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Behavioural interventions for smoking cessation: an overview and network meta-analysis (Protocol)

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[Intervention Protocol]

Behavioural interventions for smoking cessation: an overview and network meta-analysis

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

The primary objectives are to summarise the evidence from Cochrane Reviews that assessed the effect of behavioural interventions designed to support smoking cessation attempts, and address the following two questions:

1. How do modes of delivery, person delivering the intervention, and the behavioural and motivational components of behavioural interventions for smoking cessation compare with each other in achieving abstinence at follow-up of six months or longer?

2. Do the effects of behavioural interventions vary by other characteristics, including population, setting, and length of intervention?

The secondary objective of this review is to summarise the availability and principal findings of economic evaluations of behavioural interventions for smoking cessation, in terms of comparative costs and cost-effectiveness, in the form of a brief economic commentary.

BACKGROUND

Description of the condition

Smoking is hazardous to health, shortening life by an average of 10 to 11 years in people who smoke their whole lives and killing more than seven million people each year (Doll 2004; Pirie 2013; WHO 2018). Tobacco kills up to half of its users, increasing mortality primarily through cardiovascular disease, lung cancer, and chronic obstructive pulmonary disease (WHO 2018). It it also causally associated with other cancer- and non-cancer-related health conditions, giving rise to premature morbidity and mortality (USDHHS 2014). Fortunately, smoking cessation reverses much of the damage. Stopping before the age of 35 prevents almost all early mortality, stopping by age 60 improves life expectancy by three years, and stopping after 60 still reduces mortality, cardiovascular disease, and cancer risk (Doll 2004; Mons 2015; Müezzinler 2015; Ordóñez-Mena 2016).

Worldwide, over one billion people are current tobacco smokers, with approximately 80% living in low- and middle-income countries (WHO 2018). In the UK, as in many other high-income countries, smoking is a major contributory factor to health inequalities, with the burden of smoking-related disease disproportionately impacting people of lower socioeconomic status and people belonging to certain social groups, including ethnic minorities and people living with mental health conditions (ASH 2016). Aside from the risks to the individual, smoking remains the prime preventable cause of morbidity and mortality, making it an important population health concern (GBD 2016). Smoking places an enormous economic burden on societies. The economic costs of smoking include healthcare expenditures for treatment of smoking-related diseases and those affected by second-hand smoke, loss of earnings and workplace productivity, disability-adjusted life-years (DALY) lost, and other indirect costs, including fire damage and environmental harm from growing tobacco (ERS 2013). In 2012, 5.7% of global health expenditure was due to smoking-attributable diseases. Combining the costs of health expenditures and productivity losses, the total economic cost of smoking totaled an estimated USD1436 billion, which is equivalent to 1.8% of the world's annual gross domestic product (GDP). Forty percent of this cost occurred in low- and middle-income countries (Goodchild 2018).

Among smokers who know it is hazardous to their health, most want to quit (WHO 2018). However, quitting is challenging, and most smokers make multiple attempts before successfully quitting (Chaiton 2016). There is a strong evidence base showing that both behavioural therapies and pharmacotherapies can help people quit, either on their own, or in combination with one another (Cahill 2013; Hartmann-Boyce 2014a; Lancaster 2017; Stead 2013; Stead 2016; Stead 2017).

Description of the intervention

Behavioural therapies for smoking cessation vary widely in their content, delivery, and availability. Typically, they include advice to quit smoking, information on how to quit smoking, or a combination of both, but may use different techniques and theoretical frameworks to achieve these aims. They can range from one-off brief advice from a healthcare professional (Stead 2013a) or a print leaflet (Hartmann-Boyce 2014), to more intensive programmes involving multiple counselling sessions (Lancaster 2017; Stead 2013; Stead 2017), with or without added components such as financial incentives and partner support (Cahill 2015; Faseru 2018). They may be delivered in conjunction with or independent from stop-smoking pharmacotherapy, and may be delivered to people motivated to quit or to people not interested in quitting. Some interventions may be tailored to the individual or a particular subgroup (pregnant women, parents, teenagers, people with pre-existing conditions), while other interventions may be more general or applicable to all.

How the intervention might work

Behavioural therapies for smoking cessation can work by prompting a quit attempt or by helping to maintain abstinence once a person has tried to quit, or both. Factors that seem to prompt quit attempts are typically related to motivation, such as concern over the long-term health effects or the financial cost of smoking. Factors associated with long-term success after a quit attempt mostly relate to the strength of the underlying addiction to smoking (Vangeli 2011). However, most attempts are made without the aid of behavioural support, and it is plausible that factors influencing motivation, resilience to overcome the challenges of quitting, or other psychological processes may mediate the impact of various components of behavioural support.

Why it is important to do this review

Globally, smoking is the leading cause of preventable death and disease. Accordingly, governments and healthcare systems invest in stop-smoking services, but these vary in their effectiveness (West 2013). Much of this variation is the result of differences in the behavioural support provided (Brose 2011; Dobbie 2015). It is important to pinpoint which types of behavioural support work best for smoking cessation and focus available funds on the most effective approaches. This requires data on comparative effectiveness. Network meta-analysis provides an opportunity to compare many different types and components of behavioural interventions with each other simultaneously, and to make use of additional evidence from common intervention comparisons (indirect evidence) to supplement evidence for comparisons for which there are few trials (direct evidence). However, network meta-analyses are limited to studies that are 'jointly randomisable'; by conducting a Cochrane Overview of reviews we can also summarise relevant interventions that fall outside the scope of a network meta-analysis (Pollock 2018).

Given the economic impact of smoking, and the limited resources with which to provide stop-smoking services, it is important to critically evaluate and summarise current evidence on the comparative costs and cost-effectiveness of behavioural interventions for smoking cessation.

OBJECTIVES

The primary objectives are to summarise the evidence from Cochrane Reviews that assessed the effect of behavioural interventions designed to support smoking cessation attempts, and address the following two questions:

1. How do modes of delivery, person delivering the intervention, and the behavioural and motivational components of behavioural interventions for smoking cessation compare with

each other in achieving abstinence at follow-up of six months or longer?

2. Do the effects of behavioural interventions vary by other characteristics, including population, setting, and length of intervention?

The secondary objective of this review is to summarise the availability and principal findings of economic evaluations of behavioural interventions for smoking cessation, in terms of comparative costs and cost-effectiveness, in the form of a brief economic commentary.

METHODS

Criteria for considering studies for this review

Types of studies

We will restrict this overview to Cochrane Reviews of randomised controlled trials of behavioural therapies for smoking cessation. We will restrict the network meta-analysis to randomised controlled trials already included in the included Cochrane Reviews. We will query lists of excluded studies to check if those studies that have been excluded on the basis of comparator (e.g. where a study has not been included in a review because it is a head-to-head comparison of two behavioural interventions) are eligible for inclusion.

Types of participants

We will include both reviews and studies in this overview. At the overview level, we will include all participants covered by the reviews included in this overview. These will normally be adult smokers. Following the methods used by Cahill 2013, we will not include reviews that focus on particular populations of smokers, e.g. adults with mental health problems (e.g. Tsoi 2013; van der Meer 2013). These reviews cover a range of interventions beyond the behavioural interventions considered by this overview, and the relevant reviews of specific behavioural interventions will already include studies in specific subgroups (e.g. the review of 'Individual counselling for smoking cessation' includes studies conducted in people with mental health problems (Lancaster 2017)).

To ensure comparability between studies and joint randomisability, inclusion criteria for studies for the network meta-analysis will be narrower than for the overview in general. For the network meta-analysis, we will only include studies in which participants are adult cigarette smokers (18 or older), who were randomised prior to quitting, and who were not selected on the basis of a pre-existing condition (e.g. pregnancy, heart disease).

Types of interventions

We will include reviews that test behavioural interventions for smoking cessation, delivered at the individual or group level (as opposed to public health interventions such as standardised packaging), and those defined by intervention type (e.g. 'Individual counselling for smoking cessation' (Lancaster 2017)), person delivering the intervention (e.g. 'Nursing interventions for smoking cessation' (Rice 2017)), and theoretical basis of intervention (e.g. 'Motivational interviewing for smoking cessation' (Lindson-Hawley 2015)). To meet the condition of joint randomisability, we will restrict interventions in the network meta-analysis to those that an individual might receive from or be referred to by a healthcare professional (e.g. not workplace interventions (Cahill 2014)), or to which an individual could plausibly self-refer.

We will not include reviews or trials that evaluate the effects of pharmacotherapies for smoking cessation, though we will include studies in which both intervention and control arms receive the same pharmacotherapy, and which meet all other inclusion criteria (e.g. studies testing behavioural interventions as adjuncts to pharmacotherapy, as per Stead 2017).

Types of comparators

We will include reviews in the overview regardless of comparators. To be included in the network meta-analysis, trials must compare a behavioural intervention for smoking cessation with another behavioural intervention for smoking cessation, or with a 'minimal' control (e.g. usual care, no treatment, or a waiting list control).

Types of outcome measures

Primary outcomes

In accordance with standard methods from the Cochrane Tobacco Addiction Group, the primary outcome for this overview and network meta-analysis is sustained smoking cessation, i.e. for six months or longer. We anticipate that the included reviews will not include studies that do not measure this outcome. The preferred measurement of cessation will be biochemically validated continuous or prolonged abstinence, measured at the longest reported time point, and including all participants randomised in their original groups.

Studies of behavioural interventions for smoking cessation often do not measure adverse events. Where included reviews have reported on adverse events, we will summarise findings narratively and tabulate if appropriate.

Search methods for identification of studies

To identify eligible reviews, we will search the Cochrane Database of Systematic Reviews (CDSR) in the*Cochrane Library* for any reviews with 'smoking' or 'tobacco' in the title, abstract, or keyword fields. Since Cochrane Reviews strive for methodological rigour and are regularly updated, we will not include non-Cochrane reviews in this overview. Results will be reported in a PRISMA diagram.

We will identify studies to include in the network meta-analysis by screening the reviews that meet our inclusion criteria.

We will run a separate search to identify relevant economic evidence. This will include:

1. Searching the NHS Economic Evaluation Database (EED) using the following terms: tobacco OR smok* OR cigaret* OR nicotine
2. Searching MEDLINE, Embase, and CINAHL from 1 December 2015, to capture any relevant evaluations published since NHS EED ceased being updated, using specialist search terms for economic evidence derived from SIGN guidance ((SIGN 2018); see Appendix 1 for MEDLINE strategy).

Data collection and analysis

Selection of reviews

At least two authors will independently assess all potentially eligible reviews for inclusion in the overview. Any uncertainties will be raised with the broader project team. The whole project team will approve the final list of included reviews. We will list key excluded reviews in a table of excluded reviews, along with reasons for exclusion.

Selection of studies

At least two authors will independently screen the included and excluded studies in each included review for inclusion in the network meta-analysis. Any discrepancies will be resolved through discussion or by referring to a third author. We will not include ongoing studies identified from existing reviews in the network meta-analysis, as these will not have been formally screened for inclusion by the original authors. We will create tables that list studies included in the original reviews but excluded from the network meta-analysis along with reasons for exclusion from the network meta-analysis.

Data extraction and management

Two authors will independently perform data extraction; they will resolve disagreements by discussion or by referring to a third author. They will extract data in two stages: 1) review level, and 2) study level. Both are described in more detail below. They will use Microsoft Excel to collate the data.

Review level

Review level data extraction will follow the process used by Cahill 2013. Two authors will independently extract data and input them onto a pre-specified and piloted data extraction form, including details of the number of included studies, participants, interventions, comparisons, outcomes, and certainty in the evidence (as per GRADE summary of findings tables, where available).

Study level

We will only extract data from studies from the included reviews that are eligible for inclusion in the network meta-analysis. For each of these reviews, we will extract the following characteristics from eligible studies:

- Population: number randomised to each group; mean age across study population; percentage female across study population; presence of pre-existing conditions and pregnancy; socioeconomic status (with a focus on extracting years of education where multiple measures are reported); motivation to quit (motivated to quit, seeking help to quit, or both; not motivated to quit; general population not selected on motivation); mean cigarettes per day at baseline
- Intervention and comparator group content: nature of intervention focus (categorised as: intervention focused on reasons why a person might quit smoking; intervention focused on methods to quit smoking; intervention has roughly equal focus on both elements); nature of support provided (categorised as: addressing motivation; maximising self-regulation; promoting adjuvant activities, as per Michie 2011; categories are not mutually exclusive); delivery mode; setting; intervention provider; duration of intervention; session length; frequency of sessions; total number of sessions; tailoring; provision of financial incentives; type of pharmacotherapy provided
- Risk of bias (see Assessment of risk of bias in included studies)
- Smoking cessation: number who quit in each group at longest follow-up using the strictest measure available; definition of cessation; number available at follow-up

We will extract data first from information provided in the original reviews in which the studies were included; all relevant data will be directly copied from existing reviews into the current review (this stage will be done by one author, as these data have already been independently extracted in duplicate). Two authors will then independently extract any information not supplied in the original review from the full-text study report. We anticipate that some reviews will overlap, i.e. the same study may be included in more than one review. We will record where this is the case and the data from each study will only be used once in the network meta-analysis. Where there are different assessments or data extracted for the same study, two authors will extract data from the original publication in duplicate.

Assessment of methodological quality of included reviews

Two authors will independently assess the quality of each review using the AMSTAR2 measurement tool; they will resolve disagreements by discussion, or refer to a third author (Shea 2017). We will use the domains used in Cahill 2013. Where overview authors are authors on included reviews, quality assessment for the review in question will be done by two overview authors not involved in the original review.

We will not exclude reviews on the basis of AMSTAR rankings.

Assessment of risk of bias in included studies

Where risk of bias has already been assessed for the studies in reviewsincluded in the network meta-analysis, we will check that this was performed consistently in accordance with Cochrane Tobacco Addiction Group guidance for assessing each domain. Where this has been done, we will use these 'Risk of bias' assessments and not re-evaluate. Where it appears risk of bias guidance has not been consistently applied, or where specific domains have not been evaluated for specific reviews, two authors will independently assess risk of bias as part of the data extraction process, with discrepancies resolved by discussion or referral to a third author where necessary. For studies that require further assessment, we will use the Cochrane 'Risk of bias' tool for the following domains: random sequence generation, allocation concealment, blinding of outcome measure, attrition, and other bias. Random sequence generation, allocation concealment, and other bias will be assessed based on standard methods set out in the Cochrane Handbook (Higgins 2011). Following standard Cochrane Tobacco Addiction Group methods for reviews of behavioural interventions where blinding is not possible, we will not assess performance bias, and we will assess detection bias in the following way:

- We will judge studies to be at low risk of bias if smoking status was measured objectively (i.e. biochemical validation) or if smoking status was measured by self-report, but the intervention and control arms received similar amounts of face-to-face contact (or none).
- We will judge studies to be at high risk of detection bias if smoking status was measured by self-report only, and participants in the intervention arm had more personal contact than in the control arm, as results may be prone to differential misreport.

Attrition is often substantial in smoking cessation trials. To assess attrition bias, we will follow standard Cochrane Tobacco Addiction Group methods, namely:

- We will judge studies to be at low risk of bias when the following conditions were all met: numbers lost to follow-up were clearly reported for each group (not just overall, unless the overall percentage lost is less than 10%); the overall number of participants lost was not greater than 50%; and the difference in percentage followed up between groups was not greater than 20%. We will also consider results at low risk of attrition bias if the authors reported sensitivity analyses that indicated the overall direction of effect was not sensitive to different imputation methods for loss to follow-up.
- We will judge studies to be at high risk of bias when the above thresholds were not met, or in the case of cluster-randomised trials, where entire clusters were not followed-up.
- We will judge studies at unclear risk when the number lost to follow-up in each group was not clear, and authors did not report sensitivity analyses based on loss to follow-up.

We will judge studies at low risk of bias overall if we judge them to be low risk for all of the above domains. We will consider them at high risk of bias overall if they are judged to be at high risk of bias in one or more of the above domains. We will consider all other studies at unclear risk of bias overall. We will present the results of the risk of bias assessment in a risk of bias summary figure.

Measures of treatment effect

Included reviews will, for the most part, report smoking cessation at the longest follow-up using risk ratios, calculated as: (number of quitters in intervention group/number randomised to intervention group)/(number of quitters in control group/number randomised to control group). In the network meta-analysis, we will report pooled results as odds ratios with 95% confidence intervals or credibility intervals, as in Cahill 2013. However, we will also give consideration to the absolute effect sizes implied by these pooled estimates.

Unit of analysis issues

For cluster-randomised trials, we will use the effect size reported in the systematic review (or if not available, in the original trial paper), and will check that allowance for clustering was made in performing the analysis. In the majority of studies, we anticipate that the trial paper should have made allowance for clustering, and otherwise this may have been done in the review before the trial's results were entered into a meta-analysis.

Dealing with missing data

Any participants lost to follow-up will be assumed to be smoking, excluding deaths, as is standard in the field (West 2005), and is standard across reviews produced by the Cochrane Tobacco Addiction Group. For studies in the network meta-analysis, we will note in the 'Risk of bias' tables the proportion of participants for whom the outcome was imputed in this way, and whether there was either high or differential loss to follow-up. The assumption that 'missing = smoking' will give conservative absolute quit rates, and will make little difference to the odds ratio unless dropout rates differ substantially between groups.

Assessment of heterogeneity

We will consider heterogeneity between interventions first by examining how the contributing reviews reported heterogeneity. If review authors considered interventions too heterogeneous to include in a pairwise meta-analysis, we will consider whether to include the studies in our network meta-analysis. For studies that are suitable for inclusion, we will report measures of heterogeneity based on the component network meta-analysis described in Data synthesis.

Assessment of reporting biases

We will extract information from the included systematic reviews regarding any investigation or presence of reporting bias.

Data synthesis

We will synthesise data from the included reviews on both smoking cessation and adverse events (if reported), producing a table with key characteristics of each included review (title, publication year, number of included studies, number of included participants, key findings, and certainty in the evidence, where assessed) as per standard guidance for Cochrane Overviews (Pollock 2018). We will not attempt to standardise numeric results in this table, as data on effectiveness and comparative effectiveness will be derived from the network meta-analysis, and we anticipate any information on adverse events will be heterogeneously measured and reported, precluding comparisons between interventions.

We will use component network meta-analysis to evaluate the comparative effectiveness of the included interventions. Component network meta-analysis is a relatively new method that extends conventional network meta-analysis methods to dismantle and compare different intervention components (Pompoli 2018; Welton 2009). Unless stated otherwise, we will follow the methods used by Pompoli 2018. We aim to compare the following components in regards to smoking cessation at six months or longer: behavioural and motivational components of intervention; delivery mode (e.g. telephone, group counselling, individual counselling); intervention provider; setting; duration of intervention; length of sessions; frequency of sessions; total number of sessions; tailoring; and provision of financial incentives. We will consider participant characteristics (age; gender; socioeconomic status; percentage of study population with pre-existing conditions; percentage of study population pregnant at enrolment; mean cigarettes per day at baseline; whether population was selected based on motivation to quit), length of follow-up, and baseline quit rates in control arms as covariates. We will use this analysis to draw conclusions about which components, or combinations of components, are most strongly associated with smoking cessation.

If it is not possible to perform component network meta-analysis (e.g. if interventions cannot satisfactorily be coded into their constituent components, or if the structure of the resulting network leads to computational difficulties in fitting the statistical model), we will revert to a standard network meta-analysis, in which each of the component categories are analysed in separate networks. We will perform data synthesis using R and WinBUGS (R 2017; WinBUGS 2015).

We will not conduct separate subgroup analyses, but where individual reviews present these data, we will consider it when reporting their findings.

Sensitivity analysis

We plan to test if findings from our model are sensitive to the exclusion of studies at high overall risk of bias (based on risk of bias assessments for individual studies, not on overall quality or certainty judgements for the reviews in which they are contained), and to the exclusion of studies in which cessation was not biochemically validated.

Evaluating confidence in the evidence

When included reviews used a GRADE approach to evaluate confidence in the evidence, we will report these findings in the overview. We anticipate that the vast majority of included reviews will include GRADE ratings, but if these are not available, we will conduct our own GRADE assessments using the information included in the original review and following standard Cochrane methodology. For the network meta-analysis, we will evaluate confidence in the evidence using the CINeMA tool, which evaluates certainty based on study limitations, imprecision, heterogeneity, incoherence, indirectness, and publication bias for each comparison within the network (cinema.ispm.ch/).

Incorporating economic evidence

We will develop a brief economic commentary based on current methods guidelines, to summarise the availability and principal findings of trial-based and model-based full economic evaluations that compared the behavioural interventions of interest for smoking cessation in this overview (Shemilt 2018). The commentary will focus on the extent to which principal findings of eligible economic evaluations indicate that a behavioural intervention for smoking cessation might be judged favourably (or unfavourably) from an economic perspective when compared with other behavioural interventions for smoking cessation (which could include comparisons between interventions of a similar intensity, or between interventions of different intensities), when implemented in different settings.

Following Cochrane guidance, a single author will screen and select eligible studies and classify them by type and analytic framework (Higgins 2011). We will extract data on the analytic perspective, time horizon, main cost items (classified into health sector costs, other sector costs, patient and family costs, and productivity

impacts), and setting, as well as on the principal findings (verbatim text on conclusions drawn by the author of each evaluation, and text summarising uncertainty surrounding authors' principal conclusions). We will use these to inform the development of the brief economic commentary, which we will include in the discussion section of the review. We will not critically appraise any of the identified economic evaluations, as we will not attempt to draw any firm or general conclusions on the relative costs or efficiency of the included interventions.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. MEDLINE search strategy for identifying economic evidence

1. (cost? adj2 (illness or disease or sickness)).tw.
2. (burden? adj2 (illness or disease? or condition? or economic*)).tw.
3. ("quality-adjusted life years" or "quality adjusted life years" or QALY?).tw.
4. Quality-adjusted life years/
5. "cost of illness"/
6. Health expenditures/
7. (out-of-pocket adj2 (payment? or expenditure? or cost? or spending or expense?)).tw.
8. (expenditure? adj3 (health or direct or indirect)).tw.
9. ((adjusted or quality-adjusted) adj2 year?).tw.
10. or/1-9
11 tobacco OR smok* OR cigaret* OR nicotine
12 10 AND 11
Will be restricted to entries added since 1 December 2015

CONTRIBUTIONS OF AUTHORS

JHB drafted the protocol with input from all authors. All authors approved the final version of the protocol.

DECLARATIONS OF INTEREST

JHB: is an author of some of the Cochrane Reviews that are likely to be included in the overview.

TRF: is an author of some of the Cochrane Reviews that are likely to be included in the overview.

NL: was a co-applicant and collaborator on a research grant awarded by the NIHR HTA programme (09/110/01), investigating the use of pre-quit nicotine patches for smoking cessation. The excess treatment provided for this research were nicotine patches, supplied free of charge by GlaxoSmithKline (GSK). However, GSK had no further involvement in the research, and this had no impact on the reported work. This trial was completed in 2016. NL is an author of some of the systematic reviews that are likely to be included in the overview.

JLB: is an author of some of the systematic reviews that are likely to be included in the overview.

JMOM: is an author of some of the systematic reviews that are likely to be included in the overview.

PA: led a trial in which Glaxo Smith Kline donated free nicotine replacement therapy to the NHS to support the trial, but this was of no direct benefit to him or his employer. PA is an author of some of the systematic reviews that are likely to be included in the overview.

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