



STUDY PROTOCOL

REVISED

Smoking cessation programmes for women living in disadvantaged communities, “We Can Quit 2”: A systematic review protocol [version 3; peer review: 2 approved]

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Abstract

Tobacco use is the leading cause of preventable death in Ireland with almost 6,000 smokers dying each year from smoking-related diseases. Amongst younger Irish women, smoking rates are considerably higher in those from socially disadvantaged areas compared to women from affluent areas. Women from poorer areas also experience higher rates of lung cancer. To our knowledge, there are no peer reviewed published systematic reviews on the effectiveness of interventions tailored to reduce smoking rates in women from disadvantaged areas. This systematic review protocol will aim to examine the effectiveness of such interventions and to describe trial processes such as recruitment, follow-up and dropout prevention strategies, as well as barriers and enablers of successful implementation.

A systematic review will be conducted of peer-reviewed randomised controlled trials and associated process evaluations of smoking cessation interventions designed for women living in socially disadvantaged areas. If the search returns, less than five studies are review criteria will expand to include quasi-experimental studies. A number of databases of scholarly literature will be searched from inception using a detailed search strategy. Two independent reviewers will screen titles, abstracts and full-text articles to identify relevant studies using a pre-defined checklist based on PICOS. In the case of disagreement, a third reviewer will be consulted. The quality of included studies will be assessed using the 'Grading of Recommendations Assessment, Development and Evaluation' (GRADE) criteria. Quantitative data will be extracted and, if comparable, will be assessed using meta-analysis. A narrative meta-synthesis of qualitative

Open Peer Review

Reviewer Status  

	Invited Reviewers	
	1	2
version 3 (revision) 02 Dec 2019		 report
		
version 2 (revision) 28 Jun 2019	 report	 report
version 1 12 Jun 2019		

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Any reports and responses or comments on the article can be found at the end of the article.

data will be conducted.

This review aims to synthesise information from relevant studies on smoking cessation interventions tailored for women from socially disadvantaged areas. The evidence obtained from studies and presented in this review will help guide future research in this area.

Registration: This review will be registered with International Prospective Register of Systematic Reviews (PROSPERO).

Keywords

Smoking Cessation, Women and Smoking, Community-based Intervention, Social and Health Inequalities, Cluster Randomised Controlled Trial, Feasibility study, Pilot trial, Systematic Review.

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REVISED Amendments from Version 2

We have reconfigured the abstract and introduction, including examples and statistics from other countries as well as Ireland. We have added our Prospero number.

We refined our definition of disadvantage throughout the paper. To ensure clarity we have changed references within the text of the term 'deprived' to 'disadvantaged'.

We are explicit in distinguishing between intervention description and research designs. We now write that we will include any RCT, including those with accompanying process evaluations.

We have updated the quality assessment for risk of bias section, adding that two reviewers will independently check each selected article to minimise bias, using the Cochrane Risk of Bias' checklist. We have added use of the TIDierR checklist based on the reviewer's suggestion, De Bruin's methodology to properly describe the active content of control arms and we now note that no limitations will be placed on the types of usual care interventions that we will include in the review. We write that the second reviewer will extract data on a random sample of half the selected studies, using an initial batch for pilot testing before full extraction.

We write that authors of included studies will be contacted to ask for further information.

We accept that our previous specification of outcome was complex, and we have now simplified this and broadened our secondary outcome definition. We have made changes to our study selection and data extraction proposal as suggested.

We have widened our input from other research groups and hope to engage the Cochrane Tobacco Group.

We clarify that we place no limits on the proportion of women aged 18 years and above from disadvantaged communities included in the review. We have now added a new title to our paragraph on the GRADE software and more information on risk of bias.

Any further responses from the reviewers can be found at the end of the article

Introduction

Tobacco smoking remains the leading cause of morbidity and mortality globally. According to the World Health Organisation (WHO), tobacco kills more than 7 million people each year¹. WHO estimates that tobacco use is responsible for 16% of all deaths in adults over 30 years in the European Region, with many of these occurring prematurely². Although more men than women die from tobacco-related causes worldwide³, the gap in prevalence between genders is less than 5% in developed European countries e.g. Denmark, the Netherlands, Sweden and the United Kingdom⁴.

The influence of socio-economic deprivation is arguably the most important factor influencing smoking prevalence and decisions to quit. Lower socioeconomic groups likely start smoking at a younger age and smoke more cigarettes per day⁵. In European countries including Austria, the Czech Republic, Italy, Spain and the United Kingdom, smoking is more common in adolescent girls than boys⁶. The recent annual lifestyle survey in the Irish population 'Healthy Ireland'⁷ found that smoking rates were higher in socio-economically disadvantaged areas

than in affluent areas (26% versus 16%, respectively) and that women aged 18 to 29 from the lowest socioeconomic groups have almost double the smoking rates of women from affluent groups (56% versus 28%)⁸. In addition higher lung cancer rates have been observed in women from the most deprived compared to women from least deprived areas in 2016 (age standardised rate ratio, 1.56; 95% CI, 1.42 1.72)⁹.

There are also important differences between men and women with regard to the determinants of quitting. A previous systematic review of randomised controlled trials (RCTs) of smoking cessation reported that women found it more difficult to maintain long-term abstinence compared to men¹⁰. The link between age and gender is also an important determinant of smoking cessation. A general population survey in the US, Canada and UK found that amongst those aged under-50, women were more likely than men to stop smoking and maintain quitting, however in older groups, men were more likely to quit than women¹¹.

Smoking may have differential effects on women's health such as increased risk of cervical cancer, breast cancer and premature menopause¹², and there may be a cumulative effect of disadvantage on female smokers' health. It is likely that disadvantage and gender interact to accentuate these differences and there is a need to expand and explore the scope of such findings. Female smokers from more disadvantaged groups should be targeted for greater support in smoking cessation, and there have been recent calls for the development of tailored interventions in this area¹³.

To our knowledge there are no peer reviewed, published systematic reviews that examine the smoking cessation interventions targeted to socio-economically disadvantaged women. A previous narrative review assessed gender differences in smoking cessation¹⁰ but did not specifically explore the role of disadvantage. This systematic review will evaluate the effectiveness of smoking cessation interventions tailored to socio-economically disadvantaged women.

Aims and research objectives

This systematic review protocol describes the methodology to identify, appraise and synthesise the existing evidence of effectiveness of smoking cessation programmes available to socio-economically disadvantaged women.

The review will address the following research objectives:

1. Assess the effectiveness of intervention programmes for smoking cessation targeted to socio-economically disadvantaged women;
2. Identify the recruitment strategies used by these programmes and quantify their success in the recruitment of participants;
3. Identify the retention, drop-out and follow-up rates of the programmes;

4. Identify any strategies used to enhance implementation e.g. training, coaching; and
5. Identify the barriers and enablers to successful implementation of the programmes.

Methods

A systematic review of peer-reviewed literature will be conducted on smoking cessation interventions for socio-economically disadvantaged women including women living in socially deprived areas. This protocol is guided by the “Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols” (PRISMA-P) checklist¹⁴; a completed PRISMA-P checklist is available (see ‘Reporting Guidelines’). This review protocol is registered with PROSPERO (registration information: CRD42019130160).

Study design

The systematic review will consider RCTs and associated process evaluations. If the search returns fewer than five RCTs, review criteria will be expanded to include quasi-experimental studies of smoking cessation interventions designed for socio-economically disadvantaged women, including women living in disadvantaged areas.

Search strategy

The strategy aims to find published articles by a systematic search of Medline, Embase, Cochrane Library of Systematic Reviews, Cinahl, PsycINFO, Web of Science, Scopus, Sociological Abstracts, ASSIA, British Nursing Index, Google Scholar, Epistemonikos, with relevant MeSH headings. An experienced librarian (D.M.) will develop a sensitive search strategy for each individual database. A search of reference lists and citations will also be undertaken. There will be no restriction on country or year of publication; however, all papers must be in English. Where studies are not available, study authors will be contacted. This study will exclude grey literature, conference abstracts, opinion pieces, literature reviews commentaries and editorials. Bibliographies of all retrieved trials and other relevant publications, including reviews and meta-analyses will be checked for additional relevant articles.

Study eligibility

The terms of this review will be defined using PICOS (Population, Intervention, Comparison, Outcome, and Study Design).

Population. The study population will comprise women aged 18 years and older that are reported as being socio-economically disadvantaged who smoke and who have attended any type of smoking cessation programme. Our definition of socio-economic disadvantage refers to individuals’ socioeconomic resources or social position, typically low income, low educational attainment, rank in an occupational hierarchy or residence in a neighbourhood of socioeconomic disadvantage. Vulnerable populations e.g. racial and ethnic minorities will be included¹⁵.

Studies with mixed populations where the above information is reported will be included.

Inclusion criteria:

- RCTs of women aged 18 years and above who smoke and have attended any type of smoking cessation programme and are defined by the authors as socio-economically disadvantaged;
- Any definition of ‘neighbourhood socioeconomic disadvantage’ (including but not limited to disadvantaged communities, poverty, neighbourhood/area status) or any definition of ‘individually measured disadvantage’ (including but not limited to low income, entitlement to medical or other state benefits, unemployment, educational status, and social class);
- RCTs with both men and women in the same sample, if all findings are reported separately for women;
- RCTs with a sample of pregnant and non-pregnant women, if smoking cessation is reported separately for non-pregnant women;
- RCTs that include women living in any circumstances, but the results are segmented into smoking cessation for women in disadvantaged communities.

Exclusion criteria:

This review will exclude studies that are exclusive to men and to pregnant women.

Intervention. ‘Smoking cessation interventions’ will be defined as interventions or programmes that are designed to assist smoking cessation. These are predicted to consist of the following:

- Any RCTs that report individual-level interventions such as (i) brief advice to stop smoking from a health professional (e.g. physician); (ii) pharmacotherapy (nicotine replacement therapies such as the transdermal patch, chewing gum, nasal sprays, lozenges, inhalers, dissolvable strips, and prescribed or self-administered alternatives to tobacco such as bupropion/varenicline or e-cigarettes); or (iii) behavioural support (any form of encouragement, advice or discussion from a trained stop-smoking specialist).
- Any RCT which includes an accompanying process evaluation that describes recruitment and /or retention processes, implementation strategies, barriers and facilitators to the implementation of the intervention during the programmes.

We will use the 12-item TIDieR checklist to ensure there is completeness in the reporting of the included interventions¹⁶.

Comparison. Corresponding information will be extracted for the control arm of RCTs, typically ‘care as usual’. No limitations will be placed on the types of usual care interventions that

we will include in the review. Authors of included studies will be contacted to ask for further information on the active ingredient in comparison groups so as not to underreport their active content. De Bruin *et al.*'s methodology will be followed¹⁷: i) identifying the active components of smoking cessation support provided to intervention and comparison groups and their impact on effect sizes; ii) identifying mediators and moderators of the intervention effectiveness; and iii) estimating intervention effect sizes adjusted for comparison group variability.

Outcome. The primary outcome of interest will be the proportion of the population randomised who achieve smoking cessation (abstinence) at the end of the intervention and at follow up time points. Point-prevalence and continuous abstinence will also be reported where available. Smoking cessation will be defined as biochemically verified smoking abstinence.

Secondary outcomes will be proportions of the population: i) recruited from those eligible; ii) retained at the end of the intervention; and iii) retained at subsequent follow-up data collection points. We will record self-reported smoking abstinence and any other form of reported smoking behaviour defined within each study e.g. change in mean number of cigarettes smoked.

Study design

Data selection and management

The title and abstracts retrieved from the electronic databases and references will be exported to EndNote bibliographic software for storage and the removal of duplicates. After removal of duplicates, the title and abstracts will be exported to Covidence software for reviewing¹⁸. Two independent reviewers will identify relevant titles and abstracts using a pre-defined checklist based on PICOS. If the reviewers deviate in their judgement, a third reviewer will assess these abstracts. The full text version will be obtained for the remaining relevant searches. The two independent reviewers will review the full text and those deemed irrelevant will be removed. Any disagreements that arise between the two reviewers will be resolved through discussion with a third reviewer¹⁴.

Quality assessment for risk of bias

Two reviewers will independently check each selected article to minimise bias. All selected articles will be judged for their quality based on the 'Cochrane Risk of Bias' checklist¹⁹.

Confidence in cumulative evidence

All selected articles will be judged for their quality based on the Grading of Recommendations Assessment, Development and Evaluation' (GRADE) system²⁰. The five main factors that can downgrade the quality scores of RCTs²⁰, which include risk of bias, inconsistency, indirectness, imprecision and publication bias will be addressed. The GRADE approach is comprehensively described in an online manual²¹ (freely

available for [download with the GRADEpro software](#)). Studies with low quality may be excluded.

Data extraction

Using standardized data extraction forms, one reviewer will extract data from valid and selected papers for data analysis. A second reviewer will receive a random sample of half of all selected papers for independent review. This procedure will occur on an initial batch of studies, after which reviewers will pause, meet to discuss the process, and refine the method if necessary. If there are any conflicts within data extraction forms, a third reviewer will resolve these issues. The second reviewer will then continue with the data extraction of the selected papers.

The data extracted will include details specific to the review's primary and secondary outcomes. Examples of data that will be extracted include, (a) general study information e.g. author, publication year, country of origin, enrolment period, research design, recruitment methods, inclusion and exclusion criteria, proportion of randomised participants from those eligible; (b) study population details e.g. sample size, age, duration of follow up, (c) outcomes of interest as above. All corresponding authors will be contacted for key information when data are ambiguous or missing from the published study. Data extraction will be independently crosschecked, by a third reviewer who will resolve disagreements by discussion.

Data synthesis

For quantitative data, where possible, odds ratios for binary outcome data and their 95% confidence intervals will be calculated from data generated by each included RCT. Data derived via intention-to-treat analysis will be used. Results from comparable groups of studies will be pooled into statistical meta-analysis using Review Manager software from the Cochrane Collaboration²².

Statistical heterogeneity between combined studies will be tested using the I^2 method alongside the standard chi-square test. An estimate greater than or equal to 50% accompanied by a statistically significant Chi² statistic will be interpreted as evidence of statistical heterogeneity²³. If substantial levels of heterogeneity are found for the primary outcome measure, all data entered will be checked for accuracy. A visual inspection of the data will be conducted and any outlying studies removed to determine if heterogeneity persists. Sub-group analyses will be completed if sufficient data are available to examine between-study variability on categories of intervention or risk of bias.

The unit of analysis is expected to be at an individual level outcome. Where 'cluster randomisation' is used, these data will be extracted alongside an assessment of whether the authors accounted for intra-class correlation (ICC) in clustered studies. Where clusters have not been incorporated into the analysis of the trial, authors will be contacted and asked to provide the ICCs for their clustered data. These binary data derived

from randomised cluster trials will then be divided by a 'design effect', estimated using the mean number of participants per cluster (m) and the ICC using the formula ($\text{Design effect} = 1 + (m-1) \times \text{ICC}$)²⁴. If the ICC cannot be obtained, we will assume it to be 0.1²⁵.

For any particular outcome, if more than 50% of data are unaccounted for, a meta-analysis will not be conducted. A random effects model will be used in preference to a fixed-effects model to combine individual RCT primary outcome measures as it takes into account that different trials are estimating different but related intervention effects.

Where statistical pooling is not possible the findings will be presented in narrative form. Heterogeneous qualitative data will be synthesised in a narrative format focused around the review's objectives with findings presented thematically

Dissemination of findings

Findings will be disseminated in a peer reviewed journal and at conferences.

Study status

The study is currently ongoing. The search and screening of titles and abstracts has been completed. At time of publication we are performing full text screening. The expected end date for the study is December 2019.

Discussion

This review will systematically examine the available evidence of effectiveness on smoking cessation interventions

in women from socially disadvantaged areas. This work is being undertaken to inform the We Can Quit2 cluster randomised feasibility study of a smoking cessation intervention in disadvantaged women. Trial investigators will support this review and will provide advice on how the evidence may be used to develop and scale up future smoking cessation services for disadvantaged women and to inform policy and further research in this area. We also hope to engage the Cochrane Tobacco Group for further input and to benefit from their expertise.

Limitations

There are some limitations to the outlined systematic review. Most social intervention studies are unblinded. The relevance of this potential bias to our study will be discussed.

The restriction to English is acknowledged as a language bias. The cost of high-quality translations of in-depth qualitative data are beyond the resources of this review; however, non-English language studies identified at the screening stages and excluded from the synthesis will be listed in an appendix to aid future reviewers.

Data availability

Underlying data

No underlying data are associated with this article.

Reporting guidelines

Open Science Framework: PRISMA-P checklist for "Smoking cessation programmes for women living in disadvantaged communities, "We Can Quit": A systematic review protocol". <https://doi.org/10.17605/OSF.IO/J96M5>.

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Reviewer Report 05 December 2019

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Emma Hock 

Health Economics and Decision Science (HEDS), School of Health and Related Research (SchARR), University of Sheffield, Sheffield, UK

I am happy with the changes made.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Systematic reviewing, smoking cessation.

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.

Version 2

Reviewer Report 20 August 2019

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Emma Hock 

Health Economics and Decision Science (HEDS), School of Health and Related Research (SchARR), University of Sheffield, Sheffield, UK

This manuscript reports on a protocol for a systematic review of smoking cessation programmes for women living in disadvantaged communities. Strengths include the use of PRISMA-P, study selection, data extraction and quality assessment independently undertaken by two reviewers, and a novel review

question. The main limitation is slight confusion around quality assessment and strength of the evidence/confidence in cumulative evidence. Also, the protocol should be registered on PROSPERO and the registration number given here.

In my opinion, the following changes could be made to improve the clarity of the manuscript:

Abstract

In the sentence, “If the search returns, less than five studies are review criteria will expand to include quasi-experimental studies”, I suggest moving the comma to after “studies” or deleting, changing “are” to “the” (or similar) and replacing “search” to “search and screen” or similar.

I suggest moving the sentence outlining the aim (“This review aims to synthesise information from relevant studies on smoking cessation interventions tailored for women from socially disadvantaged areas”) to earlier in the abstract, or possibly replace the sentence “This systematic review protocol will aim to examine the effectiveness of such interventions...” with this one or merge the two sentences. Either way, the aim of the review needs to be stated between the background and methods (and not the aim of the protocol, which is implicit).

Introduction

The introduction provides useful information to justify the conduct of this review, however it could be more logical and flow a bit better. Paragraph 2 focuses exclusively on Ireland, with no explanation and this needs to be clarified - is there a particular issue in Ireland? Is the review focusing on Ireland? If so, this needs to be clarified in the review question and PICO (Population). Also, the statistics presented include a variety of age ranges, and incomparable statistics have been presented together. The Introduction would flow much better if either age was highlighted as an important variable (and then this was reflected in the review) with the presentation of the statistics by age, or if statistics for comparable age groups were presented together in the same paragraph/towards making the same point. In the fifth paragraph of the Introduction, data from a systematic review are presented to highlight the point that women are less likely than men to maintain abstinence longer-term, and then data from a single study that pre-dates the systematic review is presented to make the same point, although this finding would have been subsumed/superseded by the systematic review data in the first sentence. If presenting additional data to make an argument, the argument would seem more logical if the additional data was considerably different to what the systematic review data showed, or post-dated the review data. Also in this paragraph, please amend “RCTs of smoking trials” to “RCTs of smoking cessation trials” (assuming this is the intended meaning).

Methods

The first paragraph states that “The proposed review will be guided by... PRISMA-P”. Please amend this to clarify that PRISMA-P guides the protocol, not the review.

In the search strategy, please clarify whether searches of reference lists and citation searching are being undertaken. It would also be useful to include some example search terms.

Within the Study Eligibility subheading, the PICOS subheadings should be at the next level down for ease of reading (in terms of level of heading - as these are further subheadings under study eligibility). In terms of Population, it would be useful to highlight what proportion of women aged 18 years and above from disadvantaged communities (for each of these characteristics) you will be accepting, in studies with mixed populations (or whether these studies will just be excluded). Under Comparison, it would be useful to say something about the types of comparison condition you are including and excluding. In terms of

Outcome, it would be useful to specify whether you are talking about continuous abstinence or point-prevalent abstinence when abstinence is mentioned. All the bullet points (and 'exclusion criteria') under the section Study design seem to relate to the population, and so these details should go under that subheading; study design would need to include the types of study design included and excluded.

Regarding Quality assessment - it is useful that you are planning on using GRADE to assess the strength of the review findings. However, this needs to be in a separate section, possibly subheaded 'Confidence in cumulative evidence' or similar, as GRADE is more comprehensive than quality assessment in terms of judging confidence in the overall findings of your review. In the quality assessment subsection, the quality assessment checklist (or checklists, depending on the study types included) should be given here (e.g. the Cochrane Risk of Bias scale).

Under the data extraction, it would be helpful if you could specify which fields you are extracting.

Discussion

The sentence "The aim of this review RCT is to help guide..." (p.5) looks like it needs to be revised, for sense.

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

Partly

Is the study design appropriate for the research question?

Yes

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

Partly

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

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Systematic reviewing, smoking cessation.

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.

Author Response 29 Oct 2019

Emma Burke, Trinity College Dublin, Dublin, Ireland

Response One

The protocol is now published on Prospero; the registration number is: CRD42019130160. We have added our registration number to the paper (Line 106)

Response Two

Thank you for these comments. We have now made the changes suggested.

Response Three

Thank you for these comments.

The review is being conducted in Ireland, which is why we have described Irish statistics. The reviewer is correct in that this may confuse readers who could be led to believe this review concerns only Ireland. We have re-organised the 'Introduction' to read more logically but retained some of the Irish examples as they serve as illustrations of a wider phenomenon. However, in order not to mislead readers that this is an 'Irish review', we now include examples from other countries to illustrate certain points.

Response Four

Thank you for this comment. We have changed Line 103 to read, "*This protocol is guided by the 'Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols' (PRISMA-P) checklist*"

We have added the following to Line 120, "*A search of reference lists and citations will also be undertaken.*"

We have used Heading 4, the next subheading to help improve the readability of the PICOS subheadings as suggested.

We will place no limits on the proportion of women aged 18 years and older that we will accept in the review from those in studies with mixed populations. We have clarified this under the 'Population' heading (Line 131).

We will place no limitations on the types of comparison conditions that we will include in the review. We have added this to Line 183.

Due to the likely heterogeneity in outcome measures between studies, we do not intend to define whether the primary outcome is a point-prevalent or continuous measure. We have however, clarified under secondary outcomes that we will intend to record any other abstinence outcome defined within an included study (Line 201).

Thank you for the comment on our inclusion criteria under the 'Study Design' heading. We have now moved the 'Inclusion' and 'Exclusion Criteria' to the 'Population' heading as suggested.

Response Five

Thank you for this point, we have now added a new title to our paragraph on the GRADE software (Line 233)

We have added more information on our Risk of Bias section (Line 228).

We intend on extracting a wide range of information in this review. We have added examples of the kind of data we intend to collect, rather than a comprehensive list (Line 281).

Thank you for the comment on the sentence, "The aim of this review RCT...". We have now amended this sentence (Line 310).

Competing Interests: No competing interests were disclosed.

Reviewer Report 26 July 2019

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Marie Johnston 

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This paper is the protocol for a systematic review funded by HRB. The study aims to identify papers of smoking cessation intervention trials conducted with women from disadvantaged communities, to extract data on PICO and GRADE, and draw conclusions about the effectiveness of interventions in achieving smoking cessation.

The authors describe the importance of this study very clearly: the health risks of smoking, the greater prevalence of smoking in women from the lowest socioeconomic groups and the high rates of lung cancer in women living in deprived areas of Ireland. They note that 17% of women were current smokers in the 2018 Irish survey but make no comment on the trend over time – are these rates continuing to decline? They note that previous reviews have not targeted this population; for example the reviews by Bull *et al.*¹² report on smoking cessation in low income groups but do not include other wider definitions of disadvantage nor separate the data for women. The value of the results are in guiding future research and smoking cessation policy.

This is an important topic and the planned review is likely to be useful, especially within the Irish context. The following comments and queries are aimed to suggest opportunities for improving the conduct and value of the review.

First, the authors might wish to tighten or expand on their definition of 'disadvantaged' as this is likely to elicit challenges later, when publishing. They refer both to communities and to areas and these might be different for example if disadvantage was due to being a member of a minority ethnic group but the person might not be living (and/or working) in an area or workplace with people of similar ethnicity. Also, they will find very diverse types of disadvantage – would they consider grouping them by types of disadvantage? Might this be helpful in considering 'sub-groups' in the analysis?

Second, the paper does not clearly separate the intervention description from the research designs used to evaluate the interventions. Under the heading 'Intervention', two bullet points identify what interventions consist of, and refer to RCTs, but the RCTs do not define the intervention. Instead, they are defining two separate criteria for inclusion, first that the evaluation study should be an RCT and second that the RCT should evaluate the effect of a smoking cessation intervention. It was not clear how the process evaluations would add to the evidence obtained from the RCTs.

Third, it is planned to assess the quality of the trial using the GRADE system. It might prove useful to consider the recently developed [Risk of Bias 2 tool](#) which was probably published since this protocol paper was written. It is not clear how this data on bias would be used in evaluating the evidence. Would trials that have poor scores be omitted? How would they deal with the inevitable bias in personally delivered interventions?

Fourth, the protocol indicates that the data extracted about each intervention and comparison arm would be based on PICOS. They might also wish to use the [TIDieR checklist](#) and/or [CONSORT-SPI³](#) to describe the interventions, especially behavioural interventions, in more detail. It might also be worthwhile coding the active content as behaviour change techniques or using the enhanced methods described by Black *et al.* (2018)⁴ but this might require more funding for the extra work involved.

Fifth, there is ample evidence that published papers give poor descriptions of control/comparison groups and tend to underestimate the active content. This can lead to misleading results (see de Bruin *et al.* ⁵⁶). It would be beneficial if the authors were able to gain further information about inputs provided to both intervention and comparison group when they write to authors perhaps using De Bruin *et al.*'s methods.

Sixth, the specification of outcome is quite complex, requiring an 'intention-to-stop... followed by resistance of urges to smoke, resulting in a period of abstinence... corroborated by a saliva test'. Very few papers will give data on all 4 of these stages and it would be simpler to omit the intentions and urges and focus on the behaviour. It might then be useful to analyse both the self-report of abstinence and, more definitely, the objectively corroborated.

Seventh, all study selection and data extraction will be conducted by two reviewers with disagreements resolved by discussion and ultimately a third reviewer and this is good practice. It would be wise to plan to do this procedure on an initial batch of studies to refine the process rather than completing all of the data extraction before assessing agreement. Also, when procedures have been agreed, the level of agreement before discussion of disagreements, should be reported.

Eighth, the study might gain from having a wider advisory group involving likely users in Ireland as they might comment on how the evidence might be made more useful. But in addition it might be helpful to have input from other researchers involved in systematic reviews of smoking cessation trials, such as members of the Cochrane Tobacco Group or members of the IC-SMOKE group as there is a wealth of expertise which the authors might wish to draw on.

In sum, this protocol describes a competent and useful systematic review that addresses an important topic and is likely to contribute to future research and applications.

References

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2. Bull ER, McCleary N, Li X, Dombrowski SU, et al.: Interventions to Promote Healthy Eating, Physical Activity and Smoking in Low-Income Groups: a Systematic Review with Meta-Analysis of Behavior Change Techniques and Delivery/Context. *Int J Behav Med*. 2018; **25** (6): 605-616 [PubMed Abstract](#) | [Publisher Full Text](#)
3. Grant S, on behalf of the CONSORT-SPI Group: The CONSORT-SPI 2018 extension: a new guideline for reporting social and psychological intervention trials. *Addiction*. 2019; **114** (1): 4-8 [Publisher Full Text](#)
4. Black N, Williams AJ, Javornik N, Scott C, et al.: Enhancing Behavior Change Technique Coding Methods: Identifying Behavioral Targets and Delivery Styles in Smoking Cessation Trials. *Ann Behav Med*. 2019; **53** (6): 583-591 [PubMed Abstract](#) | [Publisher Full Text](#)
5. de Bruin M, Viechtbauer W, Eisma MC, Hartmann-Boyce J, et al.: Identifying effective behavioural components of Intervention and Comparison group support provided in SMOKing cEssation (IC-SMOKE) interventions: a systematic review protocol. *Syst Rev*. 2016; **5**: 77 [PubMed Abstract](#) | [Publisher Full Text](#)

6. de Bruin M, Viechtbauer W, Schaalma HP, Kok G, et al.: Standard care impact on effects of highly active antiretroviral therapy adherence interventions: A meta-analysis of randomized controlled trials. *Arch Intern Med*. 2010; **170** (3): 240-50 [PubMed Abstract](#) | [Publisher Full Text](#)

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: I have published with one of the authors. Farquharson, Barbara, Marie Johnston, Karen Smith, Brian Williams, Shaun Treweek, Stephan U. Dombrowski, Nadine Dougall, Purva Abhyankar, and Mark Grindle. "Reducing patient delay in Acute Coronary Syndrome (RAPiD): research protocol for a webbased randomized controlled trial examining the effect of a behaviour change intervention." *Journal of advanced nursing* 73, no. 5 (2017): 1220-1234.

Reviewer Expertise: Health psychology and behaviour change.

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.

Author Response 29 Oct 2019

Emma Burke, Trinity College Dublin, Dublin, Ireland

Response One

Thank you for this comment. We agree that there will likely be a diverse array of definitions of disadvantage in the papers we include. In order to have as broad a definition as possible we will use a definition of disadvantage by Braveman et al.

We have added the following to Line 133 of the study methods: "*Our definition of socio-economic disadvantage refers to individuals' socioeconomic resources or social position, typically low income, low educational attainment, rank in an occupational hierarchy or residence in a neighbourhood of socioeconomic disadvantage. Vulnerable populations e.g. racial and ethnic minorities will be included*

In order to ensure clarity we have also changed references within the text of the term 'deprived' to 'disadvantage' to ensure consistency.

Response Two

We have added the following to Line 171: "[These are predicted to consist of the following:] Any RCT which includes an accompanying process evaluation that describes recruitment and/or retention processes, implementation strategies, barriers and facilitators to the implementation of the intervention during the programmes."

Response Three

We have added the following to the 'Quality assessment for risk of bias' section, Line 229: *"Two reviewers will independently check each selected article to minimise bias. All selected articles will be judged for their quality based on the 'Cochrane Risk of Bias' checklist."*

Response Four

Thank you for this suggestion. We now intend to use the TIDierR checklist based on this suggestion. We have added the following to Line 178: *"We will use the 12-item TIDieR checklist to ensure there is completeness in the reporting of the included interventions"*

Response Five

Thank you for this comment. We have added the following to Line 183: *"No limitations will be placed on the types of usual care interventions that we will include in the review. Authors of included studies will be contacted to ask for further information on the active ingredient in comparison groups so as not to underreport their active content. De Bruin et al.'s methodology will be followed (17): i) identifying the active components of smoking cessation support provided to intervention and comparison groups and their impact on effect sizes; ii) identifying mediators and moderators of the intervention effectiveness; and iii) estimating intervention effect sizes adjusted for comparison group variability."*

Response Six

We accept this point about the overly complex specification of smoking abstinence. We have updated Line 195 to read: *"Smoking cessation will be defined as biochemically verified smoking abstinence"*.

In our secondary outcomes we have added the following to Line 201: *"We will record self-reported smoking abstinence and any other form of reported smoking behaviour defined within each study e.g. mean number of cigarettes smoked"*

Response Seven

Two reviewers will complete all study selection, however for pragmatic, resource and time reasons, one reviewer will complete all data extraction and the second reviewer will complete extraction on a consecutive sample of the first few papers, then pause and review the method in conjunction with the first reviewer and will then continue to extract data on the rest of the selected papers.

We have updated the review to reflect this (Line 251): *"A second reviewer will receive a random sample of half of all selected papers for independent review. This procedure will occur on an initial batch of studies, after which reviewers will pause, meet to discuss the process, and refine the method if necessary. If there are any conflicts within data extraction forms, a third reviewer will resolve these issues. The second reviewer will then continue with the data extraction of the selected papers."*

Response Eight

Thank you for this useful advice. We currently involve the We Can Quit2 trial team in all decisions regarding this systematic review. This team also provide practical input on the Irish smoking cessation context. Regarding the Cochrane Tobacco Group, we will attempt to link in with them and learn from their expertise.

We have added the following to Line 311: *"This work is being undertaken to inform the We Can Quit2 cluster randomised feasibility study of a smoking cessation intervention in disadvantaged women. Trial investigators will support this review and will provide advice on how the evidence may be used to develop and scale up future smoking cessation services for disadvantaged women and"*

to inform policy and further research in this area. We also hope to engage the Cochrane Tobacco Group for further input and to benefit from their expertise”

Competing Interests: No competing interests were disclosed.