readily treatable, thereby improving survival (UKLCC, 2021).

Screening in lung cancer

Many countries have recommended LCS using low-dose computed tomography (LDCT), which has demonstrated promising results of reduced mortality and improvements in lung cancer survival by the detection of early-stage lung cancer in numerous clinical trials (Krist *et al.*, 2021; Wait *et al.*, 2022). A 20% relative reduction in lung cancer-specific mortality compared with chest X-ray, was reported in the US-based National Lung Cancer Screening Trial (NLST) (The NLST Research Team, 2011). The Dutch-Belgian NELSON (NEderlands Leuvens Screening ONderzoek) trial demonstrated broadly consistent benefits and reported similar findings with a 24% (95% CI [0.61, 0.94]) and 33% (95% CI [0.38, 1.14]) relative reduction in mortality in men and women respectively (de Koning *et al.*, 2020). Accordingly, the UK National Screening Committee (2022) has officially recommended the implementation of a targeted LCS programme for those aged between 55 to 74 years with a history of smoking.

Participation in LCS

In the US, where LCS has been recommended by the United States Preventive Serves Task Force (USPSTF) for nearly a decade, rates of participation remain significantly low at 5.8% (American Lung Association, 2022). Although this may reflect in part the lack of a centrally administered screening programme, other factors implicated include uncertainty surrounding eligibility and insurance reimbursement (Rivera *et al.*, 2020). Evidence from trials and pilot studies in the UK also suggests there are challenges around achieving participation in LCS, with uptake rates varying from 20.4% to 52.6% (O'Dowd *et al.*, 2023; Quaife *et al.*, 2020; Rivera *et al.*, 2020). This is significantly lower in comparison to the uptake rates of breast, bowel, and cervical cancer screening programmes which were over 65% in 2022 (Office for Health Improvement & Disparities, 2023). Additionally, it is well established that individuals at the highest risk of developing the disease are also the least likely to participate in LCS (Ali *et al.*, 2015). For example, the Yorkshire Lung Screening Trial (YLST), the SUMMIT, and the UK Lung Cancer Screening (UKLS) trial reported those living in areas of higher deprivation and current smokers were the least likely to participate in LCS (Crosbie *et al.*, 2022; Dickson *et al.*, 2023; Field *et al.*, 2021). The low levels of participation in these groups are a significant barrier to the successful implementation of a national LCS programme, as without engagement from those that would benefit the most, the full mortality benefit may not be achieved.

Participation strategies

Supporting participation in LCS is more complex and challenging than other cancer screening programmes because of its targeted eligibility focussing on high-risk individuals (e.g., those who have a significant smoking history). Low levels of awareness of screening, the stigma associated with smoking, and cancer fear and fatalism contribute to non-participation in screening (Quaife *et al.*, 2017). Targeted identification and recruitment via general practice is suggested as the most practical means of implementing LCS in the UK (Dickson *et al.*, 2022; O'Dowd *et al.*, 2022; O'Dowd *et al.*, 2023). In combination with other strategies, including advanced notification letters, timed appointments, and reminder letters, the Lung Screen Uptake Trial (LSUT) sent invitation letters directly from general practitioners, delivering a participation rate of 53% which is significantly higher than observed previously (Quaife *et al.*, 2020). The trial used "targeted, stepped and low burden" resources which improved equity in screening uptake and therefore have the potential to increase overall screening effectiveness by engaging individuals living in socioeconomically deprived areas. Similarly, the YLST and Manchester lung cancer screening programme both identified and approached individuals using invitation letters from primary care, achieving 50.8% and 28.5% participation, respectively (Crosbie *et al.*, 2019; Crosbie *et al.*, 2022). Previously studied approaches to recruitment in other cancer screening programmes include invitation letters, reminders, decision aids and information pamphlets (Baldwin *et al.*, 2021; Hewitson *et al.*, 2011; Teo *et al.*, 2019; Wardle *et al.*, 2016). General practice has played a key role in screening programmes by providing an accessible setting for patient-centred care and health education, and engaging with deprived groups to address health inequalities (Summerton, 2000). Therefore, understanding how general practice may contribute to participation in LCS is essential in improving the effectiveness of programmes and encouraging participation from underserved communities.

Aims & objectives

To assess the effectiveness of various strategies implemented in general practice to increase participation in LCS.

Methods

A systematic review, and meta-analysis where possible, will be conducted and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Page *et al.*, 2021). The PRISMA-P checklist was used in the write up of the protocol (Shamseer *et al.*, 2015).

Eligibility

Study types

All randomised trials, non-randomised studies (e.g., controlled clinical trials or observational studies), and quantitative descriptive studies reporting participation strategies for asymptomatic lung cancer screening will be eligible for inclusion. Qualitative studies will be excluded to reduce heterogeneity between study outcome measures. Only English-language publications will be included. Studies that describe or assess participation through narrative reviews, letters to the editor, editorials, conference communications and questionnaires of participation strategies will be excluded. Where a study has multiple publications, the one with the most pertinent data will be included. All studies must report at least one of the defined participation outcome measures. Full eligibility criteria include:

Population

All studies involving adults who have been invited to asymptomatic lung cancer screening using LDCT.

Intervention

Interventions will include any planned strategies involving general practice. The strategies should be aimed at inviting or improving participation among eligible individuals and could include methods of contact, electronic tools, education, reminders, direct mail, phone calls, and community outreach.

Comparator

Eligible comparator groups could include no intervention, comparison between different intervention types, or comparison before and after the intervention.

Primary outcome

The primary outcome measure will be the attendance attained in the groups exposed to various participation strategies and offered LCS. Studies often differ in their definitions of participation rates; where possible, the participation rate for individual interventions will be recalculated by determining the percentage of participants that were exposed to the intervention and took part in LCS. Other participation measures described in studies will be reported in cases where data is insufficient to determine participation rates (e.g., response rates to invitations etc.). Participation rates will also be reported by demographic and smoking characteristics where possible.

Additional outcomes

- Cost of participation interventions (defined as direct or indirect cost per participant randomised)
- Adverse effects of participation interventions
- Other resource use

Search strategy

Searches of electronic databases and trial registries will be conducted using a combination of Medical Subject Headings (MeSH) and keywords relating to lung cancer screening. Information specialists were consulted during the development of the search strategy.

The research terms will cover lung cancer, screening, and general practice, in addition to their synonyms. An example of the search strategy in PubMed is presented below:

("Lung Neoplasms"[Mesh] OR "lung neoplasm*"[tiab] OR "pulmonary neoplasm*"[tiab] OR "bronchopulmonary neoplasm*"[tiab] OR "bronchial neoplasm*"[tiab] OR "lung cancer*"[tiab] OR "pulmonary cancer*"[tiab] OR "bronchopulmonary cancer*"[tiab] OR "broncho-pulmonary cancer*"[tiab] OR "bronchial cancer*"[tiab] OR "lung carcinoma*"[tiab] OR "pulmonary carcinoma*"[tiab] OR "bronchopulmonary carcinoma*"[tiab] OR "bronchopulmonary carcinoma*"[tiab] OR "bronchial carcinoma*"[tiab] OR "bronchogenic carcinoma*"[tiab] OR "lung blastoma*"[tiab] OR "pulmonary blastoma*"[tiab] OR "lung tumor*"[tiab] OR "pulmonary tumor*"[tiab] OR "bronchopulmonary tumor*"[tiab] OR "bronchial tumor*"[tiab]) AND ("Mass Screening"[Mesh] OR "Early Detection of Cancer"[Mesh] OR "Mass Screen*"[tiab] OR Screen*[tiab] OR "Cancer Early Detection"[tiab] OR "Cancer Screen*"[tiab] OR "Cancer Screening Test*"[tiab] OR "Early Diagnosis of Cancer"[tiab]OR "Cancer Early Diagnosis"[tiab] OR Test*[tiab] OR Detect*[tiab]) AND ("General Practice"[Mesh] OR "General Practitioners"[Mesh] OR "Primary Health Care"[Mesh] OR "Physicians, Primary Care"[Mesh] OR "Family Practice"[Mesh] OR "Physicians, Family"[Mesh] OR "General Practice"[tiab] OR "General Practitioner*"[tiab] OR "General Practice Physician*"[tiab] OR GP[tiab] OR "Primary Health Care"[tiab] OR "Primary Care"[tiab] OR "Primary Healthcare"[tiab] OR "Primary Care Physician*"[tiab] OR "Family Practice*"[tiab] OR "Family Physician*"[tiab] OR "GP"[tiab] OR "GPs"[tiab] OR "GP's"[tiab] OR "GPs'"[tiab])

The search strategy will be adapted to the requirements of each database and validated filters will be used to retrieve primary studies as needed. To further increase the sensitivity of the search, the references of studies that could potentially meet our eligibility criteria will be reviewed using CitationChaser (Haddaway *et al.*, 2021). In keeping with existing reviews and the development of LDCT as a screening modality, searches will be limited from January 2000 to March 2023. The results from each database will be exported into EndNote for deduplication. A free, open-source alternative to EndNote is Zotero.

We will search the following:
Electronic Databases: Cumulative Index to Nursing and Allied Health Literature (CINAHL); Embase; PubMed; PsycINFO; Scopus; Science Citation Index; The Cochrane Library

Trial Registries: WHO International Clinical Trials Registry Platform; ClinicalTrials.gov

Selection of studies

Titles and abstracts of identified papers will be independently assessed for eligibility by two reviewers using Rayyan (Ouzzani *et al.*, 2016). Discrepancies will be discussed and resolved through consensus. If there is more than one publication for the same study, the publication judged to be most

pertinent will be included. Two reviewers will then independently review potentially relevant studies to determine whether they fulfil the inclusion criteria with included studies and then be subjected to full-text evaluation. A third reviewer will adjudicate if disagreements arise.

Data extraction

Data extraction will be undertaken by two reviewers using a pro forma created using Microsoft Excel. The Template for Intervention Description and Republication (TIDieR) checklist will be used to ensure consistency and completeness of the extracted data (Hoffmann *et al.*, 2014). Data collected will include study type, setting, eligibility criteria, participant characteristics, interventions and control groups, outcomes, and results.

Assessment of bias

The Mixed Methods Appraisal Tool (MMAT) will be used to assess the methodological quality and risk of bias of all studies included in the narrative synthesis (Hong *et al.*, 2018). This tool has been designed to evaluate a variety of study types, including randomised controlled trials (RCTs), non-randomised studies (NRSs), quantitative descriptive studies (QDSs), qualitative studies, and mixed-method studies. The MMAT evaluated numerous domains of risk of bias criteria for each study design, resulting in a methodological rating of 0, 20, 40, 60, 80 and 100 (with 100 being the highest quality). The quality appraisal will be independently undertaken by two reviewers.

Data synthesis

All studies which meet the inclusion criteria will be considered in the narrative synthesis, regardless of their quality, and will be reported according to the Synthesis Without Meta-analysis (SWiM) guidelines (Campbell *et al.*, 2020). This will provide a comprehensive overview of the interventions that were evaluated and generate hypotheses for future research. Studies will be grouped depending on the type of intervention evaluated.

A meta-analysis will be conducted if studies are sufficiently homogeneous in the target population, delivery of the intervention and outcome. If appropriate, forest plots and the chi-square test will be used to identify visual evidence and statistical evidence of heterogeneity respectively; the degree of heterogeneity will be quantified using the I^2 statistic. The Number Needed to Treat (NNT) and 95% confidence intervals (CIs) will be used to describe the effects of varying strategies in individual studies. To ensure that the control numbers are not overrepresented, the numerator and denominator from the control participation strategy in a trial will be divided by the total number of intervention strategies in the trial, where more than two strategies have been used.

Intervention content and the BCT taxonomy. To code and compare the techniques used in different interventions, the Behaviour Change Technique (BCT) Taxonomy v1 will be used (Michie *et al.*, 2013).

BCTs are components of interventions that influence the processes resulting in behavioural change (Michie *et al.*, 2011). The BCT Taxonomy is a cross-domain and cross-discipline classification of techniques used in behaviour change interventions, with 93 BCTs organised into 16 groups (Michie *et al.*, 2013). This taxonomy enables the reporting and classification of intervention content from various contexts and has previously been used in screening recruitment studies to analyse the individual components of behaviour change strategies (Acharya *et al.*, 2021). An example of a participation intervention that may be described in a study is invitation letters with GP endorsement. Using the BTC taxonomy, these letters would be categorised under the 'credible source' subgroup which falls under the 'comparison of outcomes' cluster label. Multiple BCTs may be present in a single intervention, some of which may be unanticipated.

This mapping process will be undertaken by one reviewer and will involve the classification of components of interventions using the descriptions provided. A second independent author will validate this evaluation in at least 20% of studies. In cases where an intervention is not described adequately, protocols and pilot studies will be reviewed, and authors will be contacted to obtain specific information where necessary.

GRADE

GRADE will be used to assess the quality of the overall body of evidence for each outcome, by placing the overall evidence into high, moderate, low or very low groups. RCTs are initially deemed to be of high quality, but this may not be the case if there is a significant chance of bias imprecision, publication bias, inconsistent results, or low ecological validity.

A funnel plot will be used to investigate publication bias for the primary outcome, where ten or more studies of the same population, intervention and outcome are available.

Subgroup

Subgroup analyses will be carried out, where possible, on the following characteristics: age group; smoking status; smoking duration; socioeconomic status; and ethnicity.

Sensitivity

To determine the impact of risk of bias on effect size, we will perform a sensitivity analysis. This will involve calculating the impact of excluding studies with a higher risk of bias (i.e., studies that meet less than 60% of the MMAT quality criteria).

Amendments

The systematic review will contain a table that documents and presents any revisions made to this protocol, along with

the corresponding dates of the revisions and the justifications behind them.

Study status

The study is currently in the screening phase.

Data availability

No underlying data are associated with this article.

Reporting guidelines

Open Science Framework: PRIMSA-P checklist for 'General practice focussed strategies to increase participation in lung cancer screening – a systematic review protocol' https://doi.org/10.17605/OSF.IO/SQGX7

Protocol registration

The protocol was registered prospectively on PROSPERO (CRD42023407540).

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