Intervenciones para promover el abandono del hábito de fumar durante el embarazo

Lumley J, Oliver SS, Chamberlain C, Oakley L

Reproducción de una revisión Cochrane, traducida y publicada en *La Biblioteca Cochrane Plus*, 2006, Número 1

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Esta revisión debería citarse como:
Lumley J, Oliver SS, Chamberlain C, Oakley L. Intervenciones para promover el abandono del hábito de fumar durante el embarazo (Revisión Cochrane traducida). En: *La Biblioteca Cochrane Plus*, 2006 Número 1. Oxford: Update Software Ltd. Disponible en: http://www.update-software.com. (Traducida de *The Cochrane Library*, 2006 Issue 1. Chichester, UK: John Wiley & Sons, Ltd.).
Fecha de la modificación más reciente: 05 de agosto de 2004
Fecha de la modificación significativa más reciente: 22 de marzo de 2004

RESUMEN

Antecedentes
El hábito de fumar sigue siendo uno de los pocos factores potencialmente evitables asociados con el bajo peso al nacer, el nacimiento de prematuros y la muerte perinatal.

Objetivos
Evaluar los efectos de los programas para promover el abandono del hábito de fumar implementados durante el embarazo en cuanto a la salud del feto, el recién nacido, la madre y la familia.

Estrategia de búsqueda
Se realizaron búsquedas en el registro de ensayos del Grupo Cochrane de Embarazo y Parto (Cochrane Pregnancy and Childbirth Group), el registro de ensayos del Grupo Cochrane de Adicción al Tabaco (Cochrane Tobacco Addiction Group, julio de 2003), y las bases de datos MEDLINE (desde enero de 2002 hasta julio de 2003), EMBASE (desde enero de 2002 hasta julio de 2003), PsychLIT (desde enero de 2002 hasta julio de 2003), CINAHL (desde enero de 2002 hasta julio de 2003) y AUSTHEALTH (desde enero de 2002 hasta 2003). Se estableció contacto con los autores de los ensayos para localizar los datos adicionales inéditos. Se realizaron búsquedas manuales en las referencias de los ensayos identificados y las revistas obstétricas recientes.

Criterios de selección
Se implementaron ensayos aleatorios y cuasialeatorios de programas para el abandono del hábito de fumar durante el embarazo.

Recopilación y análisis de datos
Cuatro revisores evaluaron la calidad de los ensayos y obtuvieron los datos de forma independiente.

Resultados principales
Esta revisión incluyó 64 ensayos. Cincuenta y un ensayos controlados aleatorios (20 931 mujeres) y seis ensayos aleatorios grupales (más de 7500 mujeres) proporcionaron datos sobre el abandono del hábito de fumar o los resultados perinatales. A pesar de la variación considerable en la intensidad de la intervención y el tamaño de recordatorios y refuerzos a lo largo del embarazo, se produjo un aumento de la mediana de intensidad de la "atención habitual" y las intervenciones con el paso del tiempo.

Hubo una reducción significativa del hábito de fumar en los grupos de intervención de los 48 ensayos incluidos: (riesgo relativo [RR] 0,94; intervalo de confianza [IC] del 95%: 0,93 a 0,95), una diferencia absoluta de seis en 100 mujeres que mantuvieron el hábito. Los 36 ensayos con abandono del hábito de fumar validado tuvieron una reducción similar (RR 0,94; IC del 95%: 0,92 a 0,95). Las intervenciones para el abandono del hábito de fumar redujeron el bajo peso al nacer (RR 0,81; IC del 95%: 0,70 a 0,94) y el nacimiento de prematuros (RR 0,84; IC del 95%: 0,72 a 0,98); y hubo un aumento de 33 g (IC del 95%: 11 g a 55 g) en la media del peso al nacer. No hubo diferencias estadísticamente significativas de muy bajo peso al nacer, nacimiento de mortinatos, mortalidad perinatal o neonatal, pero estos análisis tuvieron un poder estadístico muy limitado. Una estrategia de intervención, recompensas más apoyo social (dos ensayos), produjo una reducción del hábito de fumar significativamente mayor que otras

estrategias (RR 0,77; IC del 95%: 0,72 a 0,82). Cinco ensayos sobre la prevención de recaídas del hábito de fumar (más de 800 mujeres) no mostraron una reducción estadísticamente significativa de las recaídas.

Conclusiones de los autores
Los programas para promover el abandono del hábito de fumar en el embarazo reducen la proporción de mujeres que continúan fumando, el bajo peso al nacer y el nacimiento de prematuros. Los ensayos combinados tienen un poder estadístico inadecuado para detectar reducciones de la mortalidad perinatal o el muy bajo peso al nacer.

RESUMEN EN TÉRMINOS SENCILLOS

Las estrategias pueden ayudar a apoyar a las mujeres para abandonar el hábito de fumar en el embarazo para que los recién nacidos tengan mejor salud

El hábito de fumar en el embarazo es frecuente, en particular donde hay ingresos bajos y desventaja social. El hábito de fumar en el embarazo aumenta el riesgo de los recién nacidos de que tengan bajo peso al nacer y sean muy prematuros. Los recién nacidos luchan con frecuencia para enfrentar la vida fuera del útero y pueden sufrir problemas de salud en etapas posteriores de la vida. A muchas madres les resulta difícil dejar de fumar, o reducir el hábito durante el embarazo aun conociendo los beneficios que esto puede implicar, porque el tabaco les ayuda a resistir el estrés. Existen estrategias eficaces que pueden ayudar y apoyar a las mujeres para dejar de fumar y que resultan en una menor cantidad de recién nacidos prematuros y en un mejor peso del recién nacido al nacer.

ANTECEDENTES

El hábito de fumar cigarrillos durante el embarazo es frecuente. Los estudios de prevalencia realizados en la década de los noventa muestran que una de cada cinco y una de cada tres mujeres embarazadas en países desarrollados informan tener el hábito de fumar (por ejemplo, Campion 1994; Cnattingius 1997; Dodds 1995; Husten 1996; Stewart 1995; Tappin 1997; Wiemann 1994). Las pruebas de las tendencias en la prevalencia del hábito de fumar en el embarazo son inconsistentes, aunque Noruega, Suecia y Canadá han identificado disminuciones a finales de la década de los ochenta (Cnattingius 1997; Eriksson 1996; Stewart 1995). En Australia, la prevalencia del hábito de fumar ha disminuido del 23% en 1998 al 19,5% en 2001 (AIHW 2002). En los EE.UU., el Surgeon-General's Report on Women and Smoking del 2000 mostró una disminución del 34% en 1965 al 22% a 23% a finales de la década de los noventa, pero no informó cambios desde 1998 a 2000. La estimación del hábito de fumar en el embarazo en los EE.UU difiere según el estado así como también la educación y la edad materna. En 2000 y 2001 la proporción de mujeres embarazadas fumadoras en Alabama fue del 16,9% para mujeres menores de 20 años, pero del 9,3% para mujeres de 35 años o más. En Maine, las proporciones equivalentes fueron del 34,6% y el 10,5% (MMWR 2004).

Existen diferencias sociales marcadas entre las mujeres que fuman y las que no lo hacen; el hábito continuo y el alto consumo diario demuestran una fuerte asociación con desventajas sociales, alta paridad, ausencia de pareja, ingresos bajos, o (en los EE.UU.) la atención médica de la madre financiada por Medicaid (Frost 1994; Graham 1977; Graham 1994; Graham 1996; Tappin 1996). La alta prevalencia del hábito de fumar en varios pueblos indígenas concuerdan con su privación social y material (por ejemplo, Chan 2001; Hunt 2003; Kaplan 1997; Wiemann 1994) pero, en otros grupos, las diferencias culturales pueden afectar a este gradiente social. Las mujeres inmigrantes o refugiadas en Europa del Norte, Norteamérica o Australia provenientes de sudeste asiático conservan una prevalencia inferior del hábito de fumar, a pesar de las importantes carencias sociales que sufren (por ejemplo, Potter 1996; Small 2000); en los EE.UU, las mujeres hispanas y afroamericanas presentan una prevalencia inferior del hábito de fumar en el embarazo en comparación con otras mujeres de estudios más recientes (Andreski 1995; Wiemann 1994), aunque el Surgeon-General's Report de 1998 mostró un aumento del hábito de fumar en las mujeres jóvenes de estas comunidades (CDCP 1998).

Además de los factores sociales asociados con la continuidad del hábito, existen asociaciones psicosociales comunes, especialmente depresión, estrés laboral/carga laboral, exposición a la violencia de compañeros íntimos y bajos niveles de apoyo práctico (Borelli 1996; Dejin-Karlsson 1996; McNutt 2002; Wergeland 1996). El temor al aumento de peso es otro factor que contribuye a mantener el hábito de fumar; es más probable que las mujeres no dejen de fumar para controlar su peso y, además, las campañas comerciales de tabaco están enfocadas completamente a la imagen corporal femenina (CDCP 2002).

Existe una proporción mayor de mujeres que dejan de fumar durante el embarazo en comparación con otros momentos de sus vidas. Hasta el 40% de las mujeres en los EE.UU que fuman antes del embarazo dejan el hábito antes de su primera visita prenatal (Quinn 1991; Woodby 1999), una tasa sustancialmente más alta que la informada en la población en general (Ershoff 1999; McBride 2003). "Exfumadores espontáneos" generalmente fuman menos; tienen mayor probabilidad de haber dejado de fumar anteriormente; o tienen más posibilidades de tener una pareja que no fuma, o más apoyo y estímulo en su domicilio para dejar el hábito, o fuertes creencias acerca de los peligros que implica el hábito de fumar (Baric 1976; Ryan 1980). Pero sólo un tercio de estos exfumadores siguen siendo abstinentes después de un año (CDCP 2002). McBride 2003 plantea la hipótesis de que el embarazo puede ser un "momento apropiado de aprendizaje" para el abandono del hábito de fumar: describe una mayor percepción del riesgo y los resultados personales en el embarazo que provoca respuestas afectivas o emocionales fuertes, y redefine la función social o el autoconcepto de una mujer, especialmente cuando el fracaso en el cumplimiento de una función social resulta en la estigmatización social.

El hábito de fumar sigue siendo uno de los pocos factores potencialmente evitables asociados con el bajo peso al nacer (menos de 2500 g), el nacimiento prematuro (menos de 32 semanas) y la mortalidad perinatal (Kramer 1987). Esto lo convierte en un tema de salud pública importante durante el embarazo. En contraposición a ese hallazgo, la calidad de la alimentación en el embarazo (en países desarrollados) no ha demostrado afectar la media del peso al nacer en neonatos de más de 32 semanas de gestación (Rogers 1998).

El hábito de fumar se asocia con tasas bajas de iniciación de la lactancia materna, y una duración reducida (Horta 1997; Sayers 1995); esta asociación ha persistido en algunos, pero no todos los estudios, después de la adaptación de los factores sociales y reproductivos. Existen pocas pruebas de estudios realizados en humanos o en animales de que esta asociación se deba a los efectos fisiológicos del hábito de fumar en la lactancia materna (Amir 2001; Amir 2002).

Los primeros ensayos de intervenciones contra el hábito de fumar durante el embarazo se publicaron hace más de 20 años (Baric 1977; Donovan 1977). El primer ensayo que demostró la reversibilidad de la reducción del peso al nacer asociada con el hábito de fumar mediante una intervención intensiva durante el embarazo se publicó en 1984 (Sexton 1984). Las campañas poblacionales para promover la reducción y el abandono del hábito de fumar durante el embarazo son generalizadas (Campion 1994; Eriksson 1996). Parece haber alguna adopción de los programas de intervenciones sistemáticas durante la atención prenatal (Lowe 2002; Windsor 2000b), pero todavía existen problemas generales con respecto a su implementación (Lumley 2002).

Las intervenciones utilizadas en los programas para el abandono del hábito de fumar han sido objeto de críticas debido a que no han tenido en cuenta lo suficiente el conocimiento y la teoría relevante de promoción de la salud (Solomon 1996; Stotts 1996), y han demostrado una implementación inadecuada y un proceso de evaluación escaso o nulo (Windsor 1998). Según estudios recientes, existen pruebas sólidas acerca de la falta de fiabilidad de un autoinforme como medida del nivel de consumo de tabaco en los ámbitos de asistencia sanitaria, especialmente en la atención materna. Esto incluso se observó en el primer ensayo de embarazo (Donovan 1977), aunque no se encontró en otros ensayos en la década de los ochenta (Fox 1989) (Kendrick 1995; Petersen 1992; Walsh 1997). Este hallazgo significa que los ensayos que no validan el nivel de consumo de tabaco tienen probabilidad de presentar errores de medición considerables y, por lo tanto, un poder estadístico reducido para identificar los efectos verdaderos.

Los temores de las mujeres de que la reducción del hábito de fumar aumenta la probabilidad de un parto instrumental o un trabajo de parto difícil debido al aumento del tamaño del feto rara vez se han tenido en cuenta (Sexton 1984) en el diseño y la implementación de programas para el abandono del hábito de fumar. Un estudio de cohorte pequeño en los EE.UU encontró que se asoció al abandono del hábito de fumar con una protección contra el peso al nacer inferior a través de mecanismos diferentes del aumento del peso de la madre o diversos patrones de aumento de peso (Groff 1997). Un estudio reciente realizado en Guatemala presentó ejemplos de aumentos del peso al nacer (de 2450 g a 2550 g), y encontró un mayor riesgo de cesárea debido a la obstrucción de ocho en cada 1000 casos, pero esto fue compensado por una reducción del riesgo de cesárea debido al sufrimiento fetal de 34 cada 1000 casos (Merchant 2001). Además, la consulta preliminar con especialistas en la promoción de la salud ha identificado inquietudes acerca de los efectos adversos del dejar de fumar, o la culpa cada vez mayor de mantener el hábito, en la capacidad y el bienestar psicológico de las mujeres para enfrentar circunstancias adversas, con efectos sobre el bienestar de los otros miembros de la familia como efectos adversos posibles en las intervenciones para el abandono del hábito de fumar (Oliver 1997).

Complementar lo que se conoce de la literatura de investigación acerca del hábito de fumar en el embarazo; las contribuciones directas de esta revisión se obtuvieron de mujeres que fumaron antes de o durante el embarazo. Se identificaron a las mujeres a través de las redes de la comunidad, y sus criterios destacaron la necesidad de concentrar la atención en los efectos adversos potenciales de los programas para el abandono del hábito de fumar; en particular, la culpa consiguiente, la ansiedad y el estrés adicional experimentados por aquellas mujeres que siguen fumando, especialmente a lo largo de los embarazos de "alto riesgo", y el efecto perjudicial sobre las relaciones con su familia y los proveedores de atención sanitaria de la madre.

Adams 1998, y Melvin 2000 calculan los costos de las condiciones maternas atribuidas al hábito de fumar en el embarazo (rotura de las membranas previa al trabajo de parto prematuro (RMPTP), embarazo ectópico, placenta previa, desprendimiento placentario, aborto espontáneo) con un efecto protector contra la preeclampsia también considerada como un ejemplo del hábito de fumar en el embarazo, en un total de $135 a $167 millones de dólares por año en los EE.UU, sobre la base del costo de asistencia sanitaria de los EE.UU en 1993 y la estimación del dólar. Los costos del nacimiento y el primer año tanto para los neonatos como para las madres a las que se les atribuye el hábito de fumar representan de $1142 dólares a $1358 dólares por cada mujer fumadora. Los costos implicados para el recién nacido son aproximadamente diez veces los costos para la madre y representan el 90% de los costos en el primer año. El bajo peso al nacer produce la carga económica más alta debido a que es el resultado adverso más frecuente (Miller 2001).

OBJETIVOS

El objetivo primario fue identificar si es posible reducir el hábito de fumar durante el embarazo por medio de una mayor información acerca de sus riesgos, consejos para dejar el hábito, mayor asesoramiento individual o consejos más intensivos, asesoramiento grupal, retroalimentación sobre los efectos fisiopatológicos del hábito de fumar en la madre o el feto, la provisión de un tratamiento de reemplazo de la nicotina, información/imágenes más detalladas del feto, administración de suplementos de información y consejos con manuales/videos de autoayuda o mensajes asistidos por ordenador sobre las estrategias para dejar el hábito, recompensas o incentivos, el apoyo de compañeros o el apoyo social adicional.

Otros objetivos

(1) Comparar la efectividad de la información y los consejos solos con intervenciones más intensivas durante el embarazo.
(2) Identificar si la reducción del hábito de fumar* y las intervenciones para el abandono del hábito de fumar aumentan la media del peso al nacer y reducen el bajo peso al nacer.
(3) Identificar si la reducción del hábito de fumar* y las intervenciones para el abandono del hábito de fumar reducen el nacimiento de prematuros y inmaduros.
(4) Identificar si la reducción del hábito de fumar* y las intervenciones para el abandono del hábito reducen la mortalidad perinatal.
(5) Identificar si la reducción del hábito de fumar* y las intervenciones para el abandono del hábito aumentan el parto instrumental.
(6) Identificar si la reducción del hábito de fumar* y las intervenciones para abandonar el hábito aumentan la iniciación y la duración de la lactancia materna.
(7) Identificar si la reducción del hábito de fumar* y las intervenciones para abandonar el hábito aumentan la ansiedad o la depresión, o tienen un efecto negativo sobre las medidas de salud materna o el manejo de las habilidades.
(8) Identificar las opiniones de los participantes de la/s intervención/ones.
(9) Identificar si la reducción del hábito de fumar* y las intervenciones para el abandono del hábito tienen efectos negativos sobre el funcionamiento familiar, incluida la lesión no accidental.
(10) Identificar si la reducción del hábito de fumar* y las intervenciones para el abandono del hábito aumentan la proporción de mujeres que no vuelven a fumar una vez finalizado el embarazo.
(11) Comparar los métodos de entrenamiento de los profesionales de la salud (médicos generalistas, parteras, obstetras) en la provisión de programas eficaces para el abandono del hábito de fumar.

*Debido a que la reducción del hábito de fumar no puede identificarse de manera fiable, en la actualidad, no se informan estos resultados.

Esta revisión no aborda los ensayos sobre el abandono del hábito de fumar fuera del embarazo: *ver* las revisiones realizadas por Lancaster 1997; Silagy 1997; Silagy 2002. Se consideran para la revisión los ensayos que combinan las estrategias para el abandono del hábito de fumar con otras intervenciones en el embarazo, pero no para las medidas de resultado como el peso al nacer, el nacimiento de prematuros, la lactancia materna y la mortalidad perinatal que pueden atribuirse a otros componentes de un paquete de intervenciones.

CRITERIOS PARA LA VALORACIÓN DE LOS ESTUDIOS DE ESTA REVISIÓN

Tipos de estudios

Se considerarán todos los estudios con asignación aleatoria o cuasialeatoria.

Tipos de participantes

(1) Mujeres que están embarazadas, en cualquier ámbito de atención.
(2) Mujeres que buscan una consulta previa al embarazo.
(3) Profesionales de la salud en los ensayos de las estrategias para cambiar el conocimiento, las actitudes y el comportamiento en lo que se refiere al abandono del hábito de fumar.

Tipos de intervención

(1) Información acerca de los efectos perjudiciales del hábito de fumar en el feto y el recién nacido, la madre misma u otros miembros de la familia (verbal, escrita o ambas).
(2) Consejos para "dejar de fumar" proporcionados por un profesional de la salud.
(3) Consejos suplementarios mediante el refuerzo de las visitas prenatales posteriores.
(4) Consejos suplementarios mediante el asesoramiento grupal.

(5) Consejos suplementarios mediante la provisión de apoyo de parte de los compañeros.
(6) Consejos suplementarios mediante el registro del nivel de consumo de tabaco, o la medición de los subproductos del tabaco en otras visitas prenatales.
(7) Consejos suplementarios mediante una retroalimentación de los efectos del hábito de fumar en el feto (movimientos fetales, respiración fetal, frecuencia cardíaca fetal).
(8) Consejos suplementarios mediante información positiva acerca del feto y el desarrollo fetal (por ejemplo, descripción detallada de la ecografía).
(9) Consejos y apoyo individualizados para dejar de fumar sobre la base de las "etapas del cambio".
(10) Provisión de un manual de autoayuda específico para el embarazo sobre las estrategias para dejar el hábito. Se proporciona lo siguiente como un complemento de la información y los consejos:

- tratamiento de reemplazo de la nicotina;
- seguimiento telefónico con refuerzo de consejos y estrategias para dejar el hábito;recompensas e incentivos.

(11) Estrategias para cambiar las actitudes, el conocimiento y el comportamiento de los prestadores de atención sanitaria en lo que se refiere al abandono del hábito de fumar.

Tipos de medidas de resultado

(1) Abandono del hábito de fumar al final del embarazo, autoinformado y validado.
(2) Reducción del hábito de fumar* desde la primera visita prenatal al final del embarazo, autoinformada y validada
(3) Abandono del hábito de fumar en el puerperio, autoinformado y validado.
(4) Peso al nacer (media del peso al nacer, proporción inferior a 2500 g e inferior a 1500 g).
(5) Edad gestacional al nacer (proporción de menos de 37 semanas, menor a las 32 semanas, menor a las 30 semanas).
(6) Mortalidad perinatal (nacimientos de mortinatos, muertes neonatales, todas las muertes perinatales).
(7) Método de parto.
(8) Proporción de mujeres que inician la lactancia materna; lactancia materna a los tres y seis meses después del nacimiento.
(9) Medidas de ansiedad, depresión y estado de salud materno al final del embarazo y después del nacimiento.
(10) Opiniones de los participantes acerca de las intervenciones.
(11) Medidas del funcionamiento familiar al final del embarazo y durante el postparto.
(12) Medidas de conocimiento, actitudes y comportamiento de los profesionales de la salud (obstetras, parteras y médicos de familia) en lo que se refiere a facilitar el abandono del hábito de fumar en el embarazo.

* Debido a que, en la actualidad, la reducción del hábito de fumar no puede identificarse de manera fiable, no se informa este resultado.

ESTRATEGIA DE BÚSQUEDA PARA LA IDENTIFICACIÓN DE LOS ESTUDIOS

Se realizaron búsquedas en el Registro de Ensayos del Grupo Cochrane de Embarazo y Parto (Cochrane Pregnancy and Childbirth Group) (julio 2003).

El Coordinador de Búsqueda de Ensayos mantiene el registro de ensayos del Grupo Cochrane de Embarazo y Parto, que contiene ensayos identificados mediante:
1. Búsquedas trimestrales en el Registro Cochrane Central de Ensayos Controlados (CENTRAL) Cochrane Central Register of Controlled Trials (CENTRAL);
2. búsquedas mensuales en MEDLINE;
3. búsquedas manuales en 30 revistas y en los resúmenes de los principales congresos;
4. búsqueda semanal de información actualizada en 37 revistas adicionales.

Los detalles sobre las estrategias de búsqueda en CENTRAL y MEDLINE, la lista de revistas consultadas manualmente y los resúmenes de los congresos, así como la lista de revistas revisadas por medio del servicio de información actualizada se pueden encontrar en la sección "Estrategias de búsqueda para la identificación de estudios" dentro de la información editorial sobre el Grupo Cochrane de Embarazo y Parto.

A los ensayos identificados a través de las actividades de búsqueda descritas más arriba se les asigna un código (o códigos) dependiendo del tema. Los códigos están relacionados con los temas de la revisión. El Coordinador de Búsqueda de Ensayos busca el registro para cada revisión utilizando estos códigos en lugar de palabras clave.

Además, se realizaron búsquedas en el registro de ensayos del Grupo Cochrane de Adicción al Tabaco (julio de 2003). También se buscó en la base de datos MEDLINE en OVID (desde enero de 2002 hasta julio de 2003) mediante el uso de la siguiente estrategia de búsqueda:
1 exp pregnancy
2 exp smoking
3 exp "tobacco use cessation" or "smoking cessation"
4 exp health promotion
5 exp preventive medicine or health education
6 exp prenatal care
7 exp prenatal exposure delayed effects
8 1 or 6 or 7
9 2 or 3
10 4 or 5
11 8 and 9 and 10
12 Limit to yr=2002-2003
13 Exp harm reduction
14 12 and 13

Se adaptó la estrategia de búsqueda para, EMBASE (desde enero de 2002 hasta julio de 2003), PsychLIT (desde enero de 2002 hasta julio de 2003), CINAHL (desde enero de 2002 hasta julio de 2003) y AUSTHEALTH (desde enero de 2002 hasta

2003). Se estableció contacto personal con los autores para localizar los datos adicionales inéditos. Se realizaron búsquedas manuales de las referencias de los ensayos identificados y las revistas obstétricas recientes hasta septiembre de 2003. Éstas incluyen: *American Journal of Obstetrics and Gynecology; Obstetrics & Gynaecology; BJOG: una revista internacional de obstetricia y ginecología; Acta Obstetrica et Gynecologica Scandivica; Control del consumo de tabaco; BMJ* y *TheLancet*.

MÉTODOS DE LA REVISIÓN

Extracción de los datos

Dos revisores extrajeron los datos de los informes publicados de forma independiente, sin cegamiento en cuanto a la revista, los autores o el grupo de investigación. En cada ensayo se tenían que documentar los siguientes aspectos:
(1) país de origen;
(2) población del estudio;
(3) criterios de inclusión y de exclusión;
(4) tasa de participación de la población de estudio elegible;
(5) momento del reclutamiento y las medidas de resultado en el embarazo;
(6) la naturaleza de la/s intervención/es;
(7) evaluación del proceso de la/s intervención/ones;
(8) retiros;
(9) detalles del diseño del estudio (incluidos el método de la asignación, la asignación al azar grupal o individual, el cegamiento, los métodos de evaluación de resultados, la validación del nivel de consumo de tabaco);
(10) medidas de resultado.

Se solicitó información adicional a los investigadores individuales.

Evaluación de la calidad

Se utilizó un enfoque flexible para evaluar la calidad metodológica de los estudios incluidos, según la recomendación del Manual Cochrane de Revisores (Cochrane Reviewers' Handbook 4.1.6, p. 45) (Clarke 2002).

Los criterios de calidad de esta revisión tratan:
(1) sesgo de selección: el ocultamiento de la asignación y la asignación al azar se describen como inadecuadas (alto riesgo de sesgo) si se utiliza alternancia, números de registros, fecha de nacimiento, semanas o números de lista abierta;
(2) sesgo de realización: cuidador habitual no cegado a la asignación (inevitable cuando el cuidador habitual implementó la intervención);
(3) sesgo de detección: bajo riesgo de sesgo si se valida bioquímicamente;
(4) justificación del tamaño de la muestra;
(5) sesgo de deserción: no es relevante debido a que todos los abandonos se contaron como fumadores regulares en esta revisión.

Posteriormente, dos revisores (C Chamberlain, J Lumley) codificaron todos los estudios de forma independiente:
(1) bajo riesgo de sesgo = se cumplieron todos los criterios (uno a cuatro);
(2) riesgo de sesgo moderado = se cumplieron dos o más criterios (uno a cuatro);
(3) alto riesgo de sesgo = no se cumplieron dos o más criterios (uno a cuatro).

Todos los estudios con un riesgo de sesgo de bajo a moderado se categorizaron como estudios de alta calidad.

Los dos revisores (C Chamberlain, J Lumley) también evaluaron de forma independiente la intensidad de la intervención y la clasificaron de la siguiente manera:
(1) 0 = si no se definió excepto como "atención habitual", o se limitó a consejos para dejar el hábito de fumar;
(2) 1 = provisión de información escrita sobre el hábito de fumar (carteles/folletos);
(3) 2 = consejos personales para dejar el hábito de fumar e información escrita;
(4) 3 = estrategias para dejar de fumar (escritas o personales), consejos personales e información escrita, o seguimiento escrito;
(5) 4 = seguimiento personal (llamadas telefónicas, asesoramiento, apoyo de compañeros) y estrategias para dejar el hábito, consejos personales para dejar de fumar e información escrita.

Todos los estudios clasificados con cuatro se definieron como estudios de alta intensidad; los estudios clasificados con tres se definieron como estudios de intensidad media; los estudios clasificados con menos de tres se definieron como estudios de baja intensidad.

Las medidas de validación bioquímica que definieron la exposición al humo del cigarrillo activa en lugar de pasiva (Melvin 2000) fueron:
(1) cotinina en orina mayor a 80 ng/ml;
(2) cotinina en saliva mayor a 0,30 ng/ml;
(3) monóxido de carbono espirado mayor a nueve partes por millón.

También se incluyeron otras medidas bioquímicas, como el tiocianato sérico, en la validación bioquímica del nivel de consumo de tabaco autoinformado.

Análisis de los datos:
(1) Se utilizaron métodos estadísticos descritos por Yusuf (Yusuf 1985).
(2) Se evaluó la heterogeneidad en todos los análisis combinados (Cochran 1954).
(3) Los análisis secundarios consideraron los resultados por separado para los ensayos con y sin abandono del hábito de fumar bioquímicamente validados, los ensayos con una intervención de alta intensidad y aquellos con puntuaciones de alta calidad para el diseño y la implementación de la intervención.
(4) Dada la probabilidad de sesgo de publicación (la falta de publicación de ensayos pequeños mostró poco o ningún efecto),

se señalaron las estimaciones puntuales contra el tamaño de la muestra.

DESCRIPCIÓN DE LOS ESTUDIOS

Ver tabla "Características de los estudios incluidos".

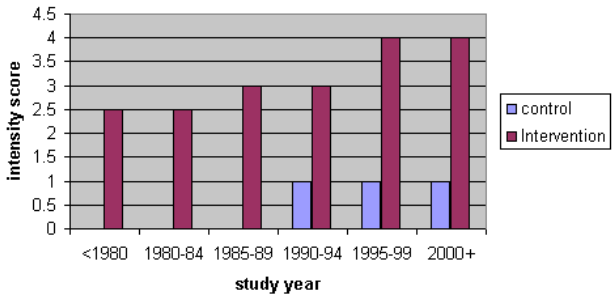
CALIDAD METODOLÓGICA

Ver tabla de "Características de los estudios incluidos" y "Características de los estudios excluidos".

RESULTADOS

Las intervenciones generalmente incluidas en estos programas fueron: la provisión de información sobre los riesgos del hábito de fumar en el feto y el recién nacido y los beneficios de dejar el hábito; recomendaciones para dejar de fumar y determinación de la fecha para dejar el hábito; retroalimentación acerca del feto; retroalimentación acerca de los niveles perjudiciales de la cotinina o el monóxido de carbono; estrategias de aprendizaje cognitivoconductuales para dejar de fumar; consejos adaptados para las "etapas del cambio"; provisión de recompensas, apoyo social o de los compañeros y tratamiento de reemplazo de la nicotina. Hubo una variación considerable en la intensidad de la intervención y el grado de recordatorios y refuerzo a lo largo del embarazo. Ha habido un aumento en la mediana de intensidad de la "atención habitual" y las intervenciones con el paso del tiempo (*ver*Figure 01).

Figure 01



Puntuación de la mediana de intensidad con el paso del tiempo

En la revisión, se identificó e incluyó un total de 64 ensayos que contaron con más de 20 000 mujeres y se realizaron entre 1975 y 2003. Seis estudios adicionales proporcionaron datos sobre más de 7500 mujeres en ensayos aleatorios grupales. Las participantes eran mujeres embarazadas sanas y el ámbito habitual fue un hospital o la clínica prenatal de la comunidad. La medida de resultado principal fue el mantenimiento del hábito de fumar al final del embarazo. Dieciséis ensayos proporcionaron alguna información sobre los resultados fetales: media del peso al nacer, bajo peso al nacer, nacimiento de prematuros y mortalidad perinatal. Un ensayo informó sobre el método de parto (Thornton 1997) sin diferencias en las proporciones de mujeres que tuvieron un parto instrumental; no existieron diferencias en el abandono del hábito en este ensayo. Un ensayo informó las proporciones de lactancia materna como el 47% versus el 46% en mujeres a las que fue posible realizar un seguimiento durante seis semanas después del parto (intervención + control = 625), y como el 22% versus el 23% en 559 mujeres (intervención + control) a las que se le realizó un seguimiento durante seis meses después del parto (Panjari 1999).

Tres estudios informaron un bienestar psicológico inicial, aunque dos de ellos no informaron hallazgos posteriores a la intervención (Cinciripini 2000; Ershoff 1999). El tercero, Panjari 1999, no encontró cambios en la proporción de mujeres con puntuaciones en el General Health Questionnaire (Cuestionario de Salud General) hacia el final del embarazo en cuanto a ansiedad probable o depresión en comparación con los valores iniciales, así como tampoco encontró diferencias en las proporciones de mujeres en los grupos control y de intervención con ansiedad probable o depresión al final del embarazo, pero la prevalencia de estos problemas de salud mental habituales fue alto (20%) en ambos grupos en las dos ocasiones. Ningún estudio ha medido el bienestar de los otros miembros de la familia.

Siete ensayos midieron las opiniones de los participantes de las intervenciones (Bakker 2001; Hajek 2001; Moore 2002; Secker-Walker 1998; Strecher 2000; Tappin 2000; Thornton 1997), y ha habido ocho ensayos recientes que han analizado el entrenamiento de los profesionales de la salud, el conocimiento, las actitudes o la práctica para proporcionar información valiosa sobre las barreras de implementación (Bakker 2001; Cooke 2001; Hajek 2001; Moore 2002; Secker-Walker 1992; Stotts 2000; Tappin 2000; Windsor 2000b).

Un ensayo mostró que el simple cambio en el formato del cuestionario (de "sí" o "no" a opciones múltiples como "Solía fumar" y "Estoy fumando menos"), aumentará el descubrimiento del hábito de fumar (Mullen 1991).

Los datos combinados de 48 ensayos revelaron una reducción significativa del mantenimiento del hábito de fumar al final del embarazo en los grupos de intervención (riesgo relativo combinado [RR] 0,94; intervalo de confianza [IC] del 95%: 0,93 a 0,95). Esto equivale a una diferencia absoluta en la proporción que mantiene el hábito del 6%. Había heterogeneidad significativa entre estos ensayos. Los hallazgos fueron similares al limitarse los análisis a los 36 ensayos con un abandono del hábito de fumar bioquímicamente validado (RR combinado 0,94; IC del 95%: 0,92 a 0,95) y una diferencia absoluta en el mantenimiento del hábito del 6%. No existieron diferencias estadísticamente significativas entre estos hallazgos y aquellos de los 25 ensayos de alta intensidad (RR combinado 0,92; IC del 95%: 0,91 a 0,94) con una diferencia absoluta en el

mantenimiento del hábito de un 8%. Tampoco se encontraron diferencias significativas en los 25 ensayos con una puntuación de alta calidad (RR combinado 0,95; IC del 95%: 0,94 a 0,97) y una diferencia absoluta en el mantenimiento del hábito del 5%, o en los 17 ensayos con un abandono del hábito de fumar validado, una intervención de alta intensidad, una puntuación de alta calidad (RR combinado 0,95; IC del 95%: 0,93 a 0,97) y una diferencia absoluta en el mantenimiento del hábito del 5%. Todos estos grupos mostraron una heterogeneidad significativa.

Al agrupar los ensayos según las estrategias de intervención, el grupo cognitivo conductual, que fue el más grande, mostró un efecto combinado similar al del grupo completo (RR 0,95; IC del 95%: 0,92 a 0,97) de los datos combinados de todos los ensayos. Los siete ensayos que utilizaron la teoría de las "etapas del cambio" no fueron eficaces (RR combinado 0,98; IC del 95%: 0,94 a 1,01), así como tampoco lo fueron los tres ensayos que utilizaron retroalimentación (RR combinado 0,92; IC del 95%: 0,77 a 1,11). Los tres ensayos sobre el tratamiento de reemplazo de la nicotina fueron de significación estadística marginal (RR combinado 0,94; IC del 95%: 0,89 a 1,00). Sólo un grupo de los ensayos (aquellos que incluyeron un apoyo social y un componente de recompensa) mostró un efecto significativamente más grande (RR combinado 0,77; IC del 95%: 0,72 a 0,82). Sus resultados fueron coherentes pero comprendieron sólo dos ensayos.

El subconjunto de 16 ensayos con información sobre los resultados perinatales reveló una reducción del bajo peso al nacer (RR combinado 0,81; IC del 95%: 0,70 a 0,94), una reducción de nacimiento de prematuros (RR combinado 0,84; IC del 95%: 0,72 a 0,98) y un aumento de 33 g en la media del peso al nacer (IC del 95%: 11 g a 55 g). No hubo heterogeneidad en el bajo peso al nacer o los hallazgos de nacimiento de prematuros, pero hubo una heterogeneidad marcada para las diferencias de la media del peso al nacer. No hubo diferencias del muy bajo peso al nacer, los nacimientos de mortinatos, las muertes neonatales o la mortalidad perinatal total. El subconjunto de ensayos en los que se evaluaron esos resultados tuvieron un poder muy bajo para detectar las diferencias clínicamente importantes de estos resultados (n = 9842). Varios ensayos excluyeron de la población de estudio a mujeres que tuvieron una muerte perinatal o un nacimiento de prematuros.

Un seguimiento del ensayo de MacArthur que había reducido el hábito de fumar y aumentado el peso al nacer evaluó el crecimiento y desarrollo posterior del niño de los nueve a diez años (MacArthur 1987). Ni la talla ni el peso, ni el coeficiente de inteligencia (CI) o una prueba de cribaje (screening) para los signos neurológicos "suaves" mostraron diferencias entre el grupo control y el grupo de intervención (datos insuficientes para tabulación).

Los seis ensayos aleatorios grupales no pueden incluirse en las tablas de RevMan pero se encuentran en una Tabla 01 adicional. Los dos ensayos más pequeños encontraron una reducción en el hábito de fumar con la intervención pero ninguno encontró la validación del hábito. Los otros cuatro ensayos incluyeron la difusión de intervenciones en la atención sistemática; tres de ellos utilizaron la partera de atención primaria para realizar la intervención (Hajek 2001; Lawrence 2003; Moore 2002); el cuarto ensayo (Kendrick 1995) se realizó en clínicas WIC (programa alimentario para mujeres, neonatos y niños).

Cinco ensayos (más de 800 mujeres) de los 64 incluyeron una intervención específica para la prevención de recaídas del hábito de fumar en mujeres que habían dejado de fumar en la primera visita prenatal. En estos, el odds-ratio combinado del hábito de fumar al final del embarazo no alcanzó significación estadística (RR 0,80; IC del 95%: 0,63 a 1,03).

Los datos de Solomon 1996 sugieren que el modelo transteórico de las etapas del cambio en la disposición para dejar de fumar (precontemplación, contemplación, preparación y acción) no puede aplicarse en el embarazo, y que no se apoyan los cambios en el estado al comienzo del embarazo. Los análisis combinados no mostraron pruebas de un efecto significativo en las etapas del cambio basadas en intervenciones, en comparación con intervenciones basadas en otras teorías. Una revisión sistemática reciente sobre el abandono del hábito de fumar concluyó que las intervenciones basadas en etapas generalmente no son más eficaces que las intervenciones que no adaptan la intervención a la etapa del cambio (Riemsma 2003).

El ofrecimiento de sesiones grupales adicionales para dejar el hábito de fumar, incluso en otros ensayos que tuvieron éxito (O'Connor 1992; Sexton 1984; Windsor 1985), no fue una intervención muy aceptada; aunque pareció tener mejor aceptación en Europa del Norte (Hegaard 2003; Valbo 1991).

DISCUSIÓN

Evaluación de la calidad de los ensayos

Rara vez se describió el método de la asignación al azar con los detalles suficientes de manera que se pueda evaluar si se ocultó la asignación en el momento de ingreso al ensayo. Por ejemplo, una afirmación común fue que "se utilizó una lista de números aleatorios generada por ordenador". La asignación cuasialeatoria no fue poco frecuente aun en los ensayos grandes. Cuando los cuidadores de la embarazada participaron en la provisión de la intervención o su refuerzo, situación esperada por muchos comentaristas para mejorar la efectividad de la intervención, no pudo ocultarse la asignación del grupo de comparación o intervención y no pudo excluirse la posibilidad de cointervenciones. No se especificó con frecuencia el ocultamiento de la asignación en el momento de la evaluación de resultados, pero este criterio se reemplazó en los ensayos posteriores por una definición del abandono del hábito de fumar que requirió validación bioquímica.

Evaluación de la calidad de la intervención

Las intervenciones para el abandono del hábito de fumar implementadas durante el embarazo difieren de manera

significativa en su intensidad, su duración y las personas que participan en su implementación. La evaluación de los procesos de la intervención ocurrió en sólo algunos ensayos, y en algunos de ellos la implementación no fue la esperada (Hajek 2001; Kendrick 1995; MacArthur 1987). Como estos ensayos se encuentran entre los ensayos publicados más grandes, esto indica que puede resultar inapropiado tomar el tamaño del ensayo como una medida sustituta de la calidad del ensayo, cuando las intervenciones son complejas.

La transferencia de una intervención de un ámbito a otro puede reducir su efectividad si se cambian los elementos o si los aspectos de los materiales son culturalmente inapropiados. Los ejemplos en estos ensayos consisten en la eficacia del manual de autoayuda de Windsor. Este se desarrolló en Birmingham y Alabama, y ha demostrado ser eficaz (Windsor 1985; Windsor 1993). Sin embargo, cuando se utilizó en Baltimore con asesores de compañeros que recibieron un entrenamiento mínimo (Gielen 1997), en lugar de realizarse con educadores de la salud entrenados, la efectividad fue mucho menor. Además, los aspectos de la intervención recomendados en el mismo manual demostraron tener muy poca aceptabilidad en Brisbane (Australia) y un nivel muy bajo de efectividad (Lowe 1998a).

En muchos casos, el grupo control o de comparación se describió como un grupo que recibía una "atención habitual" sin especificar aún más la práctica actual en ese momento y en ese ámbito con respecto al asesoramiento y la asistencia. En los ensayos recientes (por ejemplo, Lowe 1998a; Secker-Walker 1994; Walsh 1997) se especifica detalladamente la atención, y puede verse en Figure 01 que la "atención habitual" actual puede ser una intervención más sustancial que la intervención definida en algunos de los primeros ensayos (por ejemplo, MacArthur 1987).

Asignación aleatoria grupal

Existen buenas razones para considerar la asignación aleatoria de las parteras, los médicos, los educadores de la salud, los hospitales, los médicos generalistas o las clases prenatales para el grupo de comparación o de intervención, en lugar de la asignación aleatoria de las mujeres embarazadas. Puede resultar difícil para aquellos que brindan atención en el embarazo tratar a las mujeres de un modo diferente según la intervención o el protocolo de atención habitual, y no introducir cointervenciones en uno u otro grupo. Como las mujeres dentro de un grupo serán más similares unas a otras, y menos similares a las mujeres de otro grupo, los resultados deben adaptarse según la correlación intragrupo y la heterogeneidad intragrupo. La ausencia de adaptación de la agrupación fue una razón principal para la exclusión de los ensayos de esta revisión. Cuatro de los seis ensayos aleatorios grupales que están incluidos (Bakker 2001; Hajek 2001; Lawrence 2003; Moore 2002) realizaron la intervención con las parteras que fueron las prestadoras primarias de atención sanitaria de las mujeres en los ensayos. Existen pruebas del texto de estos artículos de que las parteras tenían dudas acerca de la implementación de estrategias para el abandono del hábito de fumar dentro de la atención prenatal. En un quinto ensayo (Kendrick 1995) está claro que el personal de la clínica, que atendió a las mujeres completamente desfavorecidas, se sintió abrumado por los requisitos del estudio; y no es sorprendente que cuatro de los cinco ensayos no tuvieron éxito en el aumento del abandono del hábito de fumar. La excepción (Bakker 2001) no tuvo un abandono del hábito de fumar bioquímicamente validado, por lo que su efectividad auténtica sigue siendo incierta.

Ensayos de difusión de programas

Aunque cuatro ensayos tratados bajo asignación al azar grupal fueron en muchos sentidos ensayos de difusión, este párrafo trata los ensayos diseñados para tener un impacto sobre la política y la práctica a nivel de una organización grande. Se identificaron dos ensayos, ambos realizados en Australia (Cooke 2001; Lowe 2002). Los datos disponibles de estos ensayos incluyen la captación de programas a nivel del hospital pero no, actualmente, la efectividad del abandono del hábito de fumar o los resultados perinatales. En los ensayos que evaluaron la difusión de programas para el abandono del hábito de fumar en la atención habitual de embarazos, Lowe 2002 se encontró una tasa de implementación de programas significativamente mayor al usar una intervención basada en la teoría de "Difusión de innovación" de Rogers (43% en comparación con una implementación de sólo el 9% en el grupo control después de un año). Cooke (Cooke 2001) y Windsor (Windsor 2000b) encontraron una mejor implementación con un método intensivo de difusión de programas.

Retiros

Los retiros de los ensayos fueron comunes. Al reclutar mujeres en su primera visita prenatal, algunas participantes sufrieron un aborto espontáneo o la terminación del embarazo antes del momento de volver a evaluar la conducta ante el hábito de fumar. Otras se mudaron del área o cambiaron a otro prestador de asistencia sanitaria. Esta última fue una causa común de deserción en aquellos ensayos realizados en poblaciones caracterizadas por una pobreza extrema y que reciben los beneficios para las necesidades especiales como Medicaid, o las clínicas WIC (programa alimentario para mujeres, neonatos y niños).

Exclusiones

Dos grupos de mujeres que con frecuencia fueron excluidos de la medición de resultados fueron aquellos que tuvieron una muerte perinatal o un recién nacido prematuro. Esto significa que no se confirmaron los resultados importantes vinculados con los estudios observacionales de exposición al hábito de fumar. La evaluación del hábito de fumar en el período de 20 a 28 semanas en vez del período de 36 o 38 semanas reduciría la necesidad de excluir a mujeres con resultados particularmente adversos, ya que se confirmaría su nivel de consumo de tabaco a mediados del embarazo antes de que ocurra un nacimiento de prematuros o una muerte perinatal.

Reducción del hábito de fumar y clasificación errónea del mismo mediante autoinforme

Uno de los dos primeros ensayos (Donovan 1977) demostró diferencias marcadas en los autoinformes sobre el hábito de fumar obtenidos de las mismas mujeres a comienzos del embarazo y después del nacimiento. Sin embargo, otros ensayos en la década de los ochenta concluyeron, de acuerdo a la comparación de un autoinforme con medidas bioquímicas o biofísicas del hábito de fumar, que el autoinforme era fiable (Fox 1989). Los hallazgos en estudios posteriores son completamente diferentes: todos muestran una clasificación errónea considerable de autoinformes con hasta un cuarto o un tercio de mujeres que se describen como no fumadoras pero que presentan niveles de cotinina en saliva u orina (biomarcador) incompatible con esa autodescripción (Kendrick 1995; Lowe 1998a; Walsh 1997).

Debido a que las medidas bioquímicas tienen una correlación relativamente deficiente con el número de cigarrillos fumados, no es posible utilizar, por ejemplo, los niveles de cotinina para evaluar la reducción del hábito de fumar. Una proporción muy alta de mujeres embarazadas se describen como que han "reducido el hábito", pero dados los problemas de autoinformes descritos en el párrafo anterior, las preguntas importantes acerca de la efectividad de las intervenciones para facilitar la reducción del hábito de fumar permanecen sin respuesta actualmente: sólo el abandono del hábito de fumar bioquímicamente validado puede considerarse como una medida de resultado fiable.

Windsor 1993 ha propuesto el uso de la mitad del nivel de cotinina en el ingreso al ensayo como una medida de reducción del hábito de fumar, y en 1999 promovió el uso de la medición bioquímica como un nuevo indicador de conducta de la "reducción de daños" (Windsor 1999). Sin embargo, este hallazgo no fue apoyado por el análisis posterior de Secker-Walker (Secker-Walker 2002) sobre el peso de neonatos al nacer con relación a la cotinina materna de un ensayo diferente. El último plantea la cuestión que para una persona muy fumadora la mitad del nivel de cotinina aún puede representar un nivel de consumo de tabaco peligroso para el feto. El análisis secundario de los datos del ensayo de Kendrick 1995 sugiere que la reducción de hábito de fumar a menos de ocho cigarrillos diarios es necesaria para evitar la reducción del peso del neonato al nacer (England 2001)

Resultados en la salud del feto y el neonato

Las reducciones cercanas al 20% de nacimiento de prematuros y bajo peso al nacer en el grupo de intervención de los ensayos de abandono del hábito de fumar, confirman que el abandono del hábito puede revertir los efectos adversos del tabaco en los resultados perinatales. Si todas las mujeres en los grupos de intervención dejaran de fumar y ninguna de las de los grupos control lo hicieran, la diferencia esperada en la media del peso al nacer sería alrededor de 200 g. La diferencia ponderada en la media del peso al nacer en estos ensayos fue de 30 g. La diferencia de medias esperada para el grado de abandono del hábito de fumar solo habría sido alrededor de 12 g. Esto indica que la reducción del hábito de fumar también se presenta en mayor grado en los grupos de intervención que en los grupos de comparación, de acuerdo con los cambios autoinformados. Los ensayos futuros deben tomar más seriamente la inclusión de la mortalidad perinatal como una medida de resultado.

Tratamiento de reemplazo de la nicotina (TRN) durante el embarazo

El TRN en esta revisión no parece tener una ventaja significativa sobre otros tipos de intervenciones. Sólo un estudio (Hegaard 2003) evaluó el efecto del TRN como parte de un enfoque multimodal para el abandono del hábito de fumar en el embarazo, con un RR de 0,95 (IC del 95%: 0,92 a 0,98). Una inquietud acerca de su uso en el embarazo es la posibilidad de efectos adversos de la nicotina sobre el feto, a través de alteraciones en el flujo sanguíneo, placentario o uterino o directamente en el cerebro. Dos ensayos aleatorios pequeños (fisiológicos) han comparado los efectos de la goma de mascar de nicotina (Oncken 1996) o la nicotina transdérmica (Oncken 1997) con el hábito de fumar en la madre con relación a las concentraciones de nicotina y cotinina en la sangre y a la hemodinámica materno-fetal.

En algunos países, aunque no en todos, la goma de mascar de nicotina y los parches de nicotina no pueden venderse sin una prescripción y en otros países hay advertencias en los paquetes contra su uso durante el embarazo; no obstante, este criterio ha sido objeto de discusión (Benowitz 1991; Hughes 1993). Dempsey 2001 recomienda que las dosis de nicotina prescritas en el embarazo deben ser similares a las dosis de tabaco, y que son preferibles las formas intermitentes del TRN (goma de mascar, aerosol, inhalador) a las formulaciones de uso continuo ya que la dosis total de nicotina será menor. Todos los ensayos del TRN en el embarazo hasta la fecha son de parches de nicotina (formulaciones de uso continuo). Debido a que todavía existen muy pocos ensayos que aseguran el uso inocuo de la nicotina en el embarazo, y los estudios en animales indican que la nicotina puede ser tóxica para el desarrollo del sistema nervioso central, Dempsey 2001 recomienda que se establezcan registros de mujeres que utilizan el TRN para obtener más datos de resultados.

No se informaron ensayos del antidepresivo bupropión para aumentar el abandono del hábito de fumar en el embarazo (Oncken 2003).

Nuevos desarrollos

Un área en expansión de la bibliografía sobre las intervenciones para el abandono del hábito de fumar durante el embarazo es el trabajo descriptivo sobre las barreras de implementación de las intervenciones ya comprobadas efectivas en el ámbito del hospital y la clínica (por ejemplo, Aquilino 2003; McLeod 2003; Walsh 1995).

Otra es la publicación de las intervenciones para aumentar el abandono del hábito de fumar en las parejas de las mujeres embarazadas, con el objetivo adicional de facilitar el abandono del hábito en las mujeres mismas (Stanton 2004).

CONCLUSIONES DE LOS AUTORES

Implicaciones para la práctica

Debido a que los programas para el abandono del hábito de fumar han demostrado aumentar el abandono del hábito, reducir el nacimiento de prematuros y el bajo peso al nacer, y aumentar la media del peso al nacer, tales programas para el abandono del hábito de fumar deben implementarse en todos los ámbitos de atención médica materna. La atención a la conducta ante el hábito de fumar junto con el apoyo al abandono del hábito de fumar y la prevención de recaídas debe ser una rutina de la atención prenatal como lo es la medición de la presión arterial. Un buen punto de partida serían los programas piloto locales que han demostrado ser eficaces en otros sitios. Para evitar el problema de "víctima-culpa", o la percepción de"víctima-culpa", se debe concentrar la atención en las inquietudes del consumidor mencionadas en "Implicaciones de la investigación" y en las pruebas existentes de las barreras de implementación en la atención prenatal. El uso del NNT (número necesario a tratar) como un contador para los criterios de que las intervenciones para el abandono del hábito de fumar no funcionan en el embarazo, puede ser una estrategia útil.

Se informó que las intervenciones que incluyeron sesiones grupales adicionales durante el embarazo fueron poco concurridas en la mayoría de los ámbitos; no obstante, estas intervenciones tuvieron aceptación en dos ensayos en Escandinavia.

Dadas las dificultades claras que la mayoría de las mujeres fumadoras en la primera visita prenatal presentan para dejar de fumar, las parteras, los médicos generalistas y los obstetras deben apoyar las estrategias para el control del hábito de fumar en toda la comunidad a fin de reducir la iniciación del hábito en los jóvenes: prevenir la venta de tabaco a los jóvenes, prohibir el hábito de fumar en todos los lugares públicos, aumentar el impuesto al tabaco, difundir programas para el abandono del hábito de fumar en el trabajo y prohibir el auspicio del tabaco en los eventos culturales y deportivos prestigiosos.

Debido a la fuerte asociación entre la desigualdad social y la continuidad del hábito de fumar en mujeres embarazadas, y la contribución del tabaco a la carga global de enfermedades en las economías de mercados desarrollados, las parteras, los médicos generalistas y los obstetras deben apoyar las estrategias para reducir las desigualdades sociales en la comunidad ampliada.

Implicaciones para la investigación

Los ensayos futuros deben incluir los siguientes elementos:

- Una fase de desarrollo para las intervenciones materiales y los métodos que se realizarán en mujeres similares a aquellas que estarán expuestas a la intervención, con una consideración total de las inquietudes de las mujeres (impacto negativo sobre la mujer misma y por consiguiente sobre su familia para dejar de fumar debido a su papel en el tratamiento del estrés, las ventajas percibidas en los recién nacidos como los trabajos de parto más breves y menor probabilidad de parto instrumental, los buenos resultados de los embarazos anteriores a pesar del hábito de fumar, o la buena salud de los recién nacidos de otras mujeres que fuman) y una evaluación de la adecuación cultural del material desarrollado en otros lugares.
- La participación completa del personal en cualquier aspecto de la intervención para asegurar, de una manera similar, que se han tratado sus inquietudes, y para aumentar su comprensión, participación activa y apoyo.
- Una descripción de la intervención lo suficientemente detallada para su reiteración aun cuando el detalle requiera un informe separado.
- Un componente de prevención de recaídas para aquellas personas que han dejado de fumar antes de la primera visita prenatal.
- Una evaluación de procesos que identifican el grado de implementación en cuanto a su alcance y a la satisfacción de los clientes o consumidores y el personal.
- La validación bioquímica del nivel de ausencia de consumo de tabaco.
- La recopilación de los datos de resultado sobre el peso al nacer, el nacimiento de prematuros y las muertes perinatales.
- La recopilación de los datos de resultado sobre la lactancia materna, el parto instrumental, el bienestar psicológico materno y el impacto percibido de la intervención en el funcionamiento familiar.

A los autores de esta revisión se les pregunta con frecuencia si existen pruebas de efectividad diferencial de las intervenciones según los factores sociales, económicos o demográficos, en particular la pobreza o la falta de apoyo. Hasta que se informen los análisis de subgrupos en los ensayos, no se puede responder esta pregunta importante.

Existen dos aspectos de las intervenciones para el abandono del hábito de fumar en las que hay mensajes confusos. Es probable que estos mensajes desmerezcan la efectividad general de los programas, ya que los mensajes simples y explícitos son un aspecto clave para la promoción eficaz de la salud.

- ¿Existe un lugar para incluir la reducción del hábito de fumar como una de las metas, que coincida con las estrategias de "disminución de daños" para otras sustancias y prácticas perjudiciales? Se necesitan investigaciones en esta área, con inclusión de mejores medidas de exposición al tabaco.
- Merece la pena facilitar el abandono del hábito de fumar en el embarazo para mejorar los resultados de neonatos y de embarazo y reducir las complicaciones maternas del embarazo. Algunos programas promueven el abandono del hábito de fumar en el embarazo principalmente como una estrategia para dejar de fumar en general, que es una estrategia para reducir el cáncer y las enfermedades crónicas en las etapas posteriores de la vida. Es necesaria

una recomendación sin ambigüedades de que dejar de fumar en el embarazo es una meta importante y valiosa para el feto.

AGRADECIMIENTOS

Se agradece a las Collaborative Review Group Offices (Pregnancy and Childbirth, Tobacco Addiction) por la ayuda con la recuperación de las publicaciones relevantes recientes, así como al personal del Borchardt Library, La Trobe University por el entrenamiento adicional de los revisores y la provisión de referencias para esta actualización. Se agradece a Katherine Crouch, Sally Crowe, Marilyn Fairbairn, Christine Glossop, Sarah Jones y Sue Palmer-Simmons por su tiempo al tratar esta revisión desde las perspectivas de mujeres embarazadas.

POTENCIAL CONFLICTO DE INTERÉS

El Mother and Child Health Research, anteriormente el Centre for the Study of Mothers' and Children Health (Judith Lumley) recibe una contribución económica de la Victorian Health Promotion Foundation, que tiene una responsabilidad estatutaria para reducir el consumo de tabaco en el estado de Victoria.

FUENTES DE FINANCIACIÓN

Recursos externos

- NHS Central R & D Programme, Department of Health 1995-1996 UK
- Victorian Health Promotion Foundation AUSTRALIA
- Department of Health, UK funding for EPI-Centre, London University UK
- Public Health Branch Victorian Department of Human Services AUSTRALIA

Recursos internos

- La Trobe University 1996 to date AUSTRALIA

REFERENCIAS

Referencias de los estudios incluidos en esta revisión

Albrecht 1998 *{published data only}*
Albrecht S, Cassidy B, Salamie D, Reynolds M. What's happening. A smoking cessation intervention for pregnant adolescents: implications for nurse practitioners. *Journal of American Academy of Nurse Practitioners* 1999;**11**(**4**):155-9.

Albrecht S, Cornelius M, Braxter B, Reynolds M, Stone C, Cassidy B. An assessment of nicotine dependence among pregnant adolescents. *Journal of Substance Abuse Treatment* 1999;**16**(**4**):337-44.

Albrecht S, Higgins L, Lebow H. Knowledge about the deletrious effects of smoking and its relationship to smoking cessation among pregnant adolescents. *Adolescence* 2000;**35**:709-16. 12076.

Albrecht S, Stone CA, Payne L, Reynolds MD. A preliminary study of the use of peer support in smoking cessation programs for pregnant adolescents. *Journal of the American Academy of Nurse Practitioners* 1998;**10**:119-25.

Bakker 2001 *{published data only}*
Bakker M. *Pregnancy: a window of opportunity to quit smoking! The development, implementation and evaluation of a minimal intervention strategy for pregnant women and partners [thesis]*. Netherlands: Maastricht Health Research Institute for Prevention and Care, 2001.

Baric 1976 *{published data only}*
Baric L, MacArthur C, Sherwood M. A study of health education aspects of smoking in pregnancy. *International Journal of Health Education* 1976;**19**(**2 Suppl**):1-17.

Bauman 1983 *{published data only}*
Bauman KE, Koch GG, Dent CW, Bryan ES. The influence of observing carbon monoxide level on cigarette smoking by public prenatal patients. *American Journal of Public Health* 1983;**73**:1089-91.

Belizan 1995 *{published data only}*
Belizan JM, Villar J, Victora C, Farnot U, Langer A, Barros F. Impact of health education during pregnancy on behavior and utilization of health resources. *American Journal of Obstetrics and Gynecology* 1995;**173**:894-9.

Victora CG, Langer A, Barros F, Belizan J, Farnot U, Villar J et al. The Latin American Multicenter Trial on psychosocial support during pregnancy: methodology and baseline comparability. *Controlled Clinical Trials* 1994;**15**:379-94.

Villar J, Farnot U, Barros F, Victora C, Langer A, Belizan JM. A randomized trial of psychosocial support during high-risk pregnancies. *New England Journal of Medicine* 1992;**327**:1266-71.

Bullock 1995 *{published data only}*
Bullock LF, Hornblow AR, Duff GB, Wells JE. Telephone support for pregnant women: outcome in late pregnancy. *New Zealand Medical Journal* 1995;**108**:476-8.

Burling 1991 *{published data only}*
Burling TA, Bigelow GE, Robinson JC, Mead AM. Smoking during pregnancy: reduction via objective assessment and directive advice. *Behavior Therapy* 1991;**22**:31-40.

Cinciripini 2000 *{published data only}*
Cinciripini PM, McClure JB, Wetter DW, Perry J, Blalock JA, Cinciripini LG et al. An evaluation of videotaped vignettes for smoking cessation and relapse prevention during pregnancy: The Very Important Pregnant Smokers (VIPS) Program. *Tobacco Control* 2000;**9**(**3**):iii61-iii63.

Donatelle 2000 *{published data only}*
Donatelle RJ, Prows SL, Champeau D, Hudson D. Randomised controlled trial using social support and financial incentives for high risk pregnant smokers: Significant Other Supporter (SOS) program. *Tobacco Control* 2000;**9**(**Suppl 3**):iii67-9.

Donovan 1977 *{published data only}*
Donovan J. Randomised controlled trial of anti-smoking advice in pregnancy. *British Journal of Preventive and Social Medicine* 1977;**31**:6-12.

Donovan JW. Randomised controlled trial of anti-smoking advice in pregnancy. *Journal of Epidemiology and Community Health* 1996;**50**(**3**):232-6.

Donovan JW, Burgess PL, Hossack CM, Yudkin GD. Routine advice against smoking in pregnancy. *Journal of the Royal College of General Practitioners* 1975;**25**:264-8.

Dunkley 1997 *{published data only}*
Dunkley J. Training midwives to help pregnant women stop smoking. *Nursing Times* 1997;**93**:64-6.

Ershoff 1989 *{published data only}*
Erschoff DH, Lairson DR, Mullen PD, Quinn VP. Pregnancy and medical cost outcomes of a self-help prenatal smoking cessation program in an HMO. *Public Health Reports* 1990;**105**:340-7.

Erschoff DH, Quinn VP, Mullen PD. A randomized trial of a serialized self-help smoking cessation program for pregnant women in an HMO. *American Journal of Public Health* 1989;**79**:182-7.

Ershoff 1995 *{published data only}*
Ershoff DH, Quinn VP, Mullen PD. Relapse prevention among women who stop smoking early in pregnancy: a randomized clinical trial of a self-help intervention. *American Journal of Preventive Medicine* 1995;**11**:178-84.

Ershoff 1999 *{published data only}*
*Ershoff DH, Quinn VP, Boyd NR, Stern J, Gregory M, Wirtschafter D. The Kaiser Permanente prenatal smoking cessation trial. When more isn't better, what is enough?. *American Journal of Preventive Medicine* 1999;**17**(**3**):161-68.

Ershoff DH, Quinn VP, Boyd NR, Stern J, Gregory M, Wirtschafter D. The Kaiser Permanente prenatal smoking cessation trial: when more isn't better, what is enough?. *Tobacco Control* 2000;**9**(**Suppl 3**):iii60.

Gielen 1997 *{published data only}*
Gielen AC, Windsor R, Faden RR, O'Campo P, Repke J, Davis M. Evaluation of a smoking cessation intervention for pregnant women in an urban prenatal clinic. *Health Education Research* 1997;**12**:247-54.

Haddow 1991 *{published data only}*
Haddow JE, Wald NJ, Palomaki GE, Kloza EM, Knight GJ. Cotinine-assisted intervention in pregnancy to reduce smoking and low birthweight delivery. *British Journal of Obstetrics and Gynaecology* 1991;**98**:859-65.

Hajek 2001 *{published data only}*
Hajek P, West R, Lee A, Foulds J, Owen L, Eiser JR et al. Randomized controlled trial of a midwife-delivered brief smoking cessation intervention in pregnancy. *Addiction* 2001;**96**:485-94.

Hartmann 1996 *{published data only}*
Hartmann K, Thorp J, Pahel-Short L, Koch M. A randomized controlled trial of smoking cessation intervention in pregnancy. *American Journal of Obstetrics and Gynecology* 1995;**172**:287.

Hartmann KE, Koch MA, Pahel-Short L, Thorp JM. A randomized controlled trial of smoking cessation intervention in pregnancy in an academic clinic. *Obstetrics & Gynecology* 1996;**87**:621-6.

Hegaard 2003 *{published data only}*
Hegaard H, Hjaergaard H, Moller L, Wachmann H, Ottesen B. Multimodel intervention raises smoking cessation rate during pregnancy. *Acta Obstetricia et Gynecologica Scandinavica* 2003;**82**:813-9.

Hjalmarson 1991 *{published data only}*
Hjalmarson AIM, Svanberg B, Hahn L. Stopping smoking in pregnancy: effect of a self-help manual in a controlled trial. *British Journal of Obstetrics and Gynaecology* 1991;**98**:260-4.

Svanberg B. Smoking during pregnancy: possibilities of prevention in antenatal care. *International Journal of Technology Assessment in Health Care* 1992;**8**(**Suppl 1**):96-100.

Hughes 2000 *{published data only}*
*Hughes E, Lamont D, Beecroft M, Wilson D. Randomized trial of a "stage-of-change" orientated smoking cessation intervention in infertile and pregnant women. *Fertility and Sterility* 2000;**74**(**3**):498-503.

Hughes EG, Beecroft ML, Lamont D, Rice S, Wilson D, Freebury M et al. A randomised controlled trial of a "State-of Change" smoking cessation intervention for subfertile and pregnant patients. *Fertility and Sterility* 1999;**72**(**3 Suppl 1**):S61-2.

Kapur 2001 *{published data only}*
Kapur B, Hackman R, Selby P, Klein J, Koren G. Randomized, double blind, placebo-controlled trial of nicotine replacement therapy in pregnancy. *Current Therapeutic Research* 2001;**62**(**4**):274-8.

Kendrick 1995 *{published data only}*
England LJ, Kendrick JS, Wilson HG, Merritt RK, Gargiullo PM, Zahniser SC. Effects of smoking reduction during pregnancy on the birth weight of term infants. *American Journal of Epidemiology* 2001;**154**:694-701.

Kendrick JS, Metzger RW, Sexton M, Spierto FW, Floyd RL, Gargiullo PM et al. Integrating smoking cessation into routine public prenatal care: the Smoking Cessation in Pregnancy project. *American Journal of Public Health* 1995;**85**:217-22.

Lawrence 2003 *{published data only}*
Lawrence T, Aveyard P, Evans O, Cheng KK. A cluster randomised controlled trial of smoking cessation in pregnant women comparing interventions based on the transtheoretical (stages of change) model to standard care. *Tobacco Control* 2003;**12**:168-77.

Lilley 1986 *{published data only}*
Lilley J, Forster DP. A randomised controlled trial of individual counselling of smokers in pregnancy. *Public Health* 1986;**100**:309-15.

Loeb 1983 *{published data only}*
Bailey JW, Loeb BK, Waage G. A randomized trial of smoking intervention during pregnancy. *Proceedings of the American Public Health Association 111th Annual Meeting; 1983 Nov 15; Dallas, Texas, USA*. 1983:58.

Loeb BK, Waage G, Bailey J. Smoking intervention in pregnancy. In: Forbes WG, Frecker RC, Nostbakken D, editor(s). *Proceedings of the Fifth World Conference on Smoking and Health; 1983; Winnipeg, Canada. Ottawa: Canadian Council on Smoking and Health*. 1983:389-95.

Lowe 1997 *{published data only}*
Lowe JB, Windsor R, Balanda K, Woodby L. Smoking relapse prevention methods for pregnant women: a formative evaluation. *American Journal of Health Promotion* 1997;**11**:244-6.

Lowe 1998a *{published data only}*
Lowe JB, Balanda KP, Clare G. Evaluation of antenatal smoking cessation programs for pregnant women. *Australian and New Zealand Journal of Public Health* 1998;**22**:55-9.

Lowe 1998b *{published data only}*
Lowe JB, Balanda KP, Clare G. Evaluation of antenatal smoking cessation programs for pregnant women. *Australian and New Zealand Journal of Public Health* 1998;**22**:55-9.

MacArthur 1987 *{published and unpublished data}*
MacArthur C, Knox EG. Stopping smoking in pregnancy and birthweight. *The needs of parents and infants: proceedings of a symposium*. Cambridge: The Health Promotion Trust, 1989:41-55.

MacArthur C, Knox EG, Lancashire RJ. Effects at the age of nine of maternal smoking in pregnancy: experimental and observational findings. *BJOG: an international journal of obstetrics and gynaecology* 2001;**108**(**1**):62-73.

MacArthur C, Knox EG, Newton JR. Effect of anti-smoking health education on infant size at birth: a randomized controlled trial. *British Journal of Obstetrics and Gynaecology* 1987;**94**:295-300.

Malchodi 2003 *{published data only}*
Malchodi CS, Oncken C, Dornelas EA, Caramanica L, Gregonis E. The effects of peer counselling on smoking cessation and reduction. *Obstetrics & Gynecology* 2003;**101**(**3**):504-10.

Manfredi 2000 *{published data only}*
Manfredi C, Crittenden KS, Warnecke R, Engler J, Cho YI, Shaligram C. Evaluation of a motivational smoking cessation intervention for women in public health clinics. *Preventive Medicine* 1999;**28**:51-60.

Mayer 1990 *{published data only}*
Mayer JP, Todd R, Hawkins B. A randomised evaluation of smoking cessation interventions for pregnant women at a WIC clinic. *American Journal of Public Health* 1990;**80**:76-7.

McBride 1999 *{published data only}*
Lando HA, Valanis BG, Lichtenstein E, Curry SJ, McBride CM, Pirie PL et al. Promoting smoking abstinence in pregnant and postpartum patients: a comparison of 2 approaches. *American Journal of Managed Care* 2001;**7**:685-93.

McBride CM, Curry SJ, Grothaus LC, Nelson JC. Partner smoking status and pregnant smokers' perception of support for and likelihood of smoking cessation. *Health Psychology* 1998;**17**:63-9.

McBride CM, Curry SJ, Lando HA, Pirie PL, Grothaus LC, Nelson JC. Prevention of relapse in women who quit smoking during pregnancy. *American Journal of Public Health* 1999;**89**:706-11.

Moore 2002 *{published data only}*
Moore LO, Campbell R, Whelan A, Mills N, Lupton P, Misselbrook E et al. Self help smoking cessation in pregnancy: cluster randomised controlled trial. *BMJ* 2002;**325**:1383-6.

Mullen 1991 *{published data only}*
Mullen PD, Carbonari JP, Tabak ER, Glenday MC. Improving disclosure of smoking by pregnant women. *American Journal of Obstetrics and Gynecology* 1991;**165**:409-13.

O'Connor 1992 *{published data only}*
O'Connor AM, Benzie RJ, McBride BH, Nadon C, Buhler PL, Dulberg CS et al. Effectiveness of a pregnancy smoking cessation program. *Journal of Obstetric, Gynecologic and Neonatal Nursing* 1992;**21**:385-92.

Olds 1986 *{published data only}*
Olds DL, Henderson CR, Tatelbaum R, Chamberlin R. Improving the delivery of prenatal care and outcomes of pregnancy: a randomized trial of nurse home visitation. *Pediatrics* 1986;**77**:16-28.

Panjari 1999 *{published data only}*
Panjari M, Bell R, Bishop S, Astbury J, Rice G, Doery J. A randomized controlled trial of a smoking cessation intervention during pregnancy. *Australian and New Zealand Journal of Obstetrics and Gynaecology* 1999;**39**(**3**):312-7.

Petersen 1992 *{published data only}*
Peterson L, Rosen A, Podedworny T, Kotch J, Handel J. Smoking reduction during pregnancy by a program of self-help and clinical support. *Obstetrics & Gynecology* 1992;**79**:924-30.

Price 1991 *{published data only}*
Price JH, Snyder FF, Roberts SM, Losh DP, Desmond SM, Krol RA. Comparison of three antismoking interventions among pregnant women in an urban setting: a randomized trial. *Psychological Reports* 1991;**68**:595-604.

RADIUS 1995 *{published data only}*
Ewigman B, Crane J, Frigoletto F, LeFevre M, Bain R, McNellis D. Effect of prenatal ultrasound screening on perinatal outcome. *New England Journal of Medicine* 1993;**329**:821-9.

LeFevre ML, Ewigman B, Evans JK. Is smoking an indication for prenatal ultrasonography? RADIUS Study Group. *Archives of Family Medicine* 1995;**4**:120-3.

Reading 1982 *{published data only}*
Reading AE, Sledmere CM, Cox DNB, Campbell S. Health beliefs and health care behaviour in pregnancy. *Psychological Medicine* 1982;**12**:379-83.

Rush 1992 *{published data only}*
King J, Eiser JR. A strategy for counselling pregnant smokers. *Health Education Journal* 1981;**40**:66-8.

Rush D, Butler NR, Eiser JR, King J, Orme J. A trial of health education aimed to reduce cigarette smoking. *Paediatric and Perinatal Epidemiology* 1992;**6**:285-97.

Secker-Walker 1992 *{published data only}*
Secker-Walker RH, Mead PB, Worden JK, Crammond JE, Lepage SS, Flynn BS et al. Training obstetric and family practice residents to give smoking cessation advice during prenatal care. *American Journal of Obstetrics and Gynecology* 1992;**166**:1356-63.

Secker-Walker 1994 *{published data only}*
Secker-Walker RH, Mead PB, Goodwin GD, Lepage SS, Skelly JM, Flynn BS et al. Individualised smoking cessation counseling during prenatal and early postnatal care. *American Journal of Obstetrics and Gynecology* 1994;**71**:1347-55.

Secker-Walker 1995 *{published data only}*
Secker-Walker RH, Mead PB, Goodwin GD, Lepage SS, Skelly JM, Flynn BS et al. Smoking relapse prevention counseling during prenatal and early postnatal care. *American Journal of Preventive Medicine* 1995;**11**:86-93.

Secker-Walker 1997 *{published data only}*
Secker-Walker RH, Solomon LJ, Geller BM, Flynn BS, Worden JK, Skelly JM et al. Modeling smoking cessation: exploring the use of a videotape to help pregnant women quit smoking. *Women & Health* 1997;**25**:23-35.

Secker-Walker 1998 *{published data only}*
Secker-Walker RH, Solomon LJ, Flynn BS, Skelly JM, Mead PB. Reducing smoking during pregnancy and postpartum: physician's advice supported by individual counseling. *Preventive Medicine* 1998;**27**:422-30.

Secker-Walker RH, Solomon LJ, Flynn BS, Skelly JM, Mead PB. Smoking relapse prevention during pregnancy. A trial of coordinated advice from physicians and individual counseling. *American Journal of Preventive Medicine* 1998;**15**:25-31.

Sexton 1984 *{published data only}*
Hebel JR, Sexton M, Nowicki P. The effect of antismoking intervention during pregnancy: an assessment of interactions with maternal characteristics. *American Journal of Epidemiology* 1985;**122**:135-48.

Nowicki P, Gintzig L, Hebel JR, Lathem R, Miller V, Sexton M. Effective smoking intervention during pregnancy. *Birth* 1984;**11**:217-24.

Sexton M, Hebel JR. A clinical trial of change in maternal smoking and its effect on birth weight. *JAMA* 1984;**251**:911-5.

Solomon 1996 *{published data only}*
Solomon LJ, Secker-Walker RH, Skelly JM, Flynn BS. Stages of change in smoking during pregnancy in low risk women. *Journal of Behavioral Medicine* 1996;**19**:333-4.

Solomon 2000 *{published data only}*
Solomon LJ, Secker-Walker RH, Flynn BS, Skelly JM, Capeless EL. Proactive telephone peer support to help pregnant women stop smoking. *Tobacco Control* 2000;**9**(**Suppl 3**):iii72-4.

Stotts 2000 *{published data only}*
Stotts S, DiClemente CC, Dolan-Mullen P. One-to-One: a motivational intervention for resistant pregnant smokers. *Addictive Behaviours* 2002;**27**:275-92.

Strecher 2000 *{published data only}*
Strecher VJ, Bishop KR, Bernhardt J, Thorp JM, Cheuvrout B, Potts P. Quits for keeps: tailored smoking cessation guides for pregnancy and beyond. *Tobacco Control* 2000;**9**(**Suppl 3**):iii78-9.

Tappin 2000 *{published data only}*
*Tappin DM, Lumsden MA, McIntyre D, McKay C, Gilmour WH, Webber R et al. A pilot study to establish a randomized trial methodology to test the efficacy of a behavioural intervention. *Health Education Research* 2000;**15(4)**:491-502.

Tappin DM, Lumsden MA, McKay C, McIntyre D, Gilmour H, Webber R, Cowan S, Crawford F, Currie F. The effect of home-based motivational interviewing on the smoking behaviour of pregnant women: a pilot randomised controlled efficacy study. *Ambulatory Child Health* 2000;**6 (Suppl 1)**:34-5.

Thornton 1997 *{published data only}*
Thornton L. *Smoking and pregnancy: feasibility and effectiveness of a smoking intervention programme among pregnant women*. Dublin: Dept of Public Health, 1997.

Thornton L, Gogan C, McKenna P. The rotunda stop smoking programme [abstract]. *Irish Journal of Medical Science* 1998;**167(Suppl 9)**:28.

Valbo 1991 *{published data only}*
Valbo A, Schioldborg P. Smoking cessation in pregnancy: mode of intervention and effect. *Acta Obstetricia et Gynecologica Scandinavica* 1991;**70**:309-13.

Valbo 1994 *{published data only}*
Valbo A, Nylander G. Smoking cessation in pregnancy: intervention among heavy smokers. *Acta Obstetricia et Gynecologica Scandinavica* 1994;**73**:215-9.

Valbo 1996 *{published data only}*
Valbo A, Eide T. Smoking cessation in pregnancy: the effect of hypnosis in a randomized study. *Addictive Behaviors* 1996;**21**:29-35.

Walsh 1997 *{published data only}*
Walsh RA, Melmeth A, Byrne JM, Brinsmead MW, Redman S. A smoking cessation program at a public antenatal clinic. *American Journal of Public Health* 1997;**87**:1201-4.

Windsor 1985 *{published data only}*
Windsor RA, Spanos D, Samuelsson C, Bartlett EE, Manzella B, Reese Y et al. The effectiveness of smoking cessation methods for smokers in public health maternity clinics: a randomized trial. *American Journal of Public Health* 1985;**75**:1389-92.

Windsor 1993 *{published data only}*
Windsor RA, Contreras L, Artz L, Lowe JB. Smoking cessation and pregnancy intervention trial: preliminary mid-trial results. *Progress in Clinical and Biological Research* 1990;**339**:107-17.

Windsor RA, Lowe JB, Perkins LL, Smith-Yoder D, Artz L, Crawford M et al. Health education for pregnant smokers: its behavioral impact and cost benefit. *American Journal of Public Health* 1993;**83**:201-6.

Windsor 2000a *{published data only}*
Windsor RA, Woodby L, Miller T, Hardin JM, Crawford MA, DiClemente CC. Effectiveness of agency for health care policy and research clinical practice guideline and patient education methods for pregnant smokers in medicaid maternity care. *American Journal of Obstetrics and Gynecology* 2000;**182 (1Pt1)**:68-75.

Wisborg 2000 *{published data only}*
Wisborg K, Henriksen TB, Jespersen LB, Secher NJ. Nicotine patches for pregnant smokers: a randomized controlled study. *Obstetrics & Gynecology* 2000;**96(6)**:967-71.

Referencias de los estudios excluidos de esta revisión

Byrd 1993
Byrd JC, Meade CD. Smoking cessation among pregnant women in an urban setting. *Wisconsin Medical Journal* 1993;**92**:609-12.

Cooke 2001
Cooke M, Mattick R P, Walsh RA. Differential uptake of a smoking cessation programme disseminated to doctors and midwives in antenatal in antenatal clinics. *Addiction* 2001;**96(3)**:495-505.

Cooke M, Mattick R, Campbell E. The influence of individual and organisational factors on the reported smoking intervention practices of staff in 20 antenatal clinics. *Drug and Alcohol Review* 1998;**17**:175-85.

Cooke M, Mattick RP. Implementation of the "Fresh Start" smoking cessation programme to 23 antenatal clinics: a randomised controlled trial investigating two methods of dissemination. *Drug and Alcohol Review* 2001;**20**:19-28.

Cooke M, Mattick RP, Campbell E. A description of the adoption of the 'Fresh Start' smoking cessation program by antenatal clinic managers. *Australian Journal of Advanced Nursing* 2000;**18(1)**:13-21.

Cooke M, Mattick RP, Campbell E. The dissemination of a smoking cessation program to 23 antenatal clinics: the predictors of initial program adoption by managers. *Australian and New Zealand Journal of Public Health* 1999;**23(1)**:99-103.

Cooke M, Mattick RP, Campbell E. A description of the adoption of the 'Fresh Start' smoking cessation programme by antenatal clinic managers. *Australian Journal of Advanced Nursing* 2000;**18**:13-21.

Emmons 2000
Emmons K, Sorensen G, Klar N, Digianni L, Barclay G, Schmidt K et al. Healthy baby second - hand smoke study. *Tobacco Control* 2000;**9(Suppl 3)**:iii58-60.

Ershoff 1983
Ershoff DH, Aaronson NK, Danaher BG, Wasserman FW. Behavioral, health and cost outcomes of an HMO-based prenatal health education program. *Public Health Reports* 1983;**98**:536-47.

Gebauer 1998
Gebauer C, Chung-Ying K, Haynes E, Wewers ME. A nurse-managed smoking cessation intervention during pregnancy. *Journal of Obstetric, Gynecologic and Neonatal Nursing* 1998;**21**:47-53.

Gillies 1987
Gillies PA, Power FL, Turner ID, Madely R. Successful antismoking interventions in pregnancy - behaviour change, "clinical indicators" or both?. *In: Durston B, Jamrozik K, editor(s). Tobacco and health 1990: the global war: Proceedings of the 7th World Conference on Tobacco & Health. Perth: Health Department of Western Australia*. 1990:952-8.

Graham 1992
Graham AV, Reeb KG, Kitson GC, Zyzanski SJ, Frank SH. A clinical trial to reduce the rate of low birth weight in an inner-city black population. *Family Medicine* 1992;**24**:439-46.

Haug 1994
Haug K, Fugelli P, Aaro LE, Foss OP. Is smoking intervention in general practice more successful among pregnant than non-pregnant women?. *Family Practice* 1994;**11**:111-6.

Jaakola 2001
Jaakola N, Zahlsen K, Jaakola J. Effects of a population based smoking cessation programme on smoking in pregnancy. *European Journal of Public Health* 2001;**11**:446-9.

Langford 1983
Langford ER, Thompson EG, Tripp SC. Smoking and health education during pregnancy: evaluation of a program for women in prenatal classes. *Canadian Journal of Public Health* 1983;**74**:285-9.

Lillington 1995
Lillington L, Chlebowski R, Ruvalcaba M, Novak D, Royce J. Evaluation of a smoking cessation program for pregnant minority smokers. *Cancer Practice* 1995;**3**:157-63.

Lowe 2002
Lowe JB, Balanda KP, Stanton WR, Del Mar C, O'Connor V. Dissemination of an efficacious antenatal smoking cessation program in public hospitals in Australia: a randomised controlled trial. *Health Education and Behaviour* 2002;**29**(**5**):608-619.

Messimer 1989
Messimer SR, Henry RC, Hickner JM. A comparison of two antismoking interventions among pregnant women in eleven primary care practices. *Journal of Family Practice* 1989;**28**:283-8.

Mullen 1990
Mullen PD, Quinn VP, Ershoff DH. Maintenance of nonsmoking postpartum by women who stopped smoking during pregnancy. *American Journal of Public Health* 1990;**80**:992-4.

Mullen 1997
Mullen PD, Richardson MA, Quinn VP, Ershoff DH. Postpartum return to smoking: who is at risk and when. *American Journal of Health Promotion* 1997;**11**:323-30.

Olds 1994
Olds DL, Henderson CR, Tatelbaum R. Prevention of intellectual impairment in children of women who smoke cigarettes during pregnancy. *Pediatrics* 1994;**93**:228-33.

Olds 2002
Olds D, Robinson J, O'Brien R, Luckey D, Pettit L, Henderson C et al. Home visiting by paraprofessionals and by nurses: a randomized, controlled trial. *Pediatrics* 2002;**110**(**3**):486-96.

Power 1989
Power FL, Gillies PA, Madeley R, Abbott M. Research in an antenatal clinic - the experiences of the Nottingham Mothers' Stop Smoking Project. *Midwifery* 1989;**5**:106-12.

Scott 2000
Scott WJ, McIlvain H. Interactive software: an educational/behavioural approach to smoking cessation for pregnant women and their families. *Tobacco Control* 2000;**9**(**Suppl 3**):iii56-7.

Shakespeare 1990
Shakespeare R. The development and evaluation of a smoking cessation counselling training programme for midwives. *In: Durston B, Jamrozik K, editor(s). Tobacco and health 1990: the global war: Proceedings of the 7th World Conference on Tobacco & Health. Perth: Health Department of Western Australia*. 1990:950-1.

Valanis 2001
Valanis B, Lichtenstein E, Mullooly JP, Labuhn K, Brody K, Severson H et al. Maternal smoking cessation and relapse prevention during health care visits. *American Journal of Preventive Medicine* 2001;**20**(**1**):1-8.

Wisborg 1998
Wisborg K, Henriksen TB, Secher NJ. A prospective intervention study of stopping smoking in pregnancy in a routine antenatal care setting. *British Journal of Obstetrics and Gynaecology* 1998;**105**:1171-6.

Referencias de los estudios en espera de evaluación

Cook 1995
Cook C, Ward S, Myers S, Spinnato J. A prospective, randomized evaluation of intensified therapy for smoking reduction in pregnancy. *American Journal of Obstetrics and Gynecology* 1995;**172**:290.

Hiett 2000
Hiett A, Brazus S, Hedberg J, Brown H. Smoking cessation program effectiveness during pregnancy. *American Journal of Obstetrics and Gynecology* 2000;**182(1 Pt 2)**:S150.

Windsor 1988
Windsor RA, Warner KE, Cutter GR. A cost-effectiveness analysis of self-help smoking cessation methods for pregnant women. *Public Health Reports* 1988;**103**:83-8.

Wisborg 1998a
Wisborg K. Nicotine patches to pregnant smokers - a randomised study. *1st International Conference of the Society for Research on Nicotine and Tobacco; 1998 August 22-23; Copenhagen, Denmark*. 1998.

Referencias adicionales

Adams 1998
Adams K, Melvin C. Costs of maternal conditions attributable to smoking during pregnancy. *American Journal of Preventive Medicine* 1998;**15**(**3**):212-9.

AIHW 2002
Australian Institute of Health and Welfare. 2001 National Drug Strategy Household Survey. *Canberra: AIHW, Catalogue No. PHE-35, Series 11* 2002.

Amir 2001
Amir LH. Maternal smoking and reduced duration of breastfeeding: a review of possible mechanisms. *Early Human Development* 2001;**64**:45-67.

Amir 2002
Amir LH, Donath SM. Does maternal smoking have a negative physiological effect on breastfeeding? The epidemiological evidence. *Birth* 2002;**29**:112-23.

Andreski 1995
Andreski P, Breslau N. Maternal smoking among blacks and whites. *Social Science and Medicine* 1995;**41**:227-33.

Aquilino 2003
Aquilino ML, Goody CM, Lowe JB. WIC providers' perspectives on offering smoking cessation interventions. *MCN American Journal of Maternal and Child Nursing* 2003;**28**(**5**):326-32.

Baric 1977
Baric L, MacArthur C. Health norms in pregnancy. *British Journal of Preventive and Social Medicine* 1977;**31**:30-8.

Benowitz 1991
Benowitz NL. Nicotine replacement therapy during pregnancy. *JAMA* 1991;**266**:3174-7.

Borelli 1996
Borelli B, Bock B, King T, Pinto B, Marcus BH. The impact of depression on smoking cessation in women. *American Journal of Preventive Medicine* 1996;**12**:378-87.

Campion 1994
Campion P, Owen L, McNeill A, McGuire C. Evaluation of a mass media campaign on smoking and pregnancy. *Addiction* 1994;**89**:1245-54.

CDCP 1998
Centers for Disease Control and Prevention. Incidence of initiation of cigarette smoking - United States, 1965-1996. *Morbidity and Mortality Weekly Report* 1998;**47**(**39**):837-41.

CDCP 2002
Centers for Disease Control and Prevention. Women and smoking: a report of the Surgeon General (Executive Summary). *Morbidity and Mortality Weekly Report 51 (No. RR-12)* 2002.

Chan 2001
Chan A, Keane R J, Robinson J S. The contribution of maternal smoking to preterm birth, small for gestational age and low birth weight among aboriginal and non-aboriginal births in South Australia. *Medical Journal of Australia* 2001;**174**(**8**):389-93.

Clarke 2002
Clarke M, Oxman AD, editors. Cochrane Reviewers' Handbook 4.1.5 [Updated April 2002]. *In: The Cochrane Library, Issue 3, 2002. Oxford: Update Software. Updated quarterly*

Cnattingius 1997
Cnattingius S, Haglund B. Decreasing smoking prevalence during pregnancy in Sweden: the effect on small-for-gestational-age births. *American Journal of Public Health* 1997;**87**:410-3.

Cochran 1954
Cochran WG. The combination of estimates from different experiments. *Biometrics* 1954;**10**:101-29.

Dejin-Karlsson 1996
Dejin-Karlsson E, Hanson BS, Ostergren PO, Ranstam J, Isacsson SO, Sjoberg NO. Psychosocial resources and persistent smoking in early pregnancy - a population study of women in their first pregnancy in Sweden. *Journal of Epidemiology and Community Health* 1996;**50**:33-9.

Dempsey 2001
Dempsey DA, Benowitz NL. Risks and benefits of nicotine to aid smoking cessation in pregnancy. *Drug Safety* 2001;**24(4)**:277-322.

Dodds 1995
Dodds L. Prevalence of smoking among pregnant women in Nova Scotia from 1988 to 1992. *Canadian Medical Association Journal* 1995;**152**:185-90.

England 2001
England LJ, Kendrick JS, Wilson HG, Merritt RK, Gargiullo PM, Zahniser SC. Effects of smoking reduction during pregnancy on the birth weight of term infants. *American Journal of Epidemiology* 2001;**154**:694-701.

Eriksson 1996
Eriksson KM, Salvesen KA, Haug K, Eik-Nes SH. Smoking habits among pregnant women in a Norwegian county 1987-94. *Acta Obstetricia et Gynecologica Scandinavica* 1996;**75**:355-9.

Fox 1989
Fox NL, Sexton M, Hebel JR, Thompson B. The reliability of self-reports of smoking and alcohol consumption by pregnant women. *Addictive Behaviors* 1989;**14(2)**:187-95.

Frost 1994
Frost FJ, Cawthorn ML, Tollestrup K, Kenny FW, Schrager LS, Nordlund DJ. Smoking prevalence during pregnancy for women who are and women who are not Medicaid-funded. *American Journal of Preventive Medicine* 1994;**10**:91-6.

Graham 1977
Graham H. Smoking in pregnancy: the attitudes of pregnant mothers. *Social Science and Medicine* 1977;**10**:399-405.

Graham 1994
Graham H. Gender and class as determinants of smoking behaviour in Britain: insights from a survey of mothers. *Social Science and Medicine* 1994;**38**:691-8.

Graham 1996
Graham H. Smoking prevalence among women in the European community 1950-1990. *Social Science and Medicine* 1996;**43**:243-54.

Groff 1997
Groff JY, Mullen PD, Mongoven M, Burau K. Prenatal weight gain patterns and infant birthweight associated with maternal smoking. *Birth* 1997;**24(4)**:234-9.

Horta 1997
Horta BL, Barros FC, Memezes AM, Victora CG. Environmental tobacco smoke and breastfeeding duration. *American Journal of Epidemiology* 1997;**146**:128-33.

Hughes 1993
Hughes JR. Risk-benefit assessment of nicotine preparations in smoking cessation. *Drug Safety* 1993;**8**:49-56.

Hunt 2003
Hunt J. Trying to make a difference: improving pregnancy outcomes, care and services for Australian indigenous women. *PhD Thesis, LaTrobe University* 2003:56.

Husten 1996
Husten CG, Chrismon JH, Reddy MN. Trends and effects of cigarette smoking among girls and women in the United States, 1965-1993. *Journal of the American Medical Women's Association* 1996;**51**:11-8.

Kaplan 1997
Kaplan SD, Lanier AP, Merritt RK, Siegel PZ. Prevalence of tobacco use among Alaska natives: a review. *Preventive Medicine* 1997;**26**:460-5.

Kramer 1987
Kramer MS. Determinants of low birth weight: methodological assessment and meta-analysis. *Bulletin of the World Health Organisation* 1987;**65**:663-737.

Lancaster 1997
Lancaster T, Silagy C, Fowler G. Training health professionals in smoking cessation (Cochrane Review). In: *The Cochrane Library*, 3, 2004. Chichester, UK: John Wiley & Sons, Ltd. CD000214.

Lumley 2002
Lumley J, Brown S, Darcy MA, Bruisma F. Smoking in pregnancy by Victorian women and what hospitals do to help them stop. *6th Annual Congress of Perinatal Society of Australia and New Zealand and the Federation of the Asia and Oceania Perinatal Societies 12th Annual Congress; 2002 March; Christchurch, New Zealand*. 2002.

McBride 2003
McBride CM, Emmons KM, Lipkus IM. Understanding the potential of teachable moments: the case of smoking cessation. *Health Education Research* 2003;**18(2)**:156-70.

McLeod 2003
McLeod D, Benn C, Pullon S, Viccars A, White S, Cookson T et al. The midwife's role in facilitating smoking change during pregnancy. *Midwifery 19* 2003;**4**:265-97.

McNutt 2002
McNutt LA, Carlson BE, Persaud M, Postmus J. Cumulative abuse experiences, physical health and health behaviours. *Annals of Epidemiology* 2002;**12(2)**:123-30.

Melvin 2000
Melvin CL, Adams EK, Miller V. Costs of smoking during pregnancy: development of the Maternal and Child Health Smoking Attributable Mortality Morbidity and economic costs (MCHSAMMEC) software. *Tobacco Control 9* 2000;**(Suppl 3)**:iii12-iii15.

Merchant 2001
Merchant KM, Villar J, Kestler E. Maternal height and newborn size relative to risk of intrapartum caesarean delivery and perinatal distress. *BJOG: an international journal of obstetrics and gynaecology* 2001;**108**:689-96.

Miller 2001
Miller DP, Villa KF, Hogue SL, Sivapathasundaram D. Birth and first-year costs for mothers and infants attributable to maternal smoking. *Nicotine and Tobacco Research* 2001;**3**:25-35.

MMWR 2004
Phares TM, Morrow B, Lansky A, Barfield WD, Prince CB, Marchi KS et al. Surveillance for disparities in maternal health behaviors. Selected sites, Pregnancy Risk Monitoring Systems (PRAMS). *Morbidity and Mortality Weekly Report 53* 2004;**(SS04)**:1-13.

Oliver 1997
Oliver S. Exploring lay perspectives on questions of effectiveness. In: Maynard A, Chalmers I, editor(s). *Non-random reflections on health services research*. London: BMJ Publishing, 1997:272-91.

Oncken 1996
Oncken CA, Hatsukama DK, Luop V, Lando H, Gibeau L, Hansen B. Effects of short term nicotine gum use in pregnant smokers. *Journal of Clinical Pharmacoloy and Therapeutics* 1996;**59**:654-61.

Oncken 1997
Oncken CA, Hardardottir H, Hatsukami DK, Lupo VR, Rodis JF, Smeltzer JS. Effects of transdermal nicotine or smoking on nicotine concentrations and maternal-fetal hemodynamics. *Obstetrics & Gynecology* 1997;**90**:569-74.

Oncken 2003
Oncken CA, Kranzler HR. Pharmacotherapies to enhance smoking cessation during pregnancy. *Drug and Alcohol Review* 2003;**22**(**2**):191-202.

Potter 1996
Potter A, Lumley J, Watson L. The 'new' risk factors for SIDS: is there an association with ethnic and place of birth differences in incidence in Victoria?. *Early Human Development* 1996;**45**:119-31.

Quinn 1991
Quinn VP, Mullen PD, Ershoff DH. Women who stop smoking spontaneously prior to prenatal care and predictors of relapse before delivery. *Addictive Behaviour* 1991;**16**(**1-2**):29-40.

Riemsma 2003
Riemsma RP, Pattenden J, Bridle C, Sowden AJ, Mather L, Watt IS et al. Systematic review of the effectiveness of stage based interventions to promote smoking cessation. *BMJ* 2003;**326**:1175-7.

Rogers 1998
Rogers I, Emmett P, Baker D, Golding J, ASLPAC Study Team. Financial difficulties, smoking habits, composition of the diet and birthweight in a population of pregnant women in the South West of England. *European Journal of Clinical Nutrition* 1998;**52**:251-60.

Ryan 1980
Ryan P, Booth R, Coates D, Chapman A, Healy P. Experiences of pregnancy. Pregnant Pause Campaign. *Health Commission of New South Wales, Division of Drug and Alcohol Services, 1980*

Sayers 1995
Sayers G, Burke M, Corcoran R, Thornton L. Influences on breast feeding initiation and duration. *Irish Journal of Medical Science* 1995;**164**:281-4.

Secker-Walker 2002
Secker-Walker RH, Vacek PM. Infant birth weight as a measure of harm reduction during smoking cessation trials in pregnancy. *Health Education and Behaviour* 2002;**29**(**5**):557-69.

Silagy 2002
Silagy C, Lancaster T, Stead L, Mant D, Fowler G. Nicotine replacement therapy for smoking cessation (Cochrane Review). In: *The Cochrane Library*, 3, 2004. Chichester, UK: John Wiley & Sons, Ltd. CD000146.

Silagy 1997
Silagy C, Ketteridge S. Physician advice for smoking cessation (Cochrane Review). In: *The Cochrane Library*, 3, 2004. Chichester, UK: John Wiley & Sons, Ltd. CD000165.

Small 2000
Small R. Mothers in a New Country (MINC). *PhD Thesis, LaTrobe University* 2000.

Stanton 2004
Stanton WR, Lowe JB, Moffat J, Del Mar CB. Randomised trial of a smoking cessation intervention directed at men whose partners are pregnant. *Preventive Medicine* 2004;**38**(**1**):6-9.

Stewart 1995
Stewart P, Potter J, Dulberg C, Niday P, Nimrod C, Tawagi G. Change in smoking prevalence among pregnant women 1982-93. *Canadian Journal of Public Health* 1995;**86**:37-41.

Stotts 1996
Stotts AL, DiClemente CC, Carbonari JP, Mullen PD. Pregnancy smoking cessation: a case of mistaken identity. *Addictive Behaviors* 1996;**21**:459-471.

Tappin 1996
Tappin DM, Ford RP, Nelson KP, Wild CJ. Prevalence of smoking in early pregnancy by census area, measured by anonymous cotinine testing of residual antenatal blood samples. *New Zealand Medical Journal* 1996;**109**:101-3.

Tappin 1997
Tappin DM, Ford RP, Schluter PJ. Smoking during pregnancy measured by population cotinine testing. *New Zealand Medical Journal* 1997;**110**:311-4.

Walsh 1995
Walsh RA, Redman S, Brinsmead MW, Arnold B. Smoking cessation in pregnancy: a survey of the medical and nursing directors of public antenatal clinics in Australia. *Australian and New Zealand Journal of Obstetrics and Gynaecology* 1995;**35**:144-50.

Wergeland 1996
Wergeland E, Strand K, Bjerkedal T. Smoking in pregnancy: a way to cope with excessive workload. *Scandinavian Journal of Primary Health Care* 1996;**14**:21-8.

Wiemann 1994
Wiemann CM, Berenson AB, San Miguel VV. Tobacco, alcohol and illicit drug use among pregnant women: age and racial/ethnic differences. *Journal of Reproductive Medicine* 1994;**39**:769-76.

Windsor 1998
Windsor RA, Boyd NR, Orleans CT. A meta-evaluation of smoking cessation intervention research among pregnant women: improving the science and art. *Health Education Research* 1998;**13**(**3**):419-438.

Windsor 1999
Windsor RA, Li CQ, Boyd NR, Hartmann KE. The use of significant reduction rates to evaluate health education methods for pregnant smokers. *Health Education and Behaviour* 1999;**26**:648-62.

Windsor 2000b
Windsor RA, Whiteside HP, Solomon LJ, Donatelle RJ, Cinciripini PM, McIlvain HE. A process evaluation for patient education programs for pregnant smokers. *Tobacco Control 9* 2000;**(Suppl 3)**:iii28-iii35.

Woodby 1999
Woodby LL, Windsor RA, Snyder SW, Kohler CL, Diclemente CC. Predictors of smoking cessation during pregnancy. *Addiction* 1999;**94**(**2**):283-92.

Yusuf 1985
Yusuf S, Peto R, Lewis J. Beta blockade during and after myocardial infraction: an overview of the randomised trials. *Progress in Cardiovascular Diseases* 1985;**27**:335-71.

Referencias de otras versiones de esta revisión

CDSR 2004
Lumley J, Oliver S, Waters E. Interventions for promoting smoking cessation during pregnancy (Cochrane Review). In: *The Cochrane Library*, 3, 2004. Chichester, UK: John Wiley & Sons, Ltd. CD001055.

Lumley 1995a
Lumley J. Advice as a strategy for reducing smoking in pregnancy. [revised 02 October 1993]. *In: Enkin MW, Keirse MJNC, Renfrew MJ, Neilson JP, Crowther C (eds.) Pregnancy and Childbirth Module. In: The Cochrane Pregnancy and Childbirth Database [database on disk and CDROM] The Cochrane Collaboration; Issue 2, Oxford: Update Software; 1995*

Lumley 1995b
Lumley J. Behavioural strategies for reducing smoking in pregnancy. [revised 27 September 1993]. *In: Enkin MW, Keirse MJNC, Renfrew MJ, Neilson JP, Crowther C (eds.) Pregnancy and Childbirth Module. In: The*

Cochrane Pregnancy and Childbirth Database [database on disk and CDROM] The Cochrane Collaboration; Issue 2, Oxford: Update Software; 1995

Lumley 1995c
Lumley J. Counselling for reducing smoking in pregnancy. [revised 02 October 1993]. *In: Enkin MW, Keirse MJNC, Renfrew MJ, Neilson JP, Crowther C (eds.) Pregnancy and Childbirth Module. In: The Cochrane Pregnancy and Childbirth Database [database on disk and CDROM] The Cochrane Collaboration; Issue 2, Oxford: Update Software; 1995*

Lumley 1995d
Lumley J. Feedback as a strategy for reducing smoking in pregnancy. [revised 27 September 1993]. *In: Enkin MW, Keirse MJNC, Renfrew MJ, Neilson JP, Crowther C (eds.) Pregnancy and Childbirth Module. In: The Cochrane Pregnancy and Childbirth Database [database on disk and CDROM] The Cochrane Collaboration; Issue 2, Oxford: Update Software; 1995*

Lumley 1995e
Lumley J. Strategies for reducing smoking in pregnancy. [revised 02 October 1993]. *In: Enkin MW, Keirse MJNC, Renfrew MJ, Neilson JP, Crowther C (eds.) Pregnancy and Childbirth Module. In: The Cochrane Pregnancy and Childbirth Database [database on disk and CDROM] The Cochrane Collaboration; Issue 2, Oxford: Update Software; 1995*

** El asterisco señala los documentos más importantes para este estudio*

TABLAS

Characteristics of included studies

Study	**Albrecht 1998**
Methods	A randomised pilot study including two different interventions and usual care provided to "pregnant teens" recruited through local prenatal clinics and public schools in Pittsburgh, USA. The hypothesis was that an intervention including peer support would be more effective than the intervention alone. The aim was to develop an effective intervention which could be implemented by clinics and schools. No details of randomisation or whether usual care providers were blinded to allocation. of bias.
Participants	Inclusion criteria were: 12 to 20 years of age; 4 to 28 weeks gestation; reported smoking at least 1 cigarette a day; single; no previous live birth; able to read and write English. Exclusion criteria: pregnancy complications preventing attendance at group sessions or participation in a home study program. 84 women recruited (not known how many were eligible or approached), 53 African-American heritage, 31 European-American heritage. 29 randomised to UC, 29 to TFS and 26 to TFSB. 46/84 had outcome data post-intervention. Mean cigarettes/day at first visit: UC = 6.44; TFS = 5.87; TFSB = 6.81.
Interventions	Usual Care (UC) 30 minutes individual educational session with project nurse including information about the risks of smoking to the mother and the fetus + brochures on smoking and pregnancy. Teen Fresh Start (TFS): cognitive behavioural group model designed specifically for adolescents: 8 modules to heighten awareness and attention to smoking messages; build and enhance smoking cessation skills; teach skills for maintenance of smoking control; includes experiential learning and round robin discussion. TFS was modified to include additional information on smoking and the fetus, body image changes and overall health. The intervention also included social activities, immediate rewards and adult modelling. Teen Fresh Start + peer support (TFSB) utilised all the components of TFS plus one-to-one support through a non-smoking peer (buddy) chosen by the young woman. Buddies were asked to attend all 8 sessions and to be available at other times for reinforcement of techniques learned and encouragement for continued cessation. High intensity intervention.
Outcomes	Smoking cessation at 4-6 weeks post baseline, validated by exhaled CO. Only 46/84 had outcome data (high attrition rate = 45%), UC = 12 (41%), TFS = 13 (46%), TFSB = 13 (50%). Modified Fagerstrom Tolerance Questionnaire for adolescents to assess nicotine dependence.
Notes	TFS and UC outcomes were combined in this preliminary paper.
Allocation concealment	B
Study	**Bakker 2001**
Methods	Cluster-randomised trial measuring (i) the short-term effects of routine prenatal care provider (midwife) smoking cessation counselling and provision of smoking cessation materials. All midwives in a province were allocated to either intervention or control care. Only 24.2% of chairs of midwifery agreed to approach midwives in their region to participate. The first 40 practices (118 midwives) were selected, from 4 provinces, which were then matched (by location and level of urbanisation) into 2 pairs. (ii)measuring the longer-term effects.

Characteristics of included studies

Participants	Women using public health services, who smoke more than 1 cigarette per day, literate in Dutch, and gravidity less than or equal to 4. 80% eligible population approached. Participation rate 72% (n = 318). Mean cigarettes per day at intake I = 9.1, C = 7.7. Mean gest at intake I = 12.4, C = 13.5. (ii) included women from trial (i) and spontaneous quitters; n = 253 (I) and 303 (C); 80% approached. 72% participation.
Interventions	Control group received routine smoking cessation counselling + a folder about smoking cessation in pregnancy, (Both trials i and ii) Intervention group received routine care + a minimum of counselling sessions from their midwife, who received a 3 hour training session on smoking cessation counselling and a booklet); a video; self help guide; partner booklet; midwife booklet and post-delivery booklet. Information was based on the stages of change model.
Outcomes	Self reported quit attempts at 6 weeks postpartum, with urine cotinine biochemical validation in a small proportion of participants (n = 14). Self reported partner smoking status. Attrition 12.8%, not different in I and C arms, detailed process evaluation, including views of participants and midwives Attrition rate 12.8%, with NS difference in attrition between experimental and control groups. (ii) Self-reported quit attempts at 6 weeks and 6 months postpartum; attrition 9.1% (I), 7.9% (C) Detailed assessment of participant and midwifery views of interventions, including an analysis of psychosocial motives which are thought to be associated with implementation.
Notes	inconsistent information on gravidity criteria. Good process evaluation documented poor implementation in some aspects. A separate detailed paper published on process evaluation issues. (ii) Only 16.7% of women received the post-delivery booklet. No validation of longer-term self-reported smoking.
Allocation concealment	D
Study	**Baric 1976**
Methods	A randomised pilot study of the effect of medical advice on smoking cessation in pregnancy, in two public antenatal clinics in Bolton and District General Hospital, England. No sample size or randomisation details.
Participants	Women smokers or ex-smokers, at their first antenatal visit, less than 20 weeks gestation. 110 women, mostly working-class, mostly long-term and heavy smokers. I n = 63 C: n = 47.
Interventions	Control group received usual care, which was advice at the discretion of the doctor. Intervention group received counselling from a senior medical student which involved discussion of the disadvantages of smoking during pregnancy: risk to the fetus; long-term risks of physical and intellectual impairment and possible reasons for this; possible effects on the mother's own health; costs of smoking; special dangers of smoking in late pregnancy; various ways to help someone to stop smoking. Given strong encouragement to quit and to make a commitment to do so. If this was not agreed then reduction to less than 5 cigarettes a day. Half the intervention group were given a diary to record each cigarette smoked and a gift of a free smoking diary. No theoretical basis of intervention specified. Intervention intensity = 3.
Outcomes	Smoking cessation assessed by self report in a home interview 11 weeks after baseline visit. No biochemical validation of smoking status.
Notes	
Allocation concealment	B

Characteristics of included studies

Study	Bauman 1983
Methods	Randomised trial of effectiveness of use of exhaled carbon monoxide feedback for promoting smoking cessation in pregnancy, in Guildford County, North Carolina. Trial over 6 months in 1981. Allocation by a computer-generated random number table to experimental or control group. No randomisation details or sample size justification.
Participants	Women currently or recently smoking, attending public clinics. No exclusion criteria details or characteristics of participants in each group. 47% were current smokers, 43% had completed high school education, 56% were black, 80% classified as having no pregnancy risks other than smoking. 38% in the first trimester and 46% in the second trimester of pregnancy.
Interventions	Experimental group provided breath specimen in which carbon monoxide was measured, with feedback of the result, and a 135 word script describing the relationship between CO and cigarette smoking + harmful effects of smoking during pregnancy, by health educator. Women in the control group were read the script only. Intervention carried out by regular health educators.
Outcomes	Smoking cessation 6 weeks after intervention confirmed by subsequent CO <= 9 ppm in breath specimen. Outcome measurement for 170/226 women. Attrition rate 24.8%, and allocation not reported.
Notes	Not clear whether this was a group intervention - in which case there was no adjustment for clustering.
Allocation concealment	B
Study	**Belizan 1995**
Methods	Randomised trial of psychosocial support in pregnancy in 4 hospitals in Latin America (Argentina, Brazil, Cuba, Mexico). January 1989 - March 1991. Randomisation in balanced blocks of 20, prepared centrally, provided in sealed, opaque envelopes opened after the baseline interview had been completed. Providers unaware of the allocation of women to either arm of the trial.
Participants	High-risk women whose antenatal care began at 15 - 22 weeks gestation, singleton pregnancy, 1 or more of the following: prior LBW infant; preterm birth; perinatal/infant death; < 18 years; body weight <= 50 kg; height <= 150 cm; low family income (local definitions applied); < 3 years school; crowded household (4 or more persons/bedroom); smoking; not living with husband or partner. 2235 women recruited 1115 to intervention 1120 to control. Exclusions: heart or renal failure; diastolic BP > 100 mmHg; history of cervical cerclage; Rh negative; mental disease or any chronic disease that might interfere with pregnancy.
Interventions	Control group received routine antenatal care. High intensity intervention involving flexible use of a standardised manual, based on site-specific ethnographic studies of needs, fears, expectations, social support networks, including detailed descriptions of situations likely to occur during home visits. 4 to 6 home visits of 1 to 2 hours with emphasis on psychosocial support, education on health habits including better nutrition, reducing smoking alcohol and other drugs, reducing their physical workload, recognition of alarm signs and symptoms, improved access to hospital facilities, reinforcement of health service utilization. Additional components were a poster, a booklet, hot line to project office, guided tour of hospital, encouragement of family support and participation. Intervention was provided by specially trained female social workers or obstetric nurses with previous experience of childbirth.

Characteristics of included studies

Outcomes	Self reported smoking cessation, no biochemical validation. Multiple perinatal and maternal health outcome data were collected. As there are many paths other than smoking reduction/cessation by which these outcomes might have been modified by the intervention, only smoking cessation has been abstracted in this review.
Notes	Sample size was planned for the primary trial objective. Process evaluation showing good implementation is reported.
Allocation concealment	A
Study	**Bullock 1995**
Methods	Trial of telephone support for improving outcomes in late pregnancy, in the outpatient department of a large maternity hospital in New Zealand, or its associated GP practices, or self-referral, from March to December 1993. Computer-generated random assignment to control or intervention in balanced blocks of 50. Caregiver blinded to allocation. No sample size justification. No sample size justification.
Participants	Women with telephone access, who were either single or with an unemployed partner, were recruited before 20 weeks gestation. The eligible population was 221 women of whom 131 took part (103 OPD, 22 from GPs, 6 self-referred). 49 were never located, 23 were not interested, 10 refused after explanation, 8 moved away, did not speak English or had a miscarriage. Over 50% of women smoked at recruitment.
Interventions	Introductory letter, phone call, full discussion of "Healthy Mothers/Healthy Babies". Controls: package of publicly available educational material on healthy behaviours during pregnancy. High intensity intervention: package + weekly telephone call from trained volunteer with the aim of providing minimal support until 12 weeks after birth; aim "to be a friend and a good listener"; to ask about symptoms; signs; alcohol; drugs; smoking and meals in every call; to encourage attendance at antenatal clinic appointments and to ask about "feeling stressed". Intervention provided by 19 female volunteers, trained for the project with a "case load" of 2 to 6 women each.
Outcomes	Both perinatal and maternal health outcomes were assessed but as there were other intervention components which might have influenced these outcomes only smoking cessation data were abstracted for this review. No biochemical validation of smoking status. 9 women (of 131) were lost to follow up by late pregnancy, counted as still smoking. Attrition = 7%.
Notes	No process evaluation is reported.
Allocation concealment	B
Study	**Burling 1991**
Methods	Trial of CO assessment and brief directive feedback, in a large US municipal hospital antenatal clinic, over an 18 month study period. No description of randomisation. Caregivers blinded to allocation.
Participants	All attending women screened for smoking by questionnaire + CO breath measurement (>= 9 ppm). Pregnant women, currently smoking, at any stage of gestation. Over 50% were current smokers; 40% of women were Black. Exclusion criteria were very young age (not specified) or "complications" (not specified).

Characteristics of included studies

Interventions	Control group (usual care): clinic nurse provided health education, including smoking. Intervention: usual care + personal letter from the Chief (physician) of the prenatal clinic within 3 days of the visit, mentioning the CO test, discussing the risks of smoking to herself and the fetus and urging her to stop + American Cancer Society pamphlet ("Why start life under a cloud?") about the negative effects of smoking and simple guidelines for self-directed smoking cessation.
Outcomes	CO measurements (biochemical validation) and smoking data were collected at all subsequent visits.
Notes	Simple intervention so no process evaluation. Clinic-wide implementation so no consent sought.
Allocation concealment	B
Study	**Cinciripini 2000**
Methods	Trial of provision of videotaped vignettes for promoting smoking cessation and relapse prevention in a community-based university setting, Texas, US. No details of randomisation, caregiver blinded.
Participants	Volunteers who were willing to quit within two weeks, were recruited through local media, such as newspaper, radio, subscriber letters, community business flyers, waiting room posters. Exclusion criteria: women smoking < 3 cigarettes per day; < 18 years; > 30 weeks pregnant; do not have a working VCR (approximately 12% Americans); not depressed. Participants n = 82. Mean cigarettes/day at first visit I = 17.3, C = 14.5. No significant difference in socioeconomic variables between groups.
Interventions	The control group received a quit calendar and tip guide. Intervention group were also mailed a video with 6 x 25 - 30 minutes vignettes covering a range of topics and strategies from initial quitting to relapse prevention.
Outcomes	Self reported smoking abstinence obtained within 2-3 days of quit date, 4-5 weeks after the quit date and one month postpartum. Biochemically validated with salivary cotinine. Baseline CES-D depression scale. Participant evaluation of intervention materials. Attrition rate 39%.
Notes	Authors say women in this study tend to be heavier smokers than described in previous studies. Process evaluation showed only 53% of the intervention group viewed 1 - 3 of the 6 videos. 47% did not view them.
Allocation concealment	B
Study	**Donatelle 2000**
Methods	Trial of "Significant Other Supporter" (SOS) program, of bolstered social support and direct financial rewards, for low income high-risk women in 4 Oregon WIC program sites, US. Conducted between June 1996-June 1997. No randomisation details. Quality score = moderate-risk of bias.
Participants	Women smoking (even a puff in the last 7 days); less than 28 weeks gestation; over 15 years of age; literate in English. Participation rate 71%. Mean salivary cotinine at baseline: I: 45.4 (n = 112); C: 45.7 (n = 108).

Characteristics of included studies

Interventions	Control group received verbal and written information on the importance of smoking cessation, a pregnancy specific smoking cessation self help kit, and were telephoned monthly for self reports on their smoking status. The intervention group received as for the control group + were asked to designate a social supporter (preferably a female non-smoker), and were advised both she and her supporter would receive an incentive: participant = $50 voucher/month biochemically confirmed as quit. Supporter = $50 voucher in first month and at 2 months postpartum, and $25 voucher for other months. High intensity.
Outcomes	Smoking cessation biochemically validated with salivary cotinine at 34 weeks gestation and 2 months postpartum. Attrition rate I = 32%; C = 51.5%.
Notes	Data in outcome tables is inconsistent.
Allocation concealment	B
Study	**Donovan 1977**
Methods	Randomised trial of advice to stop smoking in pregnancy, provided by a (public health) doctor, reinforced by the woman's own GP and other providers involved in shared antenatal care, in 3 UK maternity units. Randomisation details unclear. Caregivers not blinded (asked to reinforce information). Quality score = high-risk of bias.
Participants	Pregnant women < 35; currently smoking >= 5 cigarettes/day and had been smoking >= 1/day at the onset of pregnancy; < 30 weeks gestation at first visit; no prior perinatal death; not seeking, nor sought termination. Other exclusions: not pregnant; refused consent; miscarriage or termination of pregnancy; moved to another care provider; twin pregnancy or birth before 28 weeks.
Interventions	Control group received ANC usually provided by the hospital, including any anti-smoking advice which may have been given routinely. Intervention: individualised medical advice (i) tell the woman the facts about smoking in pregnancy; (ii) encourage questions about these facts; (iii) once the woman has agreed to try, discuss how she may best give up; (iv) follow up the advice at all later contacts. Medical records labelled asking other staff to reinforce advice.
Outcomes	Self reported smoking in cigarettes/day at four stages of pregnancy; mean birthweight; low birthweight; preterm birth (< 36 weeks); perinatal deaths. No data on smoking cessation. No biochemical validation of smoking status.
Notes	Details of the intervention are in Donovan et al 1975 [see Donovan 1977]. Good discussion of common problems identified when advising women to stop and on the contextual factors which encourage the continuation of smoking. Process evaluation of the reinforcement of advice showed little difference between the groups in recall of advice being given. Major inconsistency in smoking reports pre and post birth is a problem in this trial.
Allocation concealment	B
Study	**Dunkley 1997**
Methods	Trial of midwifery counselling around the "stages of change" model", in a large UK maternity. No details of randomisation and caregivers aware of allocation. Quality score = high-risk of bias.
Participants	100 women; pregnant and booked for maternity care; < 18 weeks gestation; currently smoking 1 or more cigarettes/day. 13 midwives selected for the intervention group and 13 for the control group.

Characteristics of included studies

Interventions	Intervention midwives were trained to assess the stages of change and provide a behavioural intervention, using the Health Education Authority material "Helping pregnant smokers quit: training for health professionals", 1994.
Outcomes	Smoking cessation; cigarettes/day; "stage of change" at 11 to 18 weeks vs 37 weeks. No biochemical validation of smoking status.
Notes	3700 births/year at the hospital, all women who smoked were eligible to take part so it is not clear why only 100 took part (described as "all 100"). No process evaluation reported. UK.
Allocation concealment	B
Study	**Ershoff 1989**
Methods	Prospective randomised controlled trial in 5 health centres of the same HMO in Los Angeles, 1985 - 87. Educator turned over a pre-assigned card after a brief smoking related interview to determine allocation.
Participants	English-speaking women < 18 weeks gestation; still smoking >= 7 cigarettes a week (n = 323, 165 + 158, with losses due to termination (7 + 11); miscarriage (12 + 13); disenrollment or transfer to another HMO (20 + 18); leaving 126 + 116.
Interventions	Control group: 2 page pamphlet on hazards of smoking and on the need to quit; 2 minutes discussion with a health educator (within a 45 minutes individual conference); advised of free 5 session smoking cessation program available through the HMO. Coverage in antenatal classes remained unchanged. Intervention group: as for the control group + first of series of 8 self-help booklets aimed to increase motivation for quitting; teach behavioural strategies for cessation and relapse prevention; 3 minutes introduction to these by health educator; asked to make a commitment to read the first one and list reasons for not smoking; others mailed weekly. Booklets were pregnancy-specific, multi-ethnic, and at a 9th Grade reading level.
Outcomes	Smoking cessation validated with urine cotinine; birthweight; low birthweight; preterm birth (< 37 weeks); stillbirths. Attrition I = 51%, C = 49%.
Notes	Process evaluation showed good implementation.
Allocation concealment	C
Study	**Ershoff 1995**
Methods	Ershoff 1989 trial data of relapse prevention in the women who had spontaneously quit smoking in early pregnancy.
Participants	The pre-pregnancy smokers who had quit spontaneously before the first antenatal contact: 110+ 108, with losses due to termination (5); miscarriage (17) and transfer to alternative prenatal care (25) leaving 87 + 84.
Interventions	See Ershoff 1989 except that the intervention group received the first 4 booklets at the first interview with booklets 5 to 8 mailed weekly thereafter; control group were congratulated on quitting and given a tip sheet on "staying quit".
Outcomes	Smoking data validated with urine cotinine only collected, no perinatal data.
Notes	Detailed process evaluation and analysis of factors promoting or inhibiting cessation and maintenance of non-smoking.
Allocation concealment	C

Characteristics of included studies

Study	Ershoff 1999
Methods	Trial of three alternative methods of smoking cessation interventions, in a large group model managed care organization in California, US. No details of randomisation. Caregivers blinded to allocation.
Participants	Smokers were identified at first visit as women who self report "smoking now", "smoke but have cut down since pregnancy", or "smoke from time to time". Researchers attempted to phone all women over 18 years and less than 26 weeks gestation (n = 931). 150 could not be contacted and 90 refused to be interviewed. 233 were excluded as they did not speak English (n = 44), smoked less than 7 cigarettes per week pre-pregnancy (n = 114) or experienced miscarriage (n = 34). 380/458 women (82%) agreed to participate. 60% white, approximately 50% college educated, with a mean age of 29.4. Mean cigarette/day at first visit = 6.6.
Interventions	3 interventions, based on stages of change model. Group 1: received a self-help booklet "living smoke-free". Group 2: (n = 120): received the same self help booklet and had access to a computerised interactive telephone support system, which provided customised messages from a voice model. Group 3: (n = 101): received the same self help booklet and 4-6 x 10-15 minute telephone counselling sessions by nurse educators trained in motivational interviewing. A personalised postcard sent to reinforce verbal communication.
Outcomes	Smoking cessation in the third trimester "not even a puff in the last 7 days", biochemically validated with urine cotinine. Baseline mental health index and Cohen's perceived stress scale. Number of quit attempts and movement in stages of change.
Notes	Data from group one and group three only compared in outcome tables. Good process evaluation of each of the methods.
Allocation concealment	B
Study	**Gielen 1997**
Methods	Randomised trial of a smoking cessation and relapse prevention intervention in an urban, prenatal clinic in Baltimore, US. Nov 1996 - June 1997. No details of randomisation and caregivers not blinded to allocation.
Participants	Pregnant women currently smoking (even 1 puff in the past 7 days); < 28 weeks gestation; African-American or white; 85% of whom were on medical assistance, attending the Outpatient Department at Johns Hopkins. No other exclusions specified. 2319 women assessed, 32% currently smoking by above definition, -1585 non-smokers, -72 (gestation, ethnicity, not interviewed at their first visit or changing to another care provider) leaving 662 eligible of whom 510 agreed to take part. 25 quit prior to first visit, 18 did not wish to quit, leaving 467 (232 + 235) reduced by withdrawals, miscarriage, termination and change of care provider to (193 + 193). Mean cigarettes/day at intake I = 9.7, C = 7.5 (P = 0.01).

Characteristics of included studies

Interventions	Control: a brief discussion with a nurse about the risks of smoking; a recommendation to quit and pamphlets from the areas's voluntary agencies. Intervention: Peer health counsellors recruited from local communities, received 2 sessions training from PIs who explained content, rationale and how it was to be provided, then observed in practice by PIs with feedback to her. (i) A Pregnant Woman's Guide to Quit Smoking (RA Windsor), 6th Grade level. (ii) 15 minutes 1:1 counselling session with peer health counsellor on how to use the Guide, showing how it is organised to be used daily, and discussing women's thoughts and concerns about quitting, targeting cessation or relapse prevention, as appropriate. (iii) Educational materials for cessation support persons included with the Guide. (iv) Reinforcement at each clinic visit from doctors and nurses, written prescription to stop smoking provided directly from doctor to woman; 2 letters of encouragement (from the doctor and the counsellor) mailed to the woman 1-2 weeks after her first visit.
Outcomes	Smoking cessation in third trimester, validated by salivary cotinine. Attrition I = 35.2%, C = 35.3%.
Notes	Guide developed through needs assessment with pregnant women, constructs from the PRECEDE/PROCEED diagnosis and social learning theory, tested with focus groups, additional section on relapse prevention, and on passive smoking postpartum. Process evaluation showing good implementation. Discussion by authors of the extremely disadvantaged population in inner city, with major neighbourhood level factors of unemployment, poverty, drug use, violence and crime.
Allocation concealment	B
Study	**Haddow 1991**
Methods	Randomised trial in physicians offices and clinic sites within Maine, 1984-7, of providing feedback on cotinine measured in maternal serum screening programme (for the identification of open neural tube defects) as part of an smoking cessation intervention. Random allocation through computer-generated number on maternal serum screening request form. Caregiver not blinded.
Participants	Pregnant women with a singleton live pregnancy; having maternal serum AFP screening at 15-20 weeks gestation; who smoked >= 10 cigarettes a day. 25,628 screened, 97% answered question on smoking, about 3,000 met smoking criteria (17%). 1423 intervention and 1425 control with 41 + 39 lost to follow up.
Interventions	Control: standard medical care not otherwise specified. Intervention: report on cotinine generated for her physician with interpretation relating smoking level to birthweight. Physician explained this to the woman and gave her also a copy of the report and a pregnancy-specific booklet about how to quit, using the cotinine information also + repeat measure 1 month later, 2 copies to physician, comparison of 1st and 2nd cotinine, report commenting on the change and its interpretation.
Outcomes	No smoking cessation data. Smoking data limited to comparability at first assessment and serum cotinine levels; mean birthweight; low and very low birthweight; preterm birth (< 37 weeks); fetal deaths; neonatal deaths; postneonatal deaths. 695/1343 women provided repeat serum cotinine for comparison.
Notes	Physician consent only sought. Process evaluation showed less than good implementation with differential impact on perinatal outcome by completeness with second blood samples taken for cotinine measurement.
Allocation concealment	C

Characteristics of included studies

Study	**Hajek 2001**
Methods	Cluster randomised trial of a brief midwife-delivered smoking cessation intervention in 9 hospital and community trusts in the UK. 290 midwives randomised to provide intervention or control care. Sample size justification.
Participants	Women recruited at first visit (approximately 12 weeks gestation) and considered eligible if they reported current smoking or having stopped within the last 3 months (n = 1287). 189 current smokers not motivated to stop, therefore received no intervention.
Interventions	Control group midwives received 1 hour of training to discuss the study and were asked to provide usual care and any usual pamphlets. Intervention midwives received 2 hours training which included using the CO monitor and providing "stage of change" based advice, CO assessments. Intervention group also received written advice and motivational materials for current and recent smokers, including designating a "quit date", a "quiz" and the offer of "buddying" to another pregnant smoker for support.
Outcomes	Smoking cessation biochemically validated with exhaled CO in the early postnatal period and at 6 months postpartum. Birthweight for smokers and ex-smokers recorded. Participants views of interventions reviewed. Attrition rate 7%.
Notes	Data not adjusted for clustering, so they were not included in outcome tables. Good process evaluation showed poor implementation in some areas, with only 61% of midwives actually recruiting any women for the study. Financial incentives paid to service to improve recruitment. Discussion of barriers includes 65% of midwives reporting the intervention could not be undertaken in the time they had available.
Allocation concealment	C
Study	**Hartmann 1996**
Methods	Trial of medical smoking cessation counselling and peer support, in a teaching hospital (academic) clinic in North Carolina 1991-1993. Randomised by computer-generated random number table and charts "flagged" to identify those in the intervention group.
Participants	All women receiving prenatal care at the University of North Carolina residents clinic were surveyed: 842/846 completed survey; 793/846 provided a carbon monoxide breath sample; 2 were excluded as > 36 weeks gestation; 1 for psychiatric diagnosis; leaving 266 eligible smokers (smoked at least once in the prior week) of whom 12 refused, 4 were missed, 2 were not pregnant and 1 was a private patient; 247 recruited, losses were 40 (-4 miscarriage first trimester, -3 miscarriage second trimester, - 3 terminations, -15 moved to alternative care , -12 lost to follow up) leaving 107 intervention and 100 control.

Characteristics of included studies

Interventions	All 1-4 year residents given didactic and role play training for smoking cessation counselling, including self-assessment of current techniques and skills, which they were asked to continue with for the control group. Control group: standard care; residents reminded not to alter amount or time of this; help was provided if woman sought it and prenatal classes included discussion of substance abuse including cigarettes. Intervention: (i) residents provided counselling at each visit, and a brief script aimed at setting a quit date or negotiated an alternative assignment such as a smoking diary at every contact; (ii) given Windsor's self directed 7 day smoking cessation guide; (iii) quit date patients given written prescription to quit, letter of support from doctor, contacted by volunteer smoking cessation counsellor to review the quit plan and encourage follow-through charts flagged, prompts with flow sheet, most recent CO and self report included for care provider; (iv) successful quitters sent an encouraging postcard each week.
Outcomes	Smoking cessation biochemically validated by exhaled CO at each visit. Attrition rate 16%.
Notes	Concerns about residents having to treat similar/consecutive patients differently, and self-help manuals accidentally given to some controls.
Allocation concealment	C
Study	**Hegaard 2003**
Methods	Trial of multimodel intervention to promote smoking cessation in pregnancy in a large midwifery centre in the Netherlands, 1996 - 1998. Quasi-randomised, allocation of even/uneven birth dates to designated clinic days. Usual caregivers provided intervention, so not blinded to allocation. Sample size justification.
Participants	Pregnant women attending first antenatal visit (approximately 16 weeks gestation) who identified as "daily smokers" were invited (n = 905). Exclusion criteria: inability to speak Danish; age > 18 years; gestation > 22 weeks; verified psychiatric disease, and alcohol or drug abuse. Participation rate 77% (n = 696). I = 348, C = 347. 87 in the intervention group accepted intensive smoking program (81 group & 6 individual). 75 opted to use NRT. Withdrawals = 48 (miscarriage, moving and premature birth) excluded from the smoking cessation outcomes. Mean cigarettes/day = 11 in both groups. Significant difference in partner smoking I = 67%, C = 77% (p = 0.03).
Interventions	Control group received standard smoking cessation counselling from their midwife about risk of smoking and general advice on cessation or reduction, within the standard 30 minute booking consultation. The intervention group all received an extended first antenatal visit of 40 minutes, which included a dialogue, and written information on hazards of smoking in pregnancy and for newborns. This information was reinforced in the following 5-6 antenatal visits, within the normal 20 minute visit. Women were invited to join the intensive smoking program, based on cognitive behaviour modification program, with 9 group (90 minutes) or individual sessions (15-30 minutes), conducted over 14 weeks, by specifically trained midwives. Exhaled CO monoxide levels taken at each visit, the first 3 weeks prepared women for quitting, with 6 attendance to maintain cessation and provide an NRT regime tailored to Fagerstrom nicotine dependence assessments.
Outcomes	Self reported smoking cessation at 37 weeks gestation, biochemically validated in 51% participants. Mean birthweight; low birthweight (< 2500 g); preterm births (< 37 weeks).

Characteristics of included studies

Notes	
Allocation concealment	C
Study	**Hjalmarson 1991**
Methods	Quasi-randomised (allocation by birth date) trial of smoking cessation intervention - based on RA Windsor self help manual - in 13/14 public health maternity clinics in Gothenburg, Sweden 1987-1988.
Participants	Women who spoke Swedish, smoking >= 1 cigarette/day, gestational age < 12 weeks at first antenatal visit, (no other exclusion criteria specified), leaving n = 745 of whom 22 had quit by the second antenatal visit. 15% refused to take part (-75) leaving 417 in the intervention and 231 in the control group.
Interventions	All women were advised to quit by the midwife at the first antenatal clinic; pre-intervention. Control: basic information sheet given to women by the doctor with basic facts about smoking and pregnancy + recommendation to quit. Intervention: self help manual based on Windsor 1985, revised and with new parts added, distributed by the obstetrician at the second antenatal visit.
Outcomes	Smoking cessation data; biochemically validated (blood thiocyanate < 100 ng/ml) at first and second antenatal visit and in late pregnancy, and postpartum; mean birthweight; low birthweight; preterm birth (< 36 weeks).
Notes	Same data published by Svanberg 1992. No process evaluation.
Allocation concealment	C
Study	**Hughes 2000**
Methods	Trial of tailored, scripted "stage-of-change" intervention and fact booklet, for infertile and pregnant women, in 3 university teaching hospitals in Ontario, Canada. Randomisation of consenting participants using a computer-generated, blocked schedule, administered through numbered opaque envelopes. Caregivers not blinded to allocation.
Participants	Pregnant women smoking 3 or more cigarettes per day in the past 6 months. Mean gest at enrolment I = 18.91, C = 20.55. 110 recruited. Mean number of cigarettes/day I = 13.43, C = 12.
Interventions	Control group completed a questionnaire and self identified current smoking "stage of change" and received standard information about the negative effects of smoking in pregnancy, reinforced with whatever literature was available and CO measurements. The intervention group received the same as the control group + (i) scripted advice prompted by sets of cards, which are tailored to each stage; (ii) stage specific information booklets; (iii) referral for more in depth counselling.
Outcomes	Self reported smoking levels, validated by exhaled CO, and movement in the stages of change measured at enrolment, 6 and 12 months. Number of quit attempts; triggers for resuming smoking.
Notes	Data from both infertile and pregnant women combined, so not included in tables. Process evaluation provided and only 5/56 accepted referral to a smoking cessation clinic. Concern selective intervention by the same provider may have influenced "routine" advice to the control group.
Allocation concealment	C

Characteristics of included studies

Study	Kapur 2001
Methods	Canadian double-blind, placebo controlled trial of nicotine replacement therapy (patches) in pregnancy.
Participants	Women recruited from the Motherisk Program at 12-24 weeks gestation, smoked > 15 cigarettes/day, and who reported they wanted to quit, but could not do so, in the first trimester.
Interventions	Intervention group received a 12 week NRT patch regimen: 18 hour 15 mg patch for 8 weeks; 10 mg patch for 2 weeks, and 5 mg patch for 2 weeks + counselling with a video presentation at baseline, 1, 4 and 8 weeks. Control group received as for intervention group, with a placebo patch. Weekly telephone support was given from one investigator to encourage continuation with the program, enquire about adverse effects and to co-ordinate clinic visits. All women were encouraged to call the investigative team for advice, reassurance and support.
Outcomes	Smoking cessation during second trimester, biochemically validated with serum and salivary cotinine levels.
Notes	Study ceased after only 30 women recruited due to severe withdrawal symptoms in the 30th recruit (allocated to placebo).
Allocation concealment	A
Study	**Kendrick 1995**
Methods	Cluster randomised trial of smoking cessation in public prenatal and WIC clinics in Maryland, Colorado and Missouri, USA, 1987-89. Clinics stratified by size of clinic and also by prior low birthweight programme (Colorado) or % minority clients (Maryland), and randomly assigned to deliver either intervention or continue with standard care.
Participants	5262, 6087 and 4943 pregnant women screened in Colorado, Missouri and Maryland respectively, with nearly 50% of women in each State smoking. Smoking defined as "even a puff within the last 7 days before the women knew she was pregnant" (includes recent quitters). Consent for data collection ranged from 66% to 79%. High proportions were young, < 12 years education, White, unmarried and poor. Mean gest at enrolment = 15.2 - 16.6 weeks. Mean cigarettes/day at enrolment combined for smokers = 12 cigarettes/day.
Interventions	Control: usual care not otherwise specified. Interventions based on stages of change, but differed by State, locally adapted with some detailed development. Colorado: 1-5 minutes counselling; assessing smoking status; quitting tips; supportive statements by nurse-clinicians; health care providers' Guide; 8 brochures for pregnant smokers; additional one for women postpartum. Maryland: brief clinic-based counselling program + self help material focussing on the stages of quitting. Missouri: "becoming a life-long smoker" 6 minutes with clinic patient brochures, flip charts; 1 - 2 minutes at WIC clinics training staff, chart documentation and forms. All included effects of smoking on the fetus; benefits of quitting; quitting techniques; developing social support; preventing relapse and limiting exposure to environmental tobacco smoke. All materials were at 6th Grade reading level.
Outcomes	Smoking cessation biochemically validated with urine cotinine. The necessary adjustment for clustering means that the data cannot be put into the standard table of comparisons. Adjusted data showed no differences in verified quitting, mean birthweight or low birthweight.

Characteristics of included studies

Notes	Substantial misclassification of self report as non-smoking: 28% at enrollment; 35% at 8th month; 49% of self reported quitters at intervention clinics; 32% of self reported quitters at control clinics. Process evaluation suggested less difference between I and C clinics than might have been expected. Project staff felt that the use of existing staff to deliver the new interventions and to collect data affected the study negatively especially given the time needed to process questionnaires and urine samples. This led to less than full implementation and variable motivation to promote smoking cessation counselling among staff.
Allocation concealment	B
Study	**Lawrence 2003**
Methods	Cluster-randomised trial of two different interventions, in community midwife clinics in the West Midlands region of the UK. A computerised minimisation programme was used to allocate 72 eligible practices into 3 equal groups from 101 available practices. Caregivers not blinded (implementing intervention). Sample size calculation given, but unable to recruit sufficient numbers. 17 practices added to arm A, 12 to arm B and 0 to arm c to increase recruitment.
Participants	Inclusion criteria were all women seen in routine antenatal appointments who were aged 16 years or over, a current smoker at booking. Women not fluent in English were excluded. Initial target of 1440 participants was reduced to 900 due to slow recruitment (particularly in standard care arm). Eligible smokers approached A = 34%, B = 47%, C = 75%. Refusal rate A = 13.4%, B = 7.2%, C = 22.5%. Mean cigarettes per day at baseline were similar between groups.
Interventions	Control group (A) received standard care. Midwives received a half day training on research protocol, and asked all midwives to give women the Health Education Authority booklet "Thinking about stopping". Group B midwives received two and a half days training on theory of transtheoretical model. Participants received a set of 6 stage based self help manuals "Pro-Change programme for a healthy pregnancy". The midwife assessed participants stage of change and pointed the woman to the appropriate manual. No more than 15 minutes was spent on the intervention. Group C midwives received the same training as for Group B, and participants received the same self help manual and intervention as group B. Additionally the participants used a computer programme on the occasions, which consisted of questions to stage the woman with auto feedback of what stage they were in and what this meant, and a range of other concepts. It took about 20 minutes for the woman to complete. Printed information of the feedback was sent to the participant within a week of the intervention.
Outcomes	Biochemically validated smoking cessation at 28 - 30 weeks gestation and 10 days post birth. Point prevalence and sustained abstinence of 10 weeks or more were calculated. Effect of midwife training (attitudes, expectations, confidence, concerns and routine practice) was assessed by pre-post training questionnaires. 207 women (22.5%) withdrew from the study, 77 due to early end of pregnancy, 38 changed practice, 32 declined further participation and 60 left for other reasons, with similar rates of withdrawal between groups, except for failure to complete the questionnaire and provide a urine sample, with highest compliance in Group C.
Notes	
Allocation concealment	C

Characteristics of included studies

Study	Lilley 1986
Methods	A randomised trial in Newcastle Hospital antenatal clinic (UK) and with other shared antenatal care providers of individual counselling to promote smoking cessation over 3 months in 1982. Simple randomisation in balanced blocks of 8. Unclear whether caregivers masked.
Participants	All pregnant women currently smoking >= 1 cigarette a day at the time of the first antenatal clinic, and < 28 weeks gestation. 156 contacted, -5 > 28 weeks leaving 151, 5 exclusions (not pregnant, guilt over previous stillbirth, and 3 miscarriages), leaving 72 (I) + 73 (C).
Interventions	Control: usual antenatal care + possible exposure to a concurrent television series (6 x 10 minute programme on stopping smoking in pregnancy). Intervention: (i) 10 minutes anti-smoking advice from SHO (Resident) based on Health Education Council Booklet "So you want to stop smoking.. for you and your baby", an additional leaflet from the same source, and copies of the booklet for other family members; (ii) woman's GP sent a letter describing the purpose of the study and a booklet, asked to reinforce the information at usual contacts; (iii) 2 weeks later a letter of reinforcement was sent to the woman; (iv) 4 weeks later there was a preplanned home visit to provide anti-smoking advice with a letter of the same advice sent if the woman was not at home; (v) possible exposure to the concurrent TV series.
Outcomes	Smoking status and smoking/day assessed 6 weeks later. Not biochemically validated.
Notes	Short interval between intervention and assessment.
Allocation concealment	C
Study	**Loeb 1983**
Methods	Trial of anti-smoking interventions (individual and group) based on the MRFIT trial, carried out in Oregon where 95% of pregnant women attending one of the two hospitals were enrolled in the Kaiser Permanente HMO, 1979-1980. No details of randomisation or whether caregivers masked to allocation.
Participants	, questionnaire response rate 25%. Pregnant women contacted at first antenatal visit: 3856 asked about smoking; 963 self reported current smokers (25%). 21% of them in receipt of public assistance but only 7% of non-smokers. Poor participation in the study: 83.6% contacted; refusal rate 37%.
Interventions	Planned intervention: (i) letter of invitation with sae, reminder letter; (ii) group information meeting on programme for respondents with short information session by physician; (iii) individual session with trained smoking counsellor; (iv) 6 x 1.5 hour group sessions, once a week; (v) subsequent support groups, individual sessions and phone calls.
Outcomes	Smoking cessation by late pregnancy, biochemically validated with cord blood thiocyanate in a subsample, but no misclassification of self reported non-smoking.
Notes	Very poor response to group sessions so intervention changed over the course of the trial to individual counselling, which also had very low participation overall: 18% active; 25.2% dropped out; 38% did not participate; 18% could not be contacted.
Allocation concealment	B

Characteristics of included studies

Study	Lowe 1997
Methods	A randomised trial of relapse prevention among women who had stopped smoking since the beginning of pregnancy, in the public maternity clinics of a large hospital in Birmingham, Alabama 1987-1989, USA. No details of randomisation and caregivers not masked.
Participants	Pregnant women recruited at their first prenatal visit reporting as having quit since conception, no exclusions mentioned, n = 115, 9 refused to participate leaving 106 of whom 3 had a miscarriage, 4 moved and 2 had babies for adoption, leaving 54 (I) and 45 (C), Follow up data were available on 80%.
Interventions	Control: nurses' advice to all women not to smoke. Intervention: 10 minute counselling by health educator using smoking relapse prevention materials on effects of smoking; benefits of maintaining cessation; possible problems; smoking triggers; solutions to smoking cues; strategies for staying quit + contract + flip chart (5th Grade reading material + 'stay quit buddy' encouragement = non-smoking gifts and pamphlets) + clinic reinforcement by prenatal staff through reminder form in the notes + staff training to confirm abstinence, praise, encourage continuing cessation.
Outcomes	Smoking cessation in late pregnancy, biochemically validated with salivary thiocyanate. Included in relapse prevention outcome tables only.
Notes	Concurrent trial with Windsor 1993. Process evaluation showed good implementation. Issues of possible 'contamination' in clinics with individual randomisation discussed.
Allocation concealment	A
Study	**Lowe 1998a**
Methods	Quasi-randomised study using alternate allocation within antenatal clinic of a large metropolitan public hospital in Brisbane to assess the effectiveness of a self-help booklet developed by Windsor (for women of low socioeconomic status - mostly black women - in Alabama), in urban Australian women. This first trial (i) was followed by a second one (ii) with a modified intervention, but no other change to the methods
Participants	All pregnant women attending for a first antenatal clinic, who identified themselves as current smokers, had no current complications of pregnancy and were not planning to have the child adopted, were approached at their first antenatal clinic appointment (n = 244 - 27 who declined = 217).(ii) Participation rate of 91%, 108 women recruited, 8 had a miscarriage or fetal death or discontinued care at the hospital; 2 withdrew from the study and 19 were lost to follow up (LTFU) by 20 weeks. All those LTFU were counted as continuing smokers
Interventions	Control: given the self help booklet and a midwife caution against smoking. Intervention: as for control + a 15 minutes 1:1 motivational counselling session provided by the midwife, focussing on the booklet (based on cognitive behaviour strategies), a flip chart which demonstrated the effects of smoking on the fetus, being shown how to use the manual, two contracts developed (partner and non-smoking friend) and these people contacted to sign. Aim was to increase self-efficacy and create a social support structure for women during her attempts to quit and motivating her to use the booklet. (ii) Booklet modified through focus groups with input from health promotion specialists, medical specialists and GPs, to a glossy format with coverage of additional topics (growth and development of the fetus, enjoyment of certain foods and sex during pregnancy, emotional and physical aspects of pregnancy and stopping smoking. (C): only the midwifery caution against smoking; (I): the midwife provided the booklet without any additional discussion or counselling.

Characteristics of included studies

Outcomes	Smoking reduction and cessation assessed at the 20 week visit. Biochemical validation of smoking status in self reported non-smokers, same for (i) and (ii).
Notes	Process evaluation showed poor response to the booklet. Focus groups with women from I and C identified problems with the material and made suggestions about changes. Discussions with staff showed time pressures over counselling component. Trial stopped and redesigned, see (ii). Second trial (ii) had a positive process evaluation though staff identified a range of barriers to implementing smoking cessation counselling.
Allocation concealment	C
Study	**Lowe 1998b**
Methods	See Lowe 1998a for setting as this trial followed immediately after the first one. Quasi-randomised trial with alternate weeks allocated to control and intervention.
Participants	See Lowe 1998a. The participation rate was 91% with 108 women recruited of whom 8 had a miscarriage, or a fetal death or discontinued care at the hospital. Two more withdrew and 19 were lost to follow up by 20 weeks. All those lost to follow up were counted as continuing smokers.
Interventions	Booklet modified from the one used in Lowe 1998a, through focus group discussions with input from health promotion specialists, medical specialists and GPs to a glossy format with coverage of other topics (growth and development of the fetus, enjoyment of certain foods and sex during pregnancy, emotional and physical aspects of pregnancy and stopping smoking). Control group: only the midwifery caution against smoking. Intervention: the midwife provided the booklet without any additional discussion or counselling.
Outcomes	Smoking behaviour and smoking cessation at 20 weeks, biochemically validated.
Notes	Process evaluation of materials was positive, though staff identified a range of barriers to implementing smoking cessation counselling.
Allocation concealment	D
Study	**MacArthur 1987**
Methods	Quasi-randomised trial with alternation of 4 week blocks to intervention or control in a large English city maternity hospital to identify effects on fetal size at birth mediated by an anti-smoking intervention, 1981-1982. MacArthur 2001 reported follow up when the children were nine
Participants	Pregnant women smoking at booking: 29% had been pre-pregnancy smokers, 23% were smoking at booking. 1008/1156 women identified as smokers interviewed, 48 lost (early discharge, infection/isolation, changed surname); Exclusions were multiple births (6 (I) + 8 (C); records not linked to hospital data 8 (I) + 4 (C)) leaving 493 (I) and 489 (C). Mean cigarettes/day at booking I = 14.4, C = 13.7.
Interventions	Intervention: advice to stop smoking + information or discussion of the effects of smoking on the fetus offered by the obstetrician at the first antenatal (booking) visit, supported by giving her a leaflet to be shared with the partner, family and friends. If leaflet not given by obstetrician, the midwife was asked to give it to the woman and advise her to stop smoking. Control: routine advice, not specified further.

Characteristics of included studies

Outcomes	Smoking cessation and reduction - biochemical validation commenced, but abandoned when it became clear it did not distinguish levels of smoking. Birthweight, length and head circumference; Height, weight, IQ and neuromaturity at 9.4 years. Experimental results only discussed in this review (data according to group allocation). Report includes observational data (according to smoking behaviour) smoking status not biochemically validated.
Notes	Consent not sought from individual women, implementation of the trial across all clinics routinely. Process evaluation shows poor implementation, with only 10% receiving "full intervention". No details of the content of the leaflet. Follow-up data not sufficient for tabulation.
Allocation concealment	C
Study	**Malchodi 2003**
Methods	Trial of effects of peer counselling on smoking cessation and reduction in a large urban clinic. Hartford Hospital, US, Jan 1998-Feb 2000. Computer-generated random allocation, with usual care providers masked to allocation.
Participants	Low income, uninsured women, who smoke "at least one cigarette per day before pregnancy, less than 20 weeks gestation, literate in English or Spanish, and intending to carry to term. High smoking prevalence in pregnancy (29%). Recruited n = 142 (I = 67, C = 75). Mean cigarettes/day at baseline significantly higher in intervention group. I = 13.3, C = 11.2.
Interventions	The control group received routine care, which included the program of "Ask, Advise, Arrange and Assist", based on cognitive behaviour, described by Windsor et al, 2000. The intervention received as for the control group + peer counselling from lay community health outreach workers (telephone or home visits). Peer counsellors received 2 x 3 hours of training.
Outcomes	Smoking cessation and reduction at 36 weeks gestation, biochemically validated with urine cotinine and exhaled CO. Nicotine addiction assessments (Fagerstrom Tolerance Questionnaire), and breastfeeding at 6 months postpartum. Infant birth weight correlated with cigarettes/day in late pregnancy. Attrition rate I = 43%, C = 36%.
Notes	
Allocation concealment	C
Study	**Manfredi 2000**
Methods	Cluster randomised trial of a smoking cessation program in 10 public clinics in Chicago, US, 1994-6. Randomisation to study group within matched pairs of clinics.
Participants	Clinics matched on size, type, location, and racial mix of clientele. Smokers in intervention group more likely to be African-American. Participation rate I = 76% (n = 1025), C = 86% (n = 784). Mean cigarettes/day at intake.
Interventions	Control group received smoking cessation advice and available brochures, dependant on the clinician. The intervention group received brief advice to quit (from a variety of clinicians), a written agreement on a quit date, a take home motivational self-help booklet "Its Time", a reminder letter, and a 15 minute telephone motivational interview. High intensity intervention based on stages of change theory and Millers brief motivational interviewing approach.

Characteristics of included studies

Outcomes	Self reported smoking cessation, not biochemically validated. Movement in stages of change. Attrition rate I = 38%, C = 41%.
Notes	Data not included in outcome tables due to inconsistent data reporting (baseline and control groups combined) and data not adjusted for clustering. Good process analysis provides outcomes by exposure to intervention.
Allocation concealment	C
Study	**Mayer 1990**
Methods	Trial comparing three smoking cessation interventions in WIC clinics in Grand Rapids, Michigan, USA, 1985-86. Not details of randomisation or whether caregivers masked to allocation.
Participants	Women currently smoking (>= 1 cigarette/day) comprised 271/641 attending the clinics (42%), 219 agreed to take part, data on 186. Losses to follow up were that a quarter refused, and the rest either moved, changed their source of antenatal care or had a miscarriage (no details of numbers). Mean cigarettes/day prior to pregnancy I = 19.9, C = 20.3.
Interventions	Control: printed information about the risks of smoking in pregnancy. Intervention (a) risk information: 10 minute discussion with a health educator using a flip chart and a brochure but with no behaviour change counselling or self-help manual. Intervention (b) multi-component: 20 minute 1:1 counselling including risk information ("Because I Love My Baby" Am Lung Assoc + flip chart + brochure to take away), and behavioural change manual adapted from RA Windsor and the Am Lung Assoc "Freedom from Smoking" focussing on contracting and self monitoring (cognitive behaviour therapy).
Outcomes	Smoking cessation in late pregnancy and postpartum, biochemically validated with salivary thiocyanate in approximately a third of participants, but no adjustment for misclassification.
Notes	No process evaluation.
Allocation concealment	B
Study	**McBride 1999**
Methods	Randomised trial of relapse prevention at the Group Health Cooperative of Puget Sound (Seattle, USA) (HMO), and Park-Nicollet of Minnesota (USA), a multispecialty group practice. No details of randomisation. Caregivers masked to allocation.
Participants	Women booked for a first prenatal visit were offered, by letter, study participation and unless they opted out were given a baseline telephone interview. Women who had completed the baseline survey, were < 20 weeks of pregnancy, were currently smoking or had smoked in the 30 days before pregnancy but had quit at the time of the baseline survey. They were stratified by baseline smoking status. 9152 approached, 714 ineligible because of miscarriage, pregnancy termination, inability to speak English; 697 refused; 262 could not be reaches by telephone after repeated attempts. 7479 completed survey. 1007 were randomised: 88 miscarried and were excluded; 22 were sent wrong intervention material; 897 participated (457 from Seattle, 440 from Minnesota). Mean cigarettes/day 4.8 in intervention and control groups.
Interventions	There were 3 stage of change based interventions, all delivered by mail or telephone without involving prenatal care providers. (1) Self help booklet "Stop now for your baby"; 5th grade reading level; health effects of smoking during pregnancy; specific suggestions for quitting (setting date, enlisting

Characteristics of included studies

	support). For recent quitters: stress reduction techniques; suggestions for handling high-risk situations; pregnancy-appropriate behavioural alternatives to smoking. 2. & 3. High intensity interventions in pre and postpartum groups also received: (i) a personalised letter acknowledging baseline readiness for change, personal health concerns, motivation to quit, comparison with other pregnant women who had successfully quit. (ii) relapse prevention kit within 2 weeks of completing the 28 week follow-up survey. (iii) a booklet which discussed transition from pregnancy and factors that influence cessation and relapse; practical tips for high-risk situations, strategies for avoiding self-defeating reactions to slips, personal anecdotes from women who quit. (iv) 3 antenatal counselling phone calls: 2 weeks after the booklet and 1 and 2 months later. Calls were open-ended but with standardised protocol based on motivational interviewing and with stage-based objectives average 8.5 min. 3. The pre-post group received an additional 3 counselling calls in the first four months after birth reinforcing themes from the Relapse Prevention booklet; 3 newsletters at 2, 6 and 12 months postpartum about health effects of environmental tobacco smoke and the importance of being a non-smoking parent.
Outcomes	Smoking cessation; relapse prevention and patterns of smoking; biochemically validated with salivary cotinine at 28 weeks gestation; 8 weeks PP; 6 months PP; and 12 months PP. Response rates were 92% at 28 weeks; 91% at 8 weeks postpartum; 89% at 6 months postpartum; 87% at 12 months postpartum. Salivary cotinine requested from all who reported abstaining for 7 days (< 20 ng/ml as cut off).
Notes	Process evaluation describes participation in specific intervention components, including relapse prevention.
Allocation concealment	B
Study	**Moore 2002**
Methods	Cluster randomised trial of provision of self help in 3 UK NHS hospital trusts, 1998-2000. 118 midwives stratified according to workload and randomly allocated to provide intervention or control care. Computer-generated randomisation, caregivers not masked to allocation. Sample size justification.
Participants	Women attending first visit; > 16 years; < 17 weeks gestation; literate in English. Smokers counted as those who reported "I smoke now", "I smoke now but have cut down since I thought I might be pregnant", or "I have stopped smoking since I thought I might be pregnant". Mean number of cigarettes per day at baseline I = 16, C = 15.1.
Interventions	Control group midwives continued to give routine advice according to usual practice. Intervention midwives gave their usual care + spent at least 5 minutes introducing a series of 5 self help booklets "Stop for Good", based on Stages of Change theory, and gave them a copy of the first booklet. Subsequent booklets were mailed directly to the woman.
Outcomes	Self reported smoking cessation validated by urine cotinine (94%). Perinatal outcomes: birthweight, gestation at birth. Stillbirths, perinatal, neonatal and childhood deaths not reported but available on request. Attrition rate 8%.
Notes	Data not included in outcome tables as it was not adjusted for clustering. Good qualitative and quantitative process analysis of participants and midwives views of the intervention, which suggested poor implementation in some areas. Some concerns about contamination of control group.
Allocation concealment	C

Characteristics of included studies

Study	**Mullen 1991**
Methods	Randomised, factorial design to identify the best way of encouraging the disclosure of smoking in pregnant women, in a HMO, Texas, 1988-1990. No randomisation details.
Participants	Pregnant women enrolled in an HMO; >= 18 years; able to speak and read English; free of mental or sensory handicap; mental retardation or mental illness. 1078/1206 recruited. 121 refused others were < 18 or non-English speaking.
Interventions	The 4 options compared were: (1) Format (i) a single yes/no question vs (ii) a multiple choice. (2) Channel (iii) oral vs (iv) written forms of the two questions. Oral vs written forms of the two questions.
Outcomes	Proportion of women smokers who disclosed smoking, biochemically validated with urine cotinine cutoff >= 50 ng/ml. No smoking cessation data.
Notes	Those who refused urine testing were classified as "smoking disclosed". Misclassification of self-report as non-smoking was low in this study (3%).
Allocation concealment	B
Study	**O'Connor 1992**
Methods	Quasi-randomised (allocation by alternate days) trial of a new smoking cessation programme provided by public health nurses in the antenatal clinic of an Ontario (Canada) teaching hospital, compared with previous standard care. No details of randomisation and unclear whether caregivers masked.
Participants	1028 women screened, 267 daily smokers (673 non-smokers, 88 spontaneous quitters). Ineligible (39) late gestation; miscarriage; missed abortion; termination; malformation; mental illness; mental retardation. Refusal (4). 224 at baseline; 202 at 1 month follow up; 174 at 36 weeks; 190 at 4 weeks postpartum. Reasons for dropout: miscarriage (17), no further clinic visit (3), subsequent refusal (2), and preterm birth (16 - all of these seen postpartum), and 12 lost to follow up. Mean cigarettes/day at intake I = 13, C = 12.8.
Interventions	Control: 3-5 minutes explanation of the risks of smoking during pregnancy + pamphlet inviting women to a 2 hour cessation class in the evenings where the Windsor self help manual would be taught/provided. Intervention (provided in English or French): 20 minutes 1:1 session with a public health nurse going through the Windsor self help manual program + follow-up telephone call at a mutually agreed time. High intensity intervention.
Outcomes	Smoking cessation biochemically validated by urine cotinine.
Notes	No one attended the evening group class which was offered and was free. Interesting discussion of women's perceptions of risk based on personal experiences. Process evaluation showed 93% received the intervention by second visit.
Allocation concealment	D
Study	**Olds 1986**
Methods	Randomised trial with 4 arms whose aims were to improve the uptake of prenatal care and pregnancy outcomes, especially low birthweight, in a semi-rural county of New York State, USA, 1978-1980. No details of randomisation and unclear whether caregivers were masked to allocation.

Characteristics of included studies

Participants	Active recruitment of pregnant women with no prior live births + any of the following: < 19 years; single; low socioeconomic status, and any other women with no prior live births who wished to participate in the program. Exclusions were > 25 weeks gestation (though some were enrolled at 25 - 29 weeks). Recruitment was through private obstetricians' offices, planned parenthood, public schools health department antenatal clinics and other health and human service agencies. 10% of target population entered prenatal care too late, 10% were not referred from private care, 500 interviewed, 400 participated; 47% < 19, 62% single, 61% low ses. Non-Whites (46) excluded because too few; serious maternal or fetal conditions (20) excluded. Mean cigarettes per day at intake: C = 6.94, I = 7.65.
Interventions	Control (i) health and developmental screening of the baby at 12 and 24 months (ii) (i) + free transport to pregnancy and well-child visits (control) (iii) (i) + (ii) + nurse home visits during pregnancy (intervention) (iv) (i) + (ii) + (iii) + nurse home visits in child's first 2 years. The focus of the home visiting was individualised from a detailed curriculum dealing with information on fetal and infant development; improvement of maternal diet; monitoring weight gain; elimination of cigarettes, alcohol and drugs; identifying pregnancy complications; encouraging rest, exercise and hygiene; preparing for labour birth and early newborn care. The intervention was also described as enhancement of informal support systems and linkage of parents to community services. High intensity intervention.
Outcomes	Smoking cessation with biochemical cotinine validation in a subsample (n = 116). Data not included in high intensity outcome tables, as smoking was not the focus of the intervention.
Notes	
Allocation concealment	A
Study	**Panjari 1999**
Methods	Trial of personalised smoking cessation interventions in a low socioeconomic population in Australia. No details of randomisation methods or whether caregivers were masked to allocation.
Participants	Women who identified as "current smokers" at their first antenatal visit at approximately 12 weeks gestation ("even a puff in the last 7 days"). Exclusion criteria: > 20 weeks gestation; twin pregnancy; not literate in English; drug dependency. Mean cigarettes per day = 11 in both groups. Participation rate = 52% (n = 1013), with the majority of eligible nonparticipants refusing to enter the study.
Interventions	Control group received usual care, which included advice at the discretion of the caregiver, a group counselling session, and a pamphlet "Smoking & Pregnancy". The intervention group received as for the control group + 4 counselling sessions by a midwife specifically trained and employed to provide smoking cessation counselling, using cognitive behaviour therapy. Sessions included video presentation, interactive discussion and strong verbal messages. These were followed up with a 5 - 10 minute personalised counselling session. High intensity intervention.
Outcomes	Self reported smoking cessation biochemically validated with urine cotinine at 36 weeks gestation, 6 weeks postpartum, and 6 months postpartum. Breastfeeding at 6 weeks and 6 months postpartum. General health assessment at first visit and 36 weeks. Preterm delivery rate, mean birth weight, proportion LBW (< 2500 g). Attrition rate = 15%.

Characteristics of included studies

Notes	Process evaluation showed 71% women in the intervention group received the full intervention.
Allocation concealment	B
Study	**Petersen 1992**
Methods	A randomised trial comparing the impact on smoking cessation of two different packages of material mailed to current smokers and recent quitters at a large Boston HMO, USA, 1986-1988. Randomisation using table of random numbers for one intervention. Clinic staff were not aware of the allocation. Allocation to intervention 2 was not randomised but offered to all eligible enrollees at one clinic: data on this intervention is not included in the review.
Participants	English-speaking women enrolling in prenatal care; >= 18 years; < 24 weeks gestation who reported themselves as currently occasional or regular smokers or who had quit smoking in the previous 3 months. 1439/1442 screened (3 refused), 317 current/ recent smokers, 93 dropped out because of miscarriage, termination, moved away or left the HMO; 274 at second assessment and 224 at 8 weeks postpartum. 78 control and 71 intervention at baseline.
Interventions	Usual care: routine obstetric care, mailed list of community-based smoking cessation resources other pregnancy-related health education materials. Intervention: pregnancy-specific self-help manual (Am Lung Assoc + Harvard Community Health Plan (HMO)) and audiotape on safe aerobic exercise and pregnancy-related relaxation, mailed with other health-related education. Smoking component emphasised behavioural strategies for quitting, issues and concerns specific to pregnant women, non-smoking as part of a continuum of care in pregnancy; included a maintenance section for the postpartum period. Intervention based on cognitive behaviour therapy.
Outcomes	Smoking cessation for smokers and spontaneous quitters at mid-pregnancy and 6 months, postpartum. Biochemical validation in 50% women. Mean birthweight, low birthweight (< 2500 g) and very low birthweight (< 1500 g) outcomes.
Notes	Refusal of urine test = coded as smoking. Substantial misclassification of non-smoking self-report at 6 months gestation 24% controls 21% intervention (and 30% in clinic where the intervention was more intensive). Data from two interventions combined in relapse prevention outcomes, so not included in tables.
Allocation concealment	A
Study	**Price 1991**
Methods	A randomised comparison of two different minimal contact interventions to encourage smoking cessation and reduction during pregnancy, in women of low ses and low education, compared with usual care in an inner urban setting, Toledo, Ohio, USA, 1987-89. Randomisation by dice, which did not work well (no allocation to usual care some of the time). Unclear whether allocation masked to caregivers.
Participants	"Typically low income, single and poor". 1164 approached, 486 (42%) were current smokers: 60% not enrolled (exclusion criteria not listed, though includes gestation > 28 weeks and refusal); 193 entered the study. Relatively low participation and 57% dropout from enrolment to completion.

Characteristics of included studies

Interventions	Control: usual care not specified or assessed but "usual for physicians to address this issue with participants at least one prenatal visit". Intervention (i): tailored educational videotape 6.5 minutes, potential fetal risks, benefits if mother quit + pamphlet on how to quit and opportunity to ask questions of the health educator. Intervention (ii): American Lung Association self help booklet (with brief overview and explanation) emphasising behaviour modification skills, relation techniques and the support of significant others, + opportunity to ask questions of the health educator.
Outcomes	Smoking reduction and cessation, validated by exhaled CO monitoring.
Notes	Program was developed with input from a questionnaire and open-ended questions about the advantages and disadvantages of smoking when pregnant from local population to inform Health Belief Model used in program. Commentary on the contextual factors in the lives of indigent women which lead them to have different perceptions about the relative importance of smoking.
Allocation concealment	C
Study	**RADIUS 1995**
Methods	An analysis within a subset of births in the RADIUS trial (births in Missouri, USA) to see whether ultrasound of the fetus at 18 - 21 weeks and 31 - 33 weeks promoted maternal smoking cessation during pregnancy. Randomisation by microcomputer based sequencing. Not clear whether caregivers were blinded to allocation.
Participants	53,367 pregnant women; -32,317 ineligible or excluded; leaving 21,050 -3,163 refused; -2,357 had miscarriage or change of provider; leaving 15,530 (7,812 intervention + 7,718 controls). subsequently - 64 + 63 miscarriage, -131+121 records lost or women moved, leaving 7,617 + 7,534; 1,768 smoking (I) and 1,803 smoking (C). Smoking defined as any smoking within the year before their enrolment. Inclusion criteria = last menstrual period known within one week, gest age < 18 weeks, no plans to change providers. Exclusion criteria include medical or obstetric complications, planning an ultrasound for other reasons, twin pregnancy, not intending to continue pregnancy.
Interventions	Ultrasound only, at 18 - 20 and 31 - 33 weeks, no details about feedback to the mother or others. The women in the control group only had ultrasounds if ordered by their physician for medical reasons.
Outcomes	Self reporting smoking cessation, recorded on birth certificate, not biochemically validated (not included in outcome tables). Mean birthweight, preterm birth (< 36 weeks) and very preterm birth (< 33 weeks).
Notes	
Allocation concealment	B
Study	**Reading 1982**
Methods	A randomised comparison of the effects on health behaviours (including smoking) of providing specific verbal and visual feedback to the mother about fetal size, shape and movement during an ultrasound examination (or having the screen not visible and providing no specific feedback) at the first antenatal visit, in London, UK. No details of randomisation or whether caregivers blinded to allocation.
Participants	Pregnant women at 10 - 14 weeks gestation; 18 to 32 years; stable relationship; Caucasian; 85% had planned pregnancy, at low risk of complications; 86% nulliparous. Exclusions: prior miscarriage or extended infertility investigations.

Characteristics of included studies

Interventions	Control: no/low feedback. Intervention: high feedback about the fetus, with the fetus visible.
Outcomes	Self reported smoking cessation at 16 weeks gestation, without biochemical validation.
Notes	Not clear whether quitting was recent or not - no time period specified. 3/62 low feedback group did not attend next visit at 16 weeks. Cites evidence for the reliability of self report (Pettiti).
Allocation concealment	C
Study	**Rush 1992**
Methods	Quasi-randomised study (allocation by alternate weeks) of the effectiveness of a health education intervention provided by a psychologist from booking to birth, compared with standard care, at a large maternity hospital in England, 1978-1979. Caregivers not masked to allocation.
Participants	Pregnant women registering for maternity care: 371/1645 were currently smoking at least 1 cigarette/day, 25 refused participation and 27 were lost because of miscarriage, termination or transfer to another care provider, leaving 319. No exclusions were mentioned or mean cigarettes/day pre-pregnancy.
Interventions	Control: standard care not otherwise specified. Intervention: counselling begun in antenatal clinic at 1st visit, with follow-up visit 2 weeks after booking at home, then monthly to the birth, each visit 15 - 20 minutes, (5 on average). Focus of counselling was help and support to change smoking, focus also on short and long term benefits; advice on stopping/cutting down, strategy planned with woman, follow up planned with clear objectives, involvement of other family members, friends and partner in support.
Outcomes	Smoking cessation, biochemically validated with exhaled CO and serum thiocyanate. Mean birthweight in subgroup smoking >= 5 cigarettes at booking.
Notes	Detailed account of the intervention in King and Eiser 1981. Subgroup analysis seems not to have been a pre-specified one. Apparent problems with the thiocyanate measures and with loss of some data files (see paper).
Allocation concealment	C
Study	**Secker-Walker 1992**
Methods	Evaluation of a program to train obstetric and family practice residents to give smoking advice during antenatal care, using pre- and post- training evaluation of their skills with a simulated patient, and exit interviews with women participating in a randomised trial of individualised smoking cessation counselling. 1988-1990, Vermont, USA.
Participants	All residents providing (supervised) prenatal care, at the University of Vermont.
Interventions	Description of training and copies of 4 papers on smoking cessation advice + small group training by physician and psychologist during 1 hour workshop. Workshop: review of the project; description of advice and rationale for each step; use of protocol prompt sheet; video of advice being offered by GP and Obstetrician; role play with corrective feedback; basic care description; (individual training for residents unable to attend) + 30 minute refresher session with counsellor before the rotation + counsellor discussed actual progress and adherence.

Characteristics of included studies

Outcomes	Scores on video/simulated patient (blinded assessment, systematic scoring) significantly increased with no change in the time required to provide the advice; exit interviews showed good adherence to the protocol by 96/99 (intervention) and 66/67 (control) interviewees, as did women's proposed actions post-intervention, also in exit interviews.
Notes	Useful for dissemination trials of smoking cessation in hospitals.
Allocation concealment	D
Study	**Secker-Walker 1994**
Methods	A randomised trial comparing the effectiveness of individualised, but protocol-based smoking cessation counselling provided by a specially trained health educator, compared with usual care, at the University of Vermont, USA, 1984-1987. No details of randomisation and it is unclear whether caregivers were masked to allocation.
Participants	Women receiving prenatal care from obstetricians + nurse-midwives, or residents; private and public including Maternal, Infant & Child clinic for under-insured or non-insured women (23% Medicaid in study); < 25 weeks pregnant (mean gest 13/40), smoking at least 1 cigarette a day, no exclusions mentioned. 808 interviewed, 33 refused, 175 sp quitters went into separate study of relapse prevention, leaving 300 + 300; (-49: 27 miscarriage, 7 fetal deaths, 5 infant deaths), further losses were 24 + 24 changed care provider, 37 (I) + 4 (C) withdrew and 31 + 28 were lost to follow up. Mean cigarettes/day pre-pregnancy I = 24.4, C = 25.1.
Interventions	Control: usual care, not otherwise specified. Intervention, from a trained health educator: addressed concerns re smoking and pregnancy, health benefits of stopping, perception of the advantages and disadvantages of stopping, problem solving around those issues and coming to a decision, if yes to quitting formulating a plan, skills rehearsal + pregnancy-specific booklet. Follow up at second antenatal clinic, 36 weeks and 6 week check (where infant health and parental role modelling was discussed) and re-encouraged to quit. Health educators given selected readings, discussion, rehearsal with psychologist + health educator (both former smokers) about smoking and smoking cessation counselling techniques + Am Lung Association training group for class leaders + 4 week pilot.
Outcomes	Smoking cessation at 36 weeks gestation, 75% biochemically validated with cotinine. Mean birthweight, low birthweight, other smoking-related complications (pPROM, placental abruption and placenta praevia).
Notes	Sample size calculated for 10% increase (from 10% to 20%) in quitting. Differential withdrawal in I and C groups a concern; good information collected on drop-outs being different. Allocation for fetal and infant deaths not reported. No adjustment for misclassification.
Allocation concealment	B
Study	**Secker-Walker 1995**
Methods	Trial of relapse prevention counselling for spontaneous quitters, Vermont USA.. See Secker-Walker 1994 for methodology details.
Participants	Those from Secker-Walker 1994 who had stopped smoking spontaneously before their first prenatal clinic visit (n = 175, 89 (I) and 86 (C) among whom there were 5 miscarriages, 1 termination, 1 fetal death and 1 infant death leaving 85 (I) and 80 (C). Further losses were 15 transferred to other care, 9 dropped out and 8 lost to follow up.

Characteristics of included studies

Interventions	Control: usual care by own provider. Intervention: see Secker-Walker 1994 for training of health educators and cessation planning; in this group dealt with concerns about staying away from smoking, her perceptions of the advantages and disadvantages of maintaining cessation, problem-solving and skills practice, + booklet; 39 weeks and postpartum visits focused on infant risks and benefits.
Outcomes	Smoking cessation, biochemically validated). Mean birthweight, low birthweight, preterm birth.
Notes	Exclusion of fetal and infant deaths. Biochemically validated smoking cessation showed substantial misclassification at 36 weeks in this study, more so than for the continuing smokers.
Allocation concealment	B
Study	**Secker-Walker 1997**
Methods	Trial comparing the added effectiveness for smoking cessation during pregnancy of a free videotape using peer role models, Vermont, USA, 1992-1993. No details of randomisation. Caregivers not masked to allocation.
Participants	Women in a state supported clinic for underinsured women, currently smoking at least 1 cigarette/day, 7/67 refused leaving 30 (I) + 30 (C), 4 had miscarriage leaving 26 + 30, 3 lost to follow-up and 7 moved to another care-provider leaving 17 + 27 seen at 36 weeks. Mean cigarettes per day pre-pregnancy = 22.6.
Interventions	Control: advice from obstetrician or nurse-midwife + tip sheet on quitting. Intervention: as above + 29 minute videotape of 4 women going through the process of quitting during pregnancy; talking about feelings; coping with weight gain; getting support, which could be borrowed and taken home. Based on social learning theory.
Outcomes	Smoking cessation in late pregnancy (36/40), biochemically validated with exhaled CO measurements..
Notes	Process evaluation included perceptions of the videotape contents and showed 53% viewed the videotape. 17% had no VCR, and 10% reported having no time.
Allocation concealment	B
Study	**Secker-Walker 1998**
Methods	A trial of structured physician's advice supported by individual counselling (I) provided to pregnant women during prenatal care compared with usual care (UC), Vermont, USA, 1988-92. Sample size justification. The study included a relapse prevention component, reported separately. No details of randomisation. Caregivers could not be masked to allocation.

Characteristics of included studies

Participants	Woman attending the state-supported (Maternal and Infant Care) prenatal clinic for underserved women or attending the Adolescent clinic for women 12 to 18 years. 544 women smoking at pregnancy onset approached: 21 refused 124 had quit spontaneously- relapse prevention trial; 399 into cessation trial - 197 (I), 202 (UC); 14 miscarriages, 5 fetal deaths 5 infant deaths (allocation not reported); 34 in each group moved or transferred their care; 12 women withdrew from study (7 (I), 5 (UC)) 17 delivered before 36 weeks (9 (I), 8 (UC)) 135 (I) and 141 (UC) remained 114 (I) and 110 (UC) were contacted 1 year after birth, including 16(I) and 18 (UC) lost to follow up during pregnancy Mean cigarettes/day pre-pregnancy I = 26.1, C = 25.1.
Interventions	All participants received: baseline questionnaire, measurement of exhaled CO, and brief standardised health risk message from a research nurse about the effects of smoking on the fetus and pregnancy. UC was: physician acknowledged women's smoking , gave a rationale for quitting, strong recommendation to quit and provided smoking cessation booklet designed for pregnant women. I was smoking cessation protocol provided by physicians trained in its use (Secker-Walker et al, 1992): acknowledging the woman's smoking, her exhaled CO level, any progress towards quitting, rationale for & unambiguous recommendation to quit, asking how she felt about quitting and acknowledging her response, asking how she could be helped and telling her about the counsellor, eliciting a commitment to change smoking behaviour before the next prenatal visit and referring her to the counsellor. The aim was to gain her agreement to set a quit date, a date when she would quit for 24 hours or a date when she would cut her consumption by half. Counsellor advised women on ways to accomplish the behaviour change. 2nd visit same with praise for those who had quit + referral to counsellor for help in staying quit, 3rd 5th 7 36 week visits a briefer protocol was followed with referral for those who wanted to change, praise for success and referral.
Outcomes	Smoking cessation maintained in late pregnancy (36/40) and 1 year postpartum, biochemically validated with exhaled CO and urine cotinine. Mean birthweight Low birthweight
Notes	Methods included a detailed process evaluation.
Allocation concealment	B
Study	**Sexton 1984**
Methods	A randomised trial of an intervention to increase birthweight by changing maternal smoking, carried out in Baltimore, USA. No details of randomisation and it is unclear whether usual caregivers were masked to allocation.
Participants	Pregnant women who were smoking >= 10 cigarettes/day immediately prior to pregnancy (71% of whom were spontaneous quitters), < 18 weeks gestation, attending 52 private physicians and the hospital antenatal clinic. Heterogeneous population, including large inner-city and suburban. 89% of those eligible were recruited n = 935, 463 (I), 472 (C). Mean cigarettes/day pre-pregnancy I = 20.9, C = 20.7.

Characteristics of included studies

Interventions	Control: usual care, not further specified. Intervention: at least 1 personal visit, supplemented by frequent mail and telephone contacts (at least 1 visit and 1 call/month) from 1 of 2 health educators (MEd level, trained in pregnancy counselling and smoking intervention), providing information, support, practical guidance and behavioural strategies for quitting. Information on quitting + health risks of smoking was mailed every 2 weeks with 'homework' linked to telephone calls; group sessions were also available. There was a monthly lottery and in the last year of the study a monthly newsletter.
Outcomes	Smoking in late pregnancy, 97% biochemically validated with salivary thiocynate. Miscarriage; fetal deaths; mean birthweight; low birthweight; very low birthweight; % Apgar scores < 7 at 1 minute and 5 minutes; length and head circumference.
Notes	Change of criteria for enrollment after the first 185 as 35% of these had smoked < 10/day and 71% of that group had quit spontaneously with little relapse. Detailed account of the intervention is in Nowicki et al 1984. Group sessions in the intervention were not readily accepted.
Allocation concealment	D
Study	**Solomon 1996**
Methods	A trial of a smoking cessation intervention on women's 'stages of change' (precontemplation, contemplation, preparation and action) was assessed. No details of randomisation process.
Participants	Low income pregnant women enrolled in a state-supported service for uninsured and under-insured women, receiving care in a large obstetric group practice. 521 women smoking >= 1 cigarette/day at the onset of pregnancy enrolled, 349 (67%) completed assessments at 1st, 2nd and 36 week visits. Mean cigarettes/day pre-pregnancy I = 22.8, C = 23.6.
Interventions	Control: 3 minute physician-delivered protocol at first visit, acknowledging her smoking, concerns re quitting or staying quit; strong recommendation to quit + cessation pamphlet designed for pregnant women. Intervention: as control + quit date or date to cut down set + on-site counselling, 10-30 minutes at 1st, 2nd, 3rd 5th and 36 week visits from trained obstetric nurse: encouragement and reinforcement of small changes, problem solving around barriers to cessation, and prevention of relapse, including dealing with other smokers, coping with the urge to smoke, withdrawals symptoms, weight gain, eliciting support for quitting.
Outcomes	Shifts in 'Stage of change' at 2nd visit and 36 weeks gestation. No smoking cessation data to include in tables.
Notes	Comment made that stages of change at the first visit are not sustained. "Enthusiasm for behaviour change may wane towards the end of the gestational period when attention may be focused on labour and delivery". Pattern of 'stages' at first visit different from community-based studies i.e. more women were in the later stages than would be expected at the study onset. No difference in late pregnancy.
Allocation concealment	B
Study	**Solomon 2000**
Methods	Trial of proactive telephone peer support in a large obstetric practice in Vermont, US, 1996-7. No description of randomisation procedure. Caregivers not able to be masked to allocation.

Characteristics of included studies

Participants	Women reporting smoking at least 1 cigarette in the past week at their first antenatal visit, were approached. Refusal rate = 19%. Women tended to be white, English speaking, and of lower income and education. No exclusion criteria specified. Control n = 74, Intervention n = 77. Mean cigarettes/day before pregnancy I = 22.6, C = 20.2.
Interventions	Control group received brief smoking cessation advice from a MW/Obst at each of the 3 prenatal visits and stage appropriate printed materials. MWs/Obst were provided with a 45 minute training session. The intervention group received the same as the control group + offered telephone peer support (from a female ex-smoker, who received 8 hours of training) for women with moderate or high intentions of quitting. who called the participant within several days to provide support for positive changes in smoking behaviour.
Outcomes	Self reported abstinence at 28 - 34/40 gestation, defined as no smoking for the past 7 days, biochemically validated with urine cotinine measurement. Movement in stages of change and proportion of smoking reduction by more than 50%. Attrition = 16 (10.6%).
Notes	Process evaluation showed 53% received the peer intervention.
Allocation concealment	B
Study	**Stotts 2000**
Methods	Trial of individualized stage of change, motivational smoking cessation intervention ("one-to-one"), with personalized feedback for "resistant" pregnant smokers, in 3 large multispecialty clinics in Texas, US. Random allocation determined by a computer generated list. Unclear whether caregivers masked to allocation.
Participants	Women who continue to smoke at 28 week gestation, after having counselling and 8 self help booklets earlier in pregnancy care. Inclusion criteria were women fluent in English, over 18 yrs, over 20 weeks gestation at first an visit, and smoke more than 5 cigarettes per week prior to pregnancy. All women had group insurance. Eligibility interview participation rate 97%. All eligible included in randomised sample (n = 269), as data collection and implementation were adopted as routine procedures, and required to formal written consent. Women in the intervention group had significantly higher proportion of women smoking > 61 cigarettes/week before pregnancy (I = 57.9%, C = 43%) and a higher proportion of partners who smoke (I = 69.6%, C = 62.5%).
Interventions	All women smoking at intake (< 20 weeks), were provided with MI counselling and motivational self help books, based on "stage of change" program shown to be effective by Ershoff et al. Women still smoking at 28 weeks were randomised to this study. The high intensity intervention group (and their partners) then received: a 20-30 min MI telephone counselling call (conducted by trained counsellors and nurse health educators), a personalised, stages of change based feedback letter, and a final MI-base telephone call conducted 4 - 5 days after the feedback letter was sent.
Outcomes	Self reported smoking cessation at 34 weeks gestation, validated by an anonymous urine cotinine subsample. Postpartum follow up (6w, 3m, 6m) interview response rate 61% (data collected from a separate survey, with financial incentives). Movement in "Stages of Change". Breastfeeding rates and general health behaviours obtained but not reported.
Notes	Only 55% of the experimental group received the full intervention (32% were never able to be reached). Implementation analysis suggested an effect in women who received full implementation: 43% vs 34% control group.
Allocation concealment	B

Characteristics of included studies

Study	**Strecher 2000**
Methods	Trial of personalised, computer generated, smoking cessation messages, in 2 university hospitals in North Carolina & Michigan, USA, Dec 1996-97. Randomisation by computer algorithm. Unclear whether caregivers masked to allocation.
Participants	Women who have "smoked 100 cigarettes in their lifetime and still smoking" or "had quit since becoming pregnant", completed a self administered computer screening program to determine eligibility (no details of inclusion or exclusion criteria). 173 women participated. Mean cigarettes/day smoked before pregnancy I = 20.3, C = 18.7 (ns).
Interventions	Control group received "a pregnant woman's guide to quit smoking" at the first visit. The intervention group entered personal data into a hand-held computer at antenatal visits, which subsequently generated personalized tailored messages, which were posted to the woman.
Outcomes	Self reported smoking cessation validated by urine cotinine at first visit, 24/40 and 6 weeks postpartum. Attrition rate 14% in control group, and 15.2% in experimental group.
Notes	Numbers in paper inconsistent: I = 88, C = 85 in methods section, I = 104, C = 87 in results section. No justification for change of denominators - assumption was ITFV were smokers. Participant evaluation of using hand-held computers and reactions to computerised materials.
Allocation concealment	B
Study	**Tappin 2000**
Methods	Pilot study of home based motivational interviewing for smoking cessation in a Glasgow Hospital, Scotland, March-May 1997. Consenting women stratified and randomly allocated to 2 equal groups using blinded telephone allocation. Unclear whether caregivers masked to
Participants	Self reported women who identified as smokers on a questionnaire at antenatal clinic booking. Participation rate 75%, 27 refused. (n = 100). Mean cigarettes/day pre-pregnancy I = 19.6, C = 18.1.
Interventions	The control group received usual advice from their prenatal providers, which should include information about smoking. The intervention group received 2 - 5 motivational interviewing sessions, based on stages of change, in the clients home conducted by a midwife trained in smoking cessation counselling. High intensity intervention.
Outcomes	Self reported smoking cessation, at 27/40 or more, with urine cotinine validation in 93%. Mean birthweight, preterm births. Ranking interviews measured movement around the "cycle of change". Detailed evaluation of participant and midwifery views of interventions. Attrition rate 2%.
Notes	Good process evaluation of implementation quality according to Millers rating tool, showed 79% of women in the intervention group received at least 2 counselling sessions, and less than 20% of the control group recalled being given smoking information at the time of booking.
Allocation concealment	A
Study	**Thornton 1997**
Methods	Trial of smoking cessation counselling and information packs in a large public antenatal clinic, in Rotunda Ireland, during 3 months in 1995. Randomisation by random number tables, allocation concealed by opaque sealed envelopes and restricted in groups of ten. Intervention provided by trained facilitator, with staff unaware of allocation.

Characteristics of included studies

Participants	Inclusion criteria: women who currently smoke or had spontaneously quit since becoming pregnant; have a viable pregnancy; and intend to deliver in the hospital. Participation rate = 81% (n = 418). Intervention group were less likely to have spontaneously quit, or be employed. Mean gest at first visit I = 15.5, C = 15.3. Number of daily cigarettes at intake: 1-9 I = 61, C = 54; 10-19 I = 74, C = 73; 20+ I = 68, C = 65.
Interventions	The control group completed a questionnaire at first visit, followed by routine prenatal advice on a range of health issues, from midwives and obstetricians. The intervention group received as for the control group + structured one to one counselling by a trained facilitator (based on stages of change theory); partners invited to be involved in the program; an information pack; and invited to join a stop smoking support group. A carbon monoxide monitor was available for the intervention group, to quantify smoking habit and act as a motivational tool. High intensity intervention.
Outcomes	Smoking cessation at delivery, biochemically validated by exhaled CO. Reduction in mean cigarettes/day, quit attempts, comparisons of quitters and non quitters at various stages. Infant outcomes (singleton births): delivery type, mean gestation, mean birthweight, proportion LBW (2500 g), preterm births, NNICU admissions, infant outcomes at 3 months. Attrition at delivery: I = 6.2%, C = 8.6%.
Notes	Good process analysis and participant feedback of program implementation. A high baseline smoking prevalence rate (58.7%). Limited exhaled CO measurement on postnatal ward.
Allocation concealment	A
Study	**Valbo 1991**
Methods	Quasi-randomised trial of smoking cessation interventions (allocation to 1 of 4 arms, 3 intervention and 1 control, by date of enrollment for care, with the four time blocks assigned randomly) in women smoking at the time of the 18 week ultrasound scan, at a regional hospital in Norway, 1988. Caregivers not masked to allocation.
Participants	283 women reported current smoking and wanted to quit. (mean 9-11 cigarettes/day) at the 18 weeks scan: 200 recruited, 50 in each arm. 1/3 receiving private obstetric care.
Interventions	Control: not specified. Intervention (i): information provided by a physician to women in groups of 10 about the harmful effects of smoking on mother and child; (ii) 2 page pamphlet mailed 3 weeks after the ultrasound scan, with information on the harmful effects of smoking + advice on how to quit; (iii) smoking cessation group of 12 - 13 people; 5 x 2 hour meetings over 5 weeks, offered a cognitive behaviour modification program, including self-monitoring, stimulus control, response control, reinforcement control and maintenance strategies, run by a clinical psychologist.
Outcomes	Smoking cessation assessed immediately after the intervention, biochemically validated but not reported. intervention arms.

Characteristics of included studies

Notes	Biochemical validation of smoking status using salivary thiocyanate was carried out but not reported in the paper. Doctor information group treated as 'control' for the other interventions because of minimal impact at either time. Smoking assessed 12 months (96% response rate to questionnaire) after the intervention showed sustained differences by allocation though more than half the quitters had relapsed in the behaviour modification group. Process evaluation showed 20% women attended only the first of the 6 group meetings, and 12% of the women in the brochure group did not read them.
Allocation concealment	C
Study	**Valbo 1994**
Methods	Quasi-randomised trial of cognitive-behavioural modification, (using RA Windsor's self-help manual translated into Norwegian) to promote smoking cessation in women smoking heavily at the time of the 18 week ultrasound scan, in Oslo 1990-1991. No details of randomisation and caregivers not masked to allocation.
Participants	Pregnant women attending the National University Hospital Oslo at 18 weeks for ultrasound, and smoking 10 cigarettes/day. No exclusion criteria mentioned and no refusals. 112 women recruited (1800 births/year, study over 15 months). Pre-pregnancy mean cigarettes/day: I = 8, C = 11.
Interventions	Control: information on the negative effects of smoking + encouragement to quit, reinforced by a pamphlet, provided at the time of the ultrasound examination. Intervention: offered the Windsor self-help manual describing a 10 day program, 2 weeks later reminder. Letter + encouragement and appointment for 32 week scan + reinforcement at the 32 weeks scan + 2 weeks later a further letter. Both intervention and control information were provided by obstetrician or midwife.
Outcomes	Smoking cessation in late pregnancy. No biochemical validation.
Notes	Evidence is provided for an increase in smoking compared with 18 weeks, especially in the control group. Process evaluation suggested that the acceptance of the manual was low (mean score 2.6 on 7 point scale) and that it was staff involvement which had the most impact.
Allocation concealment	C
Study	**Valbo 1996**
Methods	Randomised trial of hypnosis for smoking cessation and reduction among women still smoking at the time of the 18 week ultrasound scan in a Norwegian hospital, 1990-1993. Randomised by random number tables, with usual caregivers masked to allocation.
Participants	Women were offered participation if still smoking at 18 week ultrasound visit, (after explanation including potential allocation to control) and then randomised after signing. Expected numbers of women in the recruitment period were 630, 158 (25%) agreed to participate. Of 80 allocated to intervention 13 did not receive an appointment in time, 15 did not attend leaving 52. Mean cigarettes/day prior to pregnancy I = 15.6, C = 15.0.

Characteristics of included studies

Interventions	Control: "routine pregnancy health care". Intervention: anaesthesiologist provided 2 x 45 minute sessions at 2 week interval of a protocol-based recipe (Handbook of the American Society of Clinical Hypnosis); the tape played after hypnosis was established emphasised the unpleasant effects of smoking, affirmed her wish to quit, encouraged her will and capacity to quit, and instructed her in meeting cravings with relaxation techniques and self-hypnosis, explained during the session. Second visit tape was different with more weight on her capacity and taking control. Both tapes avoided "moralizing about her responsibility for pregnancy outcome".
Outcomes	Self reported smoking cessation, reduction and increase at end of pregnancy, not biochemically validated. Perinatal deaths.
Notes	Process evaluation did not rate the intervention highly: mean score of 2.05 on a 7 point scale. Norway
Allocation concealment	A
Study	**Walsh 1997**
Methods	Trial of a structured, cognitive-behavioural, smoking cessation program for pregnant women delivered by usual care providers in a public hospital antenatal clinic in Newcastle, Australia, 1990-1991. Randomised after consent by precoded questionnaires in opaque envelopes, with a computer generated sequence.
Participants	1909 pregnant women were screened at the first visit (approximately 12 weeks gestation). Classified as a smoker if they answered yes to the question "Are you a smoker?": 725 smokers (38%), - 187 ineligible > 26 weeks, - 47 too ill or disturbed, -11 other reasons left 538. 293 agreed to take part. 7 (I) + 7 (C) withdrew, 10 + 10 had a miscarriage or termination, 4 + 3 gave birth preterm, leaving 125 + 127. Baseline smoking data not specified.
Interventions	Control: Doctor and Midwife both informed women that smoking was an important cause of pregnancy problems and they should stop; Midwife provided a package (sticker, pamphlet on risks of smoking and 2 page cessation guide), none of which were specifically tailored to pregnant women. Intervention based on cognitive behaviour therapy: (i) 2-3 minute standardised risk information from Doctor + 14 minute video on risk information rebuttal of barriers to quitting, cessation tips + 10 minute standardised information and counselling from Midwife after the video, using a flip chart, with negotiation of a quit date whenever possible + self-help manual on risks, barriers and cessation + 4 packets of confectionary gum + lottery chance (4 prizes) for biochemically validated abstainers at the next visit + social support from accompanying adult (partner/friend/other) vis support tip sheet, contract and form letter + chart reminder vis sticker in the medical record + form-letter + sticker from 1st visit Midwife mailed within 10 days + 2nd visit and 34 to 36 week visit 5 minute counselling from Midwife and 1-2 minute risk advice from Doctor. Women still smoking at 34-36 weeks were advised to attend an external cessation course.
Outcomes	Smoking status at mid and late pregnancy and postpartum, biochemically validated with salivary cotinine (I = 86%, C = 78%).
Notes	Midwives involved in recruitment to the trial had variable 'success'. Overall participation was quite low (54%). Cotinine data inconsistent with self-report was 52% in controls and 12% in the intervention group.
Allocation concealment	A

Characteristics of included studies

Study	Windsor 1985
Methods	A randomised trial, comparing the effectiveness of 2 smoking cessation interventions with standard care, in public health clinics in Birmingham, Alabama, USA 1983-1984. No details of randomisation. Usual caregivers masked to allocation. Sample size justification.
Participants	1838 pregnant women were screened, 460 current smokers (">= 1 cigarette in the last 7 days"), -30 antenatal care entry >= 32 weeks, -9 left system or moved, -10 miscarriage or termination -10 went to group discussions (this intervention abandoned), leaving 102 I1), 103 (I2) and 104 (SC). No baseline data on cigarettes/day.
Interventions	Control: 2-3 minutes within a group prenatal education session at the 1st visit, when maternity clinic staff recommend quitting. I1: 10 minute standardised counselling session from a health educator (B Comm H Ed) + Am Lung Assoc "Freedom from smoking" (ALA) manual (17 day self-directed plan for quitting) + "Because you love your baby" pamphlet on the dangers and risk of smoking and the benefits of quitting. I2: as for I1 except that the manual was "A pregnant woman's self-help guide to quit smoking" (instead of the ALA manual).
Outcomes	Smoking cessation or reduction, biochemically validated by salivary thiocynate, at mid-pregnancy and within 48 hours of birth.
Notes	"Multiple attempts were made to bring pregnant smokers together for a peer-led, focused group discussion: not feasible in this setting". All those lost to follow up were considered smokers. Pre-trial assessment showed no nurses (n = 80) had smoking cessation training and less than 20% felt confident to advise women on how to stop.
Allocation concealment	B
Study	**Windsor 1993**
Methods	Trial of an enhanced cognitive behaviour therapy intervention, to assist in smoking cessation and smoking reduction during pregnancy in women attending public maternity clinics at a large hospital in Birmingham, Alabama, USA, 1986-91. Randomisation by a computer-generated system. Caregivers not masked to allocation.
Participants	4352 pregnant women screened at approximately 4 weeks gestation, 1381 (31.7%) reported smoking at conception, 1171 current smokers (smoked 1 cigarette even a puff in the last 7 days), -110 ineligible by entry to care > 32 weeks, did not complete first visit, did not return, in earlier trial, prisoner, reading level too poor, leaving 1061 of whom 67 refused leaving 493 (I) and 501 (C), -93 + 87 miscarriage, termination or withdrawal from public care, leaving 400 (I) + 414 (C). NS difference in baseline cotinine.
Interventions	Control: 2 minute talk in 30 minute group session at first antenatal visit in which women were urged to quit and given 2 pamphlets: "Smoking and the two of you""+ "Where to find help if you want to stop" including the name, contact phone number and cost of their local program. Intervention based on cognitive behaviour therapy: 15 minute standardised cessation skills and risk counselling session from trained female health education counsellor + 7 day self-directed cessation guide on how to quit written at 6th Grade level + reinforcement (chart sticker) + letter from Doctor within 7 days + 'buddy' letter, contract and tip sheet + monthly newsletter with testimonials, cessation tips and additional information on risks.
Outcomes	Smoking cessation at 32 weeks gestation, biochemically validated with salivary thiocyanate.

Characteristics of included studies

Notes	Separate paper on spontaneous quitters (Lowe et al, 1997). All those lost to follow up were counted as continuing smokers. Data on gestation and birthweight were collected but the published analysis is by stopping smoking and the timing of cessation rather than by allocation, so not included in outcome tables.
Allocation concealment	A
Study	**Windsor 2000a**
Methods	Evaluation trial of behavioural impact of new patient education methods ("SCRIPT"), provided by trained medicaid maternity care staff members, in Alabama, USA, 1997-2001. 17 eligible counties (> 50 pregnant smokers per year) stratified (% black: white pop; % pregnant smokers) into 8 clusters and 50% randomly selected (no details). Usual caregivers not able to be masked to allocation.
Participants	Women screened at first visit (9 - 12 weeks gestation) for self-reported smoking, validated by salivary cotinine. 2 separate phases: participation rate phase one (1997) = 95% (n = 93), phase 2 (1998) participation rate = 60% (n = 172). Phase one and 20% phase 2 group combined to form control group (n = 126), 80% phase 2 group (n = 139) formed intervention group. Both groups smoked approximately 10 cigarettes/d at baseline.
Interventions	Nurses, social workers and WIC administrators received orientation sessions. Partnerships were developed for program implementation. Control group patients had self report smoking status ("Ask", and a saliva sample, and counselling ("advise"). Intervention (based on cognitive behaviour therapy) group were provided with 2 further components "assist and arrange", which included a motivational video to take home to show partners, "A pregnant woman's guide to quit smoking", and < 5 min counselling session.
Outcomes	Self reported smoking status at 60 days after first visit, validated by salivary cotinine. Significant (> 50%) reduction in baseline cotinine (harm reduction measures). No quit attempts. Attrition rate 13% (n = 34), counted as smokers.
Notes	Mixture of RCT/sequential study with main control group being recruited in phase one of the study to identify representative sample, and small additional control group recruited in phase 2 with the intervention group. Good process evaluation showed nearly 100% experimental group received the intervention, confirming the feasibility of routine delivery by regular staff.
Allocation concealment	C
Study	**Wisborg 2000**
Methods	Double-blind, placebo controlled trial of nicotine replacement therapy (patches) in pregnant women in a Danish obstetric hospital. Women consenting to participate were randomly assigned in blocks of 6, to nicotine or placebo patches. The investigation team were blinded to allocation.
Participants	Healthy women less than 22 weeks gestation who smoked more than 10 cigarettes per day after the first trimester, were invited to participate n = 611. Participation rate 41% (n = 250).Mean cigarettes per day at intake I:n = 13.4, C: n = 14.2.
Interventions	Both groups received strong smoking cessation advice and counselling from a midwife, reinforced with printed materials. The control group received a placebo patch. The intervention group received 16 hour 15 mg nicotine patches for 8 weeks and 10 mg for 3 weeks.

Characteristics of included studies

Outcomes	Self reported abstinence of at least 7 days at 2nd, 3rd, and 4th prenatal visits, validated by salivary cotinine measurement. Telephone follow up at 3 and 12 months postpartum (self report). Mean birthweight, low birthweight (,2500 g), preterm delivery.
Notes	Very low recruitment, with non-participants smoking more cigarettes per day. Compliance lower for placebo group, who may have guessed allocation. Limited details on 3 months and 1 year follow up.
Allocation concealment	A

Notas:
AFP: alpha fetoprotein
BP: blood pressure
CO: carbon monoxide
GP: general practitioner
HMO: Health Maintenance Organisation
LBW: low birth weight
min: minutes
MRFIT: randomised trial of health promotion carried out in the US
OPD: out-patient department
Pls: principal investigators
ppm: parts per million
pPROM: preterm, prelabour rupture of the membranes
sae: stamped addressed envelope
ses: socioeconomic status
SHO: senior house officer
TFS: teen fresh start
TFSB: teen fresh start + peer support
UC: usual care
WIC: Food program for Women, Infants and Children in the US

Characteristics of excluded studies

Study	Reason for exclusion
Byrd 1993	There are no data provided by trial allocation.
Cooke 2001	Data are available on uptake of programs at a hospital level but not at present on smoking cessation effectiveness or perinatal outcomes.
Emmons 2000	Quasi-experimental evaluation study of the "Healthy Baby Second Hand Smoke Study" uses historical controls. Good documentation of implementation problems.
Ershoff 1983	The intervention took place in one HMO clinic with historical controls from the same clinic and concurrent controls from a second clinic. There was no randomisation of clinics and no adjustment of the data for clustering.
Gebauer 1998	Study of effect of one 15 minute counselling session and a follow-up telephone call, performed 1994-95, using historical controls from 1993-1994.
Gillies 1987	In this quasi-randomised study the intervention was carried out in one hospital with another hospital in the same city acting as a control, after a prior descriptive study which showed the similarity between the two in terms of social and demographic factors including smoking. There was no randomisation and recruitment differed substantially across the two sites. Data for smoking reduction and smoking cessation are combined in the paper with no separate data on cessation and no adjustment for clustering.
Graham 1992	Although the multicomponent intervention included a smoking change component there are no smoking data in the paper.

Characteristics of excluded studies

Haug 1994	General practitioners, rather than individual women, were randomly allocated to provide the intervention or not. There was no adjustment for cluster randomisation in the analysis of the study findings.
Jaakola 2001	Controlled study, not randomised, of effects of a population based smoking cessation program and its impact on smoking in pregnancy. Controls were matched on inclusion criteria from another district.
Langford 1983	Prenatal classes, rather than individual women, were randomly allocated to provide the intervention or not. The intervention was provided in late pregnancy with no outcome data collected during pregnancy but only data four months after birth. There was no adjustment for cluster randomisation in the analysis of the study findings.
Lillington 1995	Four WIC clinics in Los Angeles were matched and randomised within pairs to intervention or control status. There was no adjustment for clustered data. All those not contacted at postpartum visit (28%) were excluded even though they should be counted as smokers; their allocation is not stated so adjustment cannot be made for this. There was significant misclassification of self-reported non-smoking status and 44% did not provide a sample for cotinine analysis so that verified non-smoking cannot be calculated.
Lowe 2002	Data are available on uptake of programs at a hospital level but not at present on smoking cessation effectiveness or perinatal outcomes.
Messimer 1989	Primary care practices, rather than individual women, were randomly allocated to provide the intervention or not. There was no adjustment for cluster randomisation in the analysis of the study findings.
Mullen 1990	Data are provided on those who stopped smoking only, not data by trial allocation.
Mullen 1997	Data are provided on those who stopped smoking only, not data by trial allocation.
Olds 1994	Outcome data on child development in this paper have been excluded because the multicomponent interventions being compared might have had effects on child development other than by a change in maternal smoking.
Olds 2002	This 3 armed randomised controlled trial of home visiting by paraprofessionals and nurses was excluded as it did not contain any quitting data, only urine cotinine measurements.
Power 1989	The intervention in this trial was unusual in that the focus was on anticipated benefits of smoking cessation to women themselves (not on harm to the fetus and infant), and on alternative coping strategies, with a designated midwife-facilitator to answer queries and provide friendly advice and encouragement. The intervention was carried out in one hospital with another being a comparison setting, after a prior study which showed the similarity between the two in social and demographic factors including smoking rates. There was no randomisation. Recruitment differed significantly across the two hospitals. Data for smoking cessation and smoking reduction are combined with no separate data on cessation and no adjustment for clustering.
Scott 2000	This quasi-experimental study of the impact of using interactive software to promote smoking cessation, was excluded as it used historical controls.
Shakespeare 1990	Data on smoking reduction and smoking cessation are combined with no separate data on smoking cessation.

Characteristics of excluded studies

Valanis 2001	This prospective quasi-experimental study design to test the effect of a low intensity intervention, used historical controls.
Wisborg 1998	This quasi-randomised (clinic day allocation) study of the effect of midwifery training on smoking cessation intervention implementation and pregnancy outcomes, was excluded due to concerns about allocation concealment.

Notas:
HMO: Health Maintenance Organisation
WIC: Food program for Women, Infants and Children in the US

TABLAS ADICIONALES

Table 01 Randomised cluster trials: summary of effect

Trial ID	Outcome measurement	Adjustment	Effect	95% CI
Kendrick 1995	Biochemically validated smoking cessation at 8 months of pregnancy	Odds ratio adjusted	1.0	0.69-1.6
Manfredi 1999	Self reported smoking cessation at 5-8 weeks post birth	Odds ratio Z-score adjusted	0.67	0.38-1.15 p = 0.006
Bakker 2000b	Self reported smoking cessation at 6 weeks post birth	Odds ratio adjusted	0.42	0.18-0.97
Hajek 2001	Biochemically validated smoking cessation at birth	Odds ratio	0.86	0.48-1.57
Moore 2002	Biochemically validated smoking cessation at 6-7 months of pregnancy	Odds ratio adjusted	0.89	0.48-1.57
Lawrence 2003	Biochemically validated smoking cessation at 10 days post birth	Odds ratio adjusted	0.58	0.26-1.33

CARÁTULA

Titulo	**Intervenciones para promover el abandono del hábito de fumar durante el embarazo**
Autor(es)	**Lumley J, Oliver SS, Chamberlain C, Oakley L**
Contribución de los autores	Judith Lumley (JL) y Sandy Oliver (SO) participaron en la redacción del protocolo original de la revisión y la revisión inicial. JL, SO y Elizabeth Waters (EW) resumieron los datos del ensayo; JL realizó los análisis. Todos los revisores contribuyeron con el texto final. Laura Oakley (LO) contribuyó con el resumen de los datos y el texto de la revisión en las actualizaciones posteriores. EW no pudo contribuir con la revisión después de 2002. Catherine Chamberlain (CC) realizó las búsquedas de la presente actualización. También resumió los datos de los ensayos, como lo hicieron SO, LO y JL. JL y CC redactaron el texto con aportes de SO y LO; CC ingresó los datos y realizó los análisis, con aportes de JL.

Número de protocolo publicado inicialmente	1998/2
Número de revisión publicada inicialmente	1998/3
Fecha de la modificación más reciente"	05 agosto 2004
"Fecha de la modificación SIGNIFICATIVA más reciente	22 marzo 2004
Cambios más recientes	**Julio 2003Se han actualizado las secciones de "Resultados" y "Antecedentes" (comentarios sobre las diferencias entre las intervenciones cuando se agrupan los ensayos según la intervención).Se incluyeron 20 ensayos nuevos que informaron sobre el abandono del hábito de fumar con otros cinco ensayos aleatorios grupales (Bakker 2001;Cinciripini 2000; Donatelle 2000; Ershoff 1999; Hajek 2001; Hegaard 2003; Hughes 2000; Kapur 2001; Lawrence 2003; Malchodi 2003; Manfredi 2000; Moore 2002; Panjari 1999; Solomon 2000; Stotts 2000; Strecher 2000; Tappin 2000; Thornton 1997; Windsor 2000a; Wisborg 2000). Se excluyeron nueve ensayos adicionales. Seis ensayos proporcionaron datos nuevos sobre los resultados fetales y perinatalesLas conclusiones generales acerca de la efectividad de las intervenciones para promover el abandono del hábito de fumar no cambiaron. Los análisis nuevos que agruparon a las intervenciones por estrategias mostraron que las intervenciones cognitivas-conductuales combinadas fueron efectivas, el tratamiento de reemplazo de la nicotina fue de significación estadística marginal, y los ensayos que utilizaron retroalimentación o enfoques según las "etapas del cambio" no fueron eficaces. Los dos ensayos que utilizaron una combinación de recompensas y apoyo social fueron significativamente más eficaces que los que utilizaron otras estrategias. La información cada vez mayor sobre los resultados perinatales fortaleció los hallazgos de una reducción del nacimiento de prematuros y el bajo peso al nacer. Un ensayo proporcionó información sobre el método de parto y otro ensayo informó sobre la lactancia materna: ninguno mostró un efecto de la intervención.**
Fecha de búsqueda de nuevos estudios no localizados	El autor no facilitó la información
Fecha de localización de nuevos estudios aún no incluidos/excluidos	El autor no facilitó la información
Fecha de localización de nuevos estudios incluidos/excluidos	31 julio 2003
Fecha de modificación de la sección conclusiones de los autores	04 julio 2004

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Número de la Cochrane Library	CD001055-ES
Grupo editorial	Cochrane Pregnancy and Childbirth Group
Código del grupo editorial	HM-PREG

RESUMEN DEL METANÁLISIS

01Todos los ensayos				
Resultado	Nº de estudios	Nº de participantes	Método estadístico	Tamaño del efecto
01 Mantuvieron el hábito de fumar al final del embarazo	47	13882	Riesgo Relativo (efectos aleatorios) IC del 95%	0.94 [0.92, 0.96]
02 Media del peso al nacer	16	13618	Diferencia de medias ponderada (efectos aleatorios) IC del 95%	33.03 [11.32, 54.74]
03 Bajo peso al nacer (menos de 2500 g)	13	8930	Riesgo Relativo (efectos aleatorios) IC del 95%	0.82 [0.70, 0.95]
04 Muy bajo peso al nacer (menos de 1500 g)	3	4765	Riesgo Relativo (efectos aleatorios) IC del 95%	1.26 [0.69, 2.32]
05 Nacimiento de prematuros (menos de 37 o menos de 36 semanas)	11	10932	Riesgo Relativo (efectos aleatorios) IC del 95%	0.84 [0.72, 0.98]
07 Nacimiento de mortinatos	5	4525	Riesgo Relativo (efectos aleatorios) IC del 95%	1.16 [0.71, 1.88]
08 Muertes neonatales	3	4143	Riesgo Relativo (efectos aleatorios) IC del 95%	1.17 [0.34, 4.01]
09 Muertes perinatales	3	4335	Riesgo Relativo (efectos aleatorios) IC del 95%	1.13 [0.72, 1.77]

02 Ensayos con abandono del hábito de fumar bioquímicamente validado				
Resultado	Nº de estudios	Nº de participantes	Método estadístico	Tamaño del efecto
01 Mantuvieron el hábito de fumar al final del embarazo	35	10362	Riesgo Relativo (efectos aleatorios) IC del 95%	0.94 [0.92, 0.97]

03 Intervenciones con puntuaciones de alta calidad				
Resultado	Nº de estudios	Nº de participantes	Método estadístico	Tamaño del efecto
01 Mantuvieron el hábito de fumar al final del embarazo	25	7819	Riesgo Relativo (efectos aleatorios) IC del 95%	0.95 [0.93, 0.97]

04 Intervenciones de alta intensidad con puntuaciones de alta calidad y abandono del hábito de fumar bioquímicamente validado				
Resultado	Nº de estudios	Nº de participantes	Método estadístico	Tamaño del efecto
01 Mantuvieron el hábito de fumar al final del embarazo	17	5252	Riesgo Relativo (efectos aleatorios) IC del 95%	0.96 [0.93, 0.98]

05 Ensayos clasificados en subgrupos según la intensidad de la intervención				
Resultado	Nº de estudios	Nº de participantes	Método estadístico	Tamaño del efecto
01 Mantuvieron el hábito de fumar al final del embarazo	48	13884	Riesgo Relativo (efectos aleatorios) IC del 95%	0.94 [0.92, 0.96]

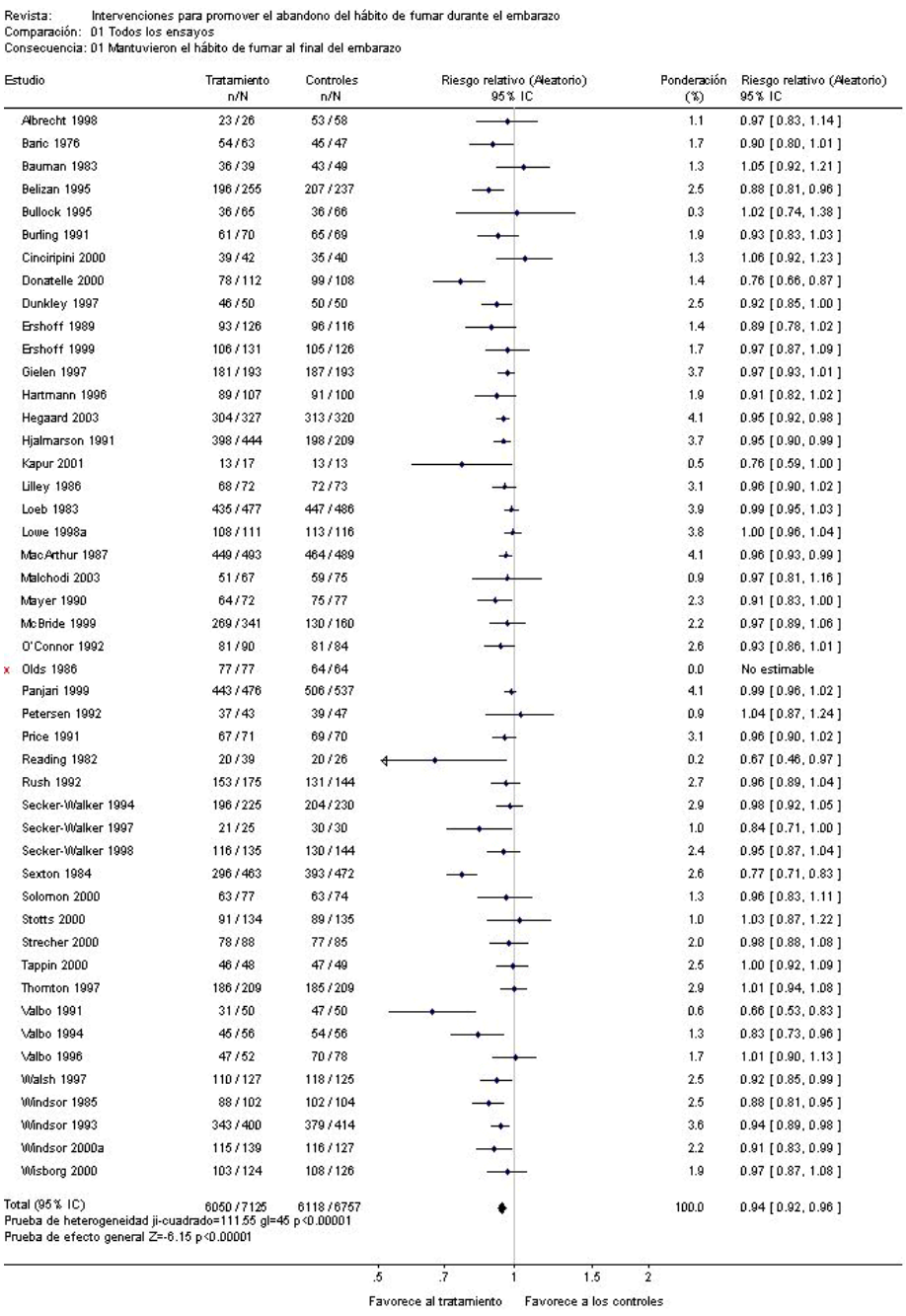
06 Ensayos clasificados en subgrupos según la estrategia de la intervención				
Resultado	Nº de estudios	Nº de participantes	Método estadístico	Tamaño del efecto
01 Mantuvieron el hábito de fumar al final del embarazo	46	13603	Riesgo Relativo (efectos aleatorios) IC del 95%	0.94 [0.92, 0.96]

07 Ensayos para prevenir la reincidencia en el hábito de fumar en las mujeres que dejaron de fumar al comienzo del embarazo				
Resultado	Nº de estudios	Nº de participantes	Método estadístico	Tamaño del efecto
01 Hábito de fumar al final del embarazo	5	843	Riesgo Relativo (efectos aleatorios) IC del 95%	0.81 [0.63, 1.04]

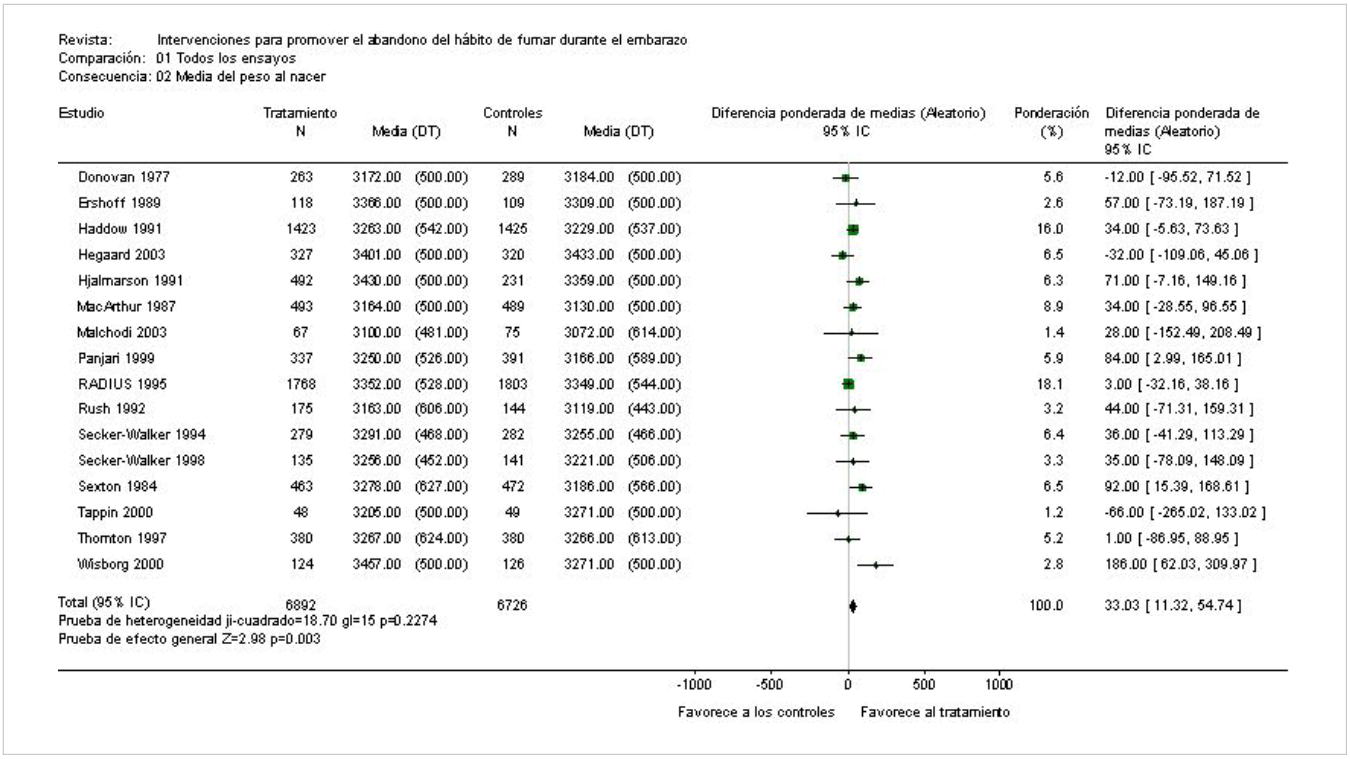
GRÁFICOS Y OTRAS TABLAS

Fig. 01Todos los ensayos

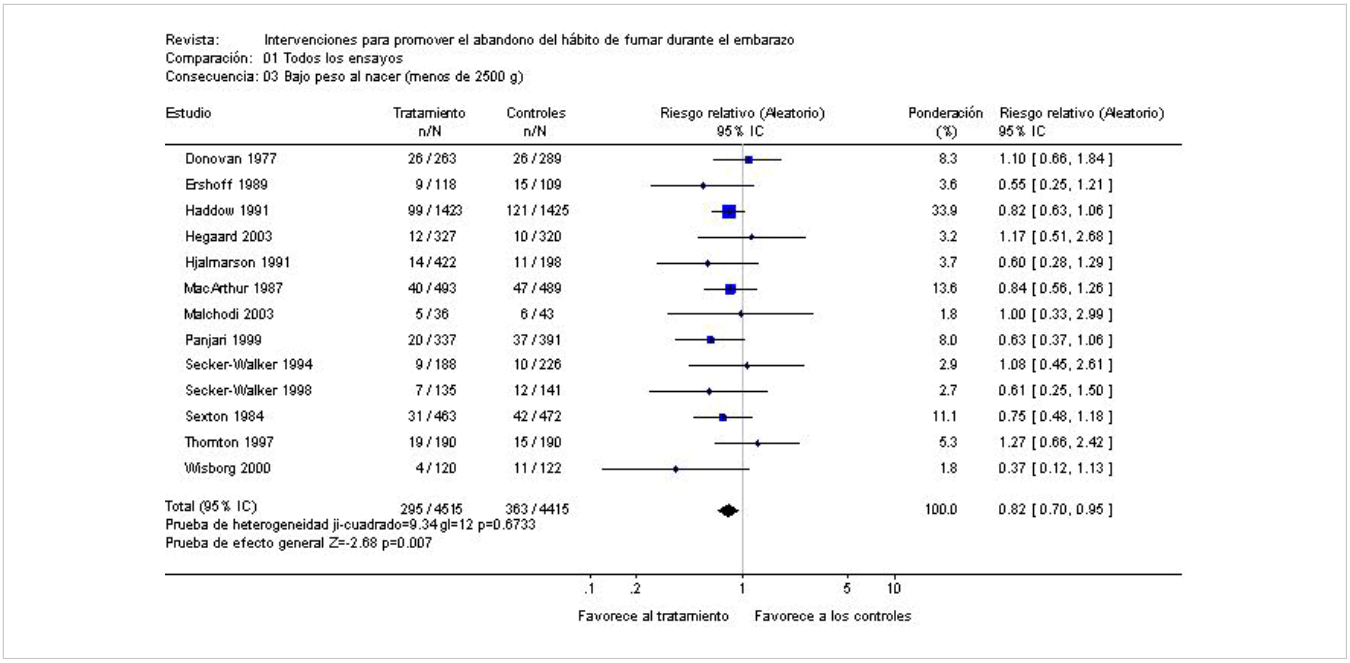
01.01 Mantuvieron el hábito de fumar al final del embarazo



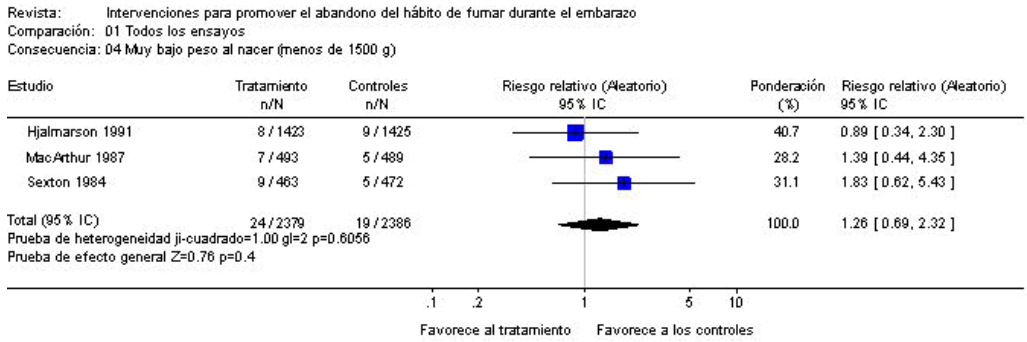
01.02 Media del peso al nacer



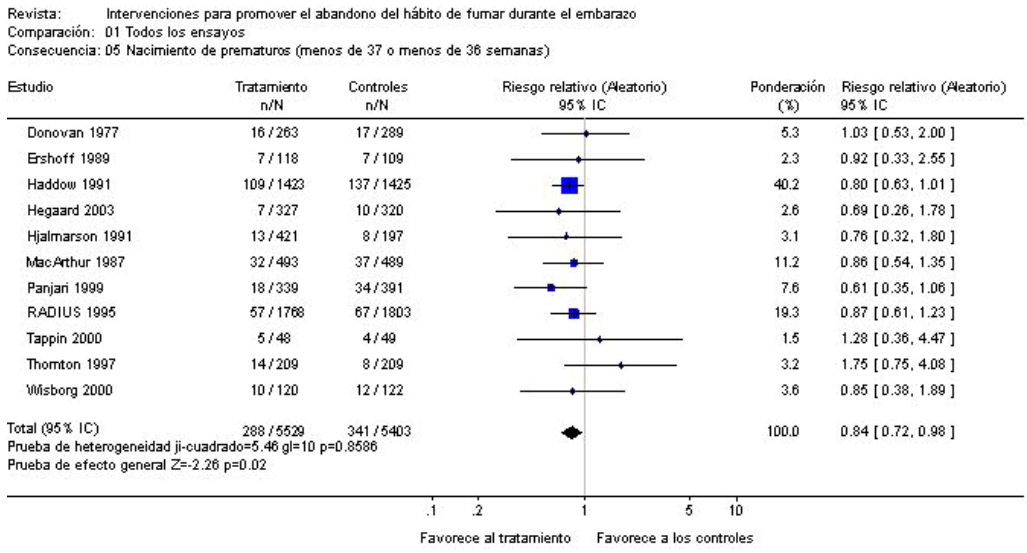
01.03 Bajo peso al nacer (menos de 2500 g)



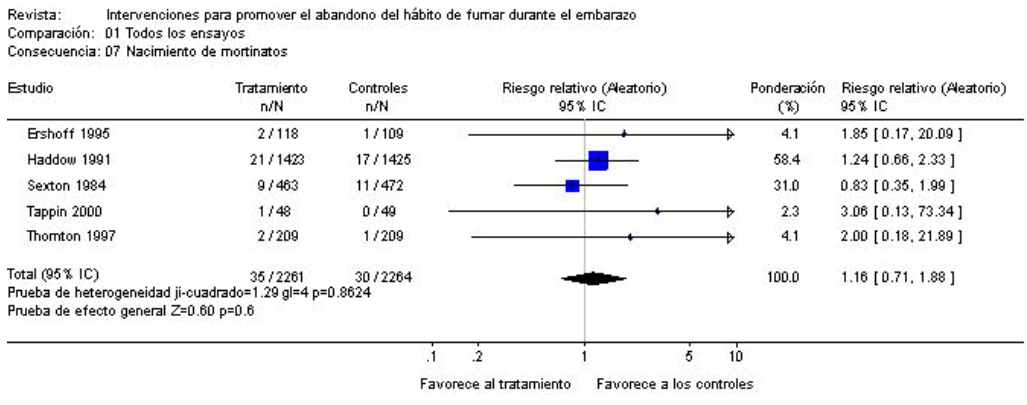
01.04 Muy bajo peso al nacer (menos de 1500 g)



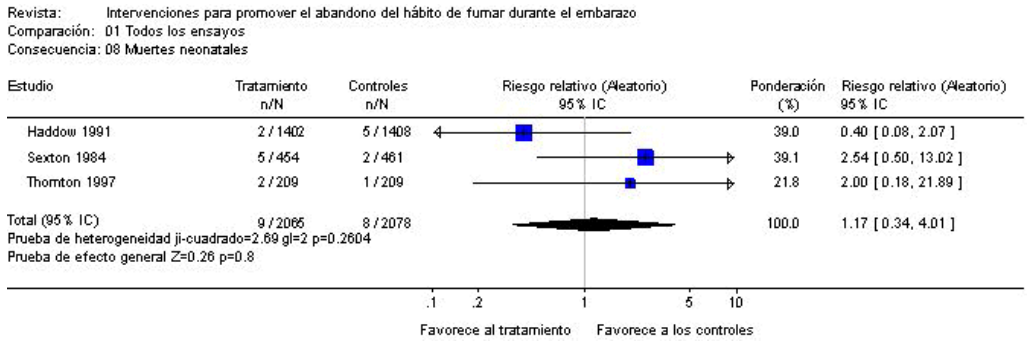
01.05 Nacimiento de prematuros (menos de 37 o menos de 36 semanas)



01.07 Nacimiento de mortinatos



01.08 Muertes neonatales



01.09 Muertes perinatales

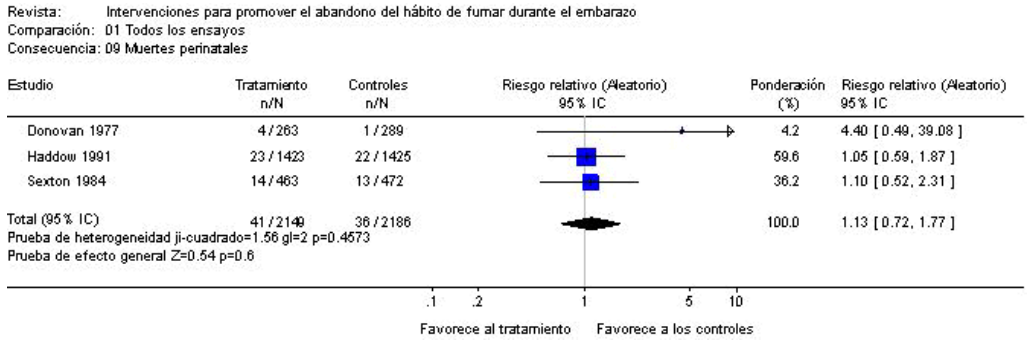


Fig. 02 Ensayos con abandono del hábito de fumar bioquímicamente validado

02.01 Mantuvieron el hábito de fumar al final del embarazo

Revista: Intervenciones para promover el abandono del hábito de fumar durante el embarazo
Comparación: 02 Ensayos con abandono del hábito de fumar bioquímicamente validado
Consecuencia: 01 Mantuvieron el hábito de fumar al final del embarazo

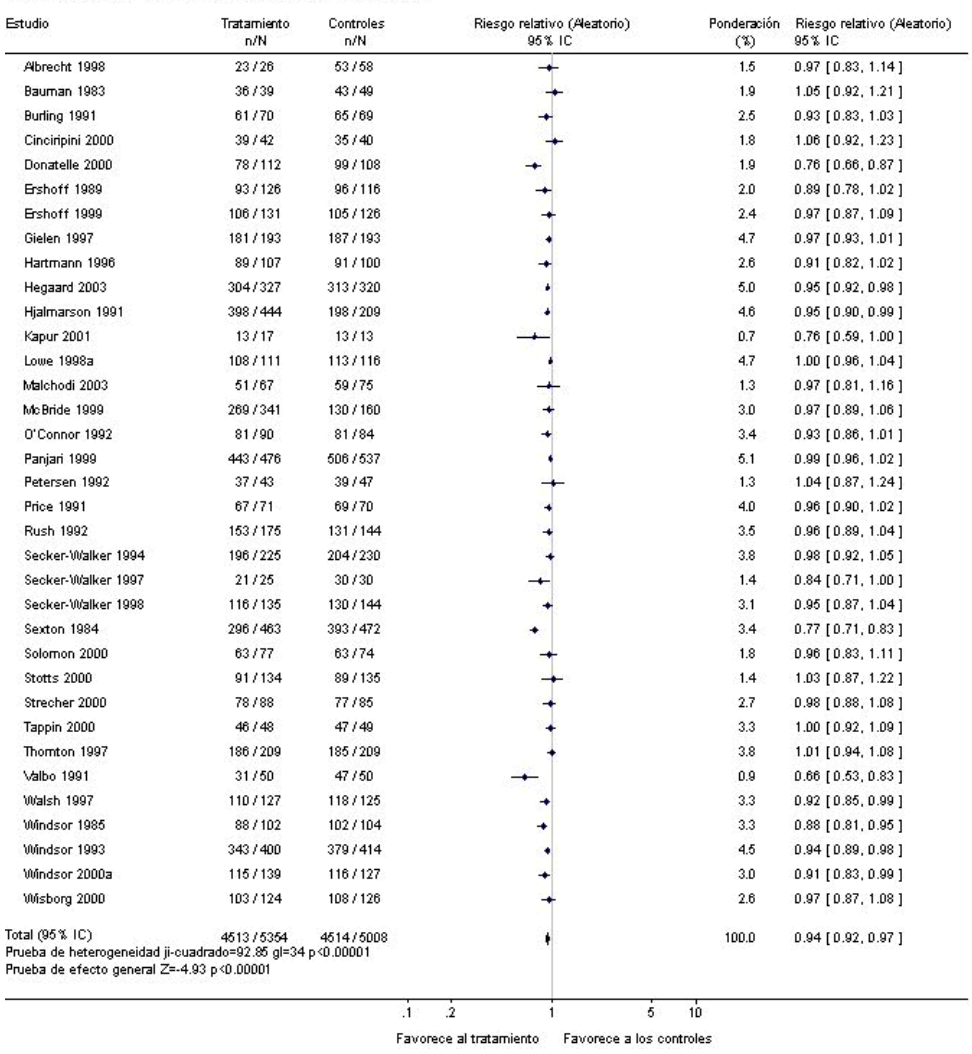


Fig. 03 Intervenciones con puntuaciones de alta calidad

03.01 Mantuvieron el hábito de fumar al final del embarazo

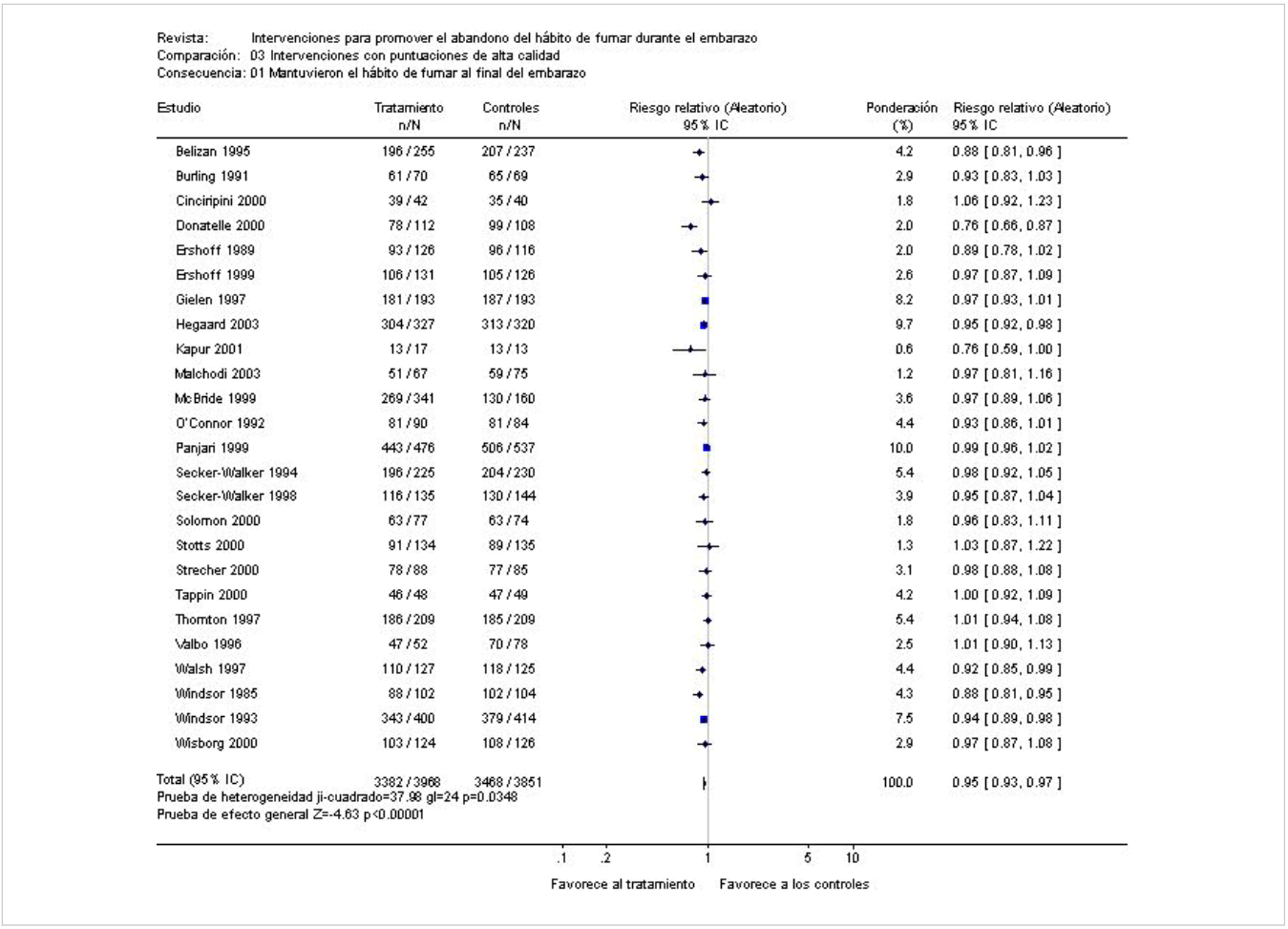


Fig. 04 Intervenciones de alta intensidad con puntuaciones de alta calidad y abandono del hábito de fumar bioquímicamente validado

04.01 Mantuvieron el hábito de fumar al final del embarazo

Revista: Intervenciones para promover el abandono del hábito de fumar durante el embarazo
Comparación: 04 Intervenciones de alta intensidad con puntuaciones de alta calidad y abandono del hábito de fumar bioquímicamente validado
Consecuencia: 01 Mantuvieron el hábito de fumar al final del embarazo

Estudio	Tratamiento n/N	Controles n/N	Riesgo relativo (Aleatorio) 95% IC	Ponderación (%)	Riesgo relativo (Aleatorio) 95% IC
Albrecht 1998	23 / 26	53 / 58		1.9	0.97 [0.83, 1.14]
Donatelle 2000	78 / 112	99 / 108		2.6	0.76 [0.66, 0.87]
Ershoff 1999	106 / 131	105 / 126		3.5	0.97 [0.87, 1.09]
Gielen 1997	181 / 193	187 / 193		13.7	0.97 [0.93, 1.01]
Hegaard 2003	304 / 327	313 / 320		17.4	0.95 [0.92, 0.98]
Kapur 2001	13 / 17	13 / 13		0.7	0.76 [0.59, 1.00]
Malchodi 2003	51 / 67	59 / 75		1.5	0.97 [0.81, 1.16]
McBride 1999	269 / 341	130 / 160		5.0	0.97 [0.89, 1.06]
Secker-Walker 1994	196 / 225	204 / 230		8.0	0.98 [0.92, 1.05]
Secker-Walker 1998	116 / 135	130 / 144		5.5	0.95 [0.87, 1.04]
Solomon 2000	63 / 77	63 / 74		2.3	0.96 [0.83, 1.11]
Stotts 2000	91 / 134	89 / 135		1.7	1.03 [0.87, 1.22]
Tappin 2000	46 / 48	47 / 49		6.0	1.00 [0.92, 1.09]
Thornton 1997	186 / 209	185 / 209		8.0	1.01 [0.94, 1.08]
Walsh 1997	110 / 127	118 / 125		6.2	0.92 [0.85, 0.99]
Windsor 1993	343 / 400	379 / 414		12.1	0.94 [0.89, 0.98]
Wisborg 2000	103 / 124	108 / 126		3.9	0.97 [0.87, 1.08]
Total (95% IC)	2279 / 2693	2282 / 2559		100.0	0.96 [0.93, 0.98]

Prueba de heterogeneidad ji-cuadrado=20.89 gl=16 p=0.1829
Prueba de efecto general Z=-3.86 p=0.0001

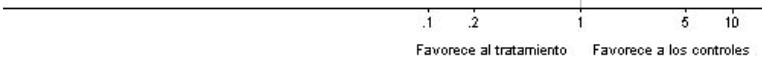


Fig. 05 Ensayos clasificados en subgrupos según la intensidad de la intervención

05.01 Mantuvieron el hábito de fumar al final del embarazo

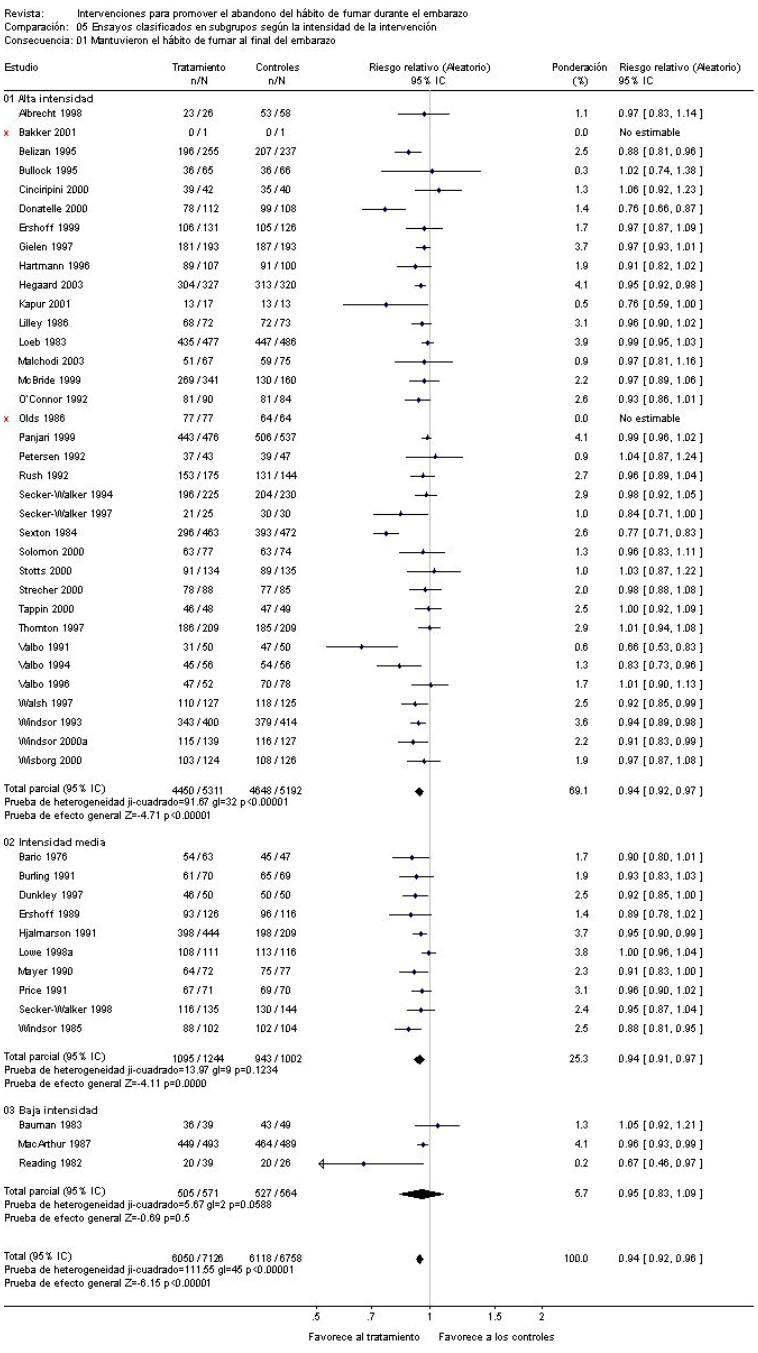


Fig. 06 Ensayos clasificados en subgrupos según la estrategia de la intervención

06.01 Mantuvieron el hábito de fumar al final del embarazo

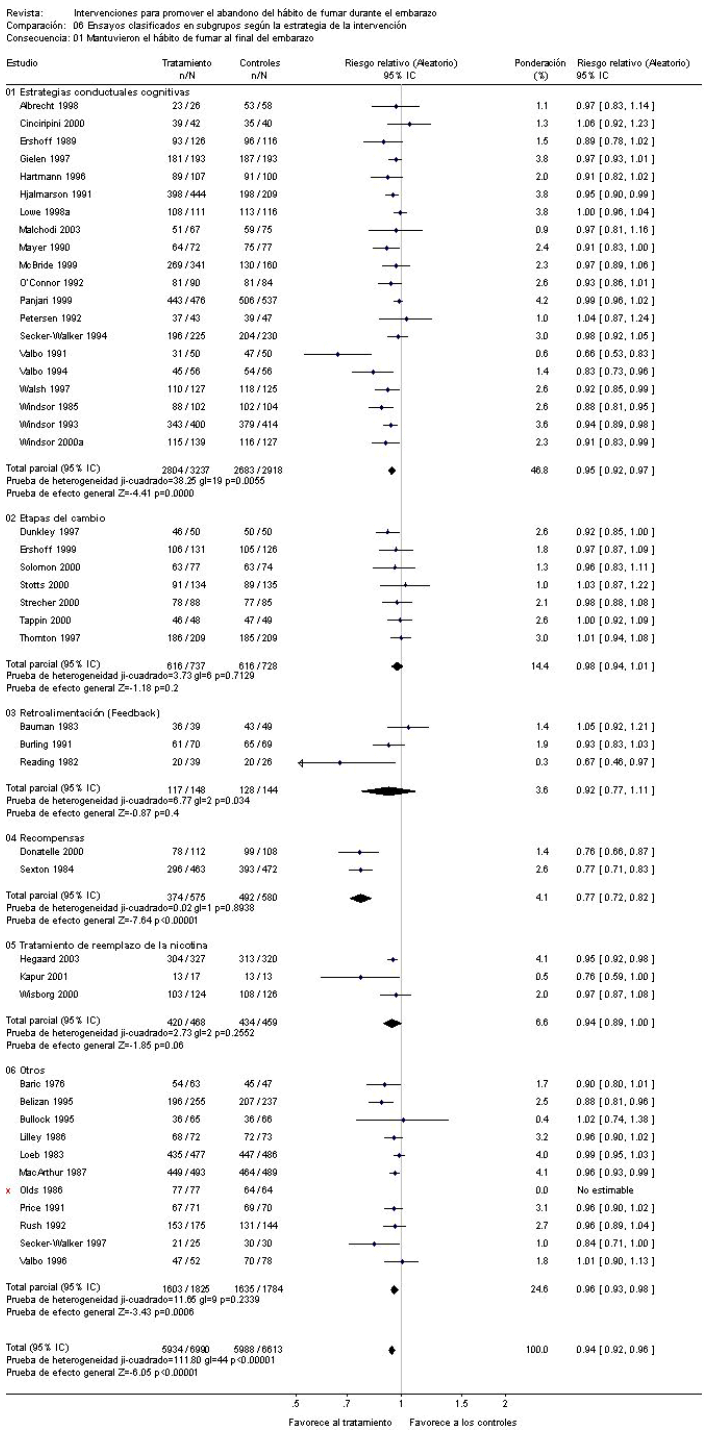


Fig. 07 Ensayos para prevenir la reincidencia en el hábito de fumar en las mujeres que dejaron de fumar al comienzo del embarazo

07.01 Hábito de fumar al final del embarazo