STUDY PROTOCOL

Smoking cessation programmes for women living in disadvantaged communities, “We Can Quit 2”: A systematic review protocol [version 2; peer review: 1 approved, 1 approved with reservations]

Emma Burke 1, Fiona Dobbie 2, Nadine Dougall 3, Mary Adebolu Oluwaseun 1, David Mockler 1, Joanne Vance 4, Nicola O’Connell 1, Catherine Darker 1, Linda Bauld 2, Catherine Hayes 1

1 School of Medicine, Trinity College Dublin, Dublin, Ireland, D24 DH74, Ireland
2 Usher Institute, College of Population Health Sciences Medicine and Informatics Veterinary Medicine, University of Edinburgh, Teviot Place, Edinburgh, EH8 9AG, UK
3 School of Health and Social Care, Edinburgh Napier University, Sighthill Court, Edinburgh, EH11 4BN, UK
4 Irish Cancer Society, Dublin, D04 VX65, Ireland

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
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.

**Corresponding author**: Emma Burke (burkee16@tcd.ie)

**Author roles**: Burke E: Methodology, Software, Writing – Original Draft Preparation, Writing – Review & Editing; Dobbie F: Conceptualization, Funding Acquisition, Writing – Original Draft Preparation, Writing – Review & Editing; Dougall N: Conceptualization, Funding Acquisition, Writing – Original Draft Preparation, Writing – Review & Editing; Adebolu Oluwaseun M: Writing – Original Draft Preparation, Writing – Review & Editing; Mockler D: Methodology; Vance J: Conceptualization, Funding Acquisition, Writing – Original Draft Preparation, Writing – Review & Editing; O’Connell N: Methodology, Writing – Review & Editing; Darker C: Conceptualization, Funding Acquisition, Investigation, Writing – Original Draft Preparation, Writing – Review & Editing; Bauld L: Conceptualization, Funding Acquisition, Writing – Original Draft Preparation, Writing – Review & Editing; Hayes C: Conceptualization, Data Curation, Funding Acquisition, Methodology, Writing – Original Draft Preparation, Writing – Review & Editing

**Competing interests**: No competing interests were disclosed.

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Introduction

Tobacco smoking remains the leading cause of morbidity and mortality globally. According to a recent World Health Organisation (WHO) report, tobacco kills more than 7 million people each year. More than 6 million of those deaths are the direct result of tobacco use, with 890,000 caused by non-smokers' exposure to second-hand smoke. Compared to the rest of the world, the WHO European Region has one of the highest proportions of deaths attributable to tobacco use. 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 prematurely.

The Healthy Ireland Survey 2018 reported 20% of people aged 15 years are current smokers; with a rate of 22% in men and 17% in women. Cigarette smoking prevalence were highest among 25 to 34-year olds, with rates declining with age.

While tobacco use was previously largely a male phenomenon, the gap in prevalence between genders is now less than 5% in countries such as Denmark, the Netherlands, Sweden and the United Kingdom. However, research has highlighted that gender remains an important factor when considering smoking prevalence in areas of deprivation. A recent report by Health Ireland Survey (2018) found that smoking rates were higher in more disadvantaged areas than in affluent areas (26% versus 16%, respectively). Women aged 18 to 29 from the lowest socioeconomic groups in Ireland have been reported to have almost double the smoking rate compared to those belonging to affluent groups (56% versus 28%). This disparity was also observed in men, although the difference was less pronounced (44% versus 31%).

Smoking perpetuates health inequalities between women from richer and poorer communities. Data from 2016 found significantly higher lung cancer rates in women from the most deprived areas of Ireland versus women from the least deprived (age standardised rate ratio, 1.56; 95% CI, 1.42 1.72). Lung cancer incidence in Irish men has declined in the period from 1994 to 2015, but has increased in women over the same period. More women in Ireland are now dying from lung cancer than breast cancer. Smoking can have differential effects on women’s health such as increased risk of cervical cancer, breast cancer and premature menopause, and there may be a cumulative effect of disadvantage on women who smoke and their health outcomes. These results suggest 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 area.

In a previous systematic review of randomised controlled trials (RCTs) of smoking trials, women had more difficulty in maintaining long-term abstinence compared to men. A general population survey across several countries found that amongst people aged under-50, women were more likely to stop smoking completely compared to men, but amongst older groups, men were more likely to quit than women. It is likely deprivation and gender interact to accentuate these differences and there is a need to expand and explore the scope of such findings.

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

Aims and research objectives

This systematic review protocol sets out to identify, appraise and synthesise the existing evidence of effectiveness of smoking cessation programmes available to women living in disadvantaged communities.

The review will address the following research objectives:

1. Assess the effectiveness of intervention programmes for smoking cessation in women living in disadvantaged communities;
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 the implementation strategies used by these programmes, e.g. training, coaching;
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 and quit-tobacco interventions for women living in socially deprived areas. The proposed review will be guided by the “Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols” (PRISMA-P) checklist; a completed PRISMA-P checklist is available. This review protocol will be registered with PROSPERO (awaiting registration number).

Study design

The systematic review will consider RCTs and associated process evaluations. If the search returns fewer than five studies, review criteria will be expanded to include quasi-experimental studies of smoking cessation interventions designed for women living in socially disadvantaged areas.
Search strategy
The strategy aims to find published articles by a systematic search of Medline, Embase, Cochrane Library of Systematic Reviews, Cinalh, 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. There will be no restriction on country or year of publication; however, all papers must be in English. Where studies are not available we will contact study authors. 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
Women aged 18 years and above that are reported as being from disadvantaged communities who smoke and who have attended any type of smoking cessation programme.

Intervention
Intervention programmes that report smoking cessation outcomes at end of programme delivery and follow-up including any recruitment strategies used in the studies.

‘Smoking cessation interventions’ will be defined as interventions 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 RCTs that report accompanying process evaluations that focus on implementation strategies, barriers and facilitators to the implementation of the intervention during the programmes.

Comparison
Corresponding information will be extracted for the control arm of RCTs, typically ‘care as usual’.

Outcome
The primary outcome of interest is the proportion of the population randomised who achieve smoking cessation (e.g. abstinence). Smoking cessation will be defined as an intention-to-stop smoking cigarettes from a given point in time (e.g., a ‘quit attempt at 4 weeks’), followed by resistance of urges to smoke, resulting in a period of abstinence, that will be corroborated by a saliva test.

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.

Study design
Inclusion criteria
- RCTs trials of women aged 18 years and above who smoke and have attended any type of smoking cessation programme and live in disadvantaged communities.
- RCTs with both men and women in the same sample, if all findings were 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.
- Any definition of “Disadvantaged communities” (including but not limited to poverty, low income, unemployment, educational status, social class, social condition, neighbourhood/area status)

Exclusion criteria. This review will exclude studies that are exclusive to pregnant women.

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 reviewing. 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 reviewer.

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 Grading of Recommendations Assessment, Development and Evaluation' (GRADE) system. The GRADE approach provides guidance on rating the quality of research evidence in health care. This system addresses the five main factors that can downgrade the quality scores of RCTs, which include risk of bias, inconsistency, indirectness, imprecision and publication bias. Evidence from non-randomised studies begins as low-quality evidence, but ratings can be upgraded (provided no other limitations have been
identified according to the five factors). Upgrading occurs if there is a large magnitude of effect, evidence of a dose-response effect, and all plausible confounding factors have been taken into account\(^\text{19}\). An advantage of GRADE is that it leads to more transparent judgements about the quality of evidence and can help indicate the strength of recommendations based on the evidence\(^\text{20}\). The GRADE approach is comprehensively described in an online manual\(^\text{19}\) (freely available for download with the GRADEpro software).

**Data extraction**

Using standardized data extraction forms, two reviewers will extract data from valid and selected papers for data analysis. The data extracted will include details specific to the review’s primary and secondary outcomes and fulfils the requirements for the both the outcomes and a potential meta-analysis. 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, reviewers will resolve disagreements by discussion, and a third reviewer will resolve unresolved disagreements.

**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. If possible, results from comparable groups of studies will be pooled into statistical meta-analysis using Review Manager software from the Cochrane Collaboration\(^\text{21}\).

Statistical heterogeneity between combined studies will be tested using the \(F\) method alongside the standard chi-square test. An estimate greater than or equal to 50% accompanied by a statistically significant \(\chi^2\) statistic will be interpreted as evidence of statistical heterogeneity\(^\text{22}\). If substantial levels of heterogeneity are found for the primary outcome measure, all data entered will be checked for accuracy, then a visual inspection of the data will take place and removal of outlying studies will be carried out to assess if heterogeneity persists. Subgroup analyses will be completed if sufficient data are available to examine between-study variability on, for example 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 (Design effect = \(1 + (m-1) \times \text{ICC}\))\(^\text{23}\). If the ICC cannot be obtained, we will assume it to be 0.1\(^\text{24}\).

For any particular outcome, if more than 50% of data were unaccounted for, we will not use these in any meta-analysis. 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; however, where possible, meta-analysis will be carried out on homogenous data.

**Dissemination of findings**

We plan to disseminate the findings in a peer reviewed journal, 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 April 2020.

**Discussion**

This review will systematically examine the available evidence of effectiveness on smoking cessation interventions in women from socially disadvantaged areas. By summarising recruitment implementation strategies and barriers. It is hoped that these findings will help direct future research and smoking cessation policy. This review will focus on RCTs and associated process evaluations. If the search returns fewer than five studies, the review criteria will expand to include quasi-experimental studies. There is no restriction to the country of origin or year of publication, however all language must be in English. The aim of this review RCT is to help guide future smoking cessation programmes for women from disadvantaged areas.

**Limitations**

There are some limitations to the outlined systematic review. 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 the review to aid future reviewers.

**Data availability**

**Underlying data**

No underlying data are associated with this article.

**Reporting guidelines**


**Grant information**

The project is funded by the Health Research Board Ireland under the Definitive Interventions and Feasibility Awards DIFA-2017-048.

The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.
References


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.

Marie Johnston
Health Psychology Group, Institute of Applied Health Sciences, University of Aberdeen, Aberdeen, UK

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. 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-SP³ 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)⁶ 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.⁵). 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
Psychologist. 2016; 18 (Supp): 574


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.