National Institute for Health and Care Excellence

Guideline version (Final)

Smoking cessation interventions and services

[B] Evidence reviews for interventions to aid smoking cessation: behavioural support and pharmacotherapy

NICE guideline NG92

Evidence reviews

March 2018

November 2021: NICE guideline NG92 (March 2018) has been updated and replaced by NG209. The recommendations labelled [2018] or [2018, amended 2021] in the updated guideline were based on these evidence reviews.
See www.nice.org.uk/guidance/NG209 for all the current recommendations and evidence reviews.

FINAL

These evidence reviews were developed by Public Health Internal Guideline Development team

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Behavioural support alone

Review question

Is behavioural support (delivered to a person or a group) effective and cost effective?

Methods and process

This evidence review was developed using the methods and process described in Developing NICE guidelines: the manual. The methods used for study identification are Methodology section (see Appendix A) and reviewing methods specific to this review question are described in the review protocol in Appendix B.

Declarations of interest were recorded according to NICE's 2014 conflicts of interest policy.

Public health evidence

Included studies

Nine Cochrane reviews and one non-Cochrane systematic review provided evidence for this review question. The interventions examined were as follows:

- Individual support (Cahill et al. 2010; Lancaster et al. 2017; Mdege & Chindove 2014)
- Group support (Stead & Lancaster. 2017)
- Mixed individual and group support (Carr & Ebbert. 2012; Huibers et al. 2007; Lindson-Hawley et al. 2015; Rice et al. 2013. Stanton & Grimshaw. 2013; Stead et al. 2013).

For the behavioural support topic (RQ3) 2 reviews focused on named behavioural approaches: stage-based (trans-theoretical model) (Cahill et al. 2010) and motivational interviewing (Lindson-Hawley et al. 2015). In addition, 1 review focused on individual counselling (Lancaster et al. 2017) and 1 review focused on group behavioural therapy (Stead & Lancaster 2017). The remaining reviews on this topic considered any type of behavioural approach or advice and placed the focus on deliverer or setting: Carr & Ebbert 2012; Huibers et al. 2007; Rice et al. 2013; Stead et al. 2013; Mdege & Chindove 2014.

All reviews included smokers, some of whom were motivated to stop smoking. All reviews excluded trials that included only pregnant women. Many of the included reviews covered mixed settings though were predominantly in primary care, secondary care/smoking cessation clinics and community settings. A number of reviews had a setting-specific focus: community pharmacy (Mdege & Chindove 2014), dental care (Carr & Ebbert 2012), primary care (Huibers et al. 2007) and primary/secondary care (Rice et al. 2013; Stead et al. 2013). Characteristics of the included reviews are presented in Table 1 and further details are in Appendix D3.

Excluded studies

See Appendix E for excluded studies.

Summary of studies included in the evidence review

Table 1: Characteristics of included studies

Author, year, title	Quality	Populations	Interventions	Comparison	Outcomes
Cahill et al. 2010. Stage-based interventions for smoking cessation.	++	13 studies of smokers of any age. Settings were mixed, but included community and primary care.	Stage-based self-help interventions (individual counselling)	Non-staged based control (lower or equal intensity). Non-intervention control or usual care	Quit rate at 6 months after the start of the intervention. Abstinence from smoking after the period of cessation (where reported).
Carr & Ebbert. 2012. Interventions for tobacco cessation in the dental setting.	+	8 studies of smokers of any age in dental practice settings.	Behavioural cessation interventions delivered by a dentist, dental hygienist, dental assistant or office staff in the dental practice	Usual care or other intervention.	Smoking and tobacco use cessation at least 6 months from the delivery of intervention.
Lancaster et al. 2017. Individual behavioural counselling for smoking cessation.	+	33 studies of any smokers (excluding pregnant women and trials recruiting only children and adolescents). Settings were mixed, but included community and primary care.	Face-to-face individual counselling sessions (> 10 minutes) with or without further telephone contact for support	Minimal-contact control (usual care, brief advice or self-help materials)	Quit rate at the longest reported follow-up. Sustained abstinence (where available)
Huibers et al. 2007. Psychosocial interventions by general practitioners.	++	2 studies of smokers of any age in GP settings.	Psychosocial interventions delivered by GPs. At least 2 face contacts and psychological process is central.	Any comparison.	Biochemically validated smoking abstinence rates.
Lindson-Hawley et al. 2015. Motivational interviewing for smoking cessation.	+	28 studies of any smokers (excluding studies that only recruited adolescents or pregnant	Motivational interviewing, (face-to-face or telephone-based) individual or group	Brief advice, a low-intensity intervention, or routine care.	Smoking cessation. Sustained abstinence(where available)

Author, year, title	Quality	Populations	Interventions	Comparison	Outcomes
		women) in mixed settings, including primary, secondary care			
Mdege & Chindove 2014. Effectiveness of tobacco use cessation interventions delivered by pharmacy personnel: A systematic review	+	2 studies of pharmacy clients who were tobacco users.	Any pharmacy personnel delivered tobacco use cessation intervention (non-pharmacological).	Usual care, no treatment or other active treatment.	Abstinence from smoking (point prevalence; continuous abstinence) or relapse (time to relapse).
Rice et al. 2013. Nursing interventions for smoking cessation.	++	35 studies of adult smokers (aged 18≥ years; excluding pregnant women only trials). Secondary care settings were predominant.	Advice delivered in an initial session (> 10 minutes, there were additional materials (e.g. manuals) and/or strategies other than simple leaflets, and usually participants had more than one follow-up contact.	Usual care or other intervention.	Smoking cessation (at least 6 months follow-up)
Stanton & Grimshaw. 2013. Tobacco cessation interventions for young people.	++	18 studies of young people (<20 years; excluding trials only recruiting pregnant women) who smoke at least one cigarette a week for at least 6 months.	Psychosocial interventions and complex programmes (with motivational enhancement) targeting young people through their families, schools or communities	No intervention, delayed intervention beyond the last date of data acquisition including follow-up, brief intervention or general tobacco education.	Change in smoking behaviour (follow-up of at least 6 months).
Stead et al. 2013. Physician advice for smoking cessation.	++	15 studies of smokers (excluding trials recruiting pregnant	Intensive physician advice (or supported by another healthcare worker).	Control or minimal advice	Smoking cessation (minimum of 6 months follow-up).

Author, year, title	Quality	Populations	Interventions	Comparison	Outcomes
		women only. The most common setting for delivery of advice was primary care.			
Stead & Lancaster. 2017. Group behaviour therapy programmes for smoking cessation.	++	13 studies of adult smokers (excluding pregnant women).	Group behavioural intervention, such as information, advice and encouragement or cognitive behavioural therapy (CBT) delivered over at least two sessions.	Any comparison.	Abstinence from cigarettes at follow-up at least 6 months after the start of treatment

Individual counselling

Cahill et al. (2010 [++]) focused on the effectiveness of staged-based interventions for smoking cessation. This review found that stage-based self-help compared with usual care or assessment only (12 trials, RR of 1.32 [95%CI 1.17 to 1.48]) and stage-based individual counselling compared with any control (13 trials, RR of 1.24 [95%CI 1.08 to 1.42]) were both effective in increasing quit rates. Expert systems, tailored self-help materials (2 trials, RR 0.93 [95%CI 0.62 to 1.39) and individual counselling (2 trials, RR of 1.00 [96% CI 0.82 to 1.22]), appear to be as effective in a stage-based intervention as they are in a non-stage-based form.

Lancaster et al. (2017 [+]) reviewed studies of individual counselling as a face-to-face encounter between a smoking patient and a counsellor trained in assisting smoking cessation. This review found that counselling alone showed significant benefit (27 trials, RR 1.57 [95%CI 1.40 to 1.77) when compared with minimal contact control. In a comparison of more intensive to less intensive counselling interventions (which still involved more than 10 minutes face-to-face contact) (4 trials RR 1.42 [95%CI 0.98 to 2.06]), there was no evidence of benefit from more intensive compared with less intensive counselling.

Group counselling

Stead & Lancaster (2017 [++]) focused on the effectiveness of group smoking cessation interventions. This review found group-based behavioural programmes were more effective (9 trials RR 2.60 [95%CI 1.80 to 3.76]) than no intervention. The review also found that group based therapy was effective when compared with self-help (13 trials, RR 1.88 (95%CI 1.52 to 2.33]) or brief advice (16 trials RR 1.25 [96=5% CI 1.07 to 1.46). There was no evidence that group style interventions are more or less effective than intensive individual counselling.

Any other behavioural intervention

Carr & Ebbert (2012 [+]) assessed the effectiveness of tobacco cessation interventions delivered in dental settings. Evidence from 8 studies suggested that behavioural interventions conducted by oral health professionals can increase tobacco abstinence rates (OR 1.74, (95%CI 1.33 to 2.27]) at six months or longer, but there was evidence of heterogeneity (I^2 = 51%). Behavioural counselling (typically brief) in conjunction with an oral examination was a consistent intervention component that was also provided in some control groups. An insufficient number of studies were available to determine what specific assistance measures delivered by a dental professional provide additional effectiveness beyond brief advice.

Huibers et al. (2007 [++]) assessed the effectiveness of psychosocial interventions by general practitioners. Only 2 included studies considered smoking and cessation outcomes. There was conflicting evidence on the effectiveness of psychosocial interventions when compared to minimal intervention on smoking behaviour.

Lindson-Hawley et al. (2015 [+]) focused on the effectiveness of trials that make explicit reference to motivational interviewing (MI) principles. In a comparison with brief advice (or usual care) the overall effect of MI across all 28 included trials gave a modestly significant greater effect (RR 1.26 [95% C1.16 to 1.36]). There is limited evidence that GPs confer greater benefit than interventions delivered by nurses or counsellors. MI delivered by GPs had a larger effect (2 trials, RR 3.49 [95%CI 1.53 to 7.94]) than counsellors (22 trials, RR 1.25 [95%CI 1.15 to 1.36]). When delivered by nurses the effect was not significant (5 trials, RR 1.24 [95%CI 0.91 to 1.68]). Lastly, interventions delivered in a single session (16 trials, RR 1.26 [95%CI 1.15 to 1.40]) had a similar effect size to multiple session interventions (11 trials, RR 1.20 [95% C 1.02 to 1.42]).

One systematic review was identified that assessed pharmacy personnel-delivered combined smoking cessation interventions for adult smokers (Mdege et al. 2014). This review included 2 studies that assessed non-pharmacological interventions, one of which was conducted in the UK. The authors did not conduct meta-analyses due to the heterogeneity of study interventions and comparisons, and presented the results as a narrative synthesis. Neither study showed a benefit in favour of the pharmacy-led intervention. Both studies showed a positive trend at follow-up with 45.5% versus 31.2% at 1 month in one study and 12.0% versus 7.4% (p = 0.09) at nine months for the other study.

Rice et al. (2013 [++]) focused on brief advice delivered by nurses. This review found that behavioural support (session lasted more than 10 minutes) with or without additional materials and usually with more than 1 follow-up contact, significantly increased quit rates compared with no advice or usual care (28 trials, RR 1.26, [95%CI 1.17 to 1.36]])

Stead et al. (2013 [++]) focused on the effectiveness of smoking cessation interventions delivered by physicians. This review found that more intensive interventions were effective in increasing quit rates compared with no advice (or usual care) (11 trials, RR 1.86 [95%CI 1.60 to 2.15]). The review found that the direct comparison between intensive and minimal (brief) advice in 15 trials suggested overall that there was a small but significant advantage of more intensive advice (RR 1.37 [95% CI 1.20 to 1.56]).

Young people

Stanton & Grimshaw (2013 [++]) focused on strategies that help young people (<20 years) to stop smoking tobacco. The authors concluded that complex interventions

including motivational enhancement are effective for smoking abstinence (12 trials, RR of 1.60 [95%CI 1.28 to 2.01]). They also found that the Not on Tobacco (NoT) programmes for smoking cessation (a structured programme based on social learning theory) in young people had a marginally significant effect (6 trials of low quality evidence, RR of 1.31 [95%CI1.01 to 1.71])]).

Summary

Overall, there was mostly consistent evidence across the 11 reviews for an effect of behavioural support. There is good evidence from 7 reviews that behavioural support interventions, across a range of intervention types and settings, delivered to an individual or group, are effective in helping people to stop smoking (Cahill et al. 2010 [++); Lancaster et al. 2017 [+); Lindson-Hawley et al. 2015 [+); Rice et al. 2013 [++); Stanton & Grimshaw 2013 [++); Stead & Lancaster 2005 [++); Stead et al. 2013 [++]). A review of interventions in dental settings also indicated that behavioural support was effective, although limitations in the evidence ruled out any firm conclusions (Carr & Ebbert 2012 [+]). Although the evidence was restricted to motivational interviewing, there was limited evidence that GPs confer a greater benefit than interventions delivered by nurses or counsellors (Lindson-Hawley et al. 2015 [+]). One review that considered psychosocial interventions by general practitioners identified there was conflicting evidence that psychosocial interventions were more or less effective than minimal intervention on smoking behaviour, based on 2 trials which were not pooled (Huibers et al. 2007 [++]).

There was evidence from 3 reviews that there is limited or no additional benefit from intensive compared with less intensive counselling (Lancaster et al. 2017 [+); Lindson-Hawley et al. 2015 [+); Stead et al. 2013 [++]).

Evidence statements

- ES4 Behavioural support – Individual or group

There is strong evidence from 7 systematic reviews to suggest that behavioural support (either delivered to an individual or a group) is effective in increasing quit rates (13 trials, RR of 1.24 [95%CI 1.08 to 1.42]), (27 trials, RR 1.57 [95%CI 1.40 to 1.77]), (28 trials, RR 1.26 [95%CI 1.16 to 1.36]), (28 trials, RR 1.26, [95%CI 1.17 to 1.36]), (12 trials, RR of 1.60 [95%CI 1.28 to 2.01]), (13 trials, RR 1.88 [95%CI 1.52 to 2.33]), (15 trials, RR 1.37, 95%CI 1.20 to 1.56]). The reviews covered a range of intervention types, including: stage based design, individual behavioural counselling, motivational interviewing and group behaviour therapy. [ES4]

Applicability: With the exception of Stead et al. 2013, the majority of the evidence in these reviews came from the USA, with only a relatively small amount of evidence from the UK. This has implications for applicability as in the UK Stop-Smoking Service combine extended face-to-face support with smoking cessation medications. In addition, most of the included reviews did not provide detailed information about the duration or frequency of interventions.

- ES5 Behavioural support – Type

There was strong evidence from a single review that effectiveness may vary according to the person delivering the intervention: motivational interviewing is effective when delivered by GPs (2 trials, RR 3.49 [95%CI 1.53 to 7.94]) or counsellors (22 trials, RR 1.25 [95%CI 1.15 to 1.36]), but not effective when delivered by nurses (5 trials, RR 1.24 [95%CI 0.91 to 1.68]).

In reviews focused on counselling delivered by nurses (28 trials, RR 1.26, [95%CI 1.17 to 1.36]) and physicians (15 trials, RR 1.37, [95%CI 1.20 to 1.56]) there was strong evidence that interventions were effective.

A review of interventions in dental settings also provided weak evidence that behavioural support was effective, although limitations in the evidence ruled out any firm conclusions (OR 1.74, [95%CI 1.33 to 2.27]).

A review focused on support provided by community pharmacy personnel provided an insufficient number of studies to determine what specific support would aid cessation. [ES5]

Applicability: With the exception of Sinclair et al. 2004 and Stead et al. 2013, the majority of the evidence in these reviews came from the USA, with only a relatively small amount of evidence from the UK. There are no obvious limits to the applicability of this evidence, although the different context of healthcare service organisation may affect the delivery of interventions. In the UK specialist stop-smoking service combines extended face-to-face support with smoking cessation medications.

Pharmacotherapy alone

Review question

Are nicotine replacement therapy (established therapies, for example patch, gum or spray or newer, licensed e-cigarettes) or bupropion, on their own or combined with behavioural support, effective and cost-effective?

Methods and process

This evidence review was developed using the methods and process described in Developing NICE guidelines: the manual. The methods used for study identification are Methodology section (see Appendix A) and reviewing methods specific to this review question are described in the review protocol in Appendix B.

Declarations of interest were recorded according to NICE's 2014 conflicts of interest policy

Public health evidence

Included studies

No evidence was identified for licensed e-cigarettes. Among the two Cochrane reviews that considered pharmacotherapy alone, the interventions examined were as follows

- Bupropion (Hughes et al. 2014)
- Nicotine Replacement Therapy (NRT) (Stead et al. 2012)

Excluded studies

See Appendix E for excluded studies.

Summary of studies included in the evidence review

No evidence was identified for licensed e-cigarettes. Among the two Cochrane reviews that considered pharmacotherapy alone, the interventions examined were as follows

- Bupropion (Hughes et al. 2014)
- Nicotine Replacement Therapy (NRT) (Stead et al. 2012)

All reviews included smokers, some of whom were motivated to stop smoking. Each review excluded trials that included pregnant women and/or young people/adolescents. Many of the included reviews covered studies carried out in mixed settings though were predominantly in primary care, secondary care/smoking cessation clinics and community settings. The included reviews are summarised in Table 2 and further details are in Appendix D.4

Table 2: Characteristics of included studies

Author, year, title	Quality	Populations	Interventions	Comparison	Outcomes
Hughes et al. 2014.	++	44 studies of Current	Bupropion	Placebo, no	Quit rates at 6 months or

Author, year, title	Quality	Populations	Interventions	Comparison	Outcomes
Antidepressants for smoking cessation.		smokers of any age		pharmacotherapy control, no other pharmacotherapy	12 months
Stead et al. 2012. Nicotine replacement therapy for smoking cessation	++	Any smokers in any settings.	NRT (patches, gum, inhaler / inhalator, tables / lozenges, intranasal spray, oral spray)	Placebo, No NRT control	Quit rates

Hughes et al. (2014 [++]) investigated the use of bupropion to aid smoking cessation. There was evidence from 44 trials that bupropion, compared with placebo, no pharmacotherapy control or no other pharmacotherapy significantly increased smoking cessation (RR 1.62 [95%CI 1.49 to 1.76]), with no substantial difference at 6 or 12 months (RR 1.69 [95%CI 1.49 to 1.97] and RR 1.59 [95%CI 1.44 to 1.76] respectively). Eight trials provided direct comparisons between bupropion and NRT: pooled results for all forms of NRT did not detect a significant difference (RR 0.96 [95%CI 0.85 to 1.09]).

Stead et al. (2012 [++]) investigated the effectiveness of NRT (in various delivery methods). The pooled risk ratio for abstinence for any form of NRT relative to control, across 117 trials, was 1.60 [95%CI 1.53 to 1.68). Each of the six forms of NRT product significantly increased the rate of cessation compared with placebo or no NRT. NRT was effective in each of the settings covered in the review 'over-the-counter' (OTC) settings (5 trials, RR 2.71 [95%CI 2.11 to 3.49]), smoking clinics (10 trials, RR 1.73 [95%CI 1.48 to 2.03]), and in primary care settings (23 trials, RR 1.52 [95%CI 1.34 to 1.71]).

Evidence statements

ES6 - NRT

There is strong evidence from a single review (117 trials) that NRT did have a significant effect for smoking cessation (RR 1.60 [95%CI 1.53 to 1.68]). There was significant effect for the range of products (lozenges, inhaler, nasal/oral spray, and patch). The use of NRT was effective in all settings 'over-the-counter' (5 trials, RR 2.71 [95%CI 2.11 to 3.49]), smoking clinics (10 trials, RR 1.73 [95%CI 1.48 to 2.03]) and primary care settings (23 trials, RR 1.52 [95%CI 1.34 to 1.71]). There is evidence from the same review (based on 9 trials that were pooled) that combination NRT is more effective than single NRT (RR 1.34 [95%CI 1.18 to 1.51]). [ES6]

Applicability: The majority of the evidence in these reviews come from the USA, with only a relatively small proportion from the UK. There are no obvious limits to the applicability of this evidence, although the different context of healthcare service organisation may affect the delivery of interventions. In the UK specialist stop-smoking service combines extended face-to-face support with smoking cessation medications.

ES7 Bupropion

There is strong evidence from a single review (based on 44 trials) that bupropion has a significant effect for smoking cessation (RR 1.62 [95%CI 1.49 to 1.76]). There were no conclusions that the efficacy of bupropion differed between lower and higher levels of behavioural support. [ES7]

Applicability: The majority of the evidence in these reviews come from the USA, with only a relatively small proportion from the UK. There are no obvious limits to the applicability of this evidence, although the different context of healthcare service organisation may affect the delivery of interventions. In the UK specialist stop-smoking service combines extended face-to-face support with smoking cessation medications.

Pharmacotherapy with behavioural support

Review question

Are nicotine replacement therapy (established therapies, for example patch, gum or spray or newer, licensed e-cigarettes) or bupropion, on their own or combined with behavioural support, effective and cost-effective?

Methods and process

This evidence review was developed using the methods and process described in Developing NICE guidelines: the manual. The methods used for study identification are Methodology section (see Appendix A) and reviewing methods specific to this review question are described in the review protocol in Appendix B.

Declarations of interest were recorded according to NICE's 2014 conflicts of interest policy.

Public heath evidence

Included studies

Five reviews were identified for inclusion in this review. Two reviews considered combined pharmacotherapy and behavioural interventions (Hughes et al. 2014 and Stead & Lancaster 2016) and 3 reviews considered behavioural support as an adjunct to pharmacotherapy (Mdege & Chindove 2014, Lancaster et al. 2017 and Stead et al. 2015).

Excluded studies

See Appendix E for excluded studies.

Summary of clinical studies included in the evidence review

All reviews included smokers, some of whom were motivated to stop smoking. Most of the reviews excluded trials that included only pregnant women and/or young people/adolescents. Many of the included reviews covered mixed settings though were predominantly in primary care, secondary care/smoking cessation clinics and community settings. The included reviews are summarised in Table 3 and further details are in Appendix D.5

Table 3: Characteristics of included studies

Author, year, title	Quality	Populations	Interventions	Comparison	Outcomes
Hughes et al. 2014. Antidepressants for smoking cessation.	++	40 studies of current smokers of any age	Combined bupropion and multisession individual/ group counselling	Placebo, no pharmacotherapy control, no other pharmacotherapy	Quit rates at 6 months or 12 months
Lancaster et al.	+	6 studies of	Face-to-face	Minimal-contact	Smoking

Author, year, title	Quality	Populations	Interventions	Comparison	Outcomes
2017. Individual behavioural counselling for smoking cessation.		any smokers (excluding pregnant women and trials recruiting only children and adolescents). Settings were mixed, but included community and primary care.	individual counselling sessions of more than 10 minutes, with most also including further telephone contact for support as an adjunct to pharmacotherapy	control (usual care, brief advice or self-help materials)	cessation at the longest reported follow-up. Sustained abstinence (where available)
Mdege et al. 2014. Effectiveness of tobacco use cessation interventions delivered by pharmacy personnel: A systematic review	+	4 studies of pharmacy clients who were tobacco users.	Any pharmacy personnel delivered tobacco use cessation intervention (pharmacotherapy plus behavioural support).	Usual care, no treatment or other active treatment.	Abstinence from smoking
Stead & Lancaster 2016. Combined pharmacotherapy and behavioural interventions for smoking cessation.	++	Any smokers (excluding adolescents & pregnant women only trials).	Combination behavioural support and medications (including, bupropion, and nicotine replacement therapies like patches or gum) help people quit smoking	Usual care, brief advice or self-help.	Smoking cessation at the longest follow-up.
Stead et al. 2015. Additional behavioural support as an adjunct to pharmacotherapy for smoking cessation.	++	47 studies of any smokers (excluding adolescents & pregnant women only trials).	Smoking cessation pharmacotherapy plus increased behavioural support	Smoking cessation pharmacotherapy plus minimal (relative to intervention group) behavioural support.	Smoking cessation at the longest follow-up (at least 6 months).

Pharmacotherapy with behavioural support

Combined pharmacotherapy and behavioural support

Hughes et al. (2014 [++]) investigated the use of bupropion to aid smoking cessation. The authors considered the effect of adding behavioural support to bupropion and found that both multi-session group behavioural support (10 trials, RR 1.76 [95%CI

1.44 to 2.16]) and multi-session individual counselling approach (30 trials, RR 1.60 [95%CI 1.46 to 1.76]) in combination with bupropion were effective. There was insufficient evidence to draw any conclusions about low intensity support (less than 30 minutes at the initial consultation, with no more than two further visits).

Stead & Lancaster (2016 [++]) found good evidence that interventions that combined pharmacotherapy and behavioural support increase smoking cessation success compared with a minimal behavioural intervention or usual care (52 trials, RR 1.83 [95%CI 1.68 to 1.98]).

Mdege et al. (2014 [+]) reviewed 2 studies (1 CCT and 1 RCT) that compared a pharmacy-led combined pharmacotherapy and behavioural support intervention for smoking cessation with usual care. The CCT reported a statistically higher odds of success at 4 weeks with usual care (OR 2.42 [95%CI 1.90 to 3.08]) compared with a pharmacist-led intervention. The RCT however reported a significant difference in the point prevalence smoking abstinence at 12 months for hospital or community pharmacy-led interventions compared with a minimal intervention (38%,24% and 4.6% respectively p=0.031) but found no significant difference between the groups for continuous abstinence at 3, 6 or 12 months.

Behavioural support as an adjunct to pharmacotherapy

Stead et al. (2015 [++]) found that the addition of increased behavioural support to pharmacotherapy interventions provided a small but statistically significant effect for smoking abstinence (47 trials, RR 1.17 [95%CI 1.11 to 1.24]) compared with pharmacotherapy with minimal behavioural support. All but four of the included studies provided four or more sessions of support to the intervention group. Most trials used NRT. There was an incremental benefit of additional behavioural support across a range of levels of baseline support.

Lancaster et al. (2017 [+]) reviewed studies of individual counselling as a face-to-face encounter between a smoking patient and a counsellor trained in assisting smoking cessation. In a subset of studies where counselling was used as an adjunct to NRT there was a modest effect which just reached significance (6 trials, RR 1.24 [95%CI 1.01 to 1.51]). In a comparison of more intensive to less intensive counselling interventions (which still involved more than 10 minutes face-to-face contact) with adjunct pharmacotherapy (8 trials, RR 1.26; [95%CI 1.04 to 1.52), there was some evidence of benefit from more intensive compared with brief counselling.

Mdege et al. (2014 [+]) reviewed 3 studies of pharmacist-led support as an adjunct to pharmacotherapy. Two of the studies showed a benefit in favour of the addition of pharmacy-led behavioural support to pharmacotherapy and the remaining study reported no statistically significant difference.

See appendix D for full evidence tables.

Evidence statements

ES9 Combined pharmacotherapy & behavioural support

There is strong evidence from 3 reviews that interventions that combine NRT and behavioural support (individual support: 18 trials, RR 1.32 [95%CI 1.18 to 1.49); group support: 20 trials, RR 1.57 [95%CI 1.40 to 1.76]), (40 trials, RR 1.82 [95%CI 1.66 to 2.00]) are effective for smoking cessation. One of the reviews (2 trials) provided evidence that combined pharmacotherapy and behavioural support was effective when delivered by a pharmacist.[ES9]

Applicability: The majority of the evidence in these reviews come from the USA, with only a relatively small proportion from the UK. There are no obvious limits to the applicability of this evidence, although the different context of healthcare service organisation may affect the delivery of interventions. In the UK specialist stop-smoking service combines extended face-to-face support with smoking cessation medications.

ES10 Behavioural support as an adjunct to pharmacotherapy

There is strong evidence from 3 reviews that the use of behavioural interventions as adjuncts to NRT (4 trials, RR 1.27 (95%CI 1.02 to 1.59)), (47 trials, RR 1.17 (95%CI 1.11 to 1.24)) are effective for smoking cessation - and more effective than NRT with minimal behavioural support. One of the review (3 trials) provided mixed evidence on the effectiveness of behavioural interventions as an adjunct to pharmacotherapy when delivered by a pharmacist. [ES10]

Applicability: The majority of the evidence in these reviews come from the USA, with only a relatively small proportion from the UK. There are no obvious limits to the applicability of this evidence, although the different context of healthcare service organisation may affect the delivery of interventions.

Recommendations

B1 Ensure the following evidence-based interventions are available for adults who smoke:

- behavioural support (individual and group)
- bupropion[a]
- nicotine replacement therapy (NRT) – short and long acting
- varenicline[b]
- very brief advice. [2018]

B2 Consider text messaging as an adjunct to behavioural support

B3 Offer varenicline as an option for adults who want to stop smoking, normally only as part of a programme of behavioural support, in line with NICE's technology appraisal guidance on varenicline. [2018]

B4 For adults, prescribe or provide varenicline, bupropion or NRT before they stop smoking. [2018]

B5 Agree a quit date set within the first 2 weeks of bupropion treatment and within the first 1 to 2 weeks of varenicline treatment. Reassess the person shortly before the prescription ends. [2018]

B6 Agree a quit date if NRT is prescribed. Ensure that the person has NRT ready to start the day before the quit date. [2018]

B7 Consider NRT[c] for young people over 12 who are smoking and dependent on nicotine. If this is prescribed, offer it with behavioural support. [2018]

a See information on bupropion hydrochloride in the British national formulary.
b See information on varenicline in the British national formulary

B8 Ensure behavioural support is provided by trained stop smoking staff (see the National Centre for Smoking Cessation and Training [NCSCT] training standard). [2018]

B9 Ensure very brief advice is delivered according to the NCSCT training module on very brief advice. [2018]

Research recommendations

How effective and cost effective are licensed nicotine-containing e-cigarettes in helping people to stop smoking and to prevent relapse, and under what circumstances are they effective?

Why this is important

Currently there is no evidence on the effectiveness of licensed nicotine-containing e-cigarettes. This includes the use of nicotine-containing e-cigarettes as part of self-help or through local stop smoking services. It is also important to know for whom they might be effective (especially in disadvantaged groups). Information is also needed on whether they help people to switch completely or partly from tobacco cigarettes, prevent relapse and whether there are as yet unknown adverse effects.

Rationale and impact

Why the committee updated the recommendations

Evidence showed that all the stop smoking interventions recommended for adults are effective. But to get the most benefit, staff delivering behavioural interventions must be trained to the NCSCT training standard. There was some evidence that NRT helped young people over 12 who smoke, and topic experts on the committee emphasised that young people are more likely to stop smoking when they also get behavioural support.

Topic experts explained that, in their experience, quit rates increase when text messaging is added to behavioural support. Evidence for text messaging alone was not reviewed so the committee did not make a recommendation for this. The text messages should be tailored to the person, give information about the health effects of smoking, provide encouragement, boost self-efficacy, motivate and give reminders of how deal with difficult situations.

Impact of the recommendations on practice

All the interventions are clinically effective, cost effective and cost saving to both NHS and local authorities. Most organisations will not need to change current practice and support to stop smoking services should remain a priority. Behavioural support in the UK is currently only provided by stop smoking services. If GPs were commissioned to provide this intervention they would be likely to contract this out to the local stop smoking services. Staff working in GP settings currently offer pharmacotherapy plus very brief advice.

Individual behavioural support involves more staff than group behavioural support. But group behavioural support can lead to delays in support for people wanting to

[c] The UK marketing authorisation for nicotine replacement therapy products varies for use in children and young people under 18. Refer to the summary of product characteristics for prescribing information on individual nicotine replacement therapy preparations.

quit because they usually need a minimum number of people before they can start. Text messaging is routinely provided in stop smoking services as an opt-out adjunct to behavioural support and because it is cheap it does not need significant investment.

The committee's discussion of the evidence

Interpreting the evidence

The outcomes that matter most

The committee agreed that quit rate was the most important outcome as it was a reliable proxy for all the benefits accrued after a smoker quits. This includes the reduction in risk to tobacco-related illnesses and the morbidity and mortality associated with these. For people with tobacco-related illness there is an increased benefit in terms of greater risk reduction, lessening of symptoms, fewer hospital admissions etc.

For people with other medical conditions, stopping smoking can reduce the risk of complications associated with those conditions, increase treatment options (for example in HIV), and reduce delays in recovery after surgery

From a population health aspect the committee noted that one of the largest risk factors for starting smoking is having a parent who smokes so any increase in quit rates in one generation will have a carry-on benefit in terms of further reducing the number of people who take up smoking in the next generation. There is an additional benefit from reduced exposure to second-hand smoke.

The quality of the evidence

The quality of the evidence reviewed for smoking cessation interventions was rated as moderate to high. The committee noted that for the most part the evidence of effectiveness in increasing quit rates for the different interventions was supported by their experiences in clinical and public health practice. There was one exception to this where the topic experts noted that the effectiveness of over the counter' NRT was not as clear-cut in practice. Having said this, the committee agreed that the evidence in favour of NRT across different setting was consistent enough to avoid the need to draft separate recommendations based on setting.

Benefits and harms

The evidence reviews showed a clear benefit in terms of increasing quit rates, for each of the recommendations. For individuals and groups from disadvantaged backgrounds behavioural support, if successful, may provide skills and confidence which will act as a buffer against the effects of disadvantage, facilitating positive behaviour change.

The evidence on adverse effects of the pharmacotherapies was severely limited but the committee noted the Summary of Product Characteristics (SPC) of the drugs do not list severe adverse effects. Thus the committee considered that it would be safe to recommend these interventions in line with their SPC's. The committee noted that there is an MHRA drug safety update on the use some medicines which may need to be adjusted if a smoker quits smoking (Smoking and smoking cessation: clinically significant interactions with commonly used medicines).

The role of personal preference in choosing a treatment option will have implications for the behavioural support and the practicalities of offering group behavioural

support. As group behavioural support will generally require a minimum number of participants there may be a delay in starting, while waiting for a group to be filled. This should be taken into account when discussing options with the person. Also as with other group therapies, care must be taken to ensure that all candidates are suitable as unsuitable candidates may have a negative impact on the rest of the group. It was also noted that staff delivering the interventions need to be supported and developed as staff who are not competent will also have a negative impact on the group.

Another potential harm of successful stop smoking interventions may be an increase in compensatory behaviour, such as over-eating resulting in a weight gain with resulting impact on self-esteem/confidence and with long-term risks for health and wellbeing.

Cost effectiveness and resource use

No review of cost effectiveness evidence was undertaken. Instead, a bespoke model was developed which explored the threshold at which interventions are cost effective and assessed the cost effectiveness of a range of interventions identified in the effectiveness reviews.

This topic area was covered in the overall health economic modelling, which indicated that all interventions were cost effective and potentially cost saving to both NHS and local authorities. Eight of the included studies involved some element of pharmacotherapy; all were found to be cost-effective.

Other factors the committee took into account

The topic experts noted that many people are using a variety of methods to quit smoking. The committee agreed that quitting should always be encouraged, but that only licensed medicinal products should be recommended. The committee noted that prescribers have a duty of care to provide information about the pharmacotherapy that they are prescribing. As such it is unlikely that pharmacotherapy would ever be offered without this advice. The committee noted that the Summary of Product Characteristics (SPC) for varenicline and bupropion are specific in how they should be used (1 to 2 weeks before the agreed quit date), monitored and in what circumstances repeat prescriptions should be used. The committee were also aware that some of these intervention are used in combinations in smoking cessation but that there was limited evidence for this.

When considering the effectiveness of licensed e-cigarettes, the committee noted that no evidence for the effectiveness of licensed nicotine-containing e-cigarettes was identified and so were not in a position to make a recommendation on this issue.

The importance of personal preferences over methods used to stop smoking was underlined by the topic experts and as such, the committee recommended that stop smoking services, GPs and other prescribers explain that a combination of pharmacotherapy and advice or behavioural support may be the best option before agreeing the approach to take with the smoker,

The topic experts noted that the evidence showing that NRT bought over the counter is not as effective as when it NRT is prescribed is supported by their experience. The committee discussed this and noted that when prescribed, NRT would have a degree of support that would be available to the person which would not be available when bought over the counter.

The committee considered that UK specialist stop smoking services are the only service currently providing behavioural support in the UK. The committee accepted that if GP's were commissioned to provide this intervention then they would be likely to contract this out to the local stop smoking service. However, the evidence to support the routine use of text messaging was a single RCT so a recommendation was made to consider text message support as an adjunct to behavioural support

In order to reduce the risk of poorly trained staff having a negative impact the committee agreed that training standards are important as a means to help improve effectiveness. The committee were aware of the National Centre for Smoking Cessation and Training (NCSCT) standards and wanted to make reference to this.

The committee noted that community pharmacies serve local communities and have the potential to reach and offer advice to smokers. They are also best placed to meet the needs of minority ethnic and disadvantaged groups and those who may have difficulty accessing other community services.

In general, stopping smoking conveys an additional benefit from reduced exposure to second-hand smoke. This might not be the case for nicotine-containing e-cigarettes as there is no evidence on the long-term toxicity on those exposed to second-hand vapour and so the committee decided to draft a research recommendation on the health impacts of nicotine-containing e-cigarettes