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Recruitment strategies and interventions to increase participation in lung cancer screening programmes: a systematic review protocol

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ABSTRACT

Introduction Despite strong evidence for the efficacy of low-radiation dose CT (LDCT) in reducing lung cancer (LC) mortality, implementing LC screening (LCS) programmes remains a challenge. We aim to systematically review the evidence on the strategies used to recruit the adult population at risk of LC to LDCT within LCS programmes and to estimate the effectiveness of interventions identified, used to reach the potentially eligible population, increase participation and informed choice, and ensure equitable access.

Methods and analysis This sequential systematic literature review will consist of three steps: (1) a scoping review of existing strategies and organisational models for LCS; (2) selecting papers reporting relevant outcomes (test coverage, screening participation and informed choice) and comparing results among different models; (3) a systematic review of interventions implemented to increase participation in LCS programmes. Each step will follow the methodological guidelines provided by the Cochrane Collaboration and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement. Data sources include electronic databases such as Medline (PubMed version), Embase, CINAHL (Ebsco version), Scopus and Cochrane CENTRAL. The search will be limited to studies published from January 2000 to March 2023 in English, Italian, French, Spanish, Serbian and Croatian language. Findings will be synthesised quantitatively and qualitatively as appropriate. Risk of bias assessment will be only applied to studies selected in the second and third steps. The quality of evidence will be summarised for each outcome using the Grading Recommendation Assessment, Development and Evaluation methodology.

Ethics and dissemination Given that this is a review of existing literature, ethics approval is not required. The results will be published in peer-reviewed scientific journals and presented at relevant conferences. The findings of this review will help guide health authorities in organising LCS programmes and developing recommendations, policies, and actions at national and regional levels.

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STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study will provide an exhaustive evidence synthesis of the recruitment modalities used in ongoing and completed lung cancer screening (LCS) programmes. Additionally, it will evaluate the effectiveness of interventions used to increase outreach and participation among underserved populations in LCS programmes.
⇒ The data included in this review will be analysed in accordance with the recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols, to maximise transparency, accuracy and significance.
⇒ Heterogeneity and limited number of studies, especially pragmatic randomised controlled trials evaluating certain interventions, may prevent a quantitative synthesis of the evidence. In such cases, a qualitative synthesis will be conducted.
⇒ Limited number of studies and a scarcity of high-level evidence specifically analysing outcomes such as informed choice and uptake are anticipated.

INTRODUCTION

Despite strong evidence in favour of low-radiation dose CT (LDCT) screening in reducing lung cancer (LC) mortality, the implementation of screening programmes and participation rates are still modest.[1]

Recruiting participants for screening programmes can be a resource-consuming and challenging task. Various factors, including behavioural, socioeconomic and organisational factors, are likely associated with the uptake of screening programmes.[2 3] In the case of LC screening (LCS), identifying the at-risk population who would benefit the most from screening requires substantial organisational and informatics support. Furthermore, there are no routinely collected administrative datasets of variables required for LCS eligibility assessment, such as detailed smoking history. In fact, most international guidelines identify the potentially eligible population for LDCT screening as active or ex-smokers (quitted within the last

15 years), aged 50/55–75/80 years who have a smoking history of 25–30 packs/year.[4 5] However, randomised controlled trials (RCTs) are generally not representative of the general population as younger, more educated individuals who smoke less tend to participate more. Furthermore, the uptake of LCS programmes already implemented is even lower compared with RCTs. In the USA, where LDCT screening has been covered by public and private insurance for eligible individuals since 2015, participation rates were 3.3% of the eligible population in 2015 and 14% in 2018.[6 7]

Despite having a higher prevalence of smoking and a higher incidence of LC, remote, underserved and socially deprived communities are under-represented in screening programmes.[1 8] Additionally, the uptake of LCS is lower among current smokers despite their eligibility being easier to identify compared with former smokers.[1]

Interventions and initiatives to increase the identification, participation and retention of eligible individuals have been adopted in screening programmes for other types of cancer. The Community Preventive Services Task Force recommends multicomponent interventions to maximise recruitment effectiveness.[9] Pre-invitation letters, scheduled appointments and personalised reminders for non-participants, and general practitioner endorsement have been shown to be effective in increasing the uptake of colorectal and breast cancer screening.[10] However, evaluation of strategies that improve participation in LCS is scarce.

A few published articles have compared different interventions to maximise outreach and participation rates in LCS, especially among underscreened populations. In the Lung Screen Uptake Trial, a reminder letter providing a second prescheduled appointment increased the uptake of LCS among non-respondents.[11] Screening navigators were very prised by participants in Ontario LCS and were considered essential in providing support throughout the screening process.[12] The Liverpool Healthy Lung Programme found that a community-based proactive approach was effective in reaching and screening for LC in deprived areas.[13] However, very few of these studies were pragmatic RCTs.

A few systematic[14 15] and narrative reviews[16] have already been published on this subject. Some of which focused on gender and social characteristics of participants,[14] while others did not specifically address outreach or uptake-related outcomes.[15] To our knowledge, there is no exhaustive evidence synthesis on effectiveness of interventions to increase LCS uptake in different populations, except for one systematic review that analysed effectiveness of strategies to inform individuals about an LCS programme in optimising informed choices regarding participation.[17]

Rationale for systematic review

The new European Council recommendations on cancer screening and the ongoing implementation of LCS in Europe highlight the urgent need for an exhaustive evidence synthesis of the recruitment strategies used in ongoing and completed LCS programmes.[18] There is an urge to provide a comprehensive and rigorous analysis of the effectiveness of interventions used to increase outreach and participation among underserved populations.

The Italian government has recently initiated planning for a targeted LCS programme. As a part of this effort, the Italian Ministry of Health has funded a project titled 'Pilot Project for a lung cancer screening program integrated with smoking cessation: pathways, selection of participants and diagnostic protocols for an HTA assessment'.[19] This project includes an implementation research pilot and an HTA (Health Technology Assessment) process, which will be conducted by a consortium of regional health authorities and other scientific partners. A stakeholder forum has been established to coordinate the organisational, ethical, legal and social impact assessment. This systematic review has been prioritised by the stakeholder forum.

Such synthesis will help health authorities design the recruitment methods to be used in LCS programmes and choose which interventions may be adopted to increase the outreach and participation of the population at risk and to possibly decrease inequalities in access.

Project aim

This study aims to: (a) systematically review the evidence regarding the strategies employed to identify, target, reach, invite, refer and recruit the adult population at risk of LC to LDCT within LCS programmes; (b) estimate effectiveness of interventions in reaching the potentially eligible population and increasing participation and informed choice; and (c) assess whether different strategies and interventions diminish or increase equity of access to screening.

METHODS

Design and amendments

The systematic literature review will be conducted between April 2023 and April 2024, and it will focus on international studies reporting on the methods used to identify, contact, inform, assess eligibility and propose screening to the adult population at risk of LC within LCS programmes. These methods will be referred to as recruitment models or strategies for the sake of simplicity.

This sequential review will be conducted in three phases:

1. The first phase will be a scoping review, which aims to identify all completed and ongoing screening programmes and to provide a summary and characterisation of the different recruitment strategies used.
2. The second phase will involve the identification of studies that report at least one of the three preselected outcomes of interest: invitation coverage, test coverage and participation. The results will be summarised according to the recruitment strategies adopted.

3. The third phase will be a systematic review that aims to identify all the interventions used within the recruitment models/strategies to increase outreach and participation and reduce inequalities. If possible, the effectiveness of these interventions will be estimated.

Each phase of the review protocol has been designed in accordance with the relevant methodological guidelines provided by the Cochrane Collaboration and the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA-P)[20] (the checklist is provided in online supplemental file 1). The protocol has been registered with the International Prospective Register of Systematic Reviews (CRD42023408357). Any amendments to the protocol will be registered with the date, description of changes and reasons for the amendments.

Research questions and population, intervention, comparison and outcome criteria

Two research questions were developed following the population, intervention, comparison and outcome framework (table 1). The first question encompasses the first two phases of the review and will have the same search strategy: 'What are the recruitment methods in the LCS programmes and what are the coverage, invitation and participation rates within different recruitment models?' The second research question is: 'What is the effectiveness of different strategies to increase the participation rate of people at risk in LCS programmes, that is, whether using different methods of contact, risk assessment, appointment, reminders or other activities will increase coverage, invitation and participation rates, informed decision and reduce inequalities?' For both questions, the focus will be on stratifying results by different subpopulations representing different forms of possible inequalities.

Research questions specific to different phases of the review are the following:

Phase 1:

- Which methods have been used in the literature to recruit adult populations at risk of LC to LCS programmes and which structures were involved?
- Can these methods, used in different models of recruitment, be grouped according to their characteristics?

Phase 2:

- What were the coverage rate, invitation rate, screening participation rate and informed choice rate by different recruitment models?
- Do recruitment strategies have different levels of invitation or contact coverage, test coverage and participation in different groups of population (eg, more or less deprived, males and female, ethnic minorities, smokers and former smokers, people with higher or lower LC risk, residing in underserved areas) that can represent sources of inequality in access?

Phase 3:

- Are there interventions able to improve informed decision-making processes, such as improving patient comprehension and supporting them in making decision?
- Are there interventions able to reduce structural barriers, such as providing transportation assistance, appointment-scheduling assistance and translation assistance?
- Are there interventions able to improve communication between health providers and patients, such as personalised navigation, coordination and scheduling of risk assessment appointments?
- Are there interventions able to improve provider delivery, such as provider education, incentives, reminders, assessment and feedback?

Inclusion and exclusion criteria

For phases 1 and 2, studies will be considered relevant if they assess or report on the methods or baseline results of targeted LCS programmes using LDCT, LDCT+biomarkers or LDCT+smoking cessation programmes. The studies should involve an adult population without a confirmed or suspected cancer diagnosis but at an elevated risk of LC.

As this review aims to inform recruitment strategies used relative to the study population, descriptive studies reporting population and screening characteristics will also be included in the scoping phase (phase 1). Qualitative studies will be excluded as they primarily focus on personal beliefs and barriers to LCS uptake. Model-based studies will also be excluded.

Regarding publication type, editorials, notes, letters, opinion pieces and discussions will be excluded from review. Conference abstracts, oral presentations and abstract dissertations and thesis not linked to full-text peer-reviewed papers will also be excluded. Detailed inclusion and exclusion criteria for phases 1 and 2, as well as for phase 3, are reported in table 1.

Outcome definition

The primary outcomes for the systematic review include test coverage and informed choice defined as the following:

- Test coverage: number of individuals who undergo LDCT screening, divided by the population at risk or potentially eligible population.
- Informed choice: number of individuals who are informed about the screening programme, have a decision consistent with their values and take action based on their decision, divided by the total population who have been contacted/informed.[21–23]

The secondary outcomes are functional in interpreting the test coverage and include:

- Invitation coverage: number of persons contacted divided by persons at risk.
- Screening participation: number of persons tested divided by those contacted/invited.

Data sources and search strategy

We will search the following five electronic databases: Medline (PubMed version), Embase, CINAHL (Ebsco

Table 1 Inclusion and exclusion criteria for the research questions 1 and 2 based on PICO scheme

Criterion	Inclusion criteria	Exclusion criteria
Research question 1		
Population	► Adults (between the ages of 50 and 80) without lung cancer (confirmed or suspected) at increased risk of lung cancer (current or previous tobacco smoking, occupational toxins (eg, radon, asbestos or fine particle exposure), COPD, lung fibrosis)	► Patients with confirmed or suspected cancer, including lung cancer ► Persons under the age of 50 and above age of 80
Intervention	► Lung cancer screening using either LDCT or LDCT+biomarkers ► Combined screening and smoking cessation programmes	► Screening with imaging technologies other than LDCT ► Using LDCT but not within the context of a formal lung cancer screening programme
Comparator	► No screening ► Screening for lung cancer using other imaging technologies, such as chest X-ray ► Lung cancer screening without smoking cessation programme ► No comparator	
Outcome	► Description of recruitment methods ► Test coverage, invitation and participation rates	► Recruitment strategy not described
Study type	► Any type of study	► Qualitative studies ► Model-based studies
Publication type	► Peer-reviewed journal articles ► Health Technology Assessment (HTA) reports ► Protocols of ongoing trials	► Editorials ► Notes ► Letters ► Opinion pieces and discussions ► Conference abstracts, oral presentations and abstract dissertations and thesis not linked to full-text peer-reviewed papers
Language	► English, Italian, Croatian, Serbian, French, Spanish	► Any other language
Research question 2		
Population	► Adults (between the ages of 50 and 80) without lung cancer (confirmed or suspected) at elevated risk of lung cancer (current or previous tobacco smoking, occupational toxins (eg, radon, asbestos or fine particle exposure), COPD, lung fibrosis)	► Patients with confirmed or suspected cancer, including lung cancer ► Persons under the age of 50 and above age of 80
Intervention	► Various interventions implemented within lung cancer screening aiming to recruit from a potentially eligible population, that is, outreach and invite potentially eligible population ► Various interventions implemented within a lung cancer screening aiming to specifically increase outreach and participation of underserved populations* ► Various interventions implemented within a lung cancer screening aiming to improve patient comprehension of risks and benefits (decision aids) of inform consent of patients	► Interventions related to screening programmes other than lung cancer ► Interventions within lung cancer screening not related to recruitment (identification, selection, outreaching and invitation)
Comparator	► A specific recruitment strategy for lung cancer screening different from the one used in the intervention group	► No comparator
Outcome	► Coverage rate ► Invitation rate ► Participation rate ► Informed choice	
Study type	► Randomised controlled trials ► Non-randomised controlled trials ► Before–after studies	► Any other type of study
Publication type	► Peer-reviewed journal articles ► HTA reports	► Editorials ► Notes ► Letters ► Opinion pieces and discussions ► Conference abstracts, oral presentations and abstract dissertations and thesis not linked to full-text peer-reviewed papers
Language	► English, Italian, Croatian, Serbian, French, Spanish	► Any other language

*Underserved populations include people who may experience difficulties in accessing secondary preventive services due to their socioeconomic status (including educational, economic and social resources, measured both at individual level and small area level), ethnicity (non-indigenous populations and minorities with particular attention to recently arrived immigrants, and other vulnerable groups due to living conditions) or geographical area of living (rural/urban).
COPD, chronic obstructive pulmonary disease; LDCT, low-radiation dose CT; PICO, population, intervention, comparison and outcome.

version), Scopus and Cochrane CENTRAL. For each database, a search strategy will be developed by an information scientist (MCB). Search terms will be defined a priori by the project team. The literature searches will combine terms related to the population (eg, LC, underserved and underscreened and inequalities), intervention (eg, recruitment strategies, outreach, enrolment and invitation) and outcomes (eg, participation, coverage, invitation and informed choice). Search period will cover papers published from 2000 until 15 March 2023. Year 2000 will be the starting date of the search since the two large-scale, randomised trials NLST and NELSON started recruitment in 2002 and 2003, respectively.[24] I-ECLAP was the only trial (non-randomised) conducted before 2000s with baseline results published in 1999,[25] and its finding will be included in the review if it fulfils inclusion criteria.

Selection of literature

The Rayyan software will be used to import and manage the search results from all the databases.[26] PRISMA Extension for Scoping Reviews checklist[27] will be used in the reporting of the results of the search and data extraction process of the scoping review (first phase).

Two independent reviewers, OD and FV, will screen titles and abstracts in a blinded fashion. Any possible discrepancy will be resolved by discussing the respective item. If any discrepancies remain, the respective paper will proceed further to the full-text review stage. Full-text review and data extraction will be conducted by OD and FV. A cross-check of the 20% of the full texts will be conducted by another reviewer (PGR). Any discrepancies will be discussed between the reviewers and if a consensus cannot be reached, the project leader (PGR) will be involved in the discussion and will make the final decision.

Reference lists of the publications that were not excluded after the title and abstract screening will be checked for any additional relevant publications. Furthermore, other sources of information and search techniques will be considered, including study registries and reference lists. A search for ongoing or unpublished studies will be conducted in ClinicalTrials.gov and the International Clinical Trials Registry Platform.

Articles retrieved and reasons for the exclusion of full-text articles will be reported in the PRISMA flow diagram.

Quality appraisal and evidence assessment

Due to the descriptive nature of the scoping review (phase I), assessment of study quality will not be conducted. However, thorough inclusion and exclusion criteria will ensure that at least some basic standards will be met by included studies.

For the identification and evaluation of the effectiveness of interventions to increase outreach to potentially eligible population (phases 2 and 3), the Cochrane's Risk of Bias 2 tool will be used.[28] For non-randomised studies, the Risk Of Bias In Non-randomized Studies-of Interventions[29] tool will be used to assess the risk of bias.

Data extraction

A data extraction form will be developed and implemented using Microsoft Excel based on the aim and objectives of this report.[30] Two reviewers (OD and FV) will independently extract data.

An overview of the items included in the final data extraction form, together with an explanation for each item, will be provided in the online supplemental material. The data extraction form will include: first author and year of publication, country, aim, study design, potentially eligible population, participants' baseline characteristics and smoking history, intervention and control description where possible, number of participants, duration of follow-up, description of recruitment methods and interventions to increase participation and equity, coverage rate, invitation rate and participation rate in intervention and control groups.

Synthesis of results

Qualitative synthesis of results (phase 1)

In the first phase of the systematic review, the results related to recruitment modalities and potentially eligible populations will be summarised qualitatively through tabulation of the characteristics and results of studies included. The potentially eligible populations considered for screening, as well as the various aspects of recruitment, such as outreach, communication, assessment of eligibility, modalities to propose and provide the test, integration with smoking cessation interventions and measures to overcome inequalities, will be described narratively. If possible, the recruitment models will be grouped according to their characteristics.

Quantitative synthesis of results (phase 2)

In phase 2, a quantitative summary of evidence will be provided whenever results permit. Results on screening relative to the potentially eligible group definition, recruitment and risk assessment by country, study design, setting, provider, time point of LCS and recruitment model group will be summarised as described in table 2.

All relevant steps in the LDCT pathway will be identified from the literature retrieved by this review (figure 1), and main patterns of recruitment strategies will be identified based on targeting and outreach organisation level and by proximity of risk assessment.

Classification of interventions (phase 3)

The classification of interventions to increase outreach, participation and equity will be based on the Centre for Disease Control and Prevention Framework for Interventions to Improve Cancer Screening.[4] This framework provides a comprehensive list of possible interventions that can be used to enhance participation in cancer screening programmes. The list has been integrated with interventions that were identified by a previous review performed by the Italian Ministry of Health on interventions to increase participation in screening programmes,[31] and interventions identified by Jepson *et*

Table 2 Description of screening population, outreach and information delivery

Patient selection	Mode
Potentially eligible group definition	▶ Definition of population at risk
Potentially eligible group identification	▶ Population registries ▶ Primary care/GP registries ▶ Other
Former smoker identification	▶ Population registries ▶ Primary care/GP registries ▶ Other
Identification of people exposed to occupational toxins and patients with COPD and lung fibrosis	▶ Population registries ▶ Primary care/GP registries ▶ Other
Outreach of potentially eligible participants	▶ Provider referral ▶ Smoking cessation referral ▶ Media (mass media, small media and social media) ▶ Community outreach ▶ Toll-free number ▶ Other
Invitation	▶ Invitation letter ▶ Invitation appointments ▶ Invitation telephone calls ▶ Other
Eligibility/risk assessment	▶ Categorical risk assessment ▶ Individual risk-prediction models
Preselection of potentially eligible participants	▶ Risk triage and then detailed risk assessment model ▶ Questionnaire vs interview
Risk–benefit discussion	▶ Decision aid
Inform consent	▶ Single approach ▶ Dual approach

COPD, chronic obstructive pulmonary disease; GP, general practitioner.

al,[21] Wait *et al*[32] and based on the results retrieved in this review (table 3). However, it is important to note that not all interventions identified may be directly applicable to the context of LCS or the specific Italian setting. Therefore, interventions that were considered irrelevant for the LCS, such as patient self-screening tests, were excluded from the review.

Quantitative synthesis of results (phase 3)

In the phase 3 of the systematic review, the outcomes will be compared between intervention and control groups whenever possible. Where suitable data are available, we will perform a random-effects meta-analysis described by DerSimonian and Laird,[33 34] and by using STATA V.17 software.[35] Statistical heterogeneity will be assessed using the I^2 statistic. Values of I^2 will be interpreted as not important (0–40%), moderate (30–60%), substantial (50–90%) and considerable (75–100%) levels of heterogeneity.[36] Results of meta-analyses will be presented graphically by the means of forest plots, with presentation of effect estimates and 95% CIs, and by the means of a 'risk of bias' graph figure and a risk of bias summary figure to present the results of the risk of bias assessment.

When sufficient data are reported, we will conduct subgroup analyses by potentially underserved groups, as defined above. If appropriate, we will conduct sensitivity analyses by excluding studies at high risk of bias.

Based on previous screening[2 22] and preliminary LCS pilots,[12 13] subgroup analyses will be performed to identify potentially underserved groups. Subgroup analyses will be conducted to examine the recruitment strategies and outcomes in different subpopulations and will focus on the following factors: sex, socioeconomic status (measured at both individual level and small area level and using various indicators such as educational attainment, economic resources and social resources), ethnicity (non-indigenous populations and minorities with special attention to recently arrived immigrants), geographical areas (rural vs urban regions), and LC

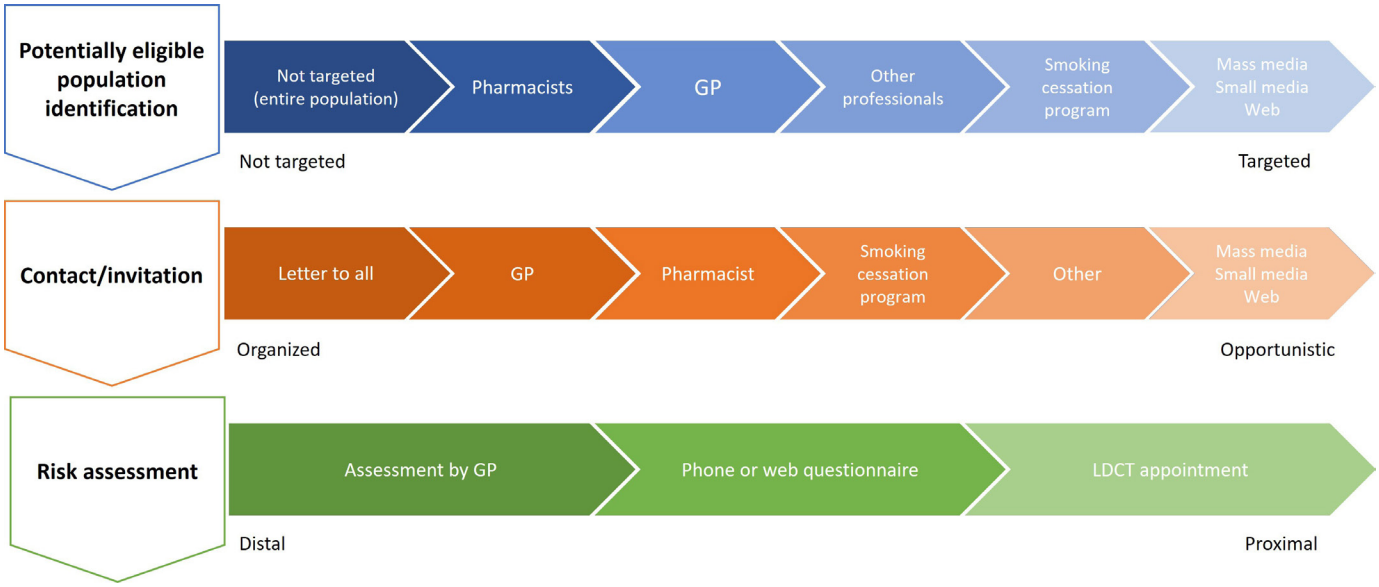

Figure 1 Main recruitment steps with gradient of targeting and outreach organisation level and by proximity of risk assessment. GP, general practitioner; LDCT, low-radiation dose CT.

Table 3 CPSTF recommendations for multicomponent interventions to increase cancer screening updated from CPSTF 2017,[9] Giorgi Rossi *et al*,[31] Jepson *et al*[21] and Wait *et al*[32]

Increase community demand	Increase community access	Increase provider delivery
► Group education ► One-on-one education ► Client reminders ► Client incentives ► Providing decision aids ► Targeted awareness initiatives (mass medium, small media)	► Interventions to reduce client out-of-pocket costs ► Reducing cultural barriers (eg, screening staff of the same sex, involvement of ethnic minority representatives) ► Reducing psychological barriers (eg, low-burden targeted information material, GP letters, message framing) ► Interventions to reduce structural barriers – Reducing administrative barriers – Providing appointment scheduling assistance – Using alternative screening sites – Using mobile screening in public spaces – Using alternative screening hours or flexible appointments – Providing transportation – Providing translation – Providing child care	► Provider education ► Provider reminders ► Provider incentives ► Provider assessment and feedback ► Involvement of community health professionals in outreach (eg, pharmacists) ► Involvement of non-medical staff (eg, navigators)

CPSTF, Community Preventive Services Task Force; GP, general practitioner.

risk factors such as smoking history and the number of pack-years.

Assessment of the certainty of the evidence

We will use the Grading Recommendation Assessment, Development and Evaluation[37] to assess the certainty of the evidence for each outcome as emerging from the analysis of the included studies. The certainty of the evidence will be downgraded by one (serious concern) or two (very serious concerns) for the following reasons: risk of bias, inconsistency (unexplained heterogeneity and inconsistency of results), indirectness (indirect population, intervention, control and outcomes), imprecision (wide CIs) and publication bias. Judgements about the certainty of the evidence (high, moderate, low or very low) will be justified and incorporated into the results for each outcome. The certainty of the evidence assessments will be integrated into the results and conclusions of the systematic review.

Patient and public involvement

This systematic review has been prioritised by the stakeholder forum of the project 'Pilot Project for a lung cancer screening program integrated with smoking cessation: pathways, selection of participants and diagnostic protocols for an HTA assessment'[19] funded by the Italian Ministry of Health, Centre for Disease Control and Prevention. The forum has the task to coordinate the organisational, ethical, legal and social impact assessment of the LDCT screening within the HTA project. The stakeholder forum included all kinds of professionals involved in the organisation of LDCT screening and linked smoking cessation programmes, public health operators, meso and macro decision-makers, and patient and citizen organisations.

ETHICS AND DISSEMINATION

No ethics approval is necessary when conducting a systematic review. The findings will be published in a peer-reviewed medical journal and presented at relevant national and international conferences. Results will be shared through specific forums, Twitter and other social media outlets to maximise impact.

DISCUSSION

The review protocol was designed to provide healthcare decision-makers with evidence syntheses supporting the design of recruitment methods to be used in LCS programmes.

Nonetheless, some difficulties in retrieving high-quality evidence, especially pragmatic RCTs that evaluated interventions and outcomes of interest, are anticipated. Organisational models are rarely the object of experimental research. Therefore, we do not expect to find trials or other comparative experimental studies comparing different models for their effectiveness in identifying, reaching, informing, assessing eligibility criteria and proposing screening. We will try to solve this issue with a scoping review.

To be useful to decision-makers, the information about model effectiveness should be somewhat generalisable. Therefore, we plan to group the models according to their characteristics. However, the feasibility and soundness of this grouping strategy are uncertain and will depend on the available evidence.

The review aims to collect evidence on effectiveness rather than efficacy, recognising that effectiveness is often context specific. As a result, high heterogeneity in the results is anticipated due to variations in the organisational models, populations and settings.

The outcome identified will be adapted from indicators used in organised cancer screening programmes. However, we acknowledge that the reporting of pilots and studies may not consistently use these outcome measures or capture all the relevant phenomena related to reaching the right people, informing them and measuring their participation. The concepts of informed choice and informed decision-making do not have a harmonised operational definition and are intrinsically difficult to capture in studies.

Furthermore, the definitions and measurability of outcomes are closely linked to the specific organisational model being evaluated. For example, the concept of invitation/contact coverage may have different meanings and approaches to measurement depending on organisational models (eg, opportunistic contact in general practitioners' clinics versus ones based on invitation letters mailed to the entire population). Sometimes, it can even be unmeasurable ontologically, such as in the case of a model based on opportunistic contact in pharmacies.

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Contributors OD, FV and PGR developed the systematic review protocol. MCB developed the search strategy. OD drafted the manuscript. GG, EP, PM and PGR critically revised the manuscript. All authors have approved the final version.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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