HHS Public Access

Author manuscript

Cochrane Database Syst Rev. Author manuscript; available in PMC 2013 December 01.

Published in final edited form as:

Cochrane Database Syst Rev. 2012 December 01; 12: 1–10. doi:10.1002/14651858.CD010274.

Interventions for tobacco use cessation in people in treatment for or recovery from substance abuse

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Abstract

This is the protocol for a review and there is no abstract. The objectives are as follows:

To evaluate the effectiveness of tobacco cessation therapy offered concurrently with treatment for drug and alcohol addiction.

BACKGROUND

Tobacco kills up to half its users, accounting for nearly six million deaths annually worldwide (WHO 2012). Tobacco-related disease is the leading preventable cause of death in the United States (Mokdad 2004), and smoking rates in alcohol, drug abuse, and mental health (ADM) populations are two to four times that of the general population (Kalman 2005). Recent estimates suggest these groups suffer approximately half of all smoking-related deaths (Mauer 2006; Schroeder 2009; Williams 2006). Less than one quarter of the U.S. population (23%) smokes and overall smoking rates have declined since the 1960s (Schroeder 2004). In ADM populations, however, smoking rates have remained constant (Lamberg 2004).

The health risks of smoking in ADM populations have frequently been viewed as less relevant than the perceived therapeutic benefits of smoking, which were presumed to calm patients with psychiatric disorders and reduce the risk of relapse for recovering addicts.

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CONTRIBUTIONS OF AUTHORS

Protocol conceived and prepared by Dorie E. Apollonio, with contributions by Rose Philipps, and reviewed by Lisa A. Bero.

DECLARATIONS OF INTEREST

No conflicts of interest to report.

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

- National Cancer Institute CA140236, USA.

Grant

These beliefs in the benefits of smoking in this population persist despite empirical findings showing the opposite effects (Guydish 2007; Philip Morris 1994; Psychiatric News 1994). They also discourage the enactment of policy interventions that would reduce the disproportionate deaths from tobacco use that ADM populations experience (Apollonio 2005; Gudrais 2008).

This review specifically addresses tobacco cessation interventions in alcohol and drug abuse populations (other reviews address mental health populations, see Tsoi 2010 and van der Meer 2009). In the United States, studies estimate that nearly 13% of the population is addicted to alcohol, other drugs, or both (CASA 2012; NIDA 2012). The median smoking rate among adults in substance abuse treatment is 76%(Guydish 2011).Due to high smoking rates, individuals in these populations face a disproportionate risk of death due to tobacco use. Alcohol addicts, for example, have a 51% risk of dying from tobacco-related disease, compared to a 34% risk of dying from alcohol-related causes (Hurt 1996). Surveys also suggest that drug and alcohol addicts in treatment or recovery want to quit smoking and are interested in receiving smoking cessation therapy (Joseph 2003). As a result, researchers now argue that access to smoking cessation therapy during treatment would be clinically appropriate and would dramatically reduce smoking-related deaths in these populations (Abrams 2010; Baca 2009; Levy 2010).

Despite these findings, neglect of tobacco addiction in ADM populations remains common. This neglect is sometimes attributed to the stigma and marginalisation faced by those experiencing mental illness or in treatment for substance abuse (Schroeder 2008). In addition, questions remain as to how to treat tobacco comorbidity and whether tobacco cessation therapy should be offered during substance abuse treatment or delayed. Concurrent treatment of tobacco addiction has been limited due to staff fears that recovery from other addictions would be compromised if clients tried to simultaneously quit smoking (Goldsmith 1993; Richter 2006). When surveyed, only one-third of US respondents representing alcohol treatment programs agreed that clients in treatment should be encouraged to quit smoking (Bobo 1995), and similar results have been reported for providers in Australia and Switzerland (Walsh 2005; Zullino 2000).

Description of the condition

Tobacco use in populations dealing with substance abuse causes significant morbidity and mortality. It is not clear how or when to address tobacco addiction in these populations. Substance abuse is highly correlated with mental illness (dual diagnosis) and 60% of people with a substance use disorder also suffer from mental illness (NIDA 2007). Smokers with a history of alcoholism are more nicotine dependent than those without a history of alcoholism (Hurt 2003;Ward 2012), and these individuals are also less likely to quit smoking (Hays 1999). Former alcoholics that seek to quit smoking request more pharmacotherapy than smokers without a history of alcoholism (Hughes 2000).

Description of the intervention

Integrating smoking cessation treatment into chemical dependency units remains challenging. First, many of the individuals staffing substance abuse treatment centres are

smokers themselves. Staff acceptance is a key factor and changing staff attitudes is a first major step toward eventually changing staff behavior (Hurt 1995). Second, individuals in substance abuse treatment do not receive care from a single source; they may begin with residential care and move to outpatient care over time or complete all treatment as outpatients. As either inpatients or outpatients, individuals seeking treatment for addiction may be counselled on tobacco cessation either by staff dealing with other addictions or by staff dealing specifically with tobacco-related disease. Pharmacotherapy is typically prescribed by a physician that handles medical issues for the client, but not issues relating to addictions. Finally, the best form of treatment has not been established. Tobacco cessation treatment can be in the form of counselling, pharmacotherapy, or both.

Given the existing literature, it is not possible to assess the treatment effects of receiving addiction treatment from current smokers, or the effect of having multiple care providers. However, in this review, we assess the effects of different types of interventions: counselling, nicotine replacement therapy (NRT), non-NRT pharmacotherapy, or a combination thereof.

How the intervention might work

Tobacco cessation treatments provide: motivation and support for change through counselling, treatment for withdrawal symptoms using NRT or non-NRT pharmacotherapy, or a combination of these. NRT success rates in the general population, when combined with counselling, range from 11% to 30% (Campbell 2003). As a result, combination therapy is recommended in the general population (Ebbert 2007). For individuals with more severe tobacco dependence, a group that encompasses most substance abusers, some research suggests both combination therapy and the use of multiple pharmacological agents (Hurt 2009).

Why it is important to do this review

Most studies demonstrate that adding smoking cessation therapy to substance abuse treatment programs yields higher overall drug and alcohol abstinence (Tsoh 2011). We will systematically review these studies and provide a meta-analysis of their results. The results will identify whether or not tobacco cessation therapy offered concurrently with drug or alcohol treatment increases abstinence from tobacco, alcohol and other drugs. Our findings will help assess whether tobacco cessation therapy should be offered concurrently with treatment for other addictive drugs or delayed. Alcoholics and substance abusers have unique needs and additional dependencies that may demand differential tobacco cessation treatment. For example, recovering addicts may require more pharmacotherapy to treat withdrawal symptoms because they are more nicotine dependent. This review will compare the timing of tobacco cessation treatment and the types of treatment in order to identify the best options for recovering addicts.

An earlier review was conducted in this area (Prochaska 2004). This analysis will update those findings and expand on the previous review by considering four specific interventions: counselling, NRT, pharmacotherapy, and combined interventions, as well as providing subgroup analyses by stage of recovery, drug of choice, and type of treatment.

OBJECTIVES

To evaluate the effectiveness of tobacco cessation therapy offered concurrently with treatment for drug and alcohol addiction.

METHODS

Criteria for considering studies for this review

Types of studies—Randomized controlled trials (RCTs) and cluster-RCTs, with no exclusions based on language of publication or publication status.

Types of participants—Adults aged 18 years or older who are undergoing inpatient or outpatient treatment for drug or alcohol addiction and are participating in a study to encourage tobacco cessation during substance abuse treatment. Interventions may target either groups (e.g. the population of a single clinic) or individuals (e.g. patients at a single clinic). We will distinguish between studies that randomize participants within clinics and those that randomize by clinic site (cluster randomization). We will include information on the nature of the addiction(s) for which the individual originally sought treatment. Participants in the included studies need not have been selected based on level of smoking (e.g. daily smokers) or their presumed suitability for particular interventions.

Types of interventions—We will include interventions designed to encourage tobacco cessation. Interventions will be organized by type in the following categories:

1. Counseling only, both individual and group sessions, delivered in a clinic setting for tobacco cessation purposes during the course of existing addictions treatment, or in addition to existing interventions for other addictions;
2. Nicotine replacement therapy (NRT) of all modalities (e.g. gum, patch), both prescription and over-the-counter, offered to individuals for tobacco cessation purposes during the course of existing addictions treatment;
3. Non-NRT pharmacology (e.g. varenicline [Chantix, Champix] or bupropion [Zyban]) offered to individuals for tobacco cessation purposes during the course of existing addictions treatment;
4. A combination of any of the above methods.

The controls in these studies must be individuals in substance abuse treatment who were offered different tobacco cessation therapies, delayed therapy, lower levels of treatment, or no tobacco-related addiction treatment.

Types of outcome measures

Primary outcomes: The preferred primary outcome will be point prevalence tobacco abstinence, as defined by self-reported tobacco use or through biochemical validation (e.g. urinary cotinine) at the longest follow-up period reported in each study. These results will be measured as the number of participants who are abstinent in each condition (treatment or control) at final follow-up relative to the number of participants enrolled in the study. We

will use biochemically validated abstinence measures if they are supplied. We rely on point prevalence abstinence rather than continuous abstinence, where both are reported, due to the difficulty of follow-up within this population. No minimum length of follow-up will be required for studies to be included.

We will record the definition of tobacco use as defined by each study. This can include current daily use, current occasional use, or, in the case of individuals released to substance abuse treatment after incarceration, regular tobacco use before arrest.

We will consider whether abstinence is sustainable by considering whether abstinence rates increase or decrease at the longest follow-up point, relative to earlier post-intervention follow-ups.

Studies reporting reduced smoking rather than abstinence will be reported separately from studies that report abstinence. These results will be measured by the number of cigarettes that participants in each condition (treatment or control) report smoking per day at the longest follow-up period reported in each study. We will use biochemically validated measures (e.g. urinary cotinine) to validate reduced smoking if they are available. If outcomes are reported separately for different categories of baseline users we will extract data for all outcomes. We will exclude studies that measure interventions included in the criteria above, but that do not report the primary outcome measure.

Secondary outcomes: If reported, the following secondary outcomes will be extracted:

1. Point prevalence abstinence from alcohol and other drugs as defined by self-reported drug use or through biochemical validation at the longest follow-up period reported in the study. We will assess abstinence from alcohol and other drugs using the same methods proposed for assessing tobacco abstinence. Similarly, studies reporting reduced drug use rather than abstinence will be reported separately from studies reporting abstinence. If outcomes are reported separately for different categories of baseline users we will extract data for all outcomes.
2. The costs of interventions will be assessed using the reporting of individual studies included in the review if these data are available. We anticipate that cost data would need to be assessed by narrative synthesis, as there are no standardized reporting measures for costs, or methods of objective verification for reported costs.

Search methods for identification of studies

Electronic searches—We will search the Cochrane Tobacco Addiction Group Specialised Register, the Cochrane Central Register of Controlled Trials (CENTRAL), and MEDLINE. The Specialised Register includes reports of trials identified from systematic and sensitive searches of resources, including MEDLINE, EMBASE and PsycINFO, for reports of trials of interventions for smoking cessation and prevention (see the Tobacco Addiction Group Module in the Cochrane Library for full details). The Specialised Register search will use topic related keywords and free text terms covering alcohol abuse and drug

dependence. The CENTRAL search will combine topic related terms and terms related to smoking cessation. The MEDLINE search will combine substance abuse terms, smoking cessation terms and study design terms (e.g., randomized controlled trial, controlled clinical trial). See Appendix 1 for the full MEDLINE search strategy.

Searching other resources—We will search through the grey literature, including conference abstracts from the Society for Research on Nicotine and Tobacco and the ProQuest database of digital dissertations.

We will search all registered trials through the National Institutes of Health's www.clinicaltrials.gov site.

Data collection and analysis

Selection of studies—From the title, abstract, or descriptors, one reviewer (RP) will independently review the literature searches to identify potentially relevant trials.

Data extraction and management—One reviewer (RP) will extract data for the trials using a standardized data extraction form prior to entry into The Cochrane Collaboration software program, Review Manager 5.1. Authors will be contacted to obtain missing or raw data. All studies that clearly do not meet the inclusion criteria in terms of study design, population or interventions will be excluded. RP will extract the data, which will be checked by a second reviewer (DA). The risks of bias for each included study will be extracted by two independent reviewers (DA and RP).

The following information will be extracted, using a tool developed by LB and modified by DA:

1. methods, including the setting of the trial, study design, study objectives, study site(s), definition of tobacco use, methods of participant recruitment, types of treatment interventions, proposed outcome measures, and methods of analysis;
2. participant data, including age, gender, ethnicity, socio-economic status, and n-values for eligibility, recruitment and completion;
3. interventions, including descriptions of interventions, duration of treatment, delivery of intervention, type and duration of behavioural support (if applicable) and components of treatment in the control group;
4. outcomes, including methods of data collection for results, definitions of abstinence, abstinence from tobacco, abstinence from other drugs, changes in abstinence rates over time, cost of treatment (when available), validation, follow-up period, other follow-ups in the course of the study, and other data as defined under' Types of outcome measures' in this protocol, and;
5. risks of bias, including methods of sequence generation for randomization, allocation concealment, blinding, incomplete outcome data, selective outcome reporting, contamination, clustering by clinic site, imbalance of outcome measures at baseline, comparability of intervention and control group

characteristics at baseline, protection against contamination, selective recruitment of participants and other potential threats to validity.

Assessment of risk of bias in included studies—Risk of bias will be evaluated by two independent reviewers, DA and RP, in line with recommendations made in the Cochrane Handbook of Systematic Review of Interventions (Higgins 2011), Chapter 8. The criteria will include allocation sequence, allocation concealment, blinding for participants and outcome assessors, incomplete outcome data, and selective outcome reporting. Three additional criteria recommended by the Cochrane EPOC group will also be included: imbalance of outcome measures at baseline; comparability of intervention and control group characteristics at baseline; and protection against contamination (EPOC 2009). As we expect to find cluster study designs, we also plan to assess the risk of bias associated with selective recruitment of participants through choice of site in these studies.

Assessment of risk of bias in each domain will be assessed as 'Low risk of bias', 'High risk of bias', or 'Unclear risk of bias', based on the guidelines from the Cochrane Handbook (Higgins 2011), with notes indicating the reasons for each assessment included in the risk of bias table. Conflicts in the assessments will be resolved either by consensus or by referring to a third party (LB).

Measures of treatment effect—Where possible, a risk ratio (RR) will be provided for the primary outcome of each trial. The RR will be defined as (number of subjects abstinent from tobacco in the intervention group/ total number randomized to the intervention group) / (number of subjects abstinent from tobacco in the control group/ total number randomized to the control group). The RR is greater than 1 if the intervention is effective, and more participants remain abstinent from tobacco in the intervention group than in the control group. If appropriate, an estimated pooled weight average for RRs will be calculated using the Mantel-Haenszel fixed-effect model, with 95% confidence intervals. We will conduct an intention-to-treat analysis, including all participants enrolled at baseline whether or not they received the intervention and counting drop-outs as continuing smokers. We will also use a dichotomous approach for change in cigarette consumption, where changes will be categorized as reduction by 50% or more, or no change/reduction <50%. The same methods will be used to calculate secondary outcomes, namely abstinence from or change in use of alcohol and other substances.

Unit of analysis issues—For cluster randomized trials, the analysis will be performed at the level of individual but accounting for clustering. For studies that do not adjust for clustering, the size of the trial will be reduced to the effective sample size (Rao 1992). We will use the original sample size from each study divided by 1.2 to account for design effects, in keeping with other tobacco cessation trials (Gail 1992) and recommendations drawn from the Cochrane Handbook (Higgins 2011), Chapter 16.

If studies that we have included use different statistical methods to address clustered data, we will record whether the results presented referenced these methods and if they did, whether this adjustment changed the significance of any observed effect.

Dealing with missing data—Missing information regarding participants will be evaluated on an available case analysis basis as described in Chapter 16 of the Cochrane Handbook (Higgins 2011). If information needed for the meta-analysis is missing and can not be calculated from other data, we will attempt to contact the authors to gain access to these data. If there has been loss of participants before baseline assessment, this review will assume that these missing data have no effect on the final results of the analysis. Attrition after baseline assessments will assessed and discussed between the coders (DA and RP). The main issue to assess will be potential differential attrition between the intervention and control groups, and differential attrition within groups that are correlated with baseline characteristics.

Whenever possible, the number of participants lost to follow-up in each condition will be recorded. Because loss to follow-up in the case of tobacco cessation treatment is typically associated with continued tobacco use, participants lost to follow-up will be coded as smokers. Analysis will be completed both including and excluding the participants lost to follow-up and coded as continuing smokers, and differences in outcomes will be reported in the findings. Participants lost to follow-up due to death will be excluded from the analysis and reported separately. Participants lost to follow-up will also be counted as continuing users of alcohol and other substances.

Assessment of heterogeneity—We will classify trials according to the subgroups listed in Types of interventions. We will combine studies within these subgroups. For our overall assessment, we will also pool studies that review different interventions (e.g. counselling only versus NRT only). We will consider where there is heterogeneity due to differential levels of baseline smoking. For example, individuals who have been abstinent before treatment due to incarceration may be more likely to remain abstinent if offered tobacco cessation treatment. Other factors contributing to heterogeneity may include level of tobacco use (e.g. packs per day smoked), demographics, time to follow-up measures, and measurement tools (e.g. self-report versus clinical assessment). If the confidence intervals of studies have poor overlap, this usually indicates the presence of statistical heterogeneity. In addition to visually inspecting data, we will use the I^2 statistic (Higgins 2011, Chapter 9) to identify inconsistencies between studies and groups. The Chi^2 test has low power when studies have small sample sizes, or when there are few studies. Recognizing that some level of statistical heterogeneity is inevitable, the I^2 statistic instead attempts to quantify the potential impact of this heterogeneity on ameta-analysis. It describes the percentage of the variability in effect estimates that is due to heterogeneity rather than sampling.

For the meta-analysis, extracted data will be pooled using a fixed-effect model. If we identify substantial heterogeneity we will consider either using only a narrative synthesis or the use of a random-effects model. This method would need to address the possible influence of smaller studies, which could over- or underestimate the population treatment effect.

Assessment of reporting biases—There are limited statistical methods to detect within-study selective reporting. If non-significant results are mentioned but not reported adequately, we will assume that there was risk of bias in the meta-analysis. Unfortunately,

information sought from authors of studies may be incomplete or unreliable (Chan 2004a; Chan 2004b). Our analysis will assess whether two key outcomes, abstinence from tobacco and abstinence from other drugs, were present in all the included studies, and report which studies included these outcomes and which did not. Measurements that are typically reported jointly (e.g. abstinence from tobacco and abstinence from other drugs) should be included in all studies, and we will assume risk of bias is high in studies where either or both do not appear.

We will assess the risk of bias due to selective reporting of outcomes for each study rather than for individual outcomes. Where we suspect selective outcome reporting we will contact study authors for additional information. Should our review retrieve more than 10 included studies, we will also create a funnel plot. Assymetrical funnel plots may be indicative of publication bias.

Data synthesis—In addition to the meta-analysis we will report findings using narrative synthesis. We will discuss studies individually in the event that their confidence intervals are large and non-overlapping (small studies or small sample sizes), suggesting inconclusive results. The results from larger and more rigorous studies will be combined. Our logic reflects the changing nature of research in this area; we anticipate that smaller studies are most likely to have been conducted in earlier research, when definitions of use and abstinence, recruitment protocols, and measures were not consistent across studies. The data will be analysed using Review Manager 5.1.

Subgroup analysis and investigation of heterogeneity—In studies that offer extended follow-up of participants, the results may be presented for several periods of follow-up including short-term (four weeks or less),medium-term (four weeks to six months) and long-term (greater than six months). If data are available, we will separately analyse studies that provide results for abstinence greater than one year. In the case of studies with more than one follow-up assessment, we will consider whether the effect at the longest follow-up period was larger or smaller than at earlier assessments. If data are available, we will divide treatment modalities by intensity, creating subgroups based on the level of pharmacotherapy or frequency of counselling.

Sensitivity analysis—Sensitivity analysis will be conducted on studies with a high risk of bias for sequence generation and allocation concealment. The studies included in this review will all be randomized controlled trials and given this restriction, which limits concerns about several methodological concerns unique to cohort or case control studies, these are the areas in which study quality is most likely to vary. As a result, we anticipate that these factors would be most likely to bias the results of studies of treatment interventions.

Appendix 1. MEDLINE search strategy

((alcohol drinking/dt[mh:noexp] OR alcohol drinking/pc[mh:noexp] OR alcohol drinking/px[mh:noexp] OR alcohol drinking/th[mh:noexp]) OR (alcoholism/dt[mh:noexp] OR alcoholism/pc[mh:noexp] OR alcoholism/px[mh:noexp] OR alcoholism/rh[mh:noexp] OR alcoholism/th[mh:noexp]) OR (heavy[tiab] AND drink*[tiab])

OR (substance withdrawal syndrome/dt[mh:noexp] OR substance withdrawal syndrome/pc[mh:noexp] OR substance withdrawal syndrome/px[mh:noexp] OR substance withdrawal syndrome/rh[mh:noexp] OR substance withdrawal syndrome/th[mh:noexp])

OR (substance-related disorders/dt[mh:noexp] OR substance-related disorders/pc[mh:noexp] OR substance-related disorders/px[mh:noexp] OR substance-related disorders/rh[mh:noexp] OR substance-related disorders/th[mh:noexp])

OR (alcohol-related disorders/dt[mh:noexp] OR alcohol-related disorders/pc[mh:noexp] OR alcohol-related disorders/px[mh:noexp] OR alcohol-related disorders/rh[mh:noexp] OR alcohol-related disorders/th[mh:noexp])

OR (amphetamine-related disorders/dt[mh:noexp] OR amphetamine-related disorders/pc[mh:noexp] OR amphetamine-related disorders/px[mh:noexp] OR amphetamine-related disorders/rh[mh:noexp] OR amphetamine-related disorders/th[mh:noexp])

OR (cocaine-related disorders/dt[mh:noexp] OR cocaine-related disorders/pc[mh:noexp] OR cocaine-related disorders/px[mh:noexp] OR cocaine-related disorders/rh[mh:noexp] OR cocaine-related disorders/th[mh:noexp])

OR (inhalant abuse/dt[mh:noexp] OR inhalant abuse/pc[mh:noexp] OR inhalant abuse/px[mh:noexp] OR inhalant abuse/rh[mh:noexp] OR inhalant abuse/th[mh:noexp])

OR (marijuana abuse/dt[mh:noexp] OR marijuana abuse/pc[mh:noexp] OR marijuana abuse/px[mh:noexp] OR marijuana abuse/rh[mh:noexp] OR marijuana abuse/th[mh:noexp])

OR (opioid-related disorders/dt[mh] OR opioid-related disorders/pc[mh] OR opioid-related disorders/px[mh] OR opioid-related disorders/rh[mh] OR opioid-related disorders/th[mh])

OR (phencyclidine abuse/dt[mh:noexp] OR phencyclidine abuse/pc[mh:noexp] OR phencyclidine abuse/px[mh:noexp] OR phencyclidine abuse/rh[mh:noexp] OR phencyclidine abuse/th[mh:noexp])

OR (substance abuse, intravenous/dt[mh:noexp] OR substance abuse, intravenous/pc[mh:noexp] OR substance abuse, intravenous/px[mh:noexp] OR substance abuse, intravenous/rh[mh:noexp] OR substance abuse, intravenous/th[mh:noexp]))

AND (((“smoking cessation” OR smoking cessation[mh]) OR (tobacco use cessation[mh:noexp]) OR (tobacco use disorder[mh:noexp]) OR (tobacco, smokeless[mh:noexp]) OR (tobacco smoke pollution[mh]) OR (tobacco[mh]) OR (nicotine[mh]) OR ((quit*[tiab] OR stop*[tiab] OR ceas*[tiab] OR giv*[tiab]) AND smoking[tiab]) OR (smoking/pc[mh] OR smoking/th[mh]))

AND ((randomized controlled trial[pt]) OR (controlled clinical trial[pt]) OR (clinical trial[pt])) NOT (animals[mh] NOT humans[mh]))

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