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Outpatient interventions for smoking cessation and reduction for adults with a mental disorder (Protocol)

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[Intervention Protocol]

Outpatient interventions for smoking cessation and reduction for adults with a mental disorder

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ABSTRACT

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

The primary objective of this review is to determine the effectiveness of smoking reduction and cessation interventions (alone, or in combination with other interventions), delivered primarily in an outpatient or community-based setting among individuals with mental disorders, on rates of abstinence at the longest follow-up (minimum six months), mental health symptoms and adverse events.

Secondary objectives are to examine the impact of such interventions on rates of abstinence at the end of the intervention, change in daily cigarette consumption, and quality-of-life or other function scores. We will explore (via subgroup analyses) potential differential effects on the basis of intervention type, control group type, recruitment setting (inpatient versus outpatient), mental disorder type, and motivation to quit at study intake.

We may come across studies testing interventions which aim to increase the uptake of smoking interventions in people with a mental disorder. This may comprise interventions that either are incorporated into the system of delivering care, aimed at health professionals (e.g. within a community mental health facility), as well as interventions aimed directly at people with a mental disorder to increase uptake. In this case we aim to examine whether these interventions increase the uptake of the smoking cessation treatment among people with a mental disorder, as well as whether they ultimately result in increased quit rates.

BACKGROUND

Tobacco use remains a leading global cause of preventable illness and premature death (GBD Risk Factors Collaborators 2016). Since 1980, smoking rates amongst the general populations of developed nations have steadily declined, and now range from 13% to 25% (GBD Tobacco Collaborators 2015; Ng 2014). However, rates of smoking among people with a mental disorder have remained unchanged over this period and are disproportionately

high (Lancet 2013).

Description of the condition

Mental disorders comprise a broad category of disorders, including: the schizophrenia spectrum and other psychotic disorders, mood disorders (including major depression and bipolar disorder), anxiety disorders (including phobias, panic disorder, and generalised anxiety disorder), obsessive-compulsive and related disorders, eating disorders, and personality disorders (American Psychiatric Association 2013). Mental disorders are globally prevalent and impart significant health burden across individuals' lifespan (Whiteford 2015). The World Health Organization (WHO) World Mental Health (WMH) survey estimated that the lifetime prevalence of mental disorders, as classified by the Diagnostic and Statistical Manual-IV (DSM-IV), ranged from 18.1% to 36.1% (Kessler 2007). Anxiety and depression are the most commonly experienced mental disorders, with estimated lifetime prevalence averaging 16% and 12% respectively (Kessler 2009).

For people with mental disorders, rates of smoking have remained unchanged for the past 20 years (Lancet 2013), and population-based studies have estimated that smoking prevalence among people with a mental disorder is at least double that of the general population (Lasser 2000; Lawrence 2009), with smoking rates increasing as the number of lifetime mental disorders increases (Lasser 2000). Prevalence of smoking among persons with a mental disorder residing in the community has been estimated to range from 33% to 36.2% in samples from New Zealand (Tobias 2008) and Australia (Lawrence 2009), and from 44.3% to 47.0% in the USA (Lasser 2000) and the UK (Farrell 2001). Prevalence of smoking has been shown to vary depending on diagnosis and severity of illness, with rates found to range between 36% and 39% for people with anxiety and personality disorders (Lineberry 2009), 36% and 49% for people with depressive and mood disorders (Hughes 1986; Lasser 2000; Lineberry 2009), and between 60% and 88% for people with psychotic disorders, including schizophrenia and schizoaffective disorders (De Leon 2005; Dickerson 2017). It has been estimated that people with a mental disorder now consume up to 30% of all tobacco in high-income countries such as the USA (Gfroerer 2013), the UK (Royal College of Physicians 2013), and New Zealand (Tobias 2008). Smokers with a mental disorder are also more likely to be nicotine dependent, inhale cigarettes more deeply and absorb higher levels of nicotine per cigarette than smokers without mental disorders (Grant 2004; Tidey 2005; Williams 2011). Consequently, smoking-related morbidity and mortality is significantly higher among persons with a mental disorder compared to the general population, and life expectancy is reduced by up to 25 years, primarily due to smoking-related causes such as heart disease, cerebrovascular disease, chronic respiratory disease and cancer (Colton 2006; Lawrence 2013). Smoking among people with a mental disorder is also associated with substantial social and economic burden, including reduced quality of life, exacerbation of poverty and substantial economic costs to society (Siahpush 2007; Access Economics 2008). Therefore, interventions that reduce smoking rates among people with a mental disorder are now recognised as both a clinical and public health priority (Royal College of Physicians 2013).

Description of the intervention

There are a number of smoking cessation interventions that have good evidence of efficacy among smokers in the general population. Pharmacological interventions are often the recommended first-line treatment for smoking cessation in the general public (Fiore 2008). Nicotine replacement therapy (NRT) has been shown to increase the likelihood of abstinence, with similar efficacy identified for the various formulations available, including nicotine patch, gum, lozenges, inhaler and nasal spray (Hartmann-Boyce 2018). In addition, nicotine receptor partial agonists, including varenicline and cytisine, have been shown to more than double the likelihood of cessation (Cahill 2016), and there is also good evidence that the antidepressant bupropion increases long-term smoking cessation (Hughes 2014).

Psychological and behavioural interventions for smoking cessation include counselling therapies such as cognitive behavioural therapy (CBT) or motivational interviewing (MI), and may be delivered individually or in groups, online, via telephone (including 'Quitlines'), text or other mobile technologies (such as mobile telephone applications, i.e. "apps"). MI and CBT have produced modest yet significant increases in quit rates (Lindson-Hawley 2015; Stead, 2017).

Other interventions, such as contingency management (Cahill 2015), use of vapourised nicotine products (Hartmann-Boyce, 2016), screening and brief intervention (Khanna 2016), provision of written or online self-help materials or resources (Hartmann-Boyce 2014; Taylor 2017), and interventions to increase adherence to smoking cessation medications (Hollands 2015), may also increase quit rates; however the number of studies currently evaluating these interventions is small.

Many of these interventions are available to the general population (and therefore also people with a mental disorder) in outpatient or community settings to varying degrees globally, including via pharmacies, community health centres, primary care facilities, outpatient mental health and substance use treatment services, or via telephone, mobile phone or the internet. In some countries, including the USA, the UK, Canada, Australia and New Zealand, national Quitlines and some cessation services (including treatment for tobacco dependence in health clinics and primary care facilities) are fully or partially cost-covered (World Health Organization 2016).

How the intervention might work

There is no compelling biological evidence that existing smoking cessation interventions are less efficacious among smokers with a mental disorder than among those without. For example, bupropion has demonstrated similar efficacy among individuals with depression (Van der Meer 2013), and those with schizophrenia (Tsoi 2013), compared to groups without these disorders (Hughes 2014). However, the lack of decline in smoking rates over time among individuals with a mental disorder indicates that smoking cessation efforts at the general population level are not effectively addressing tobacco-related disparities among this group (Cook 2014). Thus, it is likely that interventions targeting smoking among people with a mental disorder need to consider a number of additional specific factors that may be undermining successful smoking cessation in this group.

Mental illness itself may play a role in lower cessation success. There is some evidence of a common genetic link between smoking and mental disorders (Fu 2007). For some people, smoking may be used as an attempt to manage mental health symptoms such as depression and anxiety, and nicotine withdrawal symptoms (such as agitation) may be mistakenly attributed to the mental disorder rather than nicotine withdrawal. These beliefs may facilitate continued smoking in order to alleviate symptoms (Minichino 2013). Smokers with a mental disorder have also been found to have lower confidence (or self-efficacy) in their ability to refrain from smoking when faced with difficult situations (such as when around other smokers or when feeling stressed) than smokers without mental disorders, which may impact both the likelihood of making an attempt to quit, and of that attempt being successful (Clyde 2015). There is also growing evidence of a bi-directional relationship between mental health symptomology and smoking cessation outcomes. A secondary analysis of the 2009 to 2011 National Survey of Drug Use and Health found that individuals with a mental disorder who received mental health treatment were more likely to have quit smoking than those who did not receive treatment (Cook 2014). In addition, a secondary analysis of randomised controlled trials for smoking reduction found that mental health scores at follow-up were improved among smokers who quit, but not among continuing smokers (Taylor 2015). These findings indicate that more effective treatment of mental disorders may be an important component of smoking cessation interventions among this population (Prochaska 2017), and that indicators of mental health severity (such as symptom scores and hospital readmissions, etc.) are likely to be important outcome measures in such trials.

There are also a number of potential social contributors to the elevated smoking rate among people with a mental disorder, including poverty and financial stress, lower levels of education, poorer access to social support networks and more pervasive exposure to smoking at home, among peer groups and in the workplace (Hiscock 2012). Thus, engaging support persons such as friends or partners via social support smoking interventions (such as establishing a 'smoke-free' home, assistance with treatment adherence and opportunities for sharing problem solving techniques), may aid in increasing smoking cessation and reduction among people with a mental disorder (Lawn 2016).

Health system barriers to smoking cessation treatment are substantial for people with a mental disorder and may also play a role in the lower rates of cessation success among this group (Prochaska 2017). Smokers with a mental disorder have reduced access to smoking cessation resources (Prochaska 2017), and are less likely to receive support for nicotine dependence compared to people without mental disorders when in contact with healthcare services. This is evident in both outpatient (Montoya 2005), and inpatient mental healthcare settings (Wye 2010; Sohal 2016). Furthermore, a long-standing culture of tobacco use exists within mental health treatment services, where smoking has long been accepted and even condoned (Lawn 2013). Despite evidence to the contrary (Stockings 2013), it is common for clinical staff to believe that people with a mental disorder are not interested in or are unable to quit smoking, which may impact provision of treatment (Lawn 2013). Interventions that aim to improve access to, and increase the uptake of, evidence-based smoking cessation treatments (such as health provider training, e.g. Prochaska 2008) may also prove beneficial among smokers with a mental disorder. Previous studies have indicated that most smokers with a mental disorder will utilise pharmacological and behavioural smoking cessation supports, including individual telephone counselling, NRT and national Quitline support, when they are offered proactively (Metse 2016).

Why it is important to do this review

Given that smokers with a mental disorder consume greater numbers of cigarettes per day, inhale more deeply, absorb greater amounts of nicotine per cigarette, are more nicotine dependent and are substantially less likely to succeed in quitting than smokers without such disorders (De Leon 2005; Diaz 2006; Lineberry 2009), it is likely that targeted and intensive approaches are required.

There has been a growth in empirical studies testing a range of behavioural and pharmacological smoking cessation interventions for people with mental disorders (Metse 2017). However, despite the clear public health need for up-to-date evidence (Royal College of Physicians 2013), even the most recent, comprehensive reviews of smoking cessation interventions for people with mental disorders are now more than eight years old (El-Guebaly 2002; Banham 2010). Previous reviews have also often been limited to populations with specific types of mental disorders, primarily schizophrenia and psychosis (Tsoi 2013), substance use disorders (Thurgood 2016), and depression (Van der Meer 2013); or to specific types of interventions, namely pharmacotherapies such as varenicline and bupropion (Roberts 2016), or brief advice (Khanna 2016). Others have also restricted inclusion criteria to studies where participants were required to express a desire to quit at study intake

(Roberts 2016). Given the known high rates of smoking across a range of mental disorders, including depression, anxiety, bipolar disorders, and personality disorders, in addition to schizophrenia and psychosis (Greenhalgh 2016), it is crucial to evaluate smoking cessation interventions for a broader range of mental disorders, including samples where diagnoses are heterogeneous (Prochaska 2013; Stockings 2014). Examining the efficacy of smoking cessation interventions among samples with a range of mental disorders is particularly important as this is most likely to reflect the way in which care is delivered in health service settings. It is also important to consider a broader range of behavioural and pharmacological interventions, including those that utilise multi-modal approaches, given that individuals with a mental disorder have not responded to interventions with established efficacy in general population samples (Cook 2014).

However, this review will be limited to outpatient interventions only, excluding interventions aimed at psychiatric inpatients and solely delivered within the inpatient setting. Although research examining both settings is important, we propose that considerations for smoking cessation interventions delivered in the inpatient psychiatric setting - where facilities are often 'locked', smokers are typically required to abstain from smoking, and smoking cessation treatment may be provided as part of routine care - are substantially different to those delivered in outpatient settings, and should be covered in a separate review. Smoking cessation interventions in outpatient settings should consider that people are returning to normal daily living and may be exposed to environmental cues to smoke at home, work, or in social settings. It may also be a period of substantial disruption as many people discharged from an inpatient psychiatric setting require housing and intensive social support. The need for smoking cessation interventions may also change as psychiatric symptoms stabilise, and could differ between persons receiving or not receiving outpatient mental health treatment (Cook 2014).

In light of the increased public health interest (Lancet 2013), equivocal findings of existing studies, and growing research output on this topic (Metse 2017), the aim of this review is to provide a comprehensive examination of outpatient interventions for smoking cessation and reduction in individuals with a mental disorder, with no restrictions placed on type of mental disorder, intervention type, or desire to quit at study intake.

OBJECTIVES

The primary objective of this review is to determine the effectiveness of smoking reduction and cessation interventions (alone, or in combination with other interventions), delivered primarily in an outpatient or community-based setting among individuals with mental disorders, on rates of abstinence at the longest follow-up (minimum six months), mental health symptoms and adverse events.

Secondary objectives are to examine the impact of such interventions on rates of abstinence at the end of the intervention, change in daily cigarette consumption, and quality-of-life or other function scores. We will explore (via subgroup analyses) potential differential effects on the basis of intervention type, control group type, recruitment setting (inpatient versus outpatient), mental disorder type, and motivation to quit at study intake.

We may come across studies testing interventions which aim to increase the uptake of smoking interventions in people with a mental disorder. This may comprise interventions that either are incorporated into the system of delivering care, aimed at health professionals (e.g. within a community mental health facility), as well as interventions aimed directly at people with a mental disorder to increase uptake. In this case we aim to examine whether these interventions increase the uptake of the smoking cessation treatment among people with a mental disorder, as well as whether they ultimately result in increased quit rates.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) and cluster-randomised controlled trials (cluster-RCTs).

Types of participants

Included participants will be adult smokers (aged 18 years or above), with any current diagnosed mental disorder. We aim to investigate any potential heterogeneity between diagnoses through subgroup analyses where appropriate (as described below in Subgroup analysis and investigation of heterogeneity). A 'current' disorder will be defined as either a diagnosis made within the past 12 months (determined via medical record or participant self-report), or any indication that the participant is currently engaged in any therapy for the treatment of a mental disorder (e.g. use of antipsychotic medication). We will exclude studies that only recruit people with a substance use disorder, as they are covered by another review (Apollonio 2016). However, we will not exclude studies where specific diagnoses are varied across the sample, and so a subset may have substance abuse disorders.

We will place no limit on the recruitment setting. Participants are not required to express an intention to quit smoking at study intake. The whole of the sample must comprise participants with a mental disorder. Studies that present results of a subgroup of participants from a larger trial found to have current or past mental disorders will be excluded.

Types of interventions

We will include any intervention that was assessed as an aid to smoking cessation or reduction, and may include any of the following (alone or in any combination):

- pharmacotherapy (including, but not limited to, nicotine replacement therapy, nicotine antagonists and partial receptor agonists, i.e. varenicline, bupropion, cytisine);
- psychosocial and behavioural supportive therapies (including, but not limited to, face-to-face and group-based counselling, telephone support, mobile/text support);
- screening and brief intervention;
- information-based therapies (e.g. educational pamphlets, quit advice);
- other interventions (e.g. contingency management, e-cigarettes, physical activity or healthy lifestyle interventions, social support interventions).

Participants may be recruited from any setting, however the majority of the intervention component must be delivered in an outpatient or community setting, including but not limited to: community mental health facilities, general health facilities (e.g. community health centres, general practice (GP) clinics), or the home (e.g. online, via phone or mail). Interventions delivered exclusively during an inpatient psychiatric admission will be excluded for reasons outlined above. Interventions can be facilitated by any person (e.g. research officer, psychologist, community health practitioner) or via unmoderated online/phone-based methods.

We will include interventions which aim to increase the uptake of smoking cessation interventions in smokers with a mental disorder. Such interventions may comprise either those targeted towards health professionals, in order to increase care delivery, as well as those directly aimed at increasing uptake of smoking cessation interventions among individuals with a mental disorder. We will additionally include any intervention intended for another purpose (e.g. antipsychotics for treating schizophrenia, or anxiolytics for treating anxiety) if smoking cessation or reduction outcomes are reported. Such studies will be reported separately and described narratively only.

These interventions will be compared to placebo, no treatment, health information, brief advice, usual smoking cessation/reduction care or other smoking cessation/reduction interventions. We will also include trials comparing different regimens of one intervention, comparing multi-modal interventions to single types, and trials including combinations of these comparisons. We plan to use subgroup and sensitivity analyses, where appropriate, to investigate whether effect size is dependent on the control used (see: Subgroup analysis and investigation of heterogeneity and Sensitivity analysis).

We will not include trials which consider whole-of-setting policies (such as smoking bans in psychiatric settings) as an intervention for smoking cessation.

Types of outcome measures

Primary outcomes

1. Rates of abstinence from smoking, measured at the longest follow-up assessment (at least six months post-baseline as a requirement for inclusion in the review). We will use sustained cessation rates in preference to point prevalence, and biochemically validated abstinence in preference to self-report, where available, or where data can be provided by study authors. This will be considered on an intention-to-treat (ITT) basis, with participants lost to follow-up treated as continuing smokers, or as failing to achieve smoking reduction.
2. Mental health symptomatology (e.g., scores on the Kessler Psychological Distress Scale (K10)).
3. Adverse events - both adverse events and serious adverse events (number of people experiencing adverse events).

Secondary outcomes

Given the known lower quit rates and poorer physical health among smokers with a mental disorder relative to the general population, and that short-term abstinence or smoking reduction may indicate a meaningful change in smoking behaviour (Evins 2015), we will additionally examine the following outcomes (for studies with at least a six-month post-baseline assessment as a requirement for inclusion in the review).

1. Smoking abstinence at the end of the intervention (where the end of intervention assessment is not the longest follow-up assessment).
2. Change in number of cigarettes smoked per day (CPD) at six months post-baseline.
3. Quality-of-life or other function scores.
4. Number of participants beginning treatment (only for interventions which aim to increase treatment uptake).
5. Hospitalisations (e.g., incidence of hospital re-admissions for inpatient psychiatric treatment).

Search methods for identification of studies

Electronic searches

We will search the following databases for reports of trials of smoking cessation and reduction interventions among smokers with a mental disorder:

- The Cochrane Tobacco Addiction Review Group Specialised Register;
- Cochrane Central Register of Controlled Trials (CENTRAL);
- MEDLINE (OVID SP 1946 to present) & MEDLINE in-process & other non-indexed citations (OVID SP);

- Embase (OVID SP, 1947 to present); and
- PsycINFO (OVID SP,1806 to present).

The search terms will include MeSH terms and free text words relating to randomised controlled trials (e.g. RANDOMISED-CONTROLLED-TRIAL.pt), mental disorder status (e.g. "Mental Disorders"), and smoking cessation (e.g. "Tobacco-Use-Cessation"/). The search strategy for MEDLINE (Ovid SP) is shown in Appendix 1. All databases will be searched from inception to present.

We will include studies reported as full text and as abstract only, and unpublished data where these are made available to us. There will be no language or date restrictions. We will check the reference lists of published papers, and will consult with experts in the field to identify any relevant forthcoming or unpublished research (or both). We will contact the authors of ongoing studies where necessary.

Searching other resources

We will search international online clinical trials registers for ongoing and recently completed trials, including the WHO Portal; UK Clinical Trials Gateway; US Clinical Trials Register; and the Australian and New Zealand Clinical Trials Registry (ANZCTR) We will search annual meeting abstracts from the Society for Research on Nicotine and Tobacco (SRNT), to identify early reports of ongoing research in the field. We will list trials which may be candidates for inclusion (i.e. RCTs of smoking cessation interventions for people with a mental disorder, with a minimum follow-up of six months), and for which results are not yet available, in the 'Characteristics of ongoing studies' tables.

Data collection and analysis

Selection of studies

Two review authors will independently screen the titles and abstracts of search results for relevance. Two review authors will then acquire and independently screen the full texts of articles that are found to potentially be eligible for inclusion. Disagreements will be resolved by discussion or by referral to a third review author (LW).

We will complete a PRISMA flow diagram to illustrate the study selection process, and we will provide details of eligible and potentially eligible ongoing studies in 'Characteristics of included studies' and 'Characteristics of ongoing studies' tables. A list of studies that were excluded after full-text screening, and for which a reader might plausibly expect to see included in the review, will be provided in the 'Characteristics of excluded studies' table, with reasons for exclusion.

Data extraction and management

Two review authors will independently extract data and check them with each other for each study. Disagreements or errors in data extraction will be resolved by discussion, or by referral to a third review author (LW). Where available, we will include the following information in the 'Characteristics of included studies' table.

- Study details: author names, date, country.
- Methods: study design, year(s) of recruitment, recruitment setting(s), inclusion and exclusion criteria, number of study centres/locations (if multiple).
- Participants: inclusion and exclusion criteria, number (N) screened for inclusion, N consented, N analysed, N intervention/control, mental diagnosis type, mental diagnosis definition, current smoker definition, demographics (gender, mean or median age, age range, ethnicity), mean daily cigarette consumption, Fagerström Test for Nicotine Dependence (FTND) score (or other measure of nicotine dependence, e.g. Heaviness of Smoking Index; HSI), motivation to quit at study intake (as judged by eligibility criteria, author report, scores on motivation measures, and type of participant enrolment).
- Intervention(s): description of the intervention (treatment type, dosage, number of sessions (where applicable), description of comparator(s), duration, facilitator, setting, proportion of participants who elected to receive the intervention (if applicable).
- Outcomes: primary and secondary outcomes specified and collected, definitions of abstinence and smoking reduction, type of biochemical validation (if any), proportion of participants who completed follow-up assessments, timing of follow-up assessments, ITT and per-protocol analyses conducted.
- Risk of bias: in the domains specified below.
- Notes: trial funding and declared or potential conflicts of interest of trial authors.

Assessment of risk of bias in included studies

Two review authors will independently assess each included study for risks of selection bias (methods of randomised sequence generation, and allocation concealment), performance and detection bias (the presence or absence of blinding of participants, research staff and outcome assessors), attrition bias (levels and reporting of loss to follow-up), and any other potential sources of bias, as recommended in Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

Each trial will be deemed as having low, unclear, or high risk of bias for each domain, with a justification for this decision together with a direct quote from the trial in the 'Risk of bias' tables, where applicable. If the information on which the decision is based is unpublished or learnt through correspondence with an author, this will be noted in the 'Risk of bias' tables. Blinding will be considered separately for key outcomes. Risk of bias within and

across included studies will be illustrated through a risk of bias graph and a risk of bias summary.

Measures of treatment effect

We will analyse dichotomous outcomes (including abstinence, psychiatric hospital readmissions, 50% reduction in cigarettes per day, uptake of cessation treatment and adverse events) on an ITT basis by calculating the risk ratio (RR). For the outcome 'uptake of cessation treatment', we will calculate the RR at entry to treatment. For the abstinence outcome, we will calculate the RR using data from the end of intervention and the longest follow-up reported. For all other dichotomous outcomes, we will use the longest follow-up data reported. We will calculate the RR using the formula: (number of events in the intervention condition/intervention denominator) / (number of events in the control condition/control denominator). We will report RRs with a 95% confidence interval (CI).

We will analyse continuous data (including mental health symptomatology, reduction in cigarettes per day, and quality-of-life measures) by calculating the mean difference (in instances where all studies report the outcome of interest using the same scale), or the standardised mean difference (where different scales are used), using the longest follow-up data reported. We will calculate the mean difference or standardised mean difference as: ((control group mean - intervention group mean) / pooled standard deviation), with a 95% CI.

Unit of analysis issues

The unit of analysis will be the individual participant, except where the trial is cluster-randomised, in which case the relevant centre/region will be the unit of analysis. If the trial is cluster-randomised and the authors used the individual as the unit of analysis, we will report the authors' methods for adjusting their analyses for intracluster correlation coefficient (ICC). If study authors of cluster-RCTs do not report analyses that make appropriate adjustment for clustering, we will extract additional data to conduct approximately correct analyses, including: the number of clusters randomised to each intervention group or the average size of each cluster; the outcome data ignoring the cluster design for the total number of individuals; and an estimate of the ICC. If the ICC is not reported, we will draw on external estimates from similar studies. These data will be used to reduce the clusters to their effective sample size using the design effect (calculated as (1 + (average cluster size - 1) * ICC)) prior to analysis in Review Manager 5. For analysing dichotomous data, we will divide both the number of participants and the number of events in each group by the design effect. For continuous data, we will divide only the number of participants in each group by the design effect, with means and standard deviations unchanged.

Dealing with missing data

In the case of missing numerical data or key information (including key study descriptive information, primary or secondary outcome data or risk of bias domains), or where an included study is an abstract only, we will contact study authors for additional information. If point prevalence cessation rates are provided but sustained rates are not, we will contact study authors to obtain sustained cessation rates as we have preference for this outcome. Where this is not possible, and the missing data pose a serious risk of bias, we will explore the impact of including these studies in the overall assessment of results using a sensitivity analysis.

We will carry out the analyses on an ITT basis for all dichotomous outcomes, and participants who drop out or are lost to follow-up will be considered to be continuing smokers, as is standard in the field. Any deaths will be deducted from the total sample size for all analyses except for analyses of adverse events. Continuous outcomes for which data are only presented for participants who were available at follow-up and imputation is not feasible, will be analysed using available case analysis. We will make note in the 'Risk of bias' table of any imputation conducted by study authors, or where there is high attrition or differential follow-up between groups. We will note whether study authors reported any sensitivity analyses using different assumptions about dropouts, and whether these affected their findings.

Assessment of heterogeneity

We will evaluate included studies for potential sources of heterogeneity (based on study characteristics, participant characteristics, intervention type and assessment methods), to determine whether pooling data is appropriate.

If any data are pooled across studies, we will use the I^2 statistic to assess statistical heterogeneity, given by the formula [(Q - df)/Q] x 100%, where Q is the Chi² statistic and df is the associated degrees of freedom (Higgins 2003). This statistic describes the percentage of variability in effect estimates due to heterogeneity rather than to sampling error (chance). We will describe heterogeneity in the pooled estimates as being low, moderate or high according to a value of 25%, 50%, and 75%, respectively (Higgins 2003).

Assessment of reporting biases

We will create a funnel plot to assess potential publication bias, methodological flaws, or small-study effects, if the number of included studies is sufficient (10 or more studies; Higgins 2011). We will additionally search for and report studies that we know were completed, but for which results are unavailable.

Data synthesis

If we include any studies where the main aim of the intervention is to increase uptake of smoking cessation treatment, we will analyse

these separately to typical smoking cessation trials (which compare different smoking cessation treatments). We will conduct ITT analyses by calculating all dichotomous outcomes based on the numbers of participants initially randomised to intervention and control groups. Primary and secondary dichotomous outcomes will be summarised as RRs with 95% CIs using the Mantel-Haenszel random-effects model (Deeks 2011). We will use the random-effects model as the interventions and populations are likely to be heterogeneous across included studies. Any deaths will be deducted from the denominators. Primary and secondary continuous outcomes will be summarised as mean difference or standardised mean difference, with 95% CIs, using inverse variance random-effects models. Where raw data are not reported in included studies, but effect estimates and their standard errors are available, we will enter these data directly into Review Manager using the generic inverse variance random-effects model. If the data are reported as ratio measures, we will enter these data as natural logarithms (Higgins 2011). Where sufficient data are available, we will conduct sensitivity analyses restricting the denominator to those participants known to have completed the treatment/intervention.

Subgroup analysis and investigation of heterogeneity

Depending on data availability and presence of heterogeneity, we will conduct subgroup analyses to investigate the impact of:

- smoking cessation intervention type (e.g. pharmacotherapy only, behavioural intervention only, combined pharmacotherapy and behavioural intervention);
- control group type (e.g. no intervention, treatment as usual, minimal intervention or delayed/wait-list control);
- recruitment setting (inpatient versus community);
- mental disorder type (e.g. diagnostically heterogeneous samples, samples of participants with schizophrenia/psychosis only, samples of participants with depression only); and
- motivation to quit smoking at study intake (motivation indicated versus not indicated).

Sensitivity analysis

As described above, we will conduct sensitivity analyses to explore the impact of including studies with missing data that may contribute to serious risk of bias and studies at an overall high risk of bias (determined by scoring high risk on any category), and to explore the impact of restricting the denominator of the main analyses to those participants known to have completed the treatment/intervention. Further, given that studies with 'no intervention' comparators will likely have larger effect sizes than active comparators because they contain fewer effective components (Karlsson 2014), we will conduct sensitivity analyses to explore the impact of including studies with 'no intervention' comparators.

'Summary of findings' table

We will create a 'Summary of findings' table using the following outcomes: smoking abstinence at least six months from the start of treatment, changes in mental health symptomatology (primary outcomes), and the incidence of adverse events and serious adverse events. Where data are available or can be obtained from study authors, we will present outcomes separately based on the comparisons that are made (e.g. cognitive behavioural therapy versus standard care).

We will use the five GRADE considerations (risk of bias, consistency of effect, imprecision, indirectness, and publication bias) to assess the quality of the body of evidence in the review that contributes to the prespecified outcomes. We will use methods and recommendations described in section 12.2.1 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011), using GRADEpro GDT software (GRADEpro GDT 2015). We will justify decisions to downgrade the quality of evidence using footnotes, and we will include comments to aid the reader's understanding of the outcomes where necessary.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. MEDLINE search strategy

1	exp Randomized Controlled Trials as Topic/
2	exp Intention To Treat Analysis/
3	exp Pragmatic Clinical Trials as Topic/
4	exp Cluster Analysis/
5	Random-Allocation/
6	randomized-controlled trials/
7	double-blind-method/
8	single-blind-method/
9	placebos/

(*Continued*)

10	Research-Design/
11	((clin$ adj5 trial$) or placebo$ or random$).ti,ab.
12	((singl$ or doubl$ or trebl$ or tripl$) adj5 (blind$ or mask$)).ti,ab
13	(volunteer$ or prospectiv$).ti,ab.
14	exp Follow-Up-Studies/
15	exp Retrospective-Studies/
16	exp Prospective-Studies/
17	exp Evaluation-Studies/ or Program-Evaluation.mp.
18	Comparative study/
19	exp Behavior-therapy/
20	exp Health-Promotion/
21	exp Community-Health-Services/
22	exp Health-Behavior/ or exp Health-Education/
23	RANDOMIZED-CONTROLLED-TRIAL.pt.
24	CLINICAL-TRIAL.pt.
25	smoking cessation.mp. or exp Smoking Cessation/
26	"Tobacco-Use-Cessation"/
27	"Tobacco-Use-Disorder"/
28	Tobacco-Smokeless/
29	exp Tobacco-Smoke-Pollution/
30	exp Tobacco-/
31	exp Nicotine-/
32	((quit$ or stop$ or ceas$ or giv$ or reduc$) adj5 smoking).ti,ab
33	exp Smoking/pc, th

(*Continued*)

34	exp Mental Disorders/
35	Psychiatric Department, Hospital/
36	exp Mental Health Services/
37	exp Community Mental Health Centers/
38	Mental Health/
39	Mentally Ill Persons/
40	(animals not humans).sh.
41	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24
42	25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33
43	34 or 35 or 36 or 37 or 38 or 39
44	(41 and 42 and 43) not 40

CONTRIBUTIONS OF AUTHORS

ES, JAB and JW conceived and designed the review. ES led the development and writing of the protocol, with critical input provided by KB, NB, TR, JMB, AM, LW, JW and JAB.

DECLARATIONS OF INTEREST

ES: none known.

KB: none known.

NB: none known.

TR: none known.

APM: none known.

JMB: none known.

LW: none known.

LW: none known.

JAB: none known.

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