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REPORT

A SYSTEMATIC REVIEW

Cognitive therapies for smoking cessation

Norwegian Institute of Public Health

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Key Messages

Around six million people die every year due to diseases caused by smoking, most commonly cancer, cardiovascular disease and chronic obstructive pulmonary disease. Nicotine replacement therapy, medication and counselling are common methods used to help people quit smoking.

We evaluated the effect of cognitive therapies on smoking cessation. We included 21 randomised controlled trials. The included studies involved adult smokers, different patient groups, and persons at risk of heart disease.

We found that:

- Cognitive therapies combined with medication probably improve smoking abstinence rates somewhat, compared to medication only, moderate-quality evidence
- Cognitive therapies combined with nicotine replacement therapy may improve smoking abstinence rates somewhat, compared to other interventions combined with nicotine replacement therapy, low-quality evidence.
- Cognitive therapies may improve smoking abstinence rates, compared to other interventions, up to 12 months after the end of the intervention, low-quality evidence.
- Cognitive therapies may have little or no effect on smoking abstinence rates, compared to usual care or minimal intervention, low-quality evidence.
- We are uncertain whether cognitive therapies combined with medication change smoking abstinence rates compared to supportive therapy combined with medication.

Title:

Cognitive therapies for smoking cessation: a systematic review.

Publication type:

Systematic review

A review of a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise relevant research, and to collect and analyse data from the studies that are included in the review. Statistical methods (meta-analysis) may or may not be used to analyse and summarise the results of the included studies.

Doesn't answer everything:

- Excludes studies that fall outside of the inclusion criteria
- No health economic evaluation
- No recommendations

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Peer review:

Roger Hagen, professor, Department of Psychology, the Norwegian University of Science and Technology.

Anders Hovland, associate professor, Department of Psychology, University of Bergen.

Executive summary

Background

Around six million people die every year due to diseases caused by smoking. In 2013, smoking accounted for 14.5% of all deaths in Norway, primarily caused by cancer, cardiovascular disease and chronic obstructive pulmonary disease. Both pharmacological and non-pharmacological interventions, and combinations of the two, are used to help people quit smoking. Cognitive therapies are considered effective treatments for a range of disorders such as depression, anxiety, insomnia, and chronic pain. There are also documented effects of cognitive therapies when used to change health behaviours such as physical activity and dietary habits, but we do not know the effects of cognitive therapies on smoking cessation.

Objective

We carried out this systematic review to answer the question "What is the effect of cognitive therapies on smoking cessation in adults ≥ 18 years, compared to no intervention, usual care or another intervention?"

Methods

We searched systematically in five electronic databases for systematic reviews and subsequently for randomised or cluster-randomised controlled trials. We included studies that evaluated effects of cognitive therapies on smoking cessation compared to no intervention, usual care, or other interventions in adults aged 18 years and older. In addition, we searched the reference lists of included studies. Two persons independently screened titles and abstracts, selected studies based on full text publications, and assessed risk of bias in the included studies. One person extracted data from the studies and another person verified the data extraction. We summarized the results by random-effects meta-analyses, presented as relative risk and 95% confidence intervals. We rated our confidence in the effect estimates using GRADE (Grading of Recommendations Assessment, Development and Evaluation) and presented the results in summary of findings tables. In the GRADE system, high quality means that we are very confident that the estimate of the effect is close to the true effect; moderate quality that the estimate of the effect is likely to be close to the true effect, but there is a possibility that it is substantially different; low quality that the estimate of the effect may be substantially different from the true effect; and very low quality that the estimate of the effect is likely to be substantially different from the true effect.

Results

We did not find any systematic reviews that could answer our question. We found 21 randomized controlled trials with a total of 4946 participants that fulfilled our inclusion criteria. Half of the included studies involved adult smokers, six studies involved patient groups, and the remaining studies included people from specific ethnic groups or women only. The control groups received either no intervention, usual care or other interventions, and most studies reported seven-day smoking abstinence rates. Thirteen studies had follow-up times six months or more after the end of the intervention. We judged 18 studies to have an unclear risk of bias, two studies to have a low risk of bias, and one study to have a high risk of bias.

We found small effects of cognitive therapies in combination with medication or nicotine replacement therapy for smoking cessation.

- Cognitive therapies in combination with medication, resulted in a higher smoking abstinence rate compared to medication only. The relative risk based on five studies with 673 participants was 1.39 with a 95% confidence interval of 1.10 to 1.76. According to GRADE, we rated our confidence in the effect estimate as moderate.
- Cognitive therapies combined with nicotine replacement therapy resulted in a higher smoking abstinence rate, compared to other interventions combined with nicotine replacement therapy. The relative risk based on eight studies with 1 309 participants was 1.53 with a 95% confidence interval of 1.06 to 2.19. We rated our confidence in the effect estimate as low.
- Cognitive therapies resulted in a higher abstinence rate, compared to other interventions. The relative risk based on six studies with 850 participants was 2.05 with a confidence interval of 1.09 to 3.86. We rated our confidence in the effect estimate as low.

We found that cognitive therapies may have little or no effect compared to usual care or minimal intervention on smoking abstinence rate. We rated our confidence in the effect estimate as low.

We are uncertain whether cognitive therapies combined with medication compared to supportive therapy combined with medication change smoking abstinence rates. We rated our confidence in the effect estimates as very low.

Discussion

The study participants in this review were diverse and included both adult smokers and patients in hospital- or primary health care settings. The interventions involved basic elements of cognitive therapies, such as relapse prevention, coping skills, self-management, self-efficacy, social support, cognitive restructuring, and problem solving. Several different health professions delivered the interventions, although with a predominance of psychologists. There was great variation in the duration and frequency of the therapy sessions.

Exclusion of persons with co-morbidities, mental health problems, or dependence on other substances (e.g. alcohol, illicit drugs) may limit the applicability of the results. Our results may not capture how effective cognitive therapies for smoking cessation will be under routine clinical practice.

Almost all studies used biochemical validation of self-reported smoking abstinence, and most studies reported abstinence seven days before the follow-up date. This indicates a relatively homogeneous approach to measurement of smoking abstinence. Further improvement of measurement procedures include standardization of the follow-up period (e.g. sustained since quit-date or seven days before follow-up), and standardization of cut-off levels to identify regular smokers by biochemical analyses.

Research gaps include lack of direct comparison with pharmacological treatment or other active interventions such as exercise, and evaluation of sustained abstinence from intervention/quit date to follow up. Uncertainty regarding the documentation as such includes insufficient power in trials and insufficient reporting of research methods, especially procedures for randomization and allocation concealment.

Conclusion

Cognitive therapies added to medication probably improve smoking abstinence rates somewhat compared to medication only. Cognitive therapies combined with nicotine replacement therapy may improve smoking abstinence somewhat compared to other interventions combined with nicotine replacement therapy. Cognitive therapies may improve smoking abstinence rates as compared to other interventions. Cognitive therapies may have a similar effect as usual care or minimal intervention on smoking abstinence rate. We are uncertain whether cognitive therapy combined with medication changes smoking abstinence rate as compared to supportive therapy combined with medication.

Hovedbudskap

Omtrent seks millioner mennesker dør hvert år av sykdommer forårsaket av røyking, særlig kreft, hjerte- og karsykdommer og kronisk obstruktiv lungesykdom. Nikotinerstatningsprodukter, medisiner og rådgivning er vanlige metoder for å hjelpe folk til å slutte å røyke.

Vi vurderte effekten av kognitive terapier på røykeslutt i studier som involverer voksne røykere, pasientgrupper, og personer med risiko for hjerte- og karsykdom. Vi inkluderte 21 randomiserte kontrollerte studier.

Vi fant at:

- Kognitive terapier kombinert med medisiner øker trolig andel personer som slutter å røyke noe, sammenlignet med kun å få medisiner, basert på dokumentasjon av middels kvalitet.
- Kognitive terapier kombinert med nikotinerstatningsprodukter øker muligens andel personer som slutter å røyke noe, sammenlignet med andre tiltak kombinert med nikotinerstattningsprodukter, basert på dokumentasjon av lav kvalitet.
- Kognitive terapier øker muligens andel personer som slutter å røyke, sammenlignet med andre tiltak, basert på dokumentasjon av lav kvalitet.
- Kognitive terapier har muligens en lignende effekt som vanlig behandling eller minimalt tiltak, basert på dokumentasjon av lav kvalitet.
- Vi er usikre på om kognitive terapier kombinert med medisiner fører til endring i andel personer som slutter å røyke, sammenlignet med støttende terapi kombinert med medisiner.

Tittel:
Kognitive terapier for røykeslutt: en systematisk oversikt.

Publikasjonstype:
Systematisk oversikt.
En systematisk oversikt er resultatet av å
- innhente
- kritisk vurdere og
- sammenfatte

relevante forskningsresultater ved hjelp av forhåndsdefinerte og eksplisitte metoder.

Svarer ikke på alt:
- Ingen studier utenfor de eksplisitte inklusjonskriteriene
- Ingen helseøkonomisk evaluering
- Ingen anbefalinger

Hvem står bak rapporten?
Folkehelseinstituttet har gjennomført denne systematiske oversikten på oppdrag fra Helsedirektoratet.

Når ble litteratursøket utført?
Søk etter studier ble avsluttet November 2016.

Fagfeller:
Roger Hagen, professor, Psykologisk institutt, Norges teknisk-naturviteskapelige universitet.

Anders Hovland, førsteamanuensis, Institutt for klinisk psykologi, Universitetet i Bergen.

Sammendrag

Innledning

Omtrent seks millioner mennesker dør hvert år av sykdommer forårsaket av røyking. I 2013 skyldtes 14,5 % av alle dødsfall i Norge røyking primært knyttet til kreft, hjerte- og karsykdommer og kronisk obstruktiv lungesykdom (KOLS). Både farmakologiske og ikke-farmakologiske tiltak, og kombinasjoner av disse, blir brukt for å hjelpe folk å slutte å røyke. Kognitive terapier har dokumentert effekt innen flere helseområder, inkludert på levevaner som fysisk aktivitet og kosthold, men vi vet ikke effekten av kognitive terapier på røykeslutt.

Formål

Vi utførte en systematisk oversikt for å svare på spørsmålet «Hva er effekten av kognitive terapier på røykeslutt hos voksne over 18 år, sammenlignet med ingen tiltak, vanlig behandling eller annet tiltak?»

Metode

Vi søkte systematisk etter systematiske oversikter og senere etter randomiserte eller klynge-randomiserte kontrollerte studier i fem elektroniske databaser. I tillegg søkte vi i referanselister i de inkluderte studiene. Vi inkluderte studier som evaluerte effekter av kognitive terapier på røykeslutt sammenlignet med ingen tiltak, vanlig behandling eller annet tiltak hos personer over 18 år. To personer gikk uavhengig gjennom titler og sammendrag, valgte ut studier basert på fulltekstartikler, og vurderte risiko for systematiske skjevheter i de inkluderte studiene. En person hentet ut data fra studiene og en annen person verifiserte datauttrekkingen. Vi oppsummerte resultatene med «random-effects» metaanalyser og presenterte relativ risiko med 95 % konfidensintervall. Vi vurderte tilliten til effektestimatene med GRADE (Grading of Recommendations Assessment, Development and Evaluation) og presenterte resultatene i diagram og tabeller. I GRADE-systemet betyr høy kvalitet at vi har stor tillit til at effektestimatet ligger nær den sanne effekten. Middels kvalitet betyr at effektestimatet sannsynligvis er nær den sanne effekten, men det er også en mulighet for at den kan være forskjellig. Lav kvalitet betyr at den sanne effekten kan være vesentlig ulik effektestimatet. Svært lav kvalitet betyr at vi har svært liten tillit til at effektestimatet ligger nær den sanne effekten.

Resultat

Vi fant ingen systematiske oversikter som besvarte spørsmålet. Vi fant 21 randomiserte kontrollerte studier som tilfredsstilte våre inklusjonskriterier. Halvparten av studiene inkluderte voksne røykere, seks studier inkluderte pasientgrupper, og resterende studier inkluderte mennesker fra spesifikke etniske grupper eller kun kvinner. Kontrollgruppene fikk enten ingen tiltak, vanlig behandling, eller et annet tiltak. Vi vurderte 18 studier til å ha uklar risiko for systematiske skjevheter, to studier til å ha lav risiko, og én studie til å ha høy risiko for systematiske skjevheter.

Vi fant små effekter på røykeslutt når kognitive terapier ble kombinert med medisiner eller nikotinerstatningsprodukter.

- Kognitive terapier kombinert med medisiner fører til at flere slutter å røyke, sammenlignet med kun å få medisiner, relativ risko 1,39 med 95 % konfidensintervall fra 1,10 til 1,76. Resultatet er basert på fem studier med 673 deltakere. Vi vurderte, ifølge GRADE, vår tillit til effektestimatet som middels.
- Kognitive terapier kombinert med nikotinerstattningsprodukter fører til at flere slutter å røyke, sammenlignet med rådgivning kombinert med nikotinerstattningsprodukter, relativ risiko 1,60 med 95 % konfidensintervall fra 1,06 til 2,40. Resultatet er basert på åtte studier med 1 309 deltakere. Vi vurderte, ifølge GRADE, vår tillit til effektestimatet som lav.
- Kognitive terapier fører til at flere slutter å røyke, sammenlignet med andre tiltak, relativ risiko 2,05 med 95 % konfidensintervall fra 1,09 til 3,86. Resultatet er basert på seks studier med 850 deltakere. Vi vurderte, ifølge GRADE, vår tillit til effektestimatet som lav.

Vi fant at kognitive terapier muligens har en lignende effekt som vanlig behandling eller minimalt tiltak på røykeslutt. Vi vurderte, ifølge GRADE, vår tillit til effektestimatet som lav.

Resultatene for kognitive terapier kombinert med medisiner på røykeslutt sammenlignet med støttende terapi kombinert med medisiner var forbundet med stor usikkerhet Vi vurderte, ifølge GRADE, vår tillit til effektestimatet som svært lav.

Diskusjon

Det var mange forskjellige typer deltakere i studiene som ble inkludert i denne systematiske oversikten. Det var både voksne røykere og pasienter i spesialist- eller primærhelsetjeneste. Tiltakene inneholdt grunnleggende elementer av kognitive terapier som forebygging av tilbakefall, mestringsferdigheter, utvikling av ferdigheter til selvregulering, problemløsning og mestringsfølelse, sosial støtte, og kognitiv restrukturering. Flere kategorier av helsepersonell ga tiltakene. Det var stor variasjon i varighet og hyppighet av de kognitive terapiene som ble gitt.

Strenge eksklusjonskriterier, for eksempel at personer med flere sykdommer, mentale helseproblemer, eller avhengighet av for eksempel alkohol og ulovlige rusmidler ble ekskludert, kan begrense anvendbarheten av resultatene. Det kan være at resultatene

ikke fanger opp i hvilken grad kognitive terapier for røykeslutt virker når de brukes i vanlig klinisk praksis.

Nesten alle studier benyttet seg av biokjemisk validering av deltakernes rapportering om røykeslutt. De fleste studiene rapporterte avholdenhet syv dager før oppfølgingsdato. Dette tilsier at forskningsfeltet har en relativt homogen tilnærming til måling av røykeslutt. Målemetodene kan forbedres ytterligere ved å standardiser oppfølgingsperioden (for eksempel vedvarende etter sluttdato eller syv dager før oppfølgingsdato). Videre kan grenseverdier for biokjemisk analyse standardiseres.
Vi identifiserte følgende forskningshull: mangel på studier som direkte sammenlignet kognitive terapier med farmakologisk behandling og andre aktive tiltak som trening, og mangel på studier som målte vedvarende avholdenhet fra sluttdato. Manglende statistisk styrke i inkluderte studier og mangelfull rapportering av metoder, særlig randomisering og fordeling av deltakere til grupper, førte til usikkerhet om kvaliteten på den samlede dokumentasjonen.

Konklusjon

Kognitive terapier i tillegg til medisiner øker trolig andel personer som slutter å røyke, sammenlignet med kun å få medisiner. Kognitive terapier kombinert med nikotinerstatningsprodukter øker muligens andel personer som slutter å røyke, sammenlignet med andre tiltak kombinert med nikotinerstatningsprodukter. Kognitive terapier øker muligens andel personer som slutter å røyke, sammenlignet med andre tiltak. Kognitive terapier har muligens en lignende effekt som vanlig behandling eller minimalt tiltak.

Preface

The Knowledge Centre in the Norwegian Institute of Public Health carried out a systematic review of the effects of cognitive therapies for changing health behaviours related to physical activity, diet, and tobacco use. This report is the third of three and presents the findings concerning effects of cognitive therapies tobacco use. The Norwegian Directorate of Health commissioned the systematic review.

The project group consisted of:
Project leader: Eva Denison, senior researcher.
Vigdis Underland, researcher.
Annhild Mosdøl, senior researcher.
Gyri Hval Straumann, research librarian.
All at the Knowledge Centre in the Norwegian Institute of Public Health

We thank Rigmor C Berg, research director at the Knowledge Centre in the Norwegian Institute of Public Health, who was the project leader in the initial stages of the project. We also thank Liv Merete Reinar, research director at the Knowledge Centre in the Norwegian Institute of Public Health, and Ingvil Sæterdal, research director at the Knowledge Centre in the Norwegian Institute of Public Health, for reviewing and commenting on a draft of the report. Finally, we thank the reviewers Roger Hagen, professor, Department of Psychology, the Norwegian University of Science and Technology, and Anders Hovland, associate professor, Department of Psychology, University of Bergen.

All authors and reviewers declare that they have no conflicts of interest.

Signe Flottorp	Gunn E Vist	Eva Denison
Acting head of department	*Research director*	*Project leader*

Background

This is the third in a series of three systematic reviews on the effects of cognitive therapies when used to change health behaviours. In this report, we present the results concerning effects of cognitive therapy interventions designed to reduce tobacco use, here defined as smoking cigarettes. The first report presented the results concerning effects of cognitive therapies in increasing physical activity (1), and the second report presented the results concerning effects of cognitive therapies targeting two health behaviours at the same time (2).

We have chosen to write the second and third reports as "stand-alone" documents in relation to the first report (1). This means that some chapters are very similar in all three reports. This applies particularly to the introduction, methods and parts of the discussion.

There is some disagreement in Norway about the terminology concerning the intervention in this report series. The term "cognitive therapies" commonly includes "cognitive behavioural therapies" (3), and the commission by the Norwegian Directorate of Health concerned cognitive therapies in this sense. We will use the term "cognitive therapies" throughout the text even when included studies and other literature we may refer to use the term "cognitive behavioural therapies". We are aware that researchers and practitioners may disagree with this use of terminology.

Tobacco use

Tobacco comes from native plants, e.g. *Nicotina tabacum* and *Nicotina rustica*, that have been cultivated since about 5000–3000 BC. Through history, tobacco has been sniffed, smoked, chewed, eaten, drunk, and used for medical and religious reasons. The most enduring method of administration has been smoking. Tobacco seeds were brought to Europe from the Americas in the 16th century, mainly due to beliefs in tobacco's medical properties. The first cigarettes were manufactured in England in the 1850s. Since then, cigarette smoking has spread worldwide. (4). The epidemic spread of smoking is due to a complex interaction of socio-political, technical, molecular, and agricultural factors (5).

Nicotine addiction

Smoking tobacco is addictive (as are other forms of tobacco use), and nicotine is the compound in tobacco that causes addiction. Not all smokers become nicotine dependent, but the prevalence of dependence is higher than for other substance abuse. Primary criteria for nicotine dependence are highly controlled or compulsive use, psychoactive effects, and behaviour reinforced by the drug. Additional criteria concerns addictive behaviour that may involve stereotypic patterns of use, use despite harmful effects, relapse following abstinence, and recurrent drug cravings. (6).

Health consequences of tobacco use

Smoking was one of several suggested causes of the increasing prevalence of lung cancer during the early 20th century, together with asphalt dust, industrial air pollution, exposure to poisonous gas during World War I, and the influenza pandemic of 1918–1919. From the middle decades of the 20th century, research evidence from population studies, animal experiments, cellular pathology studies, and studies of cancer-causing chemicals in cigarette smoke made it possible to establish a causal link between cigarette smoking and lung cancer (5). The United States *Surgeon General's* report of 1964 recognized smoking as a cause of lung cancer in men. Since then, 15 cancers and 22 chronic diseases have been causally linked to smoking. Further, causal links have been established between second-hand smoking and four medical conditions in children and four in adults, plus reproductive effects in women (6).

In 2013, smoking accounted for 14.5% of all deaths in Norway, primarily related to cancers, cardiovascular disease and chronic obstructive pulmonary disease (7).

International and national efforts to control tobacco use

Since 1967, international conferences have been held every two to four years to mobilize and coordinate international tobacco control efforts. The World Health Organization (WHO) has increasingly taken leadership for tobacco control activities (6). The WHO Framework Convention on Tobacco Control (FCTC), adopted by the WHO World Health Assembly in 2003, was the first international health treaty negotiated by the WHO (8). The objective of the FTCT is to "protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke by providing a framework for tobacco control measures to be implemented at the national, regional and international levels in order to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke" (8, p 5).

To support the FTCT, the WHO introduced MPOWER, a set of measures to reduce tobacco use worldwide in 2008 (9).
The measures are:

- Monitoring tobacco use and prevention policies
- Protecting people from tobacco smoke
- Offering help to quit tobacco use
- Warning about the dangers of tobacco

- Enforcing bans on tobacco advertising, promotion and sponsorship
- Raising tobacco taxes

Countries are evaluated on the degree to which these measures have been implemented in national government policies. As of 2015, more than half of the world's countries have implemented at least one of the measures at the most complete policy level. This translates to a coverage of 40% of the world's population.

Norway has implemented the MPOWER measures to a high or moderately high degree (10). The Directorate of Health is the authoritative body for implementation of government tobacco policies in Norway. Among other things, the Directorate issues national guidelines for smoking cessation, provides documentation on health risks with tobacco use, provides easy access to national policy and international commitments regarding tobacco use, and carries out national mass media campaigns against tobacco use (11).

Smoking cessation interventions targeting individuals

Interventions for smoking cessation at the individual level can broadly be described as pharmacological, non-pharmacological, or combinations of the two.

Pharmacological interventions

Pharmacological interventions include over-the-counter nicotine replacement products such as nicotine patch, -gum, -nasal spray, -inhaler, or-lozenges. Non-nicotine prescription medications include antidepressants such as bupropion and nortriptyline, nicotine receptor partial agonists such as varenicline and cysticine, and opioid antagonists such as naloxone and naltrexone. These interventions are believed to block or blunt the effects on its receptor, to relieve withdrawal, and to substitute for nicotine's effects (12). Nicotine replacement products (12, 13), and antidepressants (12, 14) aid smoking cessation. Of the nicotine receptor partial agonists, varenicline currently appears to have better quit rates than cysticine (12, 15). The evidence does not suggest that opioid antagonists help people to quit smoking (16). Adverse effects from using nicotine replacement products may involve skin irritation from patches and irritation inside the mouth from gum and tablets (13). The risks of adverse effects from using non-nicotine medications are small, but there is a known risk of seizures (about 1 per 1000 users) with bupropion (12).

Non-pharmacological interventions

Non-pharmacological interventions include advice, counselling, and behavioural therapies. These interventions can be delivered face-to-face, in groups, for instance via the internet or using mobile phones. (17). Telephone quit lines often offer counselling to help people to stop smoking (18). Interventions based on the "stages of change" model suggested by Prochaska (19) appears to be as effective as similar, non-stage based, interventions, e.g. self-help materials and counselling (20). Motivational interviewing is a brief psychotherapeutic intervention intended to help people change harmful behaviours (21). It may help people to quit smoking, although there has been considerable variation in how the intervention was delivered (22). Motivational interviewing is recommended in Norway as one of several interventions to help people quit smoking (23).

Combinations of pharmacological and non-pharmacological interventions

A systematic review that investigated combination of behavioural support and use of medication found increased smoking cessation success compared to minimal intervention or usual care (24). The most common types of behavioural support identified in the systematic review (24) were brief interventions, counselling, self-help materials and motivational interviewing. Interventions based on cognitive-behavioural principles were used in four of 53 included studies (24). Another systematic review found that increasing the intensity and/or content of behavioural support increases the chances of quitting by about 10% to 25% (25). The most common types of behavioural support were the same as in the report by Stead and co-workers from 2016 (24). Where cognitive behavioural components were included, they were usually compared to another intensity of similar content (25).

Cognitive therapies

Cognitive therapies are psychological treatments that address the interactions between thoughts, emotions, and behaviour. Cognitive therapies include several treatments and practices (26) which share fundamental propositions, e.g. that our cognitions/what we think affects what we feel and how we choose to act/behave, and that desired behaviour change may be affected through changes in our cognitions (27). A range of disorders is treated by cognitive therapies, of which the majority is psychiatric disorders, e.g. major depressive disorder, generalized anxiety disorder, panic disorder, and phobias. Psychological problems, such as couple and family problems, and medical problems with psychological components, such as chronic pain, tinnitus, and insomnia are also treated by cognitive therapies (28).

Cognitive therapies are usually limited to between 10 and 20 sessions. The interventions focus on current problems and follow a structured style including problem description, goal setting, collection of data for analysis of the problem, a specific problem formulation, development of skills relevant to the problem, and relapse prevention (26). Techniques used in cognitive therapies include, for example, Socratic questioning to understand clients' perspectives and help them work out solutions to their problems, using logs for self-monitoring of thoughts, emotions, beliefs, and behaviours, graded task assignments, graded exposure, relaxation techniques, and role-play (28).

Health personnel with a primary professional qualification other than psychology may deliver cognitive therapies given sufficient training, acquired through post-qualification courses. Roth and co-workers described a model of competences to deliver cognitive therapies, regardless of primary professional qualification, (29) which comprises:

- generic competencies in psychological therapy
    - competences needed to relate to people and to carry out any form of psychological intervention
- basic cognitive and behavioural competencies
    - basic competencies used in most cognitive therapies
- specific cognitive and behavioural therapy techniques

    - specific techniques employed in most behavioural and cognitive therapies
- problem-specific skills
    - competencies needed to deliver a treatment package for a specific problem formulation
- metacompetences
    - competences used to work across all levels and to adapt cognitive therapies to each individual patient

In Norway, the health authorities recommend cognitive therapies for a range of mental health disorders and for coping with somatic disorders (30). The Norwegian Association for Cognitive Therapy holds 2-4 semester post-qualification courses in cognitive therapies for psychologists and physicians, and for health- and social welfare personnel with a bachelor's degree.

The knowledge base of cognitive therapies

Cognitive therapies are widely researched. A review from 2012 included 269 meta-analyses published from 2000 through September 2011 (31). The authors divided the included meta-analyses into 17 disorder- or population categories. Categories with 10 or more meta-analyses were disorders in children (n=66), anxiety disorders (n=48), depression (n=35), chronic medical conditions (n=23), addictions (n=18), schizophrenia or psychosis (n=18), chronic pain or fatigue (n=15), bipolar disorder (n=10), and disorders in elderly adults (n=10). The review appeared to focus solely on "disorders" and no categories concerned lifestyle habits such as physical activity (31).

The results of recently published systematic reviews suggest that cognitive therapies are effective for the treatment of adult depressive disorders (32, 33), social anxiety disorders (34), insomnia (35, 36), chronic pain (37), and subacute and chronic neck pain (38) when compared to no treatment or usual treatment. The evidence for cognitive therapies compared to other treatment seems to be limited (1, 2, 32, 37, 38). We have not found systematic reviews covering cognitive therapies for smoking cessation.

Problem formulation for this systematic review

We carried out this systematic review to answer the question "What is the effect of cognitive therapies for smoking cessation in adults ≥ 18 years, compared to no intervention, usual care or another intervention?"

Methods

We carried out a systematic review according to the Cochrane Handbook for Systematic Reviews of Interventions (39).

Selection criteria

Study design: Systematic reviews of high quality, randomised controlled trials, and cluster-randomised controlled trials.

Population:	Adults ≥ 18 years.
Intervention:	Cognitive therapies promoting smoking cessation.
Comparison:	No intervention, usual care or other intervention.
Outcome:	Primary outcome: Abstinence rate or number of cigarettes smoked per time unit. Secondary outcomes: Relevant physiological or clinical outcomes related to tobacco use.
Language:	No restrictions in the literature search. The project group read publications in English, French, and Scandinavian languages and considered publications in other languages for translation.
Exclusion criteria	• Abstracts and other publication formats that do not convey full information from a study. • Systematic reviews published before 2009. • Systematic reviews or primary studies describing o interventions without a behavioral component o interventions that are web-based or otherwise oriented towards self-help o interventions based only on mindfulness or motivational interviewing o interventions designed to help persons cope with disease or illness.

Literature search

We searched systematically in the following electronic databases for systematic reviews:

- The Cochrane Database of Systematic Reviews (CDSR)
- Database of Abstracts of Reviews of Effects (DARE)

- MEDLINE (Ovid)
- Embase (Ovid)
- PsycINFO (Ovid)

Research librarian Gyri Hval Straumann planned and carried out the searches. We initially searched for systematic reviews, without finding relevant publications. The search strategy, presented in Appendix 2, was adapted to primary studies and searched the following electronic databases:

- MEDLINE (Ovid)
- Embase (Ovid)
- PsycINFO (Ovid)
- Central
- Cinahl

The search strategy was peer-reviewed by another research librarian. We searched simultaneously for studies evaluating effects of cognitive therapies for change of several lifestyle habits, i.e. physical activity, diet, and tobacco use. This report presents the results for studies on tobacco use. We read the reference lists of included studies in addition to searching in the electronic searches.

Study selection

Two persons (ED and VU, ED and AM) independently screened titles and abstracts. Two persons (ED and VU) independently selected studies from full text publications. We based our selection on consensus and consulted a third author (GEV) to solve disagreements.

Assessment of the quality of systematic reviews

We had planned to assess the quality of any included systematic reviews with a checklist based on the EPOC Checklist for Refereeing Protocols for Reviews (40).

Assessment of risk of bias in primary studies

We (ED and VU) independently assessed risk of bias by sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other sources of bias (41). We based our final assessment on consensus and consulted a third author (GEV) to solve disagreements.

Data extraction

We had planned to extract the following data from any systematic reviews, using a data extraction form: authors and year of publication, topic, number of relevant studies included, study design and methodological quality of included studies, number of participants in the included studies, intervention, who carried out the intervention, comparison(s), outcomes, and results.

One author (ED) extracted the following data from included primary studies, using a data extraction form: authors and year of publication, topic, study design, country, population details, intervention details, comparison(s), outcomes, and length of follow-up, attrition, descriptive dichotomous and continuous data, measures and estimates of effect. Another author (VU) verified the extracted data against the full text publications.

Analyses

We had planned to present the results reported in included systematic reviews by interventions and comparisons. We also planned to present outcomes based on length of follow-up: short-term from post intervention to six months post intervention; medium-term from more than six months to one-year post intervention; long-term, more than one-year post intervention.

In synthesizing the results from the included primary studies, we adopted a broad approach assuming that cognitive therapies are used in different populations and contexts, are of varying length and intensity, and are given by a range of health professionals. We further assumed that the generalizability and usefulness of the results would increase by synthesizing studies that covered different populations, settings and modes of delivery (42). We went through the following steps to synthesize the data: We first sorted the studies by comparison (against no intervention/usual care or other intervention) and outcome. Using the software Review Manager 5.3, (43) we then carried out random-effects meta-analyses for each outcome presenting relative risk and 95% confidence intervals.

Rating our confidence in the effect estimates

We used the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach to judge our confidence in the effect estimates for critical outcomes and comparisons within each topic. The domains rated in the GRADE approach are study limitations, indirectness, inconsistency, imprecision, publication bias, and magnitude of effect, dose-response gradient, and plausible confounding affecting confidence in estimated effects (44). ED and VU carried out the GRADE ratings together, discussing issues and arriving at consensus. We consulted a third author (GEV) to solve uncertainties.
The ratings are defined as follows:

High quality: We are very confident that the true effect is close to that of the estimate of the effect.
Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

Results

Results of the literature search

We did not identify relevant systematic reviews in the initial search. The search for primary studies in electronic databases resulted in 6538 references after duplicate control. In addition, we identified two publications by searching reference lists of included publications. From 6540 references, we excluded 6440 references judged irrelevant based on title and abstract. We selected 54 full text reports for evaluation in two parallel reviews. We evaluated 46 publications in full text for this report and excluded 25 studies based on inclusion- and exclusion criteria (Appendix, Table B1). We included 21 studies.

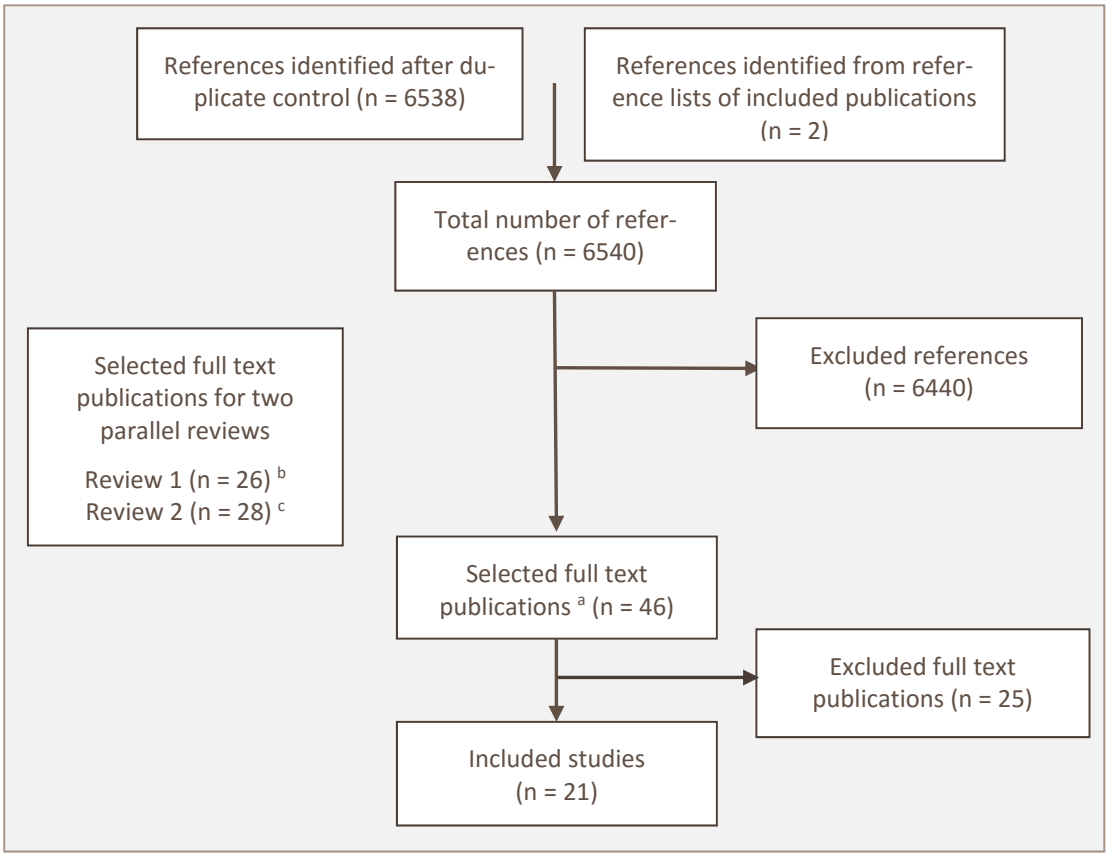

Figure 1. Flow chart of the citations reviewed in the systematic review.

[a] References relevant to the present report. [b] References relevant to a previous report on physical activity (1). [c] References relevant to a previous report on multiple health behaviours (2).

Description of the included studies

Included studies

We included 21 randomised controlled trials with 4946 participants. Sixteen studies were from the USA, and the remaining five studies were from Canada, China, Germany, Greece, and The Netherlands. Ten studies included adult smokers. Six studies included persons with acute myocardial infarction, peripheral artery disease, spontaneous pneumothorax (collapsed lung), clinically significant depressive symptoms, persons who had been in hospital for at least two days, and persons who were patients in primary care. Two studies included persons from specific ethnic groups, i.e. Korean Americans and African Americans. Finally, one study each included inmates, pregnant women, and women only. Most interventions included one or more of the following cognitive or cognitive-behavioural content, in order of frequency: relapse prevention, coping skills, self-management, self-efficacy, social support, cognitive restructuring, problem solving, motivational interview, stress management, and rearrangement of environment-person interaction. One study evaluated interventions based on an acceptance and commitment approach, and one study focused on environment-person interactions. Most studies used individual counselling. Biochemically validated abstinence rate was the primary outcome in all studies but three. Length of follow-up ranged from end of intervention to 12 months after the end of the intervention/quit date with a median value of 6 months after the end of the intervention (Table 1).

Table 1. General description of the included studies, ordered by comparison.

Study ID; country	Population	Intervention content	Comparison	Primary outcome	Length of follow-up
Cognitive therapies compared to usual care or minimal intervention					
Dornelas (45); USA	Adults mean age 55 with acute myocardial infarction; N = 100	Combination of motivational interview and relapse prevention	Minimal intervention	Abstinence, validated by family member	6 months after the end of the intervention.
McCarthy (46); USA	Adults ≥18; N = 463	Coping skills development; relapse prevention	Minimal intervention	Abstinence, biochemically validated	12 months after the quit date
Reitzel (47); USA	Pregnant women ≥ 18; N = 251	Motivation and problem-solving skills development	Usual care	Abstinence, biochemically validated	2 months after the end of the intervention
Cognitive therapies combined with NRT compared to other interventions combined with NRT					
Alterman (48); USA	Adults 21-65; N = 240	NRT + self-monitoring; coping skills development; self-efficacy; relapse prevention	NRT + Advice	Abstinence, biochemically validated	9 months after the end of the intervention
Hall (49); USA	Adults ≥50; N = 402	NRT + standard treatment + self-	NRT + standard treatment + extended NRT	Abstinence, biochemically validated	End of intervention

		management; social support; relapse prevention			
Kim (50); USA	Korean American adults ≥18; N = 30	NRT + culturally tailored self-efficacy; coping skills development; relapse prevention	NRT + counselling on medication management	Abstinence, biochemically validated	6 months after the quit date
Lifrak (51); USA	Adults 21-65; N = 69	NRT + self-monitoring; coping skills development; stress management; self-efficacy; relapse prevention	NRT + Advice	Abstinence, biochemically validated	6 months after the end of the intervention
Prapavessis (52); Canada	Inactive adult women 18-62; N = 142	NRT + Coping skills development	NRT + Exercise	Abstinence, biochemically validated	12 months after the quit date
Simon (53); USA	Adults mean age 55 hospitalized at least 2 days; N = 223	NRT + self-management; relapse prevention	NRT + minimal contact	Abstinence, biochemically validated	8 months after the end of the intervention
Smith (54); USA	Adults ≥18; N = 677	NRT + cognitive restructuring; coping strategies; relapse prevention	NRT + advice	Abstinence, biochemically validated	12 months after the quit date
Webb (55); USA	African-American adults 18-65; N = 154	NRT + self-management; relapse prevention	NRT + general health education	Abstinence, biochemically validated	6 months after the end of the intervention
Cognitive therapies compared to other interventions					
Chen (56); China	Adults ≥18; N = 190	5 A's approach: ask, advice, assess, assist, arrange; based on social cognitive theory	Advice	Abstinence, biochemically validated	End of intervention
Clarke (57); USA	Adult inmates ≥18; N = 262	Coping skills	Health education	Abstinence, biochemically validated	3 weeks after release from prison
Hennrikus (58); USA	Adults ≥18 with peripheral artery disease; N = 124	Motivational interview; problem solving; coping strategies; social support	Advice	Abstinence, biochemically validated	End of intervention
Prapavessis (52); Canada	Inactive adult women 18-62; N = 142	Coping skills development	Exercise	Abstinence, biochemically validated	12 months after the quit date
Schleicher (59); USA	College students ≥18 with clinically significant depressive symptoms; N = 58	Cognitive restructuring; self-management; relapse prevention	Diet education	Abstinence, unclear if biochemically validated	1 month after the end of the intervention

Wittchen (60); Germany	Adults ≥ 18 in primary care; N = 467	Self-management; relapse prevention	Advice	Abstinence, not biochemically validated	9 months after the end of the intervention
Cognitive therapies combined with medication compared to medication only					
Gifford (61); USA	Adults 18-75; N = 303	Medication + development of acceptance and mindfulness skills	Medication	Abstinence, biochemically validated	9.5 months after the end of the intervention
Hall (62); USA	Adults ≥18; N = 407	NRT + Medication + standard treatment + self-management; social support; relapse prevention	NRT + Medication + standard treatment	Abstinence, biochemically validated	End of intervention
McCarthy (46); USA	Adults ≥18; N = 463	Medication + Coping skills development; relapse prevention	Medication	Abstinence, biochemically validated	12 months after the quit date
Roozen (63); The Netherlands	Adults 18-65 recovered from spontaneous pneumothorax; N = 25	Medication + focus on environment-organism interactions to rearrange substance abusing lifestyle	Medication	Abstinence, biochemically validated	3 months after the end of the intervention
Rovina (64); Greece	Adults ≥ 18; N = 205	Medication + cognitive restructuring	Medication	Abstinence, biochemically validated	12 months after the end of the intervention
Cognitive therapies combined with medication compared to supportive therapy combined with medication					
Schmitz (65); USA	Adult women 30-70; N = 154	Medication + coping skills development; relapse prevention	Medication + supportive therapy	Abstinence, biochemically validated	12 months after the end of the intervention

NRT = Nicotine replacement therapy.

Participants

We describe the participants in each study further in the Appendix, Table C1. The mean age of the participants ranged between 21 and 60 years with a mean age across studies of 43.5 years. Three studies included only women. There was a mean of 38% women across the remaining studies, with a range of 3% to 62%. Seventeen studies reported the ethnicity of the participants. The mean percentage of participants reported as Caucasian across 15 studies was 76%, with a range of 36% to 100%. One study included only Korean immigrants in USA, and one study included only African Americans. Mean length of education, reported in five studies, was 14 years. The percentage of participants who had high school education or more, reported in seven studies varied between 15% and 95%, with a median value 75%. The percentage of participants who had college education or more, reported in five studies, varied between 9% and 100% with a median value of 45%. Thirteen studies reported civil status of the participants;

the mean percentage living with a partner or married was 48.5% with a range of 32% to 77%.

Interventions and comparisons

We identified five comparisons among the included studies, shown in Table 2.

Table 2. The comparisons identified among the included studies.

Comparison number	Intervention	Comparison	Number of studies/ participants[a]
1	Cognitive therapy	Usual care/minimal intervention	3/585
2	Cognitive therapy + NRT	Other interventions + NRT	8/1309
3	Cognitive therapy	Other interventions	6/850
4	Cognitive therapy + medication[b]	Medication[b]	5/673
5	Cognitive therapy + medication[c]	Supportive therapy + medication[c]	1/71

[a] Number of participants that were reported in the studies' results sections; [b] Bupropion in four studies, Naltrexone in one study; [c] Bupropion; NRT = nicotine replacement therapy.

In Comparison 1, three studies compared cognitive therapies to usual care or minimal intervention. The intervention was given in an individual format in all three studies. The duration of the intervention was five, 18, and 24 weeks, respectively. The frequency of intervention sessions was 2-3 per week. Session length varied between 10 and 20 minutes. A psychologist gave the intervention in one study, while master or doctoral level counsellors gave the intervention in another study. One study did not report profession. Motivational interviewing, problem solving, and relapse prevention were the most common elements across studies. See Appendix, Table C2 for details of each study.

In Comparison 2, eight studies compared cognitive therapies to other interventions when both the intervention group and the comparison group also received nicotine replacement therapy. The intervention was given individually in four studies and in a group format in four studies. The duration of the intervention ranged from two weeks to 40 weeks, with a median value of 12 weeks. The frequency of intervention sessions ranged from six sessions in two weeks to 11 sessions in 40 weeks. Session length varied between 30 minutes and 90 minutes. There was large variation in who gave the intervention in the included studies: "therapists", a trained clinician, nurse practitioner and social worker, trained nurse or public health educator, doctoral graduate students in psychology, and a psychologist. Motivation to quit by using decision balance charts, development of skills to deal with craving, and relapse prevention were common elements across the studies. See Appendix, Table C2 for details of each study.

In Comparison 3, six studies compared cognitive therapies to other interventions. The intervention was given individually in three studies and in a group format in two studies. One study did not report format of the intervention. The duration of the intervention ranged from six weeks to 24 weeks, with a median value 12 weeks. The frequency

of intervention sessions ranged from one per week to one per month. Session length varied between 10 minutes and 120 minutes. Trained physicians, counsellors or research assistants, or graduate students in psychology gave the interventions. Motivational interviewing, coping skills, self-management, and relapse prevention were common elements across the studies. See Appendix, Table C2 for details of each study.

In Comparison 4, five studies compared cognitive therapies to advice when both the intervention group and the comparison group also received medication treatment with bupropion or naltrexone. The intervention was given in a combined individual and group format in two studies, individually in two studies, and in a group format in one study. The duration of the intervention ranged from five weeks to 40 weeks, with a median value of 10 weeks. The frequency of intervention sessions ranged from two per week to one per month. Session length varied between 10 minutes and 60 minutes (two studies did not report session length). "Therapists", psychology students, and specialized psychologists gave the intervention. The studies had somewhat different interventional approaches: one was based on acceptance and commitment therapy, one focused on environmental aspects, one focused on thoughts, beliefs, and attitudes to smoking, and two studies focused on motivational aspects, social interaction, and development of skills to deal with craving. See Appendix, Table C2 for details of each study.

In Comparison 5, one study compared cognitive therapy to supportive therapy when both the intervention group and the comparison group also received medication treatment with bupropion. The intervention was given in a group format. It lasted for seven weeks, with once-weekly 60 minutes sessions. See Appendix, Table C2 for details of the study.

Outcomes

The primary outcome in all included studies was smoking abstinence. A majority of the studies measured seven-day self-reported abstinence prior to follow-up, validated by biochemical analysis of exhaled carbon monoxide and/or cotinine in urine, saliva or serum. Three studies did not use biochemical validation of self-reported abstinence. One of these studies used validation by a family member, another study informed the participants that biochemical validation of self-reported abstinence would be used, but it is unclear whether it was actually carried out. See Appendix, Table C3 for details of each study.

Few studies reported secondary outcomes, as defined by our inclusion criteria. One study reported airway obstruction (56), one study reported weight (52), and two studies reported adverse events (64, 65).

Risk of bias in the included studies

We judged 18 studies to have an unclear risk of bias, two studies to have a low risk of bias, and one study to have a high risk of bias (Figure 2). The rating of "unclear" was primarily due to lack of information concerning random sequence generation

and allocation concealment, and to uncertainty of consequences of non-blinding of participants and personnel and outcome assessment (41). Figure 2 shows our rating in each domain by study. Appendix D, Table D1, presents support for our judgments of risk of bias for each study.

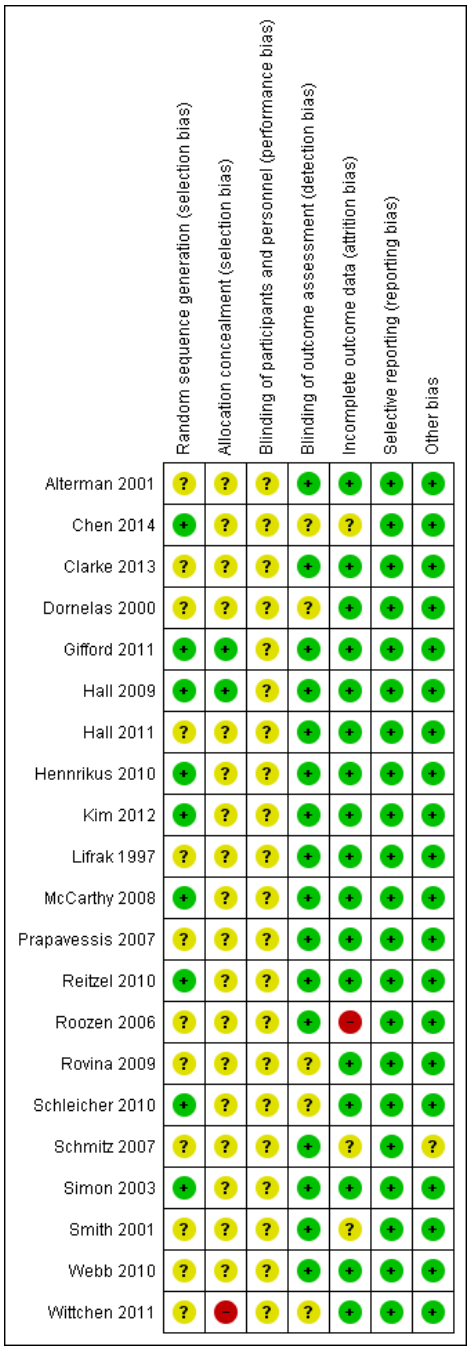

Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

Effects of cognitive therapies compared to usual care or minimal intervention

Figure 3 shows the results for the three studies that compared the intervention to usual care or minimal intervention on smoking abstinence rate.

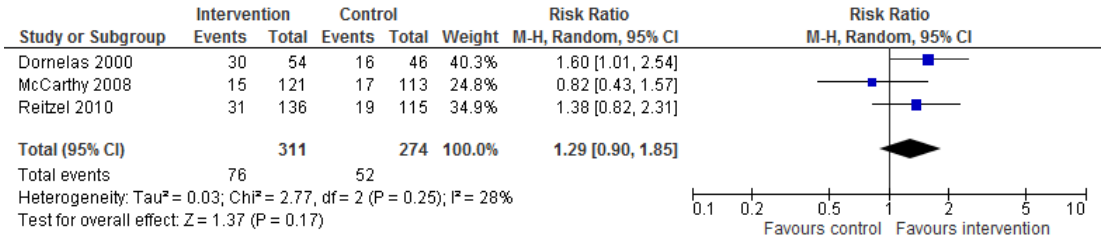

Figure 3. Effects of cognitive therapies compared to usual care or minimal intervention on smoking abstinence rate. CI = Confidence interval.

Table 3 presents the effect estimate shown in Figure 3 along with our GRADE assessment concerning the quality of the documentation. The GRADE evidence profile is presented in the Appendix, Table E1.

Uncertainty introduced by unclear risk of bias in three studies resulted in downgrading. The studies were small with few events and wide confidence intervals, which further reduced our confidence in the results.

Table 3. Summary of findings table and documentation for effects of cognitive therapies compared to usual care or minimal intervention on smoking abstinence rate.

Cognitive therapies compared to usual care for smoking cessation

Patient or population: Persons who may benefit from change of lifestyle habits
Setting: Primary health care
Intervention: Cognitive therapies
Comparison: Usual care

Outcomes	Anticipated absolute effects (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with usual care	Risk with cognitive therapies				
Abstinence rate, assessed with: self-report and biochemical validation follow-up: 6 to 12 months	190 per 1000	**245 per 1000** (171 to 351)	**RR 1.29** (0.90 to 1.85)	585 (3 RCTs)	⊕⊕OO LOW [1,2]	

CI: Confidence interval; **RR:** Risk ratio

GRADE Working Group grades of evidence
High quality: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

1. Overall unclear risk of bias
2. Confidence interval includes both negative effect and large effect.

We judged the quality of the documentation to be low. A low rating of the quality of the documentation indicates that our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

We found that:

- Cognitive therapies may have a similar effect as usual care or minimal intervention on smoking abstinence rate, six to 12 months after the end of the intervention.

Effects of cognitive therapies combined with nicotine replacement therapy compared to other interventions combined with nicotine replacement therapy

Figure 4 shows the results for the eight studies that compared cognitive therapies combined with nicotine replacement therapy compared to other interventions combined with nicotine replacement therapy.

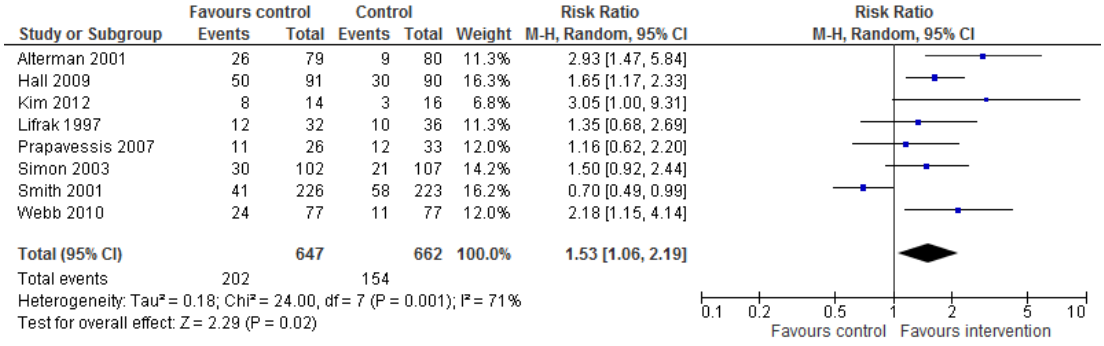

Figure 4. Effect of cognitive therapies combined with NRT compared to other interventions combined with NRT on smoking abstinence rate. CI = Confidence interval.

Table 4 presents the effect estimate shown in Figure 4 along with our GRADE assessment concerning the quality of the documentation. The GRADE evidence profile is presented in the Appendix, Table E2.

Uncertainty introduced by unclear risk of bias in all studies but one resulted in downgrading. In addition, heterogeneity in the results further reduced our confidence in the effect estimate.

Table 4. Summary of findings table and documentation for effects of cognitive combined with NRT compared to other interventions combined with NRT on smoking abstinence rate.

Cognitive therapies combined with NRT compared to other interventions combined with NRT for smoking cessation

Patient or population: Persons who may benefit from change of lifestyle habits
Setting: Primary health care
Intervention: Cognitive therapies combined with NRT
Comparison: Other interventions combined with NRT

Outcomes	Anticipated absolute effects (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with other interventions combined with NRT	Risk with cognitive therapies combined with NRT				
Abstinence rate assessed with: self-report and biochemical validation follow up: 0 to 12 months	233 per 1000	**356 per 1000** (247 to 509)	**RR 1.53** (1.06 to 2.19)	1309 (8 RCTs)	⨁⨁◯◯ LOW [1,2]	

CI: Confidence interval; **RR:** Risk ratio

1. Overall unclear risk of bias.
2. I-square 75%, one study with non-overlapping confidence interval.

We judged the quality of the documentation to be low. A low rating of the quality of the documentation indicates that our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

We found that:

- Cognitive therapies combined with nicotine replacement therapy may give a higher smoking abstinence rate as compared to other interventions combined with nicotine replacement therapy, up to 12 months after the end of the intervention.

Effects of cognitive therapies compared to other interventions

Figure 5 presents the results for the six studies that compared cognitive therapies with other interventions (e.g. advice, exercise, health education).

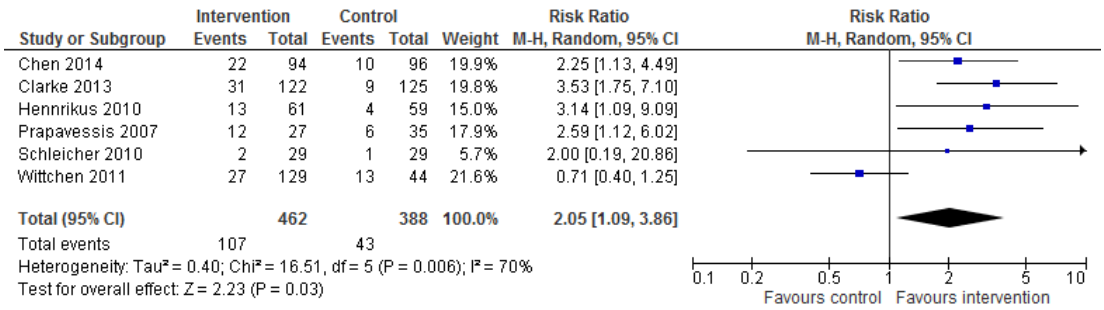

Figure 5. Effect of cognitive therapies compared to other interventions on smoking abstinence rate. CI = Confidence interval.

Table 5 presents the effect estimate shown in Figure 5 along with our GRADE assessment concerning the quality of the documentation. The GRADE evidence profile is presented in the Appendix, Table E3.

Uncertainty introduced by unclear risk of bias in all studies but one resulted in downgrading. In addition, heterogeneity in the results further reduced our confidence in the effect estimate.

Table 5. Summary of findings table and documentation for effects of cognitive therapies compared to other interventions on smoking abstinence rate

Cognitive therapies compared to other interventions for smoking cessation

Patient or population: Persons who may benefit from change of lifestyle habits
Setting: Primary health care
Intervention: Cognitive therapies
Comparison: Other interventions

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with other interventions	Risk with cognitive therapies				
Abstinence rate assessed with: self-report with biochemical validation follow up 0 to 12 months	111 per 1000	**227 per 1000** (121 to 428)	**RR 2.05** (1.09 to 3.85)	850 (6 RCTs)	⨁⨁◯◯ LOW [1,2]	

CI: Confidence interval; **RR:** Risk ratio

1. Overall unclear risk of bias.
2. I-square 75%, one study with non-overlapping confidence interval.

We judged the quality of the documentation of effect to be low. A low rating of the quality of the documentation indicates that our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

We found that:

- Cognitive therapies may give a higher smoking abstinence rate as compared to other interventions, up to 12 months after the end of the intervention.

Effects of cognitive therapies combined with medication compared to medication only

Figure 6 presents the results for the five studies that compared cognitive therapies combined with medication compared to medication only.

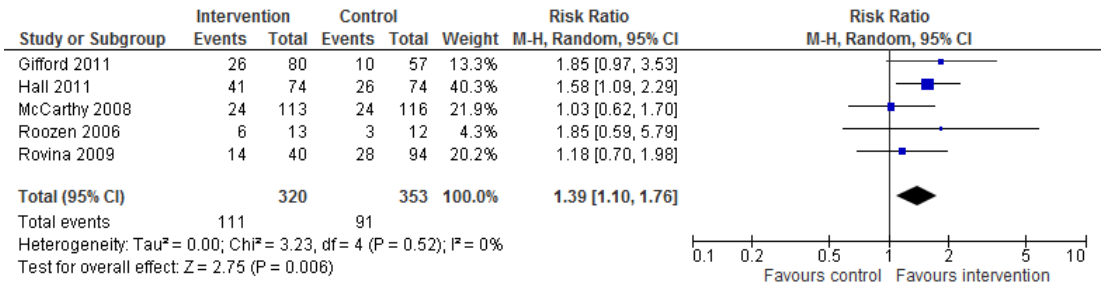

Figure 6. Effect of cognitive therapies combined with medication compared to medication only on smoking abstinence rate. CI = Confidence interval.

Table 6 presents the effect estimate shown in Figure 5 along with our GRADE assessment concerning the quality of the documentation. The GRADE evidence profile is presented in the Appendix, Table E4.

Uncertainty introduced by unclear risk of bias in four studies resulted in downgrading.

Table 6. Summary of findings table and documentation for effects of cognitive combined with medication compared to medication only on smoking abstinence rate.

Cognitive therapies combined with medication compared to medication only for smoking cessation

Patient or population: Persons who may benefit from change of lifestyle habits
Setting: Primary health care
Intervention: Cognitive therapies added to medication
Comparison: Medication

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with medication	Risk with cognitive therapies combined with medication				
Abstinence rate assessed with: Self-report with biochemical validation follow up: 0 to 12 months	258 per 1000	**358 per 1000** (284 to 454)	**RR 1.39** (1.10 to 1.76)	673 (5 RCTs)	⊕⊕⊕O MODERATE [1]	

CI: Confidence interval; **RR:** Risk ratio

1. Overall unclear risk of bias.

We judged the quality of the documentation of effect to be moderate. A moderate rating indicates our assessment that the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

We found that:

- Cognitive therapies probably improve smoking abstinence rates somewhat when combined with medication, as compared to medication only, up to 12 months after the end of the intervention.

Effects of cognitive therapy combined with medication compared to supportive therapy combined with medication

Table 7 presents the results for the one study that compared cognitive therapy combined with medication to supportive therapy combined with medication (65) along with our GRADE assessment concerning the quality of the documentation. The GRADE evidence profile is presented in the Appendix, Table E5.

Uncertainty introduced by unclear risk of bias resulted in downgrading. In addition, there was only one small study with female participants, and a wide confidence interval, which further reduced our confidence in the effect estimate.

Table 7. Summary of findings table and documentation for effects of cognitive therapy combined with medication compared to supportive therapy combined with medication.

Cognitive therapy combined with medication compared to supportive therapy combined with medication for smoking cessation

Patient or population: Persons who may benefit from change of lifestyle habits
Setting: Primary health care
Intervention: Cognitive therapy added to medication
Comparison: Supportive therapy added to medication

Outcomes	**Anticipated absolute effects** (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with supportive therapy combined with medication	**Risk with cognitive therapy combined with medication**				
Abstinence rate assessed with: self-report with biochemical validation follow up:12 months	28 per 1 000	**171 per 1 000** (22 to 1 000)	**RR 6.17** (0.78 to 48.68)	71 (1 RCT)	⨁◯◯◯ VERY LOW 1,2,3	

CI: Confidence interval; **RR:** Risk ratio

1. Unclear risk of bias
2.. One small study with 71 participants, 95% CI includes both negative effect and very large effect.

We judged the quality of the documentation of effect to be very low. This indicates that we have very little confidence in the effect estimate. Hence, we assume that the true effect can be substantially different from the estimate of effect.

We found that:

- We are uncertain whether cognitive therapy combined with medication changes smoking abstinence rate as compared to supportive therapy combined with medication, 12 months after the quit date.

Discussion

Main findings

The main findings in this systematic review were that cognitive therapies:

- combined with medication probably improve smoking abstinence rates somewhat as compared to medication only, up to 12 months after the end of the intervention,
- combined with nicotine replacement therapy may improve smoking abstinence rates somewhat as compared to other interventions combined with nicotine replacement therapy, up to 12 months after the end of the intervention,
- may improve smoking abstinence rates as compared to other interventions, up to 12 months after the end of the intervention,
- may have a similar effect as usual care or minimal intervention on smoking abstinence rates, six to 12 months after the end of the intervention.

We are uncertain whether cognitive therapy combined with medication changes smoking abstinence rates as compared to supportive therapy combined with medication, 12 months after the quit date.

The quality of the documentation

We included 21 randomised controlled trials including 4 946 participants. We judged 18 studies to have an unclear risk of bias, two to have a low risk of bias, and one study to have a high risk of bias. Twelve studies had insufficient information concerning the random sequence generation and 18 studies did not report how allocation to study groups was concealed. This introduced uncertainty about selection bias in the included studies. All studies but three used biochemical validation of self-reported smoking by exhaled carbon monoxide and/or cotinine in urine, saliva or serum. The trials were small and there were several outcomes with wide confidence intervals.

Strengths and limitations of this systematic review

Systematic reviews seek to answer specific questions; they have clear inclusion criteria, and the methods are described *a priori* in a protocol for transparency. They are based on systematic literature searches in electronic databases and other relevant sources, and describe the uncertainty of the summarized results. The methodology, including independent study selection and assessment of risk of bias by two or more researchers,

ensures that a body of evidence is summarized in a systematic and unbiased way. Potential limitations are the possibility that not all relevant studies are identified by the literature search, because of the search strategy, or because they were not published at the time of the search. Another limitation is that systematic reviews go out of date unless regularly updated.

The studies included in this systematic review are all randomised controlled trials. This is the preferred study design to answer research questions about effects of interventions.

Regardless of whether data from studies included in a systematic review are summarized descriptively or statistically (by meta-analysis), the results may be affected by how the studies are sorted in preparing the synthesis. In systematic reviews of effect of interventions studies are most commonly sorted by comparison, e.g., whether the intervention is compared to no intervention, usual care, or another intervention. A complicating factor in the present review was that two-thirds of the studies used nicotine replacement therapy or medication as part of the intervention or control condition. Trying to create as "clean" comparison groups as possible with regard to non-pharmacological and pharmacological intervention and control conditions, we ended up with seven comparisons, three of which included only one study. One of our external peer reviewers questioned our approach to organizing our comparisons. He suggested that we combine some of the comparisons. Following his advice, we reduced the number of comparisons to five, now with only one comparison containing only one study. This resulted in one changed conclusion, relative to our original synthesis approach.

How applicable are the results?

The question we aimed to answer in this systematic review was "What is the effect of cognitive therapies on smoking cessation?" We summarized the results across different populations and contexts, varying length and intensity of the intervention, different comparisons, and a range of health professionals.

One potential limitation, that is more relevant to the selection of participants than to the study design *per se*, is the exclusion of persons whose medical or mental condition may limit their benefit from the intervention or confound the results. Similar to our previous reports in cognitive therapies for behavioural change (1, 2), we commonly found exclusion criteria related to medical and psychiatric co-morbidity. In addition, abuse of, or dependence on, other substances (e.g. alcohol, opioids, and illicit drugs) was a common exclusion criterion.

This review identified some of the same factors limiting the applicability that we documented in our previous reports (1, 2). These include extensive exclusion criteria regarding co-morbidity, probably leading to under-representation of persons with co-morbidities, and possible under-representation of persons of Non-Western origin and persons with a low education level. Contrary to the previous reports (1, 2), we did not detect problems related to measurement of the outcome to the same degree. Although

smoking abstinence was measured by self-report, almost all studies used biochemical analyses to validate the reports. Most studies reported abstinence seven days prior to follow-up. Thus, the documentation reflects a more homogeneous approach to measurement of smoking abstinence than measurement of physical activity and dietary habits identified in our previous reports (1, 2). Issues of importance for improvement of smoking abstinence measurement include standardization of the period (e.g. sustained since quit-date, seven days prior to follow-up, at follow-up), and standardization of cut-off levels to identify regular smokers by biochemical analyses (66).

As documented in the previous two reports (1, 2), the findings were surprisingly homogeneous in spite of considerable variation in duration and frequency of the intervention and the profession of those who delivered the intervention. In addition, basic elements of cognitive therapies were included in the interventions, e.g. relapse prevention, coping skills, self-management, self-efficacy, social support, cognitive restructuring, and problem solving.

Agreement with other systematic reviews

We did not identify systematic reviews that could answer our research question through our systematic literature search. However, several systematic reviews address effects of interventions on smoking abstinence that fall in the categories of counselling and psychotherapy. Lindson-Hawley and co-workers (22) found that motivational interviewing might help people to quit smoking as compared to brief advice or usual care. We found that cognitive therapies might have a similar effect as usual care or minimal intervention. Cahill and co-workers (20) found that interventions based on the "stages of change" model appears to be as effective as similar, non-stage based, interventions. We found that cognitive therapies may change smoking abstinence rate as compared to other interventions. Stead and co-workers (24) found that combined pharmacotherapy and behavioural interventions increase smoking cessation success compared to minimal intervention or usual care. We found that cognitive therapies combined with medication probably improves smoking abstinence rates as compared to medication only. We also found that cognitive therapies combined with nicotine replacement therapy might improve smoking abstinence somewhat as compared to advice combined with nicotine replacement therapy.

Implications for practice

Our findings suggest that cognitive therapies targeting smoking cessation may increase smoking abstinence rates somewhat when used in combination with nicotine replacement therapy or medication such as bupropion.

Most studies included basic elements of cognitive therapies such as relapse prevention, coping skills, self-management, self-efficacy, social support, cognitive restructuring, and problem solving.

Psychologists, specialized psychologists, doctoral graduate students in psychology, graduate students in psychology, psychology students, trained counsellors, and trained health professionals gave the interventions. Associations between therapist competence and outcomes of cognitive therapies appear to be little explored (67). However, the training and competence to deliver an intervention as intended may be a more important issue than the label of the profession. Competence includes the ability to establish a therapeutic relationship, to provide basic and specific treatment, and to work with specific populations, e.g. ethnic minorities or patient groups (29, 67). It seems that psychologists of varying length of education, and counsellors have given the intervention in most studies. It is plausible that those who delivered the intervention in the included studies had more training than can be expected in routine care.

Costs of implementing such an intervention in practice will be dependent on both the level of competency required to deliver it and the extent of treatment chosen. The findings in this systematic review cannot give answers to questions about costs.

Evidence-based health services entail integration of research-based knowledge with clinical expertise and patient values while also taking into account contextual factors. The findings in this systematic review should therefore be seen in conjunction with experience-based knowledge, client knowledge, and the context before making a decision about the intervention.

Research gaps

We report effects of cognitive therapies targeting smoking cessation in adults 18 years or older. All included studies were randomised controlled trials and comprised adult smokers, and several patient groups. The interventions were carried out in a group or individual format to a similar extent. The length of the interventions varied between two weeks and 52 weeks. The content of the interventions reflect basic elements of cognitive and cognitive behavioural therapies.

We identified the following research gaps:

- None of the studies directly compared cognitive therapies to pharmacological treatment.
- Only one study directly compared cognitive therapy to treatment with exercise.
- Only two studies measured sustained abstinence from intervention/quit date to follow up.

Uncertainty regarding the documentation as such included 1) small trials and outcomes with few events, resulting in wide confidence intervals, and 2) overall poor reporting of procedures for random sequence generation and allocation concealment, resulting in uncertainty about selection bias in the included studies.

Implications for future research:

- Direct comparison with pharmacological treatment and other active interventions such as exercise is needed.

- Future studies may benefit from standardization of follow-up periods (e.g. sustained since quit-date, seven days prior to follow-up, at follow-up), and cut-off levels to identify regular smokers by biochemical analyses as suggested by Connor-Gorber and co-workers (66).

Future studies will need to ensure adequate power to improve the precision of the results. Adherence to CONSORT 2010 Guidelines (68) on reporting of randomized controlled trials is essential to prevent uncertainty concerning risk of bias. This especially applies to reporting of procedures for random sequence generation and allocation concealment.

Conclusion

Cognitive therapies combined with medication probably improve smoking abstinence rates somewhat as compared to medication only. Cognitive therapies combined with nicotine replacement therapy may improve smoking abstinence somewhat as compared to other interventions combined with nicotine replacement therapy. Cognitive may improve smoking abstinence rates as compared to other interventions. Cognitive therapies may have a similar effect as usual care or minimal intervention on smoking abstinence rate.

We are uncertain whether cognitive therapy combined with medication changes smoking abstinence rate as compared to supportive therapy combined with medication.

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Appendix

A. Search strategy

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) 1946 to Present
Search dates: 21.01.2015; 10.11.2016.

1 exp Life Style/ (72713)
2 exp Attitude to Health/ (334568)
3 Health Behavior/ (39668)
4 exp "tobacco use"/ (131734)
5 exp food habits/ (27313)
6 motor activity/ (87607)
7 exp sports/ (146409)
8 exp physical fitness/ (24049)
9 ((life adj style*) or lifestyle* or (health* adj3 (behavio* or attitude*)) or nutrit* or diet* or food* of feed* or eating or meal or meals or (physical* adj3 (exercis* or activ* or fitness)) or running or jogging or swimming or walking or skiing or cycling or climbing or smok* or tobacco* or cigarette*).ti,ab. (1171572)
10 or/1-9 (1677282)
11 Cognitive Therapy/ (18881)
12 (((cognitive or metacognitive or "acceptance and commitment" or mindfulness) adj3 (therap* or treatment*)) or (third adj wave) or cbt).ti,ab. (21320)
13 cognitive method*.ti,ab. (86)
14 cognitive approach*.ti,ab. (474)
15 or/11-14 (30687)
16 10 and 15 (6294)
17 randomized controlled trial.pt. (419601)
18 controlled clinical trial.pt. (90951)
19 random*.mp. (1024672)
20 (trial or effect).ti. (908946)
21 or/17-20 (1832124)
22 16 and 21 (2596)
23 (2005* or 2006* or 2007* or 2008* or 2009* or 2010* or 2011* or 2012* or 2013* or 2014* or 2015*).dp,ed,yr. (10667000)
24 22 and 23 (2089)

Database: Embase 1974 to 2015 January 21
Search dates: 22.01.2015; 10.11.2016.

1 lifestyle/ (84077)
2 attitude to health/ (88855)
3 health behavior/ (49903)
4 smoking/ (218061)
5 smoking cessation/ (43646)
6 exp feeding behavior/ (140549)

7 physical activity/ (98860)
8 exp sport/ (117791)
9 fitness/ (32426)
10 ((life adj style*) or lifestyle* or (health* adj3 (behavio* or attitude*)) or nutrit* or diet* or food* of feed* or eating or meal or meals or (physical* adj3 (exercis* or activ* or fitness)) or smok* or tobacco* or cigarette*).ti,ab. (1306639)
11 or/1-10 (1679644)
12 exp cognitive therapy/ (40217)
13 (((cognitive or metacognitive or "acceptance and commitment" or mindfulness) adj3 (therap* or treatment*)) or (third adj wave) or cbt).ti,ab. (31912)
14 cognitive approach*.ti,ab. (666)
15 cognitive method*.ti,ab. (137)
16 or/12-15 (53550)
17 randomized controlled trial/ (397419)
18 controlled study/ (4826117)
19 random*.mp. (1227798)
20 (trial or effect).ti. (1095944)
21 or/17-20 (6205218)
22 10 and 16 and 21 (2170)
23 (2010* or 2011* or 2012* or 2013* or 2014* or 2015*).dd,dp,yr. (9081521)
24 22 and 23 (1325)

Database: PsycINFO 1806 to January Week 4 2015
Search dates: 22.01.2015; 10.11.2016.
1 exp lifestyle/ (9547)
2 health attitudes/ (8976)
3 health behavior/ (20406)
4 tobacco smoking/ (25908)
5 smoking cessation/ (10628)
6 eating behavior/ (9233)
7 physical activity/ (12759)
8 exp sports/ (20158)
9 exp PHYSICAL FITNESS/ (3569)
10 ((life adj style*) or lifestyle* or (health* adj3 (behavio* or attitude*)) or nutrit* or diet* or food* of feed* or eating or meal or meals or (physical* adj3 (exercis* or activ* or fitness)) or running or jogging or swimming or walking or skiing or cycling or climb-ing or smok* or tobacco* or cigarette*).ti,ab. (218315)
11 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 (250241)
12 exp cognitive behavior therapy/ (14743)
13 (((cognitive or metacognitive or "acceptance and commitment" or mindfulness) adj3 (therap* or treatment*)) or (third adj wave) or cbt).ti,ab. (32203)
14 cognitive method*.ti,ab. (224)
15 cognitive approach*.ti,ab. (2225)
16 12 or 13 or 14 or 15 (37089)
17 11 and 16 (3189)
18 control:.tw. (551728)
19 random:.tw. (151568)
20 exp treatment/ (644895)
21 18 or 19 or 20 (1168682)
22 17 and 21 (2829)

Database: Central

Search dates: 22.01.2015; 10.11.2016.

#1	MeSH descriptor: [Life Style] explode all trees	3540
#2	MeSH descriptor: [Attitude to Health] explode all trees	29503
#3	MeSH descriptor: [Health Behavior] explode all trees	17682
#4	MeSH descriptor: [Smoking Cessation] explode all trees	100
#5	MeSH descriptor: [Smoking] explode all trees	136
#6	MeSH descriptor: [Food Habits] explode all trees	2000
#7	MeSH descriptor: [Motor Activity] explode all trees	19602
#8	MeSH descriptor: [Sports] explode all trees	123973
#9	MeSH descriptor: [Physical Fitness] explode all trees	54522
#10	((life next style*) or lifestyle* or (health* near/3 (behavio* or attitude*)) or nutrit* or diet* or food* of feed* or eating or meal or meals or (physical* near/3 (exercis* or activ* or fitness)) or smok* or tobacco* or cigarette*)	6337
#11	#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10	13669
#12	MeSH descriptor: [Cognitive Therapy] explode all trees	93
#13	(((cognitive or metacognitive or "acceptance and commitment" or mindfulness) near/3 (therap* or treatment*)) or (third adj wave) or cbt)	11768
#14	cognitive next (method* or approach*)	11768
#15	MeSH descriptor: [Sports] explode all trees	2446
#16	MeSH descriptor: [Physical Fitness] explode all trees	153875
#17	#12 or #13 or #14 or #15 or #16	13804
#18	#11 and #17 in Trials	2489

Database: Cinahl

Search dates: 22.01.2015; 10.11.2016.

S30	S17 AND S21 AND S28 Limiters - Exclude MEDLINE records	111
S29	S17 AND S21 AND S28	735
S28	S22 OR S23 OR S24 OR S25 OR S26 OR S27	195,853
S27	TI random* OR AB random*	124,876
S26	(MH "Intervention Trials")	5,925
S25	(MH "Clinical Trials")	84,174
S24	(MH "Randomized Controlled Trials")	25,467
S23	PT clinical trial	52,808
S22	PT randomized controlled trial	30,658

S21	S18 OR S19 OR S20	11,637
S20	TI (cognitive W0 (method* or approach*)) OR AB (cognitive W0 (method* or approach*))	140
S19	TI ((((cognitive or metacognitive or "acceptance and commitment" or mindfulness) N3 (therap* or treatment*)) or (third adj wave) or cbt)) OR AB ((((cognitive or metacognitive or "acceptance and commitment" or mindfulness) N3 (therap* or treatment*)) or (third adj wave) or cbt))	5,868
S18	(MH "Cognitive Therapy+")	8,996
S17	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16	490,440
S16	(MH "Attitude to Health")	18,295
S15	(MH "Life Style+")	113,298
S14	((life W0 style*) or lifestyle* or (health* N3 (behavio* or attitude*)) or nutrition* or diet* or food* or feed* or eating or meal or meals or ((physical or motor) N3 (activ* or exercis* or fitness)) or physical conditioning or running or jogging or swimming or walking or cycling or climbing or skiing or smok* or tobacco* or cigarette*)	405,475
S13	(MH "Snow Skiing+")	337
S12	(MH "Cycling")	4,843
S11	(MH "Walking")	11,151
S10	(MH "Running+")	6,690
S9	(MH "Swimming")	2,004
S8	(MH "Physical Activity")	19,829
S7	(MH "Exercise+")	56,422
S6	(MH "Motor Activity")	4,291
S5	(MH "Eating Behavior+")	15,426
S4	(MH "Smoking Cessation Programs")	1,463
S3	(MH "Smoking Cessation")	11,086
S2	(MH "Smoking")	30,112
S1	(MH "Tobacco")	4,253

B. Excluded studies

Table B1. Excluded studies

Study	Reason for exclusion
Barnett PG, Wong W, Jeffers A, Munoz R, Humfleet G, Hall S. Cost-effectiveness of extended cessation treatment for older smokers. Addiction 2014;109(2):314-322.	The objective was not to evaluate effects of cognitive therapies.
Byom TK. A comparison of the effectiveness of three group treatments for weight loss. Doctoral dissertation, The University of Wisconsin-Milwaukee, 2009	The study did not have behavioral outcomes.
Campos ACF, Martins LVO, Yano RN, Alvim RNT, Silva EN, Silva VA, et al. Comparison of two strategies for smoking cessation in hospitalized patients. Eur Heart J 2014;35:903.	Conference abstract.
Chambliss C, Murray, E. Cognitive procedures for smoking reduction: Symptom attribution versus efficacy attribution. Cognit Ther Res1979. p. 91-95.	Not a randomised controlled trial.
Cinciripini PM, Lapitsky LG, Wallfisch A, Mace R, Nezami E, Vunakis H. An evaluation of a multicomponent treatment program involving scheduled smoking and relapse prevention procedures: initial findings. Addict Behav1994. p. 13-22.	Not a randomised controlled trial.
Habil H, Seghatoleslam T. The effect of cognitive behavior therapy among a sample ofiranian women who smoked and were depressed in 2009- 2010: An experimental study. Eur Psychiatry 2011;26.	Conference abstract.
Hall SM, Munoz RF, Reus VI. Cognitive-behavioral intervention increases abstinence rates for depressive-history smokers. J Consult Clin Psychol 1994;62(1):141-146.	The objective was to evaluate effects of cognitive therapies in persons with a history of major depression.
Hall SM, Reus VI, Muñoz RF, Sees KL, Humfleet G, Hartz DT, et al. Nortriptyline and cognitive-behavioral therapy in the treatment of cigarette smoking. Arch Gen Psychiatry1998. p. 683-690.	The objective was to evaluate effects of cognitive therapies in persons with a history of major depression.
Hall SM, Humfleet GL, Reus VI, Muñoz RF, Hartz DT, Maude-Griffin R. Psychological intervention and antidepressant treatment in smoking cessation. Arch Gen Psychiatry2002. p. 930-936.	The objective was to evaluate effects of cognitive therapies in persons with a history of major depression.
Killen JD, Fortmann SP, Schatzberg AF, Arredondo C, Murphy G, Hayward C, et al. Extended cognitive behavior therapy for cigarette smoking cessation. Addiction 2008;103(8):1381-1390.	All participants got cognitive therapy treatment, only dose differed.

Lee M, Miller SM, Wen K-Y, Hui S-kA, Roussi P, Hernandez E. Cognitive-behavioral intervention to promote smoking cessation for pregnant and postpartum inner city women. J Behav Med 2015;38(6):932-943.	The comparison included elements from cognitive behavioural therapy.
Lou P, Zhu Y, Chen P, Zhang P, Yu J, Zhang N, et al. Supporting smoking cessation in chronic obstructive pulmonary disease with behavioral intervention: a randomized controlled trial. BMC Fam Pract 2013;14:91.	The intervention included health education but had very little cognitive content.
Marks DF, Sykes CM. Randomized controlled trial of cognitive behavioural therapy for smokers living in a deprived area of London: Outcome at one-year follow-up. PSYCHOLOGY, HEALTH & MEDICINE, 2002:7;17-24	The comparison was based on The Stages of Change theory.
Metz K, Kroger C, Donath C, Floter S, Gradl S, Piontek D. Evaluation of a motivational intervention for smokers in rehabilitation centers. Verhaltenstherapie & Verhaltensmedizin, 2006:27;445-63.	The comparison was Motivational Interviewing.
Patten CA, Drews AA, Myers MG, Martin JE, Wolter TD. Effect of depressive symptoms on smoking abstinence and treatment adherence among smokers with a history of alcohol dependence. Psychol Addict Behav2002. p. 135-142.	The objective was not to evaluate effects of cognitive therapies.
Raja M, Saha S, Mohd S, Narang R, Reddy LV, Kumari M. Cognitive Behavioural Therapy versus Basic Health Education for Tobacco Cessation among Tobacco Users: A Randomized Clinical Trail. Journal of Clinical and Diagnostic Research JCDR 2014;8(4):ZC47-49.	The reported outcome was tobacco dependence, not abstinence rate or number of cigarettes/time unit.
Rogojanski J, Vettese LC, Antony MM. Coping with cigarette cravings: Comparison of suppression versus mindfulness-based strategies. Mindfulness, 2011:2;14–26	The intervention was mindfulness therapy only.
Strong DR, Kahler CW, Leventhal AM, Abrantes AM, Lloyd-Richardson E, Niaura R, et al. Impact of bupropion and cognitive-behavioral treatment for depression on positive affect, negative affect, and urges to smoke during cessation treatment. Nicotine & Tobacco Research 2009;11(10):1142-1153.	The objective was not to evaluate effects of cognitive therapies.
Trockel M, Burg M, Jaffe A, Barbour K, Taylor CB. Smoking behavior postmyocardial infarction among ENRICHD trial participants: cognitive behavior therapy intervention for depression and low perceived social support compared with care as usual. Psychosom Med 2008;70(8):875-882.	The objective was to evaluate effects of cognitive therapies in persons post myocardial infarction with subsequent depression. Subgroup analysis.
van der Meer RM, Willemsen MC, Smit F, Cuijpers P, Schippers GM. Effectiveness of a mood management component as an adjunct to a telephone counselling smoking cessation intervention for smokers with a past major depression: a pragmatic randomized controlled trial. Addiction 2010;105(11):1991-1999.	The comparison included several cognitive therapy elements.

Ward T. Using psychological insights to help people quit smoking. J Adv Nurs 2001. p. 754-759.	Two intervention arms had nicotine replacement therapy + variations of cognitive therapies while the control group was wait-list with no intervention.
Wiggers LCW, Oort FJ, Dijkstra A, de Haes JCJM, Legemate DA, Smets EMA. Cognitive changes in cardiovascular patients following a tailored behavioral smoking cessation intervention. Preventive Medicine 40 (2005) 812– 821	The study did not report data on smoking cessation.
Yalcin BM, Unal M, Pirdal H, Karahan TF. Effects of an anger management and stress control program on smoking cessation: a randomized controlled trial. Journal of the American Board of Family Medicine: JABFM 2014;27(5):645-660.	The comparison included several cognitive therapy elements.
Zimmer D, Lindinger P, Mitschele U. Training people to stop smoking radically: I. Long-term efficacy of an individualized cognitive-behavioral treatment in smoking cessation (4.5-year follow-up). Verhaltenstherapie 1993;3(4):304-311.	Not a randomised controlled study.
Zimmer D, Lindinger P, Mitschele U. Training people to stop smoking radically: II. Prediction of success and relapse in smoking cessation programs. Verhaltenstherapie 1993;3(4):312-316.	Not a randomised controlled study. Correlational re-analysis of data.

C. Characteristics of included studies

Participants

Table C1. Participants.

Study ID	Country	Mean age	% women	Ethnicity	Education	Other
Alterman 2001	USA	40	49	62% Caucasian	Mean 15 years	85 % working or studying
Chen 2014	China	50	3		35% ≥ college	
Clarke 2013	USA	37	35	52% Caucasian	15% ≥ high school	100% inmates
Dornelas 2000	USA	55	22	94% Caucasian	75% ≥ high school	67% married
Gifford 2011	USA	46	59	87% Caucasian	71% ≥ high school	42% < $30,000/year
Hall 2009	USA	57	40	77% Caucasian	52% ≥ college	43% married or living with partner
Hall 2011	USA	41	39	70% Caucasian	45% ≥ college	38% married or living with partner
Hennrikus 2010	USA	60	15	95% Caucasian	9% ≥ college	47% married or living with partner
Kim 2012	USA	47	23	100% Korean immigrants	Mean 15 years	77% married
Lifrak 1997	USA	38	62	58% Caucasian	Mean 14 years	32% married; 78% working
McCarthy 2008	USA	39	50	90% Caucasian	95% ≥ high school	81% working; 52% married or living with partner; 31% < $25,000/year
Prapavessis 2007	Canada	38	100			
Reitzel 2010	USA	25	100	36% Caucasian	81% ≥ high school	63% living with partner; 55% < $ 30,000/year
Roozen 2006	The Netherlands	43	28		92% ≥ secondary school	56% married or living with partner
Rovina 2009	Greece	45	41	100% Caucasian	61% > high school	
Schleicher 2010	USA	21	51	85% Caucasian	100% college	
Schmitz 2007	USA	48	100	70% Caucasian	Mean 14 years	40% married; 65% employed

Simon 2003	USA	55	3	69% Caucasian	Mean 13 years	36% married or living with partner
Smith 2001	USA	42	57	95% Caucasian		
Webb 2010	USA	44	57	100% African-American	86% ≥ high school	38% married or living with partner
Wittchen 2011	Germany	43	51			42% married or living with partner

Interventions and comparisons

Table C2. Description of the interventions and comparisons.

Study ID	Mode; Duration; Frequency; Session length	Provider	Intervention content	Comparison
			Cognitive therapies compared to usual care or minimal intervention	
Dornelas 2000	Individual; 24 weeks; 1 + 7/24 weeks; 20 minutes	Psychologist	Combination of motivational interviewing and relapse prevention; 20 minutes bedside smoking cessation counselling, reinforcement of all motivational statements; follow-up by x 7 after discharge	Verbal and written recommendation to watch an on-line patient education video "Active partnership: toward a healthier heart" and referral to local branch of the American Heart Association or the American Lung Association for smoking cessation resources in the patient's community. Duration 10 minutes.
McCarthy 2008	Individual; 5 weeks; 8/5 weeks; 10 minutes	N/R	Placebo medication + 2 sessions pre-quit, 1 on quit day, 5 during 4 weeks post quit; a) preparation for quit (disposing of smoking stuff) b) coping problem solving (identify triggers for relapse, lessons learned from previous lapses/relapses, psychoeducation) c) relapse prevention (long-term planning, risk identification) d) intra-treatment social support)	Placebo medication, no counselling.
Reitzel 2010	Individual face-to-face and phone; 18 weeks; 8/18 weeks; Mean 22 minutes, mode 15 minutes	Master or doctoral level counsellors with ≈ 80 hours of training	Motivation and problem solving based on motivational interview and social cognitive theory/relapse prevention; Phase 1 - building motivation, phase 2 - strengthening commitment; wellness plan - treatment goals, addressing stressors that may affect abstinence	Usual care + self-help materials and 5-10 minutes of brief relapse prevention advice based on a clinical practice guideline from Agency for Health Care Research and Quality.

Cognitive therapies combined with NRT compared to other interventions combined with NRT				
Alterman 2001	Individual; 12 weeks; 1/week; 45-50 minutes	Master level therapist	NRT + 1) motivate patient to develop ex-smoker identity 2) identify personal smoking triggers, increase social and personal competence to counter urges through self-monitoring, processing and positive rewards 3) recognize early signs and symptoms of craving + tools to enhance coping with craving skills and problem-solving 4) increase self-efficacy to resist smoking through increased awareness, stress management and self-confidence 5) develop effective cognitive-behavioural strategies to remain smoke-free and counter slips 6) reinforce aversion to smoking	NRT + 3 15-20 minute educational sessions (weeks 3, 6 and 9). The content was similar to the National Cancer Institute's manual for physicians.
Hall 2009	Group and individual; 12 + 40 weeks; 5/12 weeks + 11/40 weeks; 40 weeks: 20-40 minutes	A "therapist"	Standard treatment (Bupropion SR + NRT + counselling based on *Clear Horizons* self-help manual for smokers) + Cognitive-behavioural treatment tailored to older smokers; 11 individual sessions: self-directed with coaching from therapist: 1) motivation with use of decisional balance chart 2) mood management 3) weight control by physical activity program 4) social support by managing current network and building larger non-smoking network, practise eliciting positive support and handling negative support 5) withdrawal/dependence working with coach to deal with emerging symptoms.	Standard treatment + extended NRT treatment.
Kim 2012	Individual; 8 weeks; 1/week; 40 minutes	Trained clinician certified in mental health counselling	NRT + Sessions targeting attitudes, perceived social norms, self-efficacy; decisional balance; quit date; skills to deal with craving and other withdrawal symptoms; management of nicotine patch; relapse prevention; graduation ceremony	NRT + 8 weekly individual 10-minute counselling sessions focusing on medication management, but also brief information about cognitive behavioural skills that are useful in dealing with smoking craving and withdrawal symptoms.
Lifrak 1997	Individual; 9 + 16 weeks; 1/week; 45 minutes	Nurse practitioner trained in addiction treatment + PhD level social worker or psychiatrist	9 weeks: NRT + smoking cessation advice + 16 weeks:1) motivate patient to develop ex-smoker identity 2) identify personal smoking triggers, increase social and personal competence to counter urges through self-monitoring, processing and positive rewards 3) recognize early signs and symptoms of craving + tools to enhance coping with craving skills and problem-solving 4) increase self-efficacy to resist smoking through increased aware-	NRT + 4 individual smoking cessation advice and instruction sessions, the first 45 minutes, then 10-15 minutes. Review of self-help material ("Cleaning the air" and "Why do you smoke"), instructions on dosing schedule and safe nicotine patch use, including possible side/adverse effects.

			ness, stress management and self-confidence 5) develop effective cognitive-behavioural strategies to remain smoke-free and counter slips 6) reinforce aversion to smoking	
Prapavessis 2007	Group; 12 weeks; 3/week; 45 minutes	N/R	NRT + Self-monitoring; coping with cravings and high-risk situations + concerns about weight gain; link between smoking and stress; health topics	NRT + 3 45-minute supervised exercise sessions/week for 12 weeks. Training intensity of 60-75% of maximum heart rate reserve on either cycle ergometer, treadmill or rower.
Simon 2003	Individual face-to-face and phone; 16 weeks; 9/16 weeks; 30 minutes	Trained nurse/public health educator	NRT + decision balance for smoking/quitting, assessment of knowledge, beliefs, attitudes, self-management techniques to counter relapse; continued skills training initiated during 1st session, new quit date if relapse	NRT + minimal contact: 1 10-minute session of counselling on the dangers of smoking and the benefits of quitting + self-help materials.
Smith 2001	Group; 5 weeks; 6/5 weeks; 90 minutes	Doctoral graduate students in psychology supervised by a licensed psychologist	NRT + 1) Coping with withdrawal 2) managing negative mood states 3) thought patterns related to negative mood 4) strategies for increasing positive mood 5) ways to deal with anger 6) social support and relapse prevention	NRT + brief individual counselling (not further described).
Webb 2010	Group; 2 weeks; 6/2 weeks; 60-90 minutes	Af-Am psychologist experienced in smoking interventions and Caucasian master-level counsellor	NRT + cessation and relapse prevention strategies, barriers to cessation, previous quit attempts, risky situations, benefits observed after quitting, assignments in session, practice of skills as homework	NRT + general health education: 2-week educational series on medical conditions associated with or caused by smoking.

Cognitive therapies compared to other interventions				
Chen 2014	Individual by phone; 22 weeks; 8/8 weeks; 3/12 weeks; 1 20-minute session; phone sessions 10 minutes	Physicians with experience of smoking cessation	Individual face-to-face counselling based on 5 A's: ask, assess, advice, assist, arrange; self-help materials; phone calls: further promote cessation and help conquer issues that occurred during smoking cessation	"Smoking cessation advice".
Clarke 2013	N/R; 6 weeks; 1/week; 30-60 minutes	Trained research assistants	Session 1 and 6 based on motivational interviewing; session 2-5 based on cognitive-behavioural therapy: 1) recognize environmental and affective triggers 2) identify behavioural and cognitive strategies to cope with triggers; brief phone counselling 24 h and 7 days after release to enhance motivation and use of skills	Videos covering a variety of health-related topics, matched to the intervention for frequency and contact.
Hennrikus 2010	Individual face-to-face and phone; 24 weeks; 6/24 weeks; N/R	Trained counsellors	Initial visit face-to-face; subsequent either phone or face-to-face; 1) education about link between smoking and peripheral artery disease 2) motivational interviewing to increase motivation to quit 3) cognitive-behavioural counselling to develop quit plan: a) problem-solving skills training approach to select quit date, prepare for quitting, identify strategies for coping with urges to smoke 4) use stop-smoking medication aides 5) select person in social network to support quit efforts	Verbal advice to quit smoking from vascular provider + a list of smoking cessation programs and community resources from study coordinator.
Prapavessis 2007	Group; 12 weeks; 3/week; 45 minutes	N/R	Self-monitoring; coping with cravings and high-risk situations + concerns about weight gain; link between smoking and stress; health topics	3 45-minute supervised exercise sessions/week for 12 weeks. Training intensity of 60-75% of maximum heart rate reserve on either cycle ergometer, treadmill or rower.
Schleicher 2010	Group; 8 weeks; 6/8 weeks; 120 minutes	Graduate students in psychology supervised by clinical psychologist	Social learning, self-management, dispute thought distortions, relapse prevention	6 group session with advice aiming to increase consumption of fruit and vegetables.
Wittchen 2011	Individual; 12 weeks; 4-5/12 weeks; 20-30 minutes	Primary care physician	Structured quit advice, non-smoking diaries, review of diary: quit day preparation, relapse prevention, managing withdrawal, self-help manual, homework	Brief oral motivational intervention to quit smoking (< 3 minutes) + a motivational information sheet ("Reasons to quit immediately").

Cognitive therapies added to medication compared to medication				
Gifford 2011	Group and individual; 10 weeks; 2/week; N/R	Substance abuse therapist + psychology doctoral student	Medication: bupropion SR regimen +Therapeutic relationship used to elicit and modify relevant classes of behaviour; triggers approached by acceptance; mindfulness exercises to identify thoughts and feelings that might lead to smoking; practise of acceptance and mindfulness skills when exposed to smoking-related items	Medication: bupropion SR regimen.
Hall 2011	Group and individual; 12 + 40 weeks; 5/12 weeks + 11/40 weeks; 40 weeks: 20-40 minutes	A "therapist"	Standard treatment (Bupropion SR + NRT + counselling based on *Clear Horizons* self-help manual for smokers) + cognitive-behavioural treatment see Hall 2009, although not tailored to older smokers.	Standard treatment.
McCarthy 2008	Individual; 5 weeks; 8/5 weeks; 10 minutes	N/R	Bupropion SR + 2 sessions pre-quit, 1 on quit day, 5 during 4 weeks post quit; a) preparation for quit (disposing of smoking stuff) b) coping problem solving (identify triggers for relapse, lessons learned from previous lapses/relapses, psychoeducation) c) relapse prevention (long-term planning, risk identification) d) intra-treatment social support)	Active medication (bupropion SR), no counselling.
Roozen 2006	Individual; 8 weeks; 5/8 weeks; N/R	Master level psychology students	Medication naltrexone + focus on environment (community)-organism interactions to rearrange a substance abusing lifestyle; development of alternative rewarding activities that are incompatible with substance use	Medication: naltrexone regimen.
Rovina 2009	Group; 19 weeks; 9/19 weeks; 60 minutes	Specialized psychologist	Bupropion SR + focus on changing thoughts, beliefs and attitudes to quitting and to alter negative mood	Medication: bupropion SR regimen
Cognitive therapies added to medication compared to supportive therapy added to medication				
Schmitz 2007	Group; 7 weeks; 1/week; 60 minutes	Master level therapist + PhD clinical psychologist	Medication: bupropion + cognitive behavioural therapy based on relapse prevention model; "unlearning" habit through coping skills acquisition, skills for managing relapse-related thoughts and behaviours, identification of triggers, handling of lapses, problem-solving.	Medication: bupropion + supportive therapy: enhance provision and receipt of social support during smoking cessation, group discussions around topics related to quitting in general.

Outcomes

Table C3. Outcomes

Study ID	Outcomes	Measurement methods
Alterman 2001	Abstinence 7 days prior to follow-up.	Self-report validated by cotinine analysis of urine samples.
Chen 2014	Sustained abstinence week 4 to month 6.	Self-report validated by exhaled carbon monoxide analysis.
Clarke 2013	Abstinence 7 days prior to follow-up.	Self-report validated by cotinine analysis of urine samples.
Dornelas 2000	Abstinence 7 days prior to follow-up.	Self-report validated by family member.
Gifford 2011	Abstinence 7 days prior to follow-up.	Self-report validated by exhaled carbon monoxide analysis.
Hall 2009	Abstinence 7 days prior to follow-up.	Self-report validated by exhaled carbon monoxide analysis.
Hall 2011	Abstinence 7 days prior to follow-up.	Self-report validated by exhaled carbon monoxide analysis.
Hennrikus 2010	Abstinence 7 days prior to follow-up.	Self-report validated by cotinine in saliva or exhaled carbon monoxide analysis.
Kim 2012	Abstinence 7 days prior to follow-up.	Self-report validated by cotinine in saliva and exhaled carbon monoxide analysis.
Lifrak 1997	Abstinence 7 days prior to follow-up.	Self-report validated by cotinine in urine and exhaled carbon monoxide analysis.
McCarthy 2008	Abstinence 7 days prior to follow-up.	Self-report validated by cotinine in serum and exhaled carbon monoxide analysis.
Prapavessis 2007	Abstinence 7 days prior to follow-up.	Self-report validated by exhaled carbon monoxide analysis.
Reitzel 2010	Sustained abstinence since delivery date.	Self-report validated by cotinine in saliva or exhaled carbon monoxide analysis.
Roozen 2006	Abstinence at follow-up.	Self-report validated by cotinine analysis of urine samples.
Rovina 2009	Abstinence at follow-up.	Self-report validated by exhaled carbon monoxide analysis.
Schleicher 2010	Abstinence at follow-up.	Self-report, probably not biochemically validated.
Schmitz 2007	Abstinence 7 days prior to follow-up.	Self-report validated by cotinine in saliva and exhaled carbon monoxide analysis.
Simon 2003	Abstinence 7 days prior to follow-up.	Self-report validated by cotinine in saliva analysis.
Smith 2001	Abstinence 7 days prior to follow-up.	Self-report validated by exhaled carbon monoxide analysis.
Webb 2010	Abstinence 24 hours prior to follow-up.	Self-report validated by exhaled carbon monoxide analysis.
Wittchen 2011	Abstinence 7 days prior to follow-up.	Self-report, not biochemically validated.

D. Risk of bias

Table D.1 Support for judgment of risk of bias.

Study ID	Bias	Judgment	Support for judgment
Alterman 2001	Random sequence generation	Unclear	"Urn randomization", no additional information.
	Allocation concealment	Unclear	Information not found.
	Blinding of participants and personnel	Unclear	Not possible.
	Blinding of outcome assessment	Low	Self-report validated by salivary cotinine assessment.
	Incomplete outcome data	Low	Intention-to-treat analysis.
	Selective reporting	Low	Not found.
	Other bias	Low	Not found.
Chen 2014	Random sequence generation	Low	A randomized digits table was used.
	Allocation concealment	Unclear	Information not found.
	Blinding of participants and personnel	Unclear	Not possible.
	Blinding of outcome assessment	Unclear	Information not found.
	Incomplete outcome data	Unclear	12/190 withdrew but no information of group assignment.
	Selective reporting	Low	Not found.
	Other bias	Low	Not found.
Clarke 2013	Random sequence generation	Unclear	"Participants were randomly assigned", no further information.
	Allocation concealment	Unclear	Information not found.
	Blinding of participants and personnel	Unclear	Not possible.
	Blinding of outcome assessment	Low	Self-report validated by cotinine.
	Incomplete outcome data	Low	Intervention group 96.7% response rate; control group 88% response rate, dropouts analysed as smokers.
	Selective reporting	Low	Not found.
	Other bias	Low	Not found.
Dornelas 2000	Random sequence generation	Unclear	Generation by "random numbers", no further information.
	Allocation concealment	Unclear	Information not found.
	Blinding of participants and personnel	Unclear	Not possible.
	Blinding of outcome assessment	Unclear	Self-report no further information.
	Incomplete outcome data	Low	Dropouts analyzed as smokers.
	Selective reporting	Low	Not found.
	Other bias	Low	Not found.
Gifford 2011	Random sequence generation	Low	Random numbers generated by computer.
	Allocation concealment	Low	Study coordinator notified of assignment after subjects were accepted into the study.

	Blinding of participants and personnel	Unclear	Not possible.
	Blinding of outcome assessment	Low	Self-report validated by exhaled carbon monoxide.
	Incomplete outcome data	Low	Intention-to-treat analysis.
	Selective reporting	Low	Not found.
	Other bias	Low	Not found.
Hall 2009	Random sequence generation	Low	Computerized allocation list.
	Allocation concealment	Low	Assignment transmitted electronically to clinical staff after subjects' consent to participate.
	Blinding of participants and personnel	Unclear	Not possible.
	Blinding of outcome assessment	Low	Self-report validated by exhaled carbon monoxide.
	Incomplete outcome data	Low	90% response rate at 1-year follow-up.
	Selective reporting	Low	Not found.
	Other bias	Low	Not found.
Hall 2011	Random sequence generation	Unclear	"Were randomly assigned", no further information.
	Allocation concealment	Unclear	Information not found.
	Blinding of participants and personnel	Unclear	Not possible.
	Blinding of outcome assessment	Low	Self-report validated by exhaled carbon monoxide.
	Incomplete outcome data	Low	90% response rate at 1-year follow-up.
	Selective reporting	Low	Not found.
	Other bias	Low	Not found.
Hennrikus 2010	Random sequence generation	Low	"Pre-determined block randomization schedule".
	Allocation concealment	Unclear	Information not found.
	Blinding of participants and personnel	Unclear	Not possible.
	Blinding of outcome assessment	Low	Self-report validated by saliva carbon monoxide.
	Incomplete outcome data	Low	Intention-to-treat analysis with dropouts analysed as smokers.
	Selective reporting	Low	Not found.
	Other bias	Low	Not found.
Kim 2012	Random sequence generation	Low	Computer-generated sequence.
	Allocation concealment	Unclear	Information not found.
	Blinding of participants and personnel	Unclear	Not possible.
	Blinding of outcome assessment	Low	Self-report validated by salivary cotinine and exhaled carbon monoxide.
	Incomplete outcome data	Low	Intention-to-treat analysis.
	Selective reporting	Low	Not found.
	Other bias	Low	Not found.
Lifrak 1997	Random sequence generation	Unclear	"Random assignment by blocks of 10", no further information.
	Allocation concealment	Unclear	Information not found.
	Blinding of participants and personnel	Unclear	Not possible.
	Blinding of outcome assessment	Low	Self-report validated by urinary cotinine and exhaled carbon monoxide.

	Incomplete outcome data	Low	Missing data treated as indication of non-abstinence.
	Selective reporting	Low	Not found.
	Other bias	Low	Not found.
McCarthy 2008	Random sequence generation	Unclear	Randomization via random number lists.
	Allocation concealment	Unclear	"Staff unaware of condition to be assigned", no further information.
	Blinding of participants and personnel	Unclear	Counseling no, medication yes.
	Blinding of outcome assessment	Low	Self-report validated by exhaled carbon monoxide.
	Incomplete outcome data	Low	Missing data treated as non-abstinence.
	Selective reporting	Low	Not found.
	Other bias	Low	Not found.
Prappavessis 2007	Random sequence generation	Unclear	Information not found.
	Allocation concealment	Unclear	Information not found.
	Blinding of participants and personnel	Unclear	Not possible.
	Blinding of outcome assessment	Low	Self-report validated by salivary cotinine and exhaled carbon monoxide.
	Incomplete outcome data	Low	Intention-to-treat analysis.
	Selective reporting	Low	Not found.
	Other bias	Low	Not found.
Reitzel 2010	Random sequence generation	Low	Computer randomization and minimization.
	Allocation concealment	Unclear	Information not found.
	Blinding of participants and personnel	Unclear	Not possible.
	Blinding of outcome assessment	Low	Self-report validated by exhaled carbon monoxide.
	Incomplete outcome data	Low	Intention-to-treat analysis with dropouts considered as smokers.
	Selective reporting	Low	Not found.
	Other bias	Low	Not found.
Roozen 2006	Random sequence generation	Unclear	Information not found.
	Allocation concealment	Unclear	Information not found.
	Blinding of participants and personnel	Unclear	Not possible.
	Blinding of outcome assessment	Low	Self-report validated by urinary cotinine.
	Incomplete outcome data	High	Overall drop-our = 32%.
	Selective reporting	Low	Not found.
	Other bias	Low	Not found.
Rovina 2009	Random sequence generation	Unclear	Information not found.
	Allocation concealment	Unclear	Information not found.
	Blinding of participants and personnel	Unclear	Not possible.
	Blinding of outcome assessment	Unclear	Self-report validated by exhaled carbon monoxide.
	Incomplete outcome data	Low	90% completed assessment at 1-year follow-up.
	Selective reporting	Low	Not found.

	Other bias	Low	Not found.
Schleicher 2010	Random sequence generation	Low	Random number table + block randomization.
	Allocation concealment	Unclear	Information not found.
	Blinding of participants and personnel	Unclear	Not possible.
	Blinding of outcome assessment	Unclear	Self-report and saliva sample collected but not analysed, no information on biochemical (cotinine, carbon monoxide, or none).
	Incomplete outcome data	Low	Intention-to-treat, missing data analyses as non-abstinence.
	Selective reporting	Low	Not found.
	Other bias	Low	Not found.
Schmitz 2007	Random sequence generation	Unclear	Randomziation by urn procedure, no further information.
	Allocation concealment	Unclear	Information not found.
	Blinding of participants and personnel	Unclear	Not possible.
	Blinding of outcome assessment	Low	Self-report validated by salivary cotinine and exhaled carbon monoxide.
	Incomplete outcome data	Unclear	Missing data 50% coded as smoker.
	Selective reporting	Low	Not found.
	Other bias	Unclear	Medication provided by producer.
Simon 2003	Random sequence generation	Low	Computerized algorithm.
	Allocation concealment	Unclear	Information not found.
	Blinding of participants and personnel	Unclear	Not possible.
	Blinding of outcome assessment	Low	Self-report validated by salivary cotinine.
	Incomplete outcome data	Low	93% response rate, missing data analysed as non-abstinence.
	Selective reporting	Low	Not found.
	Other bias	Low	Not found.
Smith 2001	Random sequence generation	Unclear	Information not found.
	Allocation concealment	Unclear	Information not found.
	Blinding of participants and personnel	Unclear	Not possible.
	Blinding of outcome assessment	Low	Self-report validated by exhaled carbon monoxide.
	Incomplete outcome data	Unclear	Insufficient information on response rate.
	Selective reporting	Low	Not found.
	Other bias	Low	Not found.
Webb 20010	Random sequence generation	Unclear	"Stratified random sampling", no information on how.
	Allocation concealment	Unclear	Information not found.
	Blinding of participants and personnel	Unclear	Not possible.
	Blinding of outcome assessment	Low	Self-report validated by exhaled carbon monoxide.
	Incomplete outcome data	Low	Intention-to-treat analysis and missing data analyzed as non-abstinence.
	Selective reporting	Low	Not found.
	Other bias	Low	Not found.

Wittchen 2011	Random sequence generation	Unclear	"Randomized order", no further information.
	Allocation concealment	High	Coloured questionnaires distributed by nurses.
	Blinding of participants and personnel	Unclear	Not possible.
	Blinding of outcome assessment	Unclear	Self-report no information on biochemical validation.
	Incomplete outcome data	Low	Intention-to-treat analysis and last value carried forward.
	Selective reporting	Low	Not found.
	Other bias	Low	Not found.

E. GRADE evidence profiles

Table E1. GRADE evidence profile for cognitive therapies compared to usual care or minimal intervention.

Author(s): Eva Denison, vigdis Underland
Date: 02.02.2016
Question: Cognitive behavioral methods compared to usual care for smoking cessation
Setting: Primary health care
Bibliography: Dornelas 2000, McCarthy 2008, Reitzel 2010

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	**Study design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Cognitive behavioral methods**	**usual care**	**Relative (95% CI)**	**Absolute (95% CI)**		
New outcome												
3	randomised trials	serious [1]	not serious	not serious	serious [2]	none	76/311 (24.4%)	52/274 (19.0%)	**RR 1.29** (0.90 to 1.85)	**55 more per 1000** (from 19 fewer to 161 more)	⊕⊕OO LOW	

CI: Confidence interval; **RR:** Risk ratio

1. Overall unclear risk of bias
2. Confidence interval includes both no effect and large effect

Table E2. GRADE evidence profile for cognitive therapies combined with nicotine replacement therapy compared to other interventions combined with nicotine replacement therapy.

Author(s): Eva Denison, Vigdis Underland
Date: 21.12.2015
Question: Cognitive therapies combined with NRT compared to other interventions combined with NRT for smoking cessation
Setting: Primary health care
Bibliography: Alterman 2001, Hall 2009, Kim 2012, Lifrak 1997, Prapavessis 2007, Simon 2003, Smith 2001, Webb 2010

Quality assessment							№ of patients		Effect		Quality	Import-ance
№ of stu-dies	Study design	Risk of bias	Inconsis-tency	In-directness	Impreci-sion	Other considera-tions	Cognitive behavioral methods combined with NRT	Advice added combined with NRT	Relative (95% CI)	Absolute (95% CI)		
Abstinence rate (assessed with: Self-report and biochemical validation)												
8	randomised tri-als	serious [1]	serious [2]	not serious	not serious	none	202/647 (31.2%)	154/662 (23.3%)	**RR 1.53** (1.06 to 2.19)	**123 more per 1 000** (from 14 more to 277 more)	⨁⨁◯◯ LOW	CRITICAL

CI: Confidence interval; **RR:** Risk ratio

1. Overall unclear risk of bias.
2. I-square 75%, one study with non-overlapping confidence interval.

Table E3. GRADE evidence profile for cognitive therapies compared to other interventions.

Author(s): Eva Denison, Vigdis Underland
Date: 21.12.2015
Question: Cognitive behavioral methods compared to advice or health education for smoking cessation
Setting: Primary health care
Bibliography: Chen 2004, Clarke 2013, Hennrikus 2010, Prapavessis 2007, Schleicher 2010, Wittchen 2011

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	**Study design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Cognitive behavioral methods**	**advice or health education**	**Relative (95% CI)**	**Absolute (95% CI)**		
Abstinence rate (assessed with: Self-report with biochemical validation)												
6	randomised trials	serious [1]	serious [2]	not serious	not serious	none	107/462 (23.2%)	43/388 (11.1%)	**RR 2.05** (1.09 to 3.86)	**116 more per 1 000** (from 10 more to 317 more)	⨁⨁◯◯ LOW	

CI: Confidence interval; **RR:** Risk ratio

1. Overall unclear risk of bias.
2. I-square 75%, one study with non-overlapping confidence interval.

Table E4. GRADE evidence profile for cognitive therapies combined with medication compared to medication only.

Author(s): Eva Denison, Vigdis Underland
Date: 02.02.2016
Question: Cognitive behavioral methods combined with medication compared to medication only for smoking cessation
Setting: Primary health care
Bibliography: Gifford 2011, Hall 2011, McCarthy 2008, Roozen 2006, Rovina 2009

Quality assessment							№ of patients		Effect		Quality	Import-ance
№ of stu-dies	Study design	Risk of bias	Inconsis-tency	In-directness	Impreci-sion	Other considera-tions	Cognitive behavioral methods combined with medi-cation	medication only	Relative (95% CI)	Absolute (95% CI)		
Abstinence rate (assessed with: Self-report with biochemical validation)												
5	randomised tri-als	serious [1]	not serious	not serious	not serious	none	111/320 (34.7%)	91/353(25.8%)	**RR 1.39** (1.10 to 1.76)	**101 more per 1000** (from 26 more to 196 more)	⊕⊕⊕O MODERATE	CRITICAL

CI: Confidence interval; **RR:** Risk ratio
1. Overall unclear risk of bias.

Table E5. GRADE evidence profile for cognitive therapies combined with medication compared to supportive therapy combined with medication.

Author(s): Eva Denison, Vigdis Underland
Date: 10.12.2016
Question: Cognitive therapies combined with medication compared to supportive therapy combined with medication for smoking cessation
Setting: Primary health care
Bibliography: Schmitz 2007

Quality assessment							№ of patients		Effect		Quality	Importance
№ of studies	**Study design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**cognitive therapies combined with medication**	**supportive therapy combined withmedication**	**Relative (95% CI)**	**Absolute (95% CI)**		
smoking abstinence rate (follow up: range 12 months to 12 months; assessed with: self-report with biochemica validation)												
1	randomised trials	serious [1]	not serious	not serious	very serious [3]	none	6/35 (17.1%)	1/36 (2.8%)	**RR 6.17** (0.78 to 48.68)	**144 more per 1 000** (from 6 fewer to 1 000 more)	⊕◯◯◯ VERY LOW	CRITICAL

CI: Confidence interval; **RR:** Risk ratio

1. Unclear risk of bias
2. One small study with 71 participants, 95% CI includes both negative effect and large effect.

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