






STUDY PROTOCOL

Co-designing a recruitment strategy for lung cancer screening in high-risk individuals: protocol for a mixed-methods study [version 1; peer review: 1 approved, 2 approved with reservations]

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V1 First published: 13 Nov 2023, 6:64
<https://doi.org/10.12688/hrbopenres.13793.1>
 Latest published: 13 Nov 2023, 6:64
<https://doi.org/10.12688/hrbopenres.13793.1>

Abstract

Background




Lung cancer is a significant cause of cancer-related mortality globally, with early detection through screening critical to improving patient outcomes. However, recruiting high-risk individuals, particularly in deprived populations, for screening remains a considerable challenge. This study aims to co-design a targeted recruitment strategy for lung cancer screening, tailored to the specific needs and experiences of high-risk individuals, in collaboration with a Patient and Public Involvement (PPI) panel and expert stakeholders in Ireland.



Methods

We will employ a mixed-methods design guided by the Medical Research Council (MRC) framework for developing complex interventions. Our approach will integrate systematic review findings on screening participation interventions, evaluation of the recruitment strategy's feasibility in an Irish context, and the application of

Open Peer Review

Approval Status 

	1	2	3
version 1 13 Nov 2023	 view	 view	 view

- Gaston Arnolda** , Macquarie University, Sydney, Australia
- Mario Mascalchi**, "Mario Serio", University of Florence, Florence, Italy
- Abbie Begnaud** , University of Minnesota Medical School, Minneapolis, USA

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behavioural science frameworks. The target population includes individuals over 55 years, either current smokers or those who quit within the last year, who reside in highly deprived areas.

Conclusion

This co-designed recruitment strategy will combine evidence-based research, local context understanding, and stakeholder input to develop a solution that is both scientifically robust and tailored to the target population's needs. This patient-centred approach aims to increase the potential for successful implementation of lung cancer screening programs, thereby improving early detection and patient outcomes.

Keywords

Lung neoplasms; Primary Health Care; Screening; Implementation Science; Health Knowledge, Attitudes, Practice

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Author roles: **Reilly M:** Writing – Original Draft Preparation; **Ali A:** Conceptualization, Data Curation, Formal Analysis, Funding Acquisition, Investigation, Methodology, Project Administration, Resources, Software, Supervision, Validation, Visualization, Writing – Original Draft Preparation, Writing – Review & Editing; **Doyle PF:** Writing – Review & Editing; **Cotter S:** Resources; **Heavey L:** Conceptualization, Visualization, Writing – Original Draft Preparation, Writing – Review & Editing; **Brain PK:** Visualization, Writing – Original Draft Preparation, Writing – Review & Editing; **Rankin PN:** Conceptualization, Validation, Writing – Original Draft Preparation, Writing – Review & Editing; **Mccutchan G:** Resources, Writing – Original Draft Preparation, Writing – Review & Editing; **Redmond PP:** Conceptualization, Data Curation, Formal Analysis, Funding Acquisition, Investigation, Methodology, Project Administration, Resources, Software, Supervision, Validation, Visualization, Writing – Original Draft Preparation, Writing – Review & Editing

Competing interests: No competing interests were disclosed.

Grant information: The author(s) declared that no grants were involved in supporting this work.

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How to cite this article: Reilly M, Ali A, Doyle PF *et al.* **Co-designing a recruitment strategy for lung cancer screening in high-risk individuals: protocol for a mixed-methods study [version 1; peer review: 1 approved, 2 approved with reservations]** HRB Open Research 2023, 6:64 <https://doi.org/10.12688/hrbopenres.13793.1>

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Introduction

Lung cancer is a significant global health concern, accounting for a substantial proportion of cancer-related mortality worldwide¹. Despite advances in treatment options, the overall prognosis for patients with lung cancer remains poor, primarily due to late-stage diagnosis². Emphasising the importance of early detection, screening programs have been identified as a key factor in improving patient outcomes, including overall survival rates³.

Challenges in lung cancer screening programmes

Screening programs, while instrumental in early detection, come with their own set of challenges. A major hurdle lies in the recruitment of eligible individuals, particularly those classified as high risk. Previous trials employing population-level approaches to recruitment^{4,5} have suffered from low participation rates. Underrepresentation of high-risk participants and participants from low socioeconomic (SES) background have been a critical challenge to lung cancer screening⁶⁻⁸. In contrast, the Lung Screen Uptake Trial (LSUT) and the Manchester Lung Health Check both used a targeted recruitment strategy, resulting in participation rates of 53% and 27% respectively^{9,10}. Although the Manchester Lung Health Check participation rate may be comparable to other trials, it is worth noting that the proportion of participants ranked in the lowest deprivation quintile was 75%, a marked increase from the overall UK Lung Screen trial^{7,10}.

Evidence regarding the impact of specific recruitment strategies on participation in cancer screening trials is limited. For examples, in the LSUT study, a reminder letter with a pre-scheduled appointment increased participation among non-responders by 24%⁹. Similar strategies such as pre-invitation letters, scheduled appointments, and reminder letters have modestly increased participation in breast and colorectal cancer screening, albeit with varying success rates¹¹⁻¹⁴. These studies demonstrate the impact that specific recruitment strategies can add to baseline recruitment rates, but they were not targeted to a specific population.

Understanding high-risk individuals

Due in part to the prevalence of smoking in deprived areas, individuals from socioeconomically disadvantaged backgrounds are often at a higher risk of developing lung cancer¹⁵⁻¹⁷. This demographic is consistently underrepresented in screening programs¹⁸, leading to disparities in lung cancer outcomes, with socioeconomically disadvantaged groups experiencing higher mortality rates¹⁹.

Barriers to screening participation are multifaceted and complex, as suggested by various systematic and literature reviews²⁰⁻²². According to Lin *et al.*, these barriers can be categorised into individual, healthcare system, and social/environmental categories²². Several potentially modifiable factors have been identified, which could be strategically addressed in recruitment interventions. These encompass health beliefs, desires to quit smoking, self-efficacy beliefs, concerns

about lung cancer, and prompts or recommendations from healthcare professionals²². Moreover, Lin *et al.* and Lam *et al.* underscore the role of psychological factors, including apprehension and fatalistic attitudes, as barriers to screening uptake. Schütte *et al.* further highlights an inverse correlation between screening uptake and poor self-reported health²⁰⁻²². As such, efforts to alleviate these anxieties could complement strategies designed to foster engagement and awareness, subsequently encouraging participation among these high-risk individuals.

Tailored recruitment strategies

Addressing these challenges requires a targeted recruitment strategy, grounded in evidence-based practices and tailored to the unique needs and preferences of high-risk groups within an Irish context. Previous strategies aimed at increasing screening attendance have been primarily invitational or proactive. The LSUT trial and the Lung Health Check trials in the UK used invitational strategies, sending letter invitations, reminders and, in the LSUT, pamphlets with low-burden information about screening through direct mail^{9,10}. The UK Bowel Cancer Screening programme trialled four different invitational strategies to decrease the socioeconomic gradient between screening participants and found enhanced reminder letters to have a modest benefit²³.

Proactive recruitment strategies have been more commonly trialled in non-lung screening programmes such as cervical, breast and colorectal cancer screening. Strategies such as flagging patient files to encourage their general practitioners to discuss screening with them or sending invitations with pre-scheduled appointments have worked to enhance general participation^{24,25}. At least two lung cancer screening trials have effectively assigned participant “navigators” to guide participants through the screening process; from calling to invite participants and checking their eligibility to booking their appointments^{26,27}.

A systematic review of lung cancer screening implementation supports the view that recruitment should be targeted to the most high-risk population and that the methodology for achieving this must be tailored to the local circumstance²⁸. However, they also note that there is currently insufficient evidence to show which methods will best enhance screening uptake, and that more research into planning recruitment strategies is needed to identify how best to attract high-risk populations²⁸.

Patient and Public Involvement

Engaging patients and the public in the design and implementation of research ensures interventions are relevant, acceptable, and effective for the target population. In the context of lung cancer screening, patients can provide invaluable insights into participation barriers and potential solutions²⁹. Hence, this study will incorporate a Patient and Public Involvement group to offer insights into the feasibility and compatibility of the recruitment strategy within the local healthcare context^{30,31}.

Aims and objectives

The overall aim of this study is to co-design an evidence-based recruitment strategy that enhances participation in lung cancer screening among high-risk individuals. This strategy will be specifically tailored to the unique needs and experiences of high-risk individuals in Ireland.

To achieve this we have established the following specific objectives:

Evidence synthesis: We will draw from the knowledge gathered through systematic reviews and observational studies to identify interventions that have demonstrated effectiveness in enhancing screening participation^{19,23,32–35}.

Addressing barriers: In collaboration with individuals who are eligible for screening, we will identify and address the barriers to participation that are unique to the Irish context. This approach will ensure the recruitment strategy is practical and directly relevant to the target population.

Theoretical grounding: We will ground the recruitment strategy in behavioural science frameworks, which will provide a theoretical basis for understanding health behaviours. This will guide the design of interventions aimed at altering these behaviours to improve screening participation³⁶.

Feasibility assessment: We will assess the feasibility of the recruitment strategy in the Irish context, employing the APEASE Criteria. This evaluation framework will ensure the intervention is affordable, practical, effective, acceptable, safe, and equitable³⁷.

Methods

Ethics

Ethical approval will be requested from RCSI Research Ethics Committee. We have routine systems in place to offer assistance and follow-up any patient who is distressed by health-related research. This includes signposting opportunities for support plus personal follow-up at participant request.

Patient and Public Involvement

Irish Lung Cancer Community (ILCC)

Framework and reporting guidance

This research employs a mixed-methods design with the aim of co-creating a targeted recruitment strategy for lung cancer screening, in collaboration with a PPI panel and expert stakeholders. The development and evaluation of the intervention will be guided by the Medical Research Council's (MRC) framework for complex interventions³⁰. The study will also adhere to guidelines for formulating complex interventions to enhance health and healthcare³⁰, and will follow the GUIDED reporting guidance for intervention development studies in health research³⁸. In accordance with the recommendations from a recent multidisciplinary expert panel review, the study will incorporate co-design methods using an Experience Based Co-Design approach³⁹.

Research-refining interviews with screening-eligible participants will be conducted to prioritise the issues specific to an Irish context. Intervention co-development workshops with expert and PPI participants will be conducted to build upon existing research evidence. These workshops will generate iterative versions of a recruitment tool until consensus on a final tool is reached^{40,41}. The feasibility and acceptability of the recruitment tool will also be evaluated at these workshops. The Consolidated Framework for Implementation Research (CFIR) will be employed to assess factors likely to impact the intervention's implementation and effectiveness. The RE-AIM framework will be used to enhance the external validity of the project and to orientate the data collection in a manner conducive to the future implementation of the final intervention⁴².

Research team and context

The research team is interdisciplinary, comprising individuals with diverse expertise: patients, academics from various disciplines (public health, epidemiology, health psychology, social sciences), healthcare professionals, and policy makers. This ensures a comprehensive approach to the development of a recruitment strategy.

The study will be conducted in Ireland, a country with a health-care system that includes both public and private sectors. The government body responsible for overseeing the public health system is the Health Service Executive (HSE), and approximately 47% of Irish citizens are covered by private health insurance. However, in May 2021, the Irish government approved the Sláintecare Implementation Strategy and Action Plan 2021 to 2023, aiming to transform this dual system to a universal healthcare structure. The National Cancer Control Programme (NCCP) is the HSE's cancer-specific division, accountable for the organisation and governance of publicly-funded cancer services in the country.

Ireland is currently grappling with significant lung cancer morbidity and mortality. Lung cancer is the fourth most common cancer, with roughly 2,749 people diagnosed each year as of 2020⁴³. Mortality rates remain high, largely due to late-stage diagnosis. The potential benefits of lung cancer screening have been recognised at the national level. Advocacy, charitable organisations, and public representatives have proposed the introduction of a community-based lung cancer screening program as a proactive approach to address the country's lung cancer burden. In preparation for this screening program, a robust recruitment strategy is needed to address inequalities that may arise from inequitable participation.

Target population

The target population for this study includes high-risk individuals for developing lung cancer who are aged over 55 years, are either current smokers or have quit within the past year, and reside in highly deprived areas. Deprived areas will be defined as Electoral Divisions (EDs) categorised as "Disadvantaged" to "Extremely Disadvantaged" by the Pobal Deprivation Index, 2016. Individual deprivation will also be assessed by educational attainment and employment

status. This population is particularly important to target for lung cancer screening due to their elevated risk and increased vulnerability. These individuals are often underrepresented in healthcare research and are less likely to participate in screening programs, despite being at the highest risk of adverse outcomes. By focusing on this population, our study aims to design a recruitment strategy that is tailored to their specific needs and experiences, thereby improving their engagement in future lung cancer screening programs in Ireland.

While our target population criteria are primarily based on age, smoking status, and socioeconomic factors, we are aware of the potential for cultural diversity within this group. Therefore, our recruitment strategy and subsequent intervention will be designed with cultural sensitivity in mind, ensuring that we respect and address the unique needs and experiences of diverse cultural groups within our target population.

Study design

The intervention development will follow a four-step process:

1. **Establishing the evidence base:** A series of systematic reviews of previous research on screening participation interventions will form the primary evidence base(19) The findings from these reviews and other relevant

studies will be presented to the stakeholder panel for feedback, which will be used to develop an initial version of the recruitment tool.

2. **Theory development:** We will conduct in-depth interviews with a sample of the target population to gain insights into their experiences and perspectives, thereby developing the theory underpinning the recruitment strategy.
3. **Modelling intervention processes and outcomes:** We will map the themes identified in steps 1 and 2 to the Capability-Opportunity-Motivation framework within the Behaviour Change Wheel (BCW) to draft a cohesive recruitment strategy (34). The research team and expert stakeholders will conceptualise the behaviour change mechanism and identify measurable processes and outcomes.
4. **Feasibility and acceptability:** We will present the initial draft of the recruitment tool to stakeholders and the PPI panel for review and refinement, assessing its feasibility and acceptability.

The study outline is described in [Figure 1](#) below.

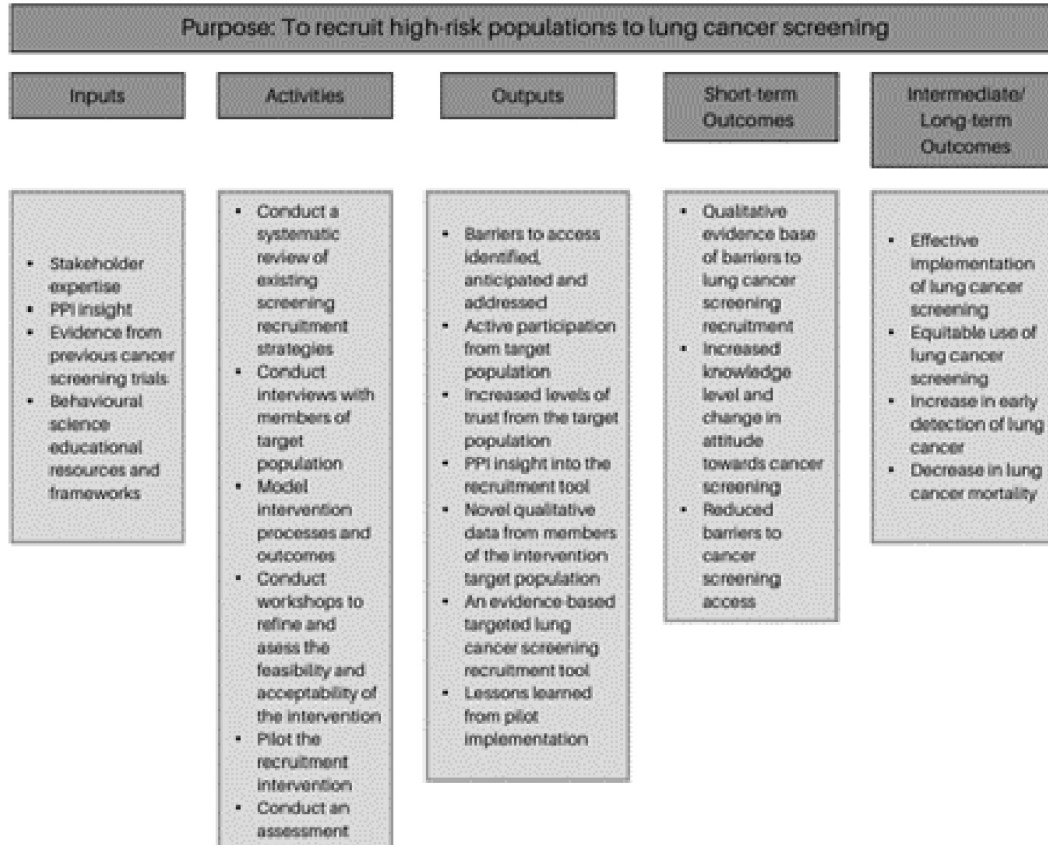


Figure 1. Logic model of proposed intervention.

Sampling, data collection & analysis

The target population will be recruited from primary care practices, screening for inclusion criteria such as age over 55 years, current smoking or having quit within the last year, and living in highly deprived areas (assessed by the Trinity National Deprivation Index, 2016)⁴⁴. Individual SES will be assessed by education level. While we have not predetermined a specific sample size, our recruitment will aim to encompass a diverse range of individuals and continue until we reach saturation in our data collection, where no new themes or insights are emerging.

The audio files of interviews will be de-identified and transcribed. NVivo 10 or higher (QSR international) will be used for analysis. For analytical rigour, 40% of the transcripts will be independently double coded by another researcher. We will use the Consolidated Framework for Implementation Research (CFIR) to classify the themes that emerge⁴⁵.

Workshops involving stakeholders, the PPI panel, and healthcare professionals will form the final evidence base to evaluate and refine the feasibility and acceptability of the recruitment strategy. The discussions during the workshops will be audio-recorded and supplemented with field notes taken by the research team.

PPI

The PPI group will consist of individuals and/or families who have experienced lung cancer well as members from the target population for lung screening. Our ILCC collaborators will facilitate the formation of a PPI panel. The panel will consist of 4-5 PPI members. Mr Cotter will act as the link between the PPI panel and the research team will the development of a schedule of meetings.

Interview topic guide design

Developing a topic guide based on behavioural science frameworks will be a collaborative endeavour. The PPI group will engage in an initial brainstorming workshop, followed by a series of feedback sessions, and they will also be invited to provide written input to refine the guide.

Training and support

All PPI members, regardless of their background, will be offered training on the research methodology, ethics, and behavioural science principles. This is to ensure that everyone is adequately equipped to provide meaningful insights and feedback throughout the project's lifecycle. Regular support, both technical and psychological, will be available to facilitate their active participation.

Schedule of meetings

A proposed series of meetings will include:

Introduction session: Overview, objectives, and roles.

Topic guide workshop: Brainstorming and initial draft creation.

Bi-monthly collaborative meetings: Progress updates, discussions, and feedback sessions.

Final review meeting: Reflecting on results and laying out the dissemination roadmap.

Oversight and dissemination

All PPI members will be encouraged to actively partake in the research dissemination process. Opportunities to co-author research outputs, present findings at conferences, and engage in outreach activities will be provided. This inclusive strategy has been shaped with valuable guidance from the RCSI PPI Ignite Office Team.

Expert panel

An expert panel consisting of primary care clinicians, psychologists, and policymakers will be convened to contribute specific expertise to this project. Each panel member has been selected based on their roles and experiences in the context of lung cancer screening. They bring critical insights that can significantly influence the future implementation of the lung cancer screening trial.

The expert panel will be actively involved in various stages of the study. They will provide feedback on the evidence gathered from systematic reviews, participate in workshops to discuss and refine the recruitment strategy, and contribute to the design of the recruitment tool based on their professional experience and understanding of the challenges and opportunities in lung cancer screening. Furthermore, they will provide critical insight into the likely barriers and facilitators for implementing the recruitment strategy in a real-world context.

To ensure a diverse range of perspectives, the Expert Panel is drawn from various sources. These include professional networks with a wealth of knowledge and experience, representative organisations that provide a broad societal perspective, and patient advocacy groups that offer the unique and essential viewpoint of those most directly affected by lung cancer.

Step 1: Evidence gathering

The initial phase of our research will involve an extensive review of existing literature including systematic reviews, observational studies, and qualitative research on interventions aimed at promoting participation in screening programs within general practice. This will encompass a series of systematic review conducted by our research team prior to this study (19). The outcomes of these reviews will be shared in a meeting with key stakeholders. Factors which the review has identified as positively influencing participation in screening will be presented to the stakeholders. Stakeholder feedback will be considered, and a decision regarding which factors should be included in the initial iteration of our recruitment tool will be reached via consensus using a modified Nominal Group Technique, which gives an equal voice to all participants^{46,47}.

Step 2: Theory formulation

We will conduct a series of in-depth semi-structured interviews with a representative sample of our target population to gauge their attitudes and beliefs towards lung cancer, as well as their likelihood to participate in a screening program. These interviews will consist of standardised, open-ended

questions and will be audio-recorded and transcribed with the interviewees' written informed consent. The interviews will be semi-structured to facilitate the participants giving a full account of their health behaviours in relation to smoking and cancer screening. Demographic data including age, sex, education and post-code, as well as smoking data (self-reported smoking status, smoking history and maximum number of cigarettes smoked per day). Subsequently, they will be subjected to thematic analysis. Our objective is not to be confined to a predetermined number but to continue interviews until saturation, where no new themes emerge. However, based on our initial estimates, we anticipate engaging with approximately 30 individuals. We will recruit participants from primary care practices and screen them based on specific inclusion criteria. These include being aged over 55, current smoking habits or quitting within the last year, and residing in highly deprived areas⁴⁴

Step 3: Intervention modelling

Behavioural science frameworks such as the Behaviour Change Wheel (BCW), the Extended Parallel Processing Model, and the Theoretical Domains Framework (TDF)^{36,48,49} will underpin our recruitment strategy. The patterns identified in the first two steps will be aligned with the Capability-Opportunity-Motivation framework within the BCW, and a coherent recruitment intervention strategy will be drafted³⁶. A consultation will be held with our expert stakeholders to conceptualise the mechanism of behavioural change and identify behavioural targets, along with measurable processes and outcomes.

Step 4: Feasibility and acceptability

Once we have an initial draft of the recruitment tool, it will be presented to our key stakeholders and PPI panel in workshops for review. The tool will be refined based on their feedback regarding the acceptability and usability of individual intervention components. This cycle of presentation, feedback, and refinement will continue until we attain agreement on the final intervention package.

Workshops

In the workshops, we will facilitate monitored discussions in small groups, each comprising no more than five members from our expert stakeholder panel or PPI group. A research team member will guide each group discussion, supplying prompts to stimulate dialogue.

Purpose of workshops

The workshops will serve as the final stage in consolidating our evidence base, allowing us to evaluate and refine the recruitment strategy's feasibility and acceptability. We will invite participants to one of four workshops, where they will review logic models prepared by the research team. In the style of World Café methodology, participants will reflect on the recruitment intervention's components and how these

integrate within existing care pathways⁵⁰. These workshops will also enable us to combine the personal narratives of patients with the clinical insights from our stakeholders. For patients, we will explore factors like burden of care, guideline appropriateness, preferences, and support types. The recurrent themes from these discussions will inform the project's feasibility. We will report our findings using the COREQ framework, ensuring comprehensive and accessible data⁵¹. The output will be the blueprint for the architecture and content of the final recruitment tool.

Workshop structure

In the workshops, we will organise small table group discussions. Each table will randomly seat no more than five members from the expert stakeholder panel or PPI group, with members rotating between tables for different discussions. A research team member will be present at each table during the World Café-style workshop to provide discussion prompts. Each table will concurrently discuss the same prompts over three rounds, with each round featuring a new prompt.

At the start of each session, we will present a PowerPoint (accompanied by handouts) summarizing findings from Step1-3. Subsequent workshops will begin with brief presentations recapping insights from previous sessions. While the workshops will not undergo pilot testing, they will follow a format similar to that used in previous health intervention co-design processes^{40,52}. The prompts given for discussion will be mapped to the APEASE criteria to ensure that the implementation of the intervention is considered at every stage of the iterative co-design process³⁷. We will hold four workshops in total, with each one building on the insights gleaned from the preceding workshop and featuring unique discussion prompts.

Workshop data collection and analysis

With the consent of all participants, we will audio record the discussions. The research team will also take field notes during the discussions. We anticipate that each workshop will last approximately one hour. Data saturation will be determined via consensus among the research team members, who will continue table discussions until no new themes emerge.

Initial pilot

Following the workshops, a preliminary pilot will be embedded in the regional lung health check programme. The proportion of participants who receive the recruitment intervention and subsequently consent to participate in the trial recorded for the duration of the pilot.

A reporting system will be established to ensure that key implementers can report any problems with the dissemination, reception or response to the recruitment tool, or any problems with the transition from positive response to the

invitation to the LDCT. Participants will have the opportunity to provide feedback on their experience of being recruited via anonymous survey which will be available at their participating GP practice. The pilot test will aim to assess the feasibility of the tool - how well it operates in a real-world setting - as well as its acceptability to patients, which is crucial for its eventual uptake. Feedback collected from the participants in this phase will be used to further optimise the tool and ensure it is both practical and user-friendly before larger scale piloting and ultimately definitive testing.

Intervention Description

At the conclusion of the intervention development process, the final intervention components will be reported according to the TIDieR guidelines to ensure completeness and replicability⁵³. We will describe the rationale and theoretical basis for the intervention in detail. We will also list the materials that are required to deliver the intervention and the training materials that are required to train staff in its use.

Study status

Our present study status indicates that we have duly submitted our ethics application and are presently awaiting their response.

Discussion

This study represents a significant step forward in the development of an effective recruitment strategy for lung cancer screening in high-risk individuals. By using a collaborative, evidence-based approach and incorporating insights from patients, public involvement contributors, and expert stakeholders, we hope to enhance the reach and impact of lung cancer screening programs.

The recruitment strategy under development has the potential to inform the design of future lung cancer screening programs, not just in Ireland, but also in other countries that may face similar challenges in reaching high-risk populations. Additionally, the evidence gathered in the course of creating this recruitment strategy will add crucial information to a currently limited evidence base on lung cancer screening in Ireland.

Dissemination

The findings of this study will be disseminated through multiple channels. These include academic journals, presentations at national and international conferences, and reports to relevant health and governmental organisations. In particular, we aim to communicate our findings to the public and to the communities most affected by lung cancer.

Limitations

There are limitations to this study. We use the Pobal National Deprivation Index to screen members of the target population for low economic status because it is a standardised

measure of deprivation specifically created for public health research⁵⁴. However, the most recent update of this index contains data from 2016, which may be out of date. It also may not accurately reflect the individual economic status of each recruited member. We have attempted to mitigate these limitations by including questions about the participants' highest educational attainment and employment status in the interview.

Additionally, much of the existing evidence on recruitment to lung cancer screening that will be reviewed in step 1 to inform the creation of our recruitment strategy is from countries that have conducted lung cancer screening trials. Some of the qualitative research regarding the beliefs and behaviour of smokers may not be directly applicable to our target population due to cultural differences. The in-depth interviews with our target population described in step (2) localise the qualitative evidence and contribute to lung cancer screening recruitment evidence in Ireland.

Conclusion

This protocol outlines the plan for the co-design of a lung cancer screening recruitment strategy. The outcome of this intervention will enable specific recommendations to be made regarding recruiting participants to maximise the efficacy of a future all-Ireland lung cancer screening programme. Such a programme may give due consideration to targeting groups which are historically underrepresented in health intervention services including screening programmes.

Data availability

Underlying data

No data are associated with this article.

Extended data

Open Science Framework: Co-designing a recruitment strategy for lung cancer screening in high-risk individuals: protocol for a mixed-methods study, <https://doi.org/10.17605/OSF.IO/XED4T>⁵⁵.

This project contains the following extended data:

- Participant consent form
- PPI Interview Participant Information Leaflet
- Interview guide
- Workshop plans
- Pilot Survey (Anonymous)

Data are available under the terms of the [Creative Commons Zero "No rights reserved" data waiver](#) (CC0 1.0 Public domain dedication).

References

- Bray F, Ferlay J, Soerjomataram I, et al.: **Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries.** *CA Cancer J Clin.* 2018; **68**(6): 394–424.
[PubMed Abstract](#) | [Publisher Full Text](#)
- Siegel RL, Miller KD, Jemal A: **Cancer statistics, 2020.** *CA Cancer J Clin.* 2020; **70**(1): 7–30.
[PubMed Abstract](#) | [Publisher Full Text](#)
- National Lung Screening Trial Research Team, Aberle DR, Adams AM, et al.: **Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening.** *N Engl J Med.* 2011; **365**(5): 395–409.
[PubMed Abstract](#) | [Publisher Full Text](#)
- de Koning HJ, van der Aalst CM, de Jong PA, et al.: **Reduced Lung-Cancer Mortality with Volume CT Screening in a Randomized Trial.** *N Engl J Med.* 2020; **382**(6): 503–513.
[PubMed Abstract](#) | [Publisher Full Text](#)
- Field JK, Duffy SW, Baldwin DR, et al.: **The UK Lung Cancer Screening Trial: a pilot randomised controlled trial of low-dose computed tomography screening for the early detection of lung cancer.** *Health Technol Assess.* 2016; **20**(40): 1–146.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Hestbech MS, Siersma V, Dirksen A, et al.: **Participation bias in a randomised trial of screening for lung cancer.** *Lung Cancer.* 2011; **73**(3): 325–331.
[PubMed Abstract](#) | [Publisher Full Text](#)
- McRonal FE, Yadegarfar G, Baldwin DR, et al.: **The UK Lung Screen (UKLS): Demographic Profile of First 88,897 Approaches Provides Recommendations for Population Screening.** *Cancer Prev Res (Phila).* 2014; **7**(3): 362–371.
[PubMed Abstract](#) | [Publisher Full Text](#)
- National Lung Screening Trial Research Team, Aberle DR, Adams AM, et al.: **Baseline Characteristics of Participants in the Randomized National Lung Screening Trial.** *J Natl Cancer Inst.* 2010; **102**(23): 1771–1779.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Quaife SL, Ruparel M, Dickson JL, et al.: **Lung Screen Uptake Trial (LSUT): Randomized Controlled Clinical Trial Testing Targeted Invitation Materials.** *Am J Respir Crit Care Med.* 2020; **201**(8): 965–975.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Crosbie PA, Balata H, Evison M, et al.: **Implementing lung cancer screening: baseline results from a community-based 'Lung Health Check' pilot in deprived areas of Manchester.** *Thorax.* 2019; **74**(4): 405–409.
[PubMed Abstract](#) | [Publisher Full Text](#)
- Libby G, Bray J, Champion J, et al.: **Pre-notification Increases Uptake of Colorectal Cancer Screening in All Demographic Groups: A Randomized Controlled Trial.** *J Med Screen.* 2011; **18**(1): 24–29.
[PubMed Abstract](#) | [Publisher Full Text](#)
- Duffy SW, Myles JP, Maroni R, et al.: **Rapid review of evaluation of interventions to improve participation in cancer screening services.** *J Med Screen.* 2017; **24**(3): 127–145.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Ghimire B, Maroni R, Vulkan D, et al.: **Evaluation of a health service adopting proactive approach to reduce high risk of lung cancer: The Liverpool Healthy Lung Programme.** *Lung Cancer.* 2019; **134**: 66–71.
[PubMed Abstract](#) | [Publisher Full Text](#)
- Hewitson P, Ward AM, Heneghan C, et al.: **Primary care endorsement letter and a patient leaflet to improve participation in colorectal cancer screening: results of a factorial randomised trial.** *Br J Cancer.* 2011; **105**(4): 475–480.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Kavanagh P: **The State of Tobacco Control in Ireland Dublin: HSE 2022.** [Reference Source](#)
- Hitchman SC, Fong GT, Zanna MP, et al.: **Socioeconomic status and smokers' number of smoking friends: Findings from the International Tobacco Control (ITC) Four Country Survey.** *Drug Alcohol Depend.* 2014; **143**: 158–166.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- van Loon AJ, Burg J, Goldbohm RA, et al.: **Differences in Cancer Incidence and Mortality Among Socio-Economic Groups.** *Scand J Soc Med.* 1995; **23**(2): 110–120.
[PubMed Abstract](#) | [Publisher Full Text](#)
- Quaife SL, Forbes LJL, Ramirez AJ, et al.: **Recognition of cancer warning signs and anticipated delay in help-seeking in a population sample of adults in the UK.** *Br J Cancer.* 2014; **110**(1): 12–18.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Sedani AE, Davis OC, Clifton SC, et al.: **Facilitators and Barriers to Implementation of Lung Cancer Screening: A Framework-Driven Systematic Review.** *J Natl Cancer Inst.* 2022; **114**(11): 1449–1467.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Lam S, Tammemagi M: **Contemporary issues in the implementation of lung cancer screening.** *Eur Respir Rev.* 2021; **30**(161): 200288.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Schütte S, Dietrich D, Montet X, et al.: **Participation in lung cancer screening programs: are there gender and social differences? A systematic review.** *Public Health Rev.* 2018; **39**(1): 23.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Lin YA, Hong YT, Lin XJ, et al.: **Barriers and facilitators to uptake of lung cancer screening: A mixed methods systematic review.** *Lung Cancer.* 2022; **172**: 9–18.
[PubMed Abstract](#) | [Publisher Full Text](#)
- Wardle J, von Wagner C, Kralj-Hans I, et al.: **Effects of evidence-based strategies to reduce the socioeconomic gradient of uptake in the English NHS Bowel Cancer Screening Programme (ASCEND): four cluster-randomised controlled trials.** *The Lancet.* 2016; **387**(10020): 751–759.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Lönnberg S, Andreassen T, Engesæter B, et al.: **Impact of scheduled appointments on cervical screening participation in Norway: a randomised intervention.** *BMJ Open.* 2016; **6**(11): e013728.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Bankhead C, Richards SH, Peters TJ, et al.: **Improving attendance for breast screening among recent non-attenders: a randomised controlled trial of two interventions in primary care.** *J Med Screen.* 2001; **8**(2): 99–105.
[PubMed Abstract](#) | [Publisher Full Text](#)
- Darling GE, Tammemägi MC, Schmidt H, et al.: **Organized Lung Cancer Screening Pilot: Informing a Province-Wide Program in Ontario, Canada.** *Ann Thorac Surg.* 2021; **111**(6): 1805–1811.
[PubMed Abstract](#) | [Publisher Full Text](#)
- Percac-Lima S, Ashburner JM, Rigotti NA, et al.: **Patient navigation for lung cancer screening among current smokers in community health centers a randomized controlled trial.** *Cancer Med.* 2018; **7**(3): 894–902.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Rankin NM, McWilliams A, Marshall HM: **Lung cancer screening implementation: Complexities and priorities.** *Respirology.* 2020; **25** Suppl 2: 5–23.
[PubMed Abstract](#) | [Publisher Full Text](#)
- Facey K, Boivin A, Gracia J, et al.: **Patients' perspectives in health technology assessment: A route to robust evidence and fair deliberation.** *Int J Technol Assess Health Care.* 2010; **26**(3): 334–340.
[PubMed Abstract](#) | [Publisher Full Text](#)
- Craig P, Dieppe P, Macintyre S, et al.: **Developing and evaluating complex interventions: the new Medical Research Council guidance.** *BMJ.* 2008; **337**: a1655.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Dodd RH, Sharman AR, McGregor D, et al.: **Education messages and strategies to inform the public, potential screening candidates and healthcare providers about lung cancer screening: A systematic review.** *Prev Med.* 2023; **169**: 107459.
[PubMed Abstract](#) | [Publisher Full Text](#)
- Mandrik O, Tolma E, Zielonka N, et al.: **Systematic reviews as a 'lens of evidence': Determinants of participation in breast cancer screening.** *J Med Screen.* 2021; **28**(2): 70–79.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Marlow LAV, Waller J, Wardle J: **Barriers to cervical cancer screening among ethnic minority women: a qualitative study.** *J Fam Plann Reprod Health Care.* 2015; **41**(4): 248–254.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Hefti A, Erhardt A: **[Effect of indomethacin on the development of periodontitis in relatively gnotobiotic rats].** *Schweiz Monatsschr Zahnmed (1984).* 1985; **95**(1): 71–6.
[PubMed Abstract](#)
- Tinmouth J, Ritvo P, McGregor SE, et al.: **ColonCancerCheck Primary Care Invitation Pilot project: family physician perceptions.** *Can Fam Physician.* 2012; **58**(10): e570–7.
[PubMed Abstract](#) | [Free Full Text](#)
- Michie S, van Stralen MM, West R: **The behaviour change wheel: A new method for characterising and designing behaviour change interventions.** *Implement Sci.* 2011; **6**(1): 42.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- West R, Michie S, Chadwick P, et al.: **Achieving behaviour change: a guide for local authorities.** (accessed Jul. 31, 2023).
[Reference Source](#)
- Duncan E, O'Cathain A, Rousseau N, et al.: **Guidance for reporting intervention development studies in health research (GUIDED): an evidence-based consensus study.** *BMJ Open.* 2020; **10**(4): e033516.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Kynoch K, Ramis MA: **Experience based co-design in acute healthcare services: a scoping review protocol.** *JBI Database System Rev Implement Rep.* 2019; **17**(1): 3–9.
[PubMed Abstract](#) | [Publisher Full Text](#)
- Heyhoe J, Reynolds C, Bec R, et al.: **The Shared Safety Net Action Plan (SSNAP): a co-designed intervention to reduce delays in cancer diagnosis.**

- Br J Gen Pract.* 2022; **72**(721): e581–e591.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
41. Quinn-Scoggins HD, Murray RL, Quaife SL, *et al.*: **Co-development of an evidence-based personalised smoking cessation intervention for use in a lung cancer screening context.** *BMC Pulm Med.* 2022; **22**(1): 478.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
 42. Glasgow RE, Vogt TM, Boles SM: **Evaluating the public health impact of health promotion interventions: the RE-AIM framework.** *Am J Public Health.* 1999; **89**(9): 1322–1327.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
 43. Browne MID: **Immunotherapy update in Lung Cancer Health Professional News.** Dec 10, 2021.
 44. Care DoPHaP: **SAHRU Index 2006-2016 - ED & SA Index (MS Excel 2 MB).** Dublin, 2016.
 45. Damschroder LJ, Aron DC, Keith RE, *et al.*: **Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science.** *Implement Sci.* 2009; **4**(1): 50.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
 46. Horton JN: **Nominal group technique. A method of decision-making by committee.** *Anaesthesia.* 1980; **35**(8): 811–814.
[PubMed Abstract](#) | [Publisher Full Text](#)
 47. Rankin NM, McGregor D, Butow PN, *et al.*: **Adapting the nominal group technique for priority setting of evidence-practice gaps in implementation science.** *BMC Med Res Methodol.* 2016; **16**(1): 110.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
 48. Popova L: **The extended parallel process model: illuminating the gaps in research.** *Health Educ Behav.* 2012; **39**(4): 455–473.
[PubMed Abstract](#) | [Publisher Full Text](#)
 49. Atkins L, Francis J, Islam R, *et al.*: **A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems.** *Implement Sci.* 2017; **12**(1): 77.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
 50. Brown J, Isaacs D, Brown J: **The World Café : shaping our futures through conversations that matter.** 1st ed. San Francisco, CA, 2005.
[Reference Source](#)
 51. Tong A, Sainsbury P, Craig J: **Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups.** *Int J Qual Health Care.* 2007; **19**(6): 349–357.
[PubMed Abstract](#) | [Publisher Full Text](#)
 52. Brown LR, Sullivan F, Treweek S, *et al.*: **Increasing uptake to a lung cancer screening programme: building with communities through co-design.** *BMC Public Health.* 2022; **22**(1): 815.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
 53. Hoffmann TC, Glasziou PP, Boutron I, *et al.*: **Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide.** *BMJ.* 2014; **348**: g1687.
[PubMed Abstract](#) | [Publisher Full Text](#)
 54. Pobal HP: **Deprivation Indices.** 2016; [cited 14Jul2023]. (accessed Jul. 31, 2023).
[Reference Source](#)
 55. Ali A: **Co-designing a Recruitment Strategy for Lung Cancer Screening in High-risk Individuals: Protocol for a Mixed-methods Study.** OSF. 2023.
<http://www.doi.org/10.17605/OSF.IO/XED4T>

Open Peer Review

Current Peer Review Status: ? ? ✓

Version 1

Reviewer Report 20 June 2024

<https://doi.org/10.21956/hrbopenres.15091.r39808>

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Abbie Begnaud 

University of Minnesota Medical School, Minneapolis, USA

This protocol is an important contribution to the field of advancing lung cancer screening uptake in Ireland. Much of the published work has occurred elsewhere and thus, needs to be adapted to the local context. Community co-design is a valid and ideal approach, integrating evidence based strategies with behavioral health frameworks and lived experience of the population of interest. Not knowing the specific guidelines or coverage for lung cancer screening in Ireland, I'm not sure if the selected population (persons aged 55 and older who have recently quit smoking or are still smoking cigarettes) is appropriate. Why not include individuals aged 50 and older or those who have quit longer ago? I also did not see mention of incentives for participants (PPI or interview participants) and expect these will be offered? Finally, it's not clear to me what "Irish Lung Cancer Community (ILCC)" is - is this a general description of people in Ireland personally affected by lung cancer or is this a specific named group or organization?

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Yes

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Lung cancer screening and implementation research

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 03 June 2024

<https://doi.org/10.21956/hrbopenres.15091.r39809>

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Mario Mascalchi

"Mario Serio", University of Florence, Florence, Italy

The project is thoroughly and redundantly described.

It aims to define a strategy suited to improve participation to Lung Cancer Screening in smokers living in deprived areas of Ireland.

Merits

The process to define an optimal recruitment strategy for the target population is well analyzed and subdivided in 4 steps with involvement of different components (clinical scientists, stakeholders etc.)

Limitations

The assumption that recruiting subjects at higher risk of LC focusing in deprived areas will yield a major benefit in term of LC screening efficacy, is at odds with the observation that, unfortunately, subjects at higher risk based on age and smoking burden are those that more likely develop more aggressive and untreatable LC (Young et al, 2022) [Ref 1]

Starting from GP is not the unique approach to identify eligible subjects. In Europe, self-referral through web is feasible and brings to recruitment of subjects with less smoking co-morbidities, primarily cardio-vascular disease and chronic obstructive pulmonary disease, which often vanish the potential benefit of a LC discovery through screening. I understand that subjects in deprived areas of Ireland are not likely to use the web, but a smartphone is probably owned by every 55-70 years old subject living in Ireland.

The Authors should provide some clearer hypotheses about which recruitment modality or mix of factors involved in recruitment modality are expected to constitute the outcome of the project.

References

1. Young R, Scott R, Gamble G: Lung function impairment in lung cancer screening: discordance between risk and screening outcomes when looking through a PRISM. *Translational Lung Cancer Research*. 2022; **11** (10): 1988-1994 [Publisher Full Text](#)

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Partly

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?

Partly

Competing Interests: No competing interests were disclosed.**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.**

Reviewer Report 30 November 2023

<https://doi.org/10.21956/hrbopenres.15091.r37037>

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**Gaston Arnolda**

Macquarie University, Sydney, New South Wales, Australia

Thank you for this protocol outlining a process of co-designing a recruitment strategy for people at higher-risk of lung cancer. Multiple methods are proposed to devise the strategy in four steps: 1) systematic review of interventions; 2) interviews with the population targeted for screening; 3) development of a strategy; and 4) assessment of feasibility and acceptability. People at higher risk are the targets in step 2, while consumer representatives with a focus on lung cancer will play a role in step 4 (and perhaps step 1 - not entirely clear). A separate expert group comprising primary care clinicians, psychologists and policy makers will be involved in steps 1-4, in various ways.

The purpose of co-developing a recruitment strategy is generally recognised as best practice and all of the proposed processes are in themselves not particularly controversial. I am unclear about many details, however, and thus unable to seek specific clarification at this point in the review process as the aim and initial logic model is not entirely clear to me (please accept my apologies for any misunderstandings on my part), and I am also unclear on what is planned in some of the steps. I will do my best to outline the main issues that I believe would be helpful to clarify in a revision.

Aim: The aim as specified in the abstract and the end of the introduction is stated as developing a strategy for recruiting older people at higher-risk of lung cancer (particularly in deprived populations). In the methods, however, the sampling for the target group is restricted to eligible low SES individuals attending (an unspecified number of) general practices. This creates crucial questions for me. If the aim is to target eligible low SES people in general, it is not clear to me that this is an appropriate sampling strategy for step 2; this would need to be justified (i.e., evidence that they all regularly attend GPs). If on the other hand the strategy is explicitly to intervene in

relation to recruitment through general practices this should be stated in both the aims and at the end of the introduction and, while the sampling of GP patients would be appropriate, the question arises as to why general practice staff are not a separate group for interview and participants in co-development of strategies (outside of the 'expert group').

Logic model: While I appreciate that the logic model is rudimentary at this stage, it would help the reader if it was re-framed to show how inputs and activities contribute to outputs and short- and longer-term outcomes; the current graphic does not make this clear. A recent paper on the subject may be helpful (Mills, T., Lawton, R. and Sheard, L., 2019. Advancing complexity science in healthcare research: the logic of logic models. BMC medical research methodology, 19(1), pp.1-11). As a trivial aside, the finalised logic model needs to have a higher optical resolution.

'High-risk' target group: I found the term high-risk distracting, as it suggests a risk threshold above which someone will be a target. My reading of your protocol, however, is that you are targeting eligible lower SES individuals in lower SES settings, regardless of their individual risk. If this is correct, I suggest reframing the terminology to refer to recruiting eligible low SES individuals in low SES communities (who are higher risk of lung cancer by virtue of this SES).

Step 1 sytematic review(?s): It is not clear to me whether the study is proposing one or more systematic reviews. If one review only, the protocol needs to justify why the already published review of interventions to promote participation in screening programs (Ref #19) was the only information required (e.g., no other information is required vs other information is required, but is adequately provided by other up to date reviews). The information needs should be depicted in the logic model.

Step 2 interviews: I may be misunderstanding this, but it seems to me inappropriately labelled 'theory formulation', which I find confusing. Rather, it seems to me that the purpose is to interview the target population to identify potential barriers and facilitators to participating in screening. Having identified these barriers and facilitators, there may then be a process, drawing on theory, to identify a subset of candidate interventions (which seems to me to be Step 3). If you agree, the title 'Identification of barriers and facilitators' seems ore appropriate.

Thanks for the opportunity to comment on what I trust will be an important piece of research.

Is the rationale for, and objectives of, the study clearly described?

No

Is the study design appropriate for the research question?

Partly

Are sufficient details of the methods provided to allow replication by others?

No

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Health Services Research

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.
