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Effect of digital health, biomarker feedback and nurse or midwife-led counselling interventions to assist pregnant smokers quit: a systematic review and meta-analysis

Chadi Tahan 1, Timothy Dobbins 1, Fran Hyslop 1, Raghu Lingam 2, Robyn Richmond 1

ABSTRACT

Objective To assess the effect of digital health (DH), biomarker feedback (BF) and nurse or midwife-led counselling (NoMC) interventions on abstinence in pregnant smokers during pregnancy and postpartum.

Settings Any healthcare setting servicing pregnant women, including any country globally.

Participants Pregnant women of any social, ethnic or geographical background who smoke.

Methods We searched Embase, Medline, Web Of Science, Google Scholar, PsychINFO, CINAHL and PubMed between 2007 and November 2021. We included published original intervention studies in English with comparators (usual care or placebo). Two independent assessors screened and abstracted data. We performed a random-effects meta-analysis, assessed risk of bias with the Cochrane Tool and used Grading of Recommendations Assessment, Development and Evaluation to assess the quality of evidence.

Results We identified 57 studies and included 54 in the meta-analysis. Sixteen studies assessed DH (n=3961), 6 BF (n=1643), 32 NoMC (n=60251), 1 assessed NoMC with BF (n=1120) and 2 NoMC with DH interventions (n=2107). DH interventions had moderate certainty evidence to achieve continuous abstinence (CA) at late pregnancy (4 studies; 2049 women; RR=1.98, 95% CI 1.08 to 3.64, p=0.03) and low certainty evidence to achieve point prevalence abstinence (PPA) postpartum (5 studies; 2238 women; RR=1.46, 95% CI 1.05 to 2.02, p=0.02). NoMC interventions had moderate certainty evidence to achieve PPA in late pregnancy (15 studies; 16 234 women; RR=1.54, 95% CI 1.16 to 2.06, p=0.01) and low certainty evidence to achieve PPA postpartum (13 studies; 5466 women; RR=1.79, 95% CI 1.14 to 2.83, p=0.01). Both DH and BF interventions did not achieve PPA at late pregnancy, nor NoMC interventions achieve CA postpartum. The certainty was reduced due to risk of bias, heterogeneity, inconsistency and/or imprecision.

Conclusion NoMC interventions can assist pregnant smokers achieve PPA and DH interventions achieve CA in late pregnancy. These interventions may achieve other outcomes.

INTRODUCTION

Tobacco smoking in pregnancy has been associated with multiple adverse health outcomes for both the mother and baby.1–4 While it is one of the few modifiable risk factors, smoking in pregnancy remains prevalent1 5 and disproportionately affects women from priority populations.5–6 Quitting, preferably early in pregnancy, rather than reduction in smoking, has consistently produced better perinatal and child-related long-term health outcomes.3–7 Preventive action produces significant cost savings.1 2 8 Therefore, determining effective interventions to support women to quit smoking and reduce the risk of adverse birth outcomes must be a public health priority.9–9

In addition to population-level strategies, such as taxation and smoking bans, a range of individual-level interventions has been evaluated and shown to be clinically effective
among pregnant smokers. Psychological interventions, include counselling, are the preferred first-line strategies for this cohort. These interventions can be delivered by a range of professionals, via a variety of channels, of various intensities, and may involve a combination of strategies. Behavioural support such as self-help material, feedback and financial incentives can improve the abstinence rate of pregnant smokers by 11%–15% and may lead to reduced preterm birth and low birth weight. Biomarker feedback (BF) aims to increase a mother’s motivation to quit by providing an objective measure of the by-products of tobacco smoking, such as breath carbon monoxide (CO), urine, saliva or serum cotinine. Financial incentives contingent on abstinence, when combined with behavioural therapy, are effective for this population. None of these interventions is associated with adverse fetal outcomes. Nicotine replacement therapy is less effective, and nicotine is potentially harmful to the fetus with evidence around its safety or perinatal outcome benefits remain unclear. Other smoking cessation interventions in pregnancy include digital health (DH). Recently, due to their ubiquitous nature and potential to improve access by overcoming space and time barriers, newer digital channels such as mobile telephone and social media have become more prominent and are used in healthcare. In their 2018 review, Griffiths et al concluded that the evidence favours DH interventions for smoking cessation in pregnancy, particularly those that are text message and computer based. Researchers have combined several types of interventions, including DH, to explore potential synergies. However, the effect for each type of interventions on smoking cessation in pregnancy remains less well defined.

The aim of this review is to estimate the effect of three specific types of interventions, individually, on smoking abstinence of pregnant women. These interventions, which may be combined in a perinatal service setting, comprise nurse or midwife-led counselling (NoMC), BF and/or DH interventions.

METHOD
The study followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines for systematic review and meta-analyses and used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to assess the certainty of evidence.

Data sources
We searched Embase, Medline, Medline IP, Web of Science, Google Scholar, PsychINFO and CINAHL between 2007 and September 2019. The search was further updated to November 2021 using PubMed. An academic librarian assisted with the database searches, and the strategies for each database are attached in online supplemental file 1.

Eligibility criteria
We included published original quantitative efficacy studies (ie, randomised, quasi-experimental evaluation, real-life and prospective intervention trials) involving pregnant smokers, a comparator arm, the intervention(s) of interest, at least one abstinence outcome (Population, Interventions, Comparators and Outcome—PICO inclusion criteria) and were available in full text and English language. We identified additional studies through hand searches of references from search results and contacted authors of studies where full text were not available. The study cohort included smokers older than 16 years at any stage of pregnancy or recent quitters for the purpose of becoming pregnant.

Studies were included if the involved counselling, advice, coaching, home visitation or other psychological interventions that were delivered by nurses or midwives. DH interventions were defined as those that could be delivered by a handheld device or a computer; including mobile telephone text messaging, email, other messaging applications, social media, smoking cessation applications, YouTube videos, DVD, electronic voice programmes, online websites or any other intervention that can be delivered by a handheld device or a digital device. BF interventions, which aimed to motivate rather than validate smoking status during pregnancy were also included.

Pregnant adolescent only studies, studies that did not quantify effect of intervention on pregnant smokers, post hoc analysis of original studies, feasibility, acceptability and development of interventions only, and studies with no comparator, no full text or non-English were excluded. A full list of inclusion and exclusion criteria can be found in online supplemental file 1.

Data management and study selection
Data were stored and managed in EndNote software. Results from different databases were grouped by the type of intervention, and duplicates removed. One author (CT) initially reviewed and screened all titles and abstracts. Another author (FH) performed a validation screening and reviewed a select sample of these results to measure the inter-rater reliability for the screening step. A kappa value of 0.91 indicated a strong agreement between the reviewers. Any disagreements involved discussions between the reviewers until agreement was achieved.

Data extraction
The second stage involved a full text appraisal of the selected articles for each intervention and the extraction of data from the articles that met the PICO inclusion criteria (online supplemental file 1).

We included self-reported and biochemically validated, point prevalence abstinence (PPA) for 7 days, 14 days, 4 weeks, other time periods as well as continuous abstinence (CA) of various time periods. In case of multiple results,
biochemically validated results were preferred over self-report, intent-to-treat results (ie, including those lost to follow-up) over sensitivity analysis and raw/unadjusted ORs over adjusted ORs. We included all follow-up results, including those postpartum. Additionally, for NoMC intervention, we recorded the types of professionals delivering the intervention.

The data extraction was validated by having a second reviewer (FH) independently extract data from a representative sample of included studies for all interventions, and a comparison between the two reviewers indicated good agreement. Any uncertainties around the article selection and data extraction were discussed with a third author (RR) who reviewed them.

Risk of bias assessment and certainty of evidence
To assess the risk of bias (RoB) in studies for each of the interventions, one reviewer (CT) used the Cochrane RoB Tool (V.2.0 August 2019). For studies where information was not explicitly provided in the publication or could not be implicitly concluded to a high degree of confidence from the study design, ‘some concerns’ or ‘high risk’ ratings were applied. This was particularly the case for non-RCT studies such as quasi-experimental, real-life controlled and prospective intervention studies.

We used the GRADE tool to assess the overall certainty of the evidence taking into account (and downgrading for) risk of bias of studies, inconsistency, indirectness, imprecision and publication bias. The certainty of evidence ranges from:

- High (we are very confident that the true effect lies close to that of the estimate).
- Moderate (we are moderately confident in the effect estimate and the true effect is likely to be close to the estimate, but there is a possibility that it is substantially different).
- Low (our confidence in the effect estimate is limited and the true effect may be substantially different from the estimate), to
- Very low (we have very little confidence in the effect estimate and the true effect is likely to be substantially different from the estimate).

Data analysis
Unadjusted ORs were used where available. For studies that reported only adjusted ORs, HRs, relative risks or proportions, the effect sizes were transformed into relative effect sizes and included in the analysis. A meta-analysis was conducted to estimate the overall effect size for each type of intervention.

We used R software along with specific meta-analytic packages (meta, metafor, devtools, dplyr and dmetar) to perform the analysis. A random effect model was used to estimate the effect with 95% CI and a significance level of 5%. We assessed statistical heterogeneity using the I² statistic and produced forest plots for each outcome measure for each of the interventions where applicable (ie, where two or more similar results could be pooled). We considered statistical heterogeneity of 40%–60% to be moderate and more than 60% to be substantial.

We used a contour-enhanced funnel plot, Duval and Tweedie trim and fill method, and the P-curve test to assess potential publication bias. Additionally, we included a summary of the narrative synthesis to provide context for the interventions in conjunction with the meta-analysis results.

Participants and public involvement
No participants were involved in the design or conduct of the study, development of participants relevant outcomes, interpretation of the results or writing or editing of the manuscript.

For each intervention type, a number of outcome measures (determined to be clinically relevant) were assessed for various combination of intervention subtypes and comparators and reported in a summary of findings table.

RESULTS
Results of the search
As shown in figure 1, a total 11 637 articles were identified through the bibliographic databases in the initial as well as the follow-up search (up to November 2021). A total of 4163 articles underwent title and abstract screening, and 298 articles underwent full-text screening, resulting in inclusion of 57 articles in the review and 54 in the meta-analysis. The numbers of articles identified, screened and subsequently included from each database for the specific interventions, as well as the characteristics of the selected studies, are shown in online supplemental file 1.

Description of included studies
This review included a total of 57 studies (16 studies had DH (n=3961), 6 had BF (n=1643) and 32 on nurse or midwife-led counselling interventions (n=60251). One study included both nurse counselling with BF and DH (n=1120) and 2 had a DH with nurse counselling (n=2107).

The review includes a total of 41 randomised controlled trials (RCTs), out of which 4 were clustered RCTs. Additionally, there were nine quasi-experimental evaluation trials, three prospective intervention studies (including one randomised open label), and three were real-life controlled trials/projects. Most of the studies were conducted in the USA (25), followed by the UK (11) and the rest of Europe (12). Two studies were conducted in Australia and Canada each, and one each in Argentina, South Africa, Turkey and New Zealand. The studies were published between 1982 and 2021 and a summary of information is available in online supplemental file 1.

Interventions
Digital health (DH)
This review encompasses a total of 19 studies, including four mobile telephone application studies: SmokeBeat (a
smoking monitoring app), DynamiCare (a reward app), SmokeFree (a behavioural change-based app) and Tobbstop (a gaming app).80–83 Additionally, 8 studies evaluated text messaging programmes that provided abstaining information, support and reminders: Scheduled Gradual Reduction or support with trans-theoretical model (TTM) psychological type support,84–86 SMS programme with usual care,87 88 Quit4baby89 and MiQuit.88 90 91 Two website-based programmes were included: Motiv8, which combined a contingency management component9 92 and MumsQuit, an automated and tailored cessation platform.93 Two studies assessed delivering clinical assessment and behaviour change through computer-based programmes: ask, advise, assess, assist and arrange or 5A94 and TTM.78 One study included a Commit to quit video,95 and another an automated Interactive Voice Recording.95

**Biomarker feedback (BF)**

Two studies evaluated the effect of providing smoking explanations to pregnant mothers along with urine cotinine measurements.9 96 Additionally, two studies measured the impact of breath CO feedback along with an explanation of the effect on mother and child,97 98 and another two studies evaluated this effect when combined with self-help support and counselling.97 99 All of these interventions were provided during antenatal visits.
Nurse or midwife-led counselling (NoMC)

Fourteen studies involved face-to-face counselling intervention by nurses, midwives and/or other professionals. The interventions ranged from brief to intensive and included multi-sessions, follow-up with or without incentives, self-help material, partner counselling, behavioural intervention strategies, educational material and support, BF as motivator or DH.

Another common NoMC intervention was part of a pregnant mother’s antenatal home visiting programme. Such programmes often involved other components, such as the provision of self-help material and education. Five studies assessed the impact of this type of counselling.

Five studies measured the effect of the 5A-based brief counselling when delivered by nurses or midwives, or with other professionals. The 5A counselling was either intensive or part of interventions that also included reminders, DH, educational and self-help material or telephone follow-up.

Four studies evaluated the effect of the TTM-based counselling by nurses, midwives and/or other professionals. Three studies assessed cognitive behavioural therapy (CBT) based counselling. Only one study involving a nurse or midwife using motivational interviewing-type counselling was included in this review.

Twenty one of the 35 counselling intervention studies involved nurses or midwives as the sole provider of the intervention. The counselling interventions ranged from 3 min to 2.5 years in duration.

Comparators

DH studies: comparators for DH interventions varied across studies, including usual care or brief advice, DH as attention control, self-help materials and an active comparator of telephone counselling.

BF studies: comparators included usual care, information on effect of biomarker only and an active comparator of 5A-based counselling.

NoMC studies: comparators mostly involved usual care alone or with additional components. Ten studies did not specify the type of usual care used, nine provided a leaflet with usual care, seven used a pamphlet or other material, four used brief advice, but three did not specify if this was part of usual care. One study provided a smoking cessation seminar in addition to usual care, and two used no participation or no counselling as comparators.

Participants

The total number of participants across all studies involving DH intervention was 6070. The total number of participants included in all BF interventions was 2763, of whom at least 1520 were smokers. Furthermore, a total of 63,478 pregnant women were recruited in all included studies measuring NoMC, among whom 55,423 were smokers. For BF and NoMC intervention studies, only pregnant smokers were considered for analysis in this review.

Outcomes

Fifteen studies that measured the effect of DH interventions included self-reported abstinence or 7-day PPA. Five studies reported CA of various durations from 2 weeks to 140 days after starting the intervention. Outcomes in all but one study of the studies (14/16) were biochemically validated.

In BF intervention studies, reported abstinence outcomes varied, with 3 studies using self-reported abstinence, 1 study as 7-day PPA, and 1 study using biochemical validation such as measuring breath CO levels below 9 ppm.

Similar to the other interventions, most studies (17) assessing NoMC interventions reported self-reported abstinence, followed by 7-day PPA (8 studies) and CA (7 studies). Two studies reported biochemically validated PPA and 1 reported 30-day PPA. Only five out of the 35 studies reported on outcomes with no biochemical validation.

Quality assessment

Risk of bias of included studies

A summary of the risk of bias assessment for DH, BF and NoMC interventions using the RoB V.2.0 tool is included in online supplemental file 2.

Regarding DH interventions, four studies had a low risk of bias, five had some concerns and nine were at high risk. High risk studies were rated mainly due to lack of intention to treat (ITT) analysis, potential missing outcomes, selective reporting and deviation from original intervention or lack of prespecified analysis.

The use of self-reported abstinence without biochemical confirmation, which could potentially exaggerate the results, was also considered a source for high risk of bias. Bias concerns were mainly related to randomisation, binding and allocation concealment, including when measuring outcome by assessors.

Two of the six included studies for BF interventions were considered at low risk of bias, and four were considered at high risk. The use of self-reported abstinence outcome without biochemical validation, selective reporting of results, lack of ITT analysis and missing outcome data was the reason for high risk of bias.

Similarly, of the 35 studies included for NoMC intervention, only 8 were considered at low risk of bias in all fields. Nine studies had some concerns regarding one or more fields, including randomisation, allocation and allocation concealment, and application of ITT analysis or selective reporting. Eighteen studies were considered at high risk of bias, five due to non-validated self-reported abstinence and five had at least three fields considered at high risk.

As shown in table 1, pooled analyses show a statistically significant association between DH interventions and PPA in late pregnancy, the results from the Dynamicare mobile application study actually showed an increase in PPA (OR=3.76, 95% CI=1.04 to 13.65). Additionally, some individual studies such as the TTM behaviour intervention with computer programme study and two MiQuit text message studies did not show a statistically significant increase in CA in late pregnancy.

The Quit4Baby text message intervention study by Abroms et al demonstrated an increase in 7-day PPA (RR=1.35, 95% CI=1.14 to 1.61) and 30-day PPA (RR=1.27, 95% CI=1.06 to 1.52) in late pregnancy, although the significance levels were not reported. However, the Quit4baby text message study, the scheduled gradual reduction text message programme study by Pollack et al and the 5A with Commit to Quit video study by Windsor et al in 2011 did not show significant association between DH and PPA in the postpartum period.
The TTM behaviour intervention with computer programme study had reported and showed no statistically significant increase in CA postpartum (OR=2.72, 95% CI 0.73 to 10.17).78

The P-curve test for publication bias of DH interventions indicated that there were not enough studies available to determine if p-hacking or publication bias were pronounced (online supplemental file 2).

BF interventions

The pooled analyses of all 4 included studies did not show a significant association between BF interventions and PPA in late pregnancy (RR=1.32, 95% CI 0.75 to 2.32, p=0.34, 4 studies) (figure 5) nor between BF interventions and CA in the postpartum period (RR=1.05, 95% CI 0.84 to 1.30, p=0.66, 1 study) (figure 6). Insufficient data were available to pool effect estimates for PPA postpartum or CA in late pregnancy.

One study by Patten et al showed no difference in PPA when comparing urine cotinine as feedback to pregnant mothers with 5As counselling.96 Another study showed that breath CO did not increase the abstinence rate in late pregnancy when compared with one on one counselling alone (RR=1.01, 95% CI 0.94 to 1.09, p=0.803).99 However, Cope et al reported a higher rate of abstinence in the urine cotinine as feedback group to the usual care and anti-smoking counselling group, although significance levels were not reported.9

A study compared breath CO (combined with self-help material and brief counselling) with anti-smoking counselling and leaflet as usual care, showing a higher PPA rate in late pregnancy (OR=6.11, p<0.05), and a higher CA rate at 3 months postpartum (58% vs 50%) but not at 6 months postpartum (23% vs 25%).135 Two other BF studies not included in the pooled analyses due to uncertainty around the timing in outcome measures demonstrated an increase in abstinence in the breath CO group when compared with the control group.97 98

The P-curve test for publication bias of BF intervention studies indicated that publication bias and p-hacking for this type of interventions may be less pronounced and a true value is more likely. Full results can be found in online supplemental file 2.

NoMC interventions

In the pooled analyses, there was a statistically significant association between NoMC interventions and PPA in late pregnancy (RR=1.54, 95% CI 1.16 to 2.06, p<0.01, 15 studies) (figure 7) and in the postpartum period (RR=1.79, 95% CI 1.14 to 2.83, p=0.01, 13 studies) (figure 8). The statistical heterogeneity was considerate for PPA in late pregnancy outcome (I^2=61%) and moderate for the post-partum period outcome (I^2=40%). However, the pooled analyses did not demonstrate an association between NoMC interventions and CA (RR=2.06, 95% CI 0.90 to 4.71, p=0.09, 1 study) (figure 9) in late pregnancy or...
postpartum (RR=1.43, 95% CI 0.84 to 2.45, p=0.19, 6 studies) (Figure 10).

In most NoMC interventions, a higher intensity, frequency, attendance and number of components in the intervention programme appear to be associated with an increase in abstinence at all time points. This trend was apparent in face-to-face,101–106 109–111 122 5As,79 117 119 120 136 TTM78 121–123  and CBT124–126  interventions but not in nurse home visiting programme.112–116  None of the five included nurse visiting programme studies could demonstrate a significant association between nurse counselling and abstinence, regardless of the duration or intensity.112–116

Most CBT and TTM-based NoMC interventions showed an increases in PPA in late pregnancy and postpartum, supporting the pooled estimate.77 100 104 105 109 and during postpartum.101 104 However, unlike the pooled estimates, some TTM-based studies have also reported increases in CA at various postpartum periods.121–126  As for 5A-based NoMC interventions, two out of five studies reported increases in PPA at postpartum79 119  and one at follow-up,120  respectively, in line with the pooled estimate. However, both Loukopoulou et al and Althabe et al did not find a significant association between this type of intervention and PPA in late pregnancy117 and postpartum,136 respectively.

Compared with other types of NoMC interventions, the face-to-face type had the most varied intervention components and outcomes. Several face-to-face NoMC studies reported outcomes in support of the pooled estimate, with a significant association with PPA in late pregnancy77 100 104 105 109 and during postpartum.101 104 However, unlike the pooled estimates, other outcomes from these studies as well as other studies could not report a significant association with PPA in late pregnancy161 110 111 113 nor during the postpartum period.166 Furthermore, Hajek

<table>
<thead>
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<th>Study</th>
<th>Experimental Events</th>
<th>Control Events</th>
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<th>RR</th>
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<td>Naughton 2017</td>
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<td>[0.82; 2.94]</td>
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<td>Balmumcu &amp; Unsal Atan 2021</td>
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<tr>
<td>Prediction interval</td>
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<tr>
<td>Heterogeneity: $I^2 = 0%$, $\tau^2 = 0.0160$, $p = 0.62$</td>
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| intervention_subtype = web based program | 1 7 3 10 | | 0.48 | [0.06; 3.69] | 4.7% |
| Harris & Reynolds 2015        | 7 10   | | 0.48 | [0.06; 3.69] | 4.7% |
| Prediction interval           | -        | -              | -          | -    | -      | --     |
| Heterogeneity: not applicable | | | |

| intervention_subtype = desktop program | 18 324 5 289 | | 3.21 | [1.21; 8.54] | 12.6% |
| Lawrence 2003                  | 324 289   | | 3.21 | [1.21; 8.54] | 12.6% |
| Prediction interval            | -        | -              | -          | -    | -      | --     |
| Heterogeneity: not applicable  | | | |

| intervention_subtype = computerised voice message | 22 133 58 257 | | 0.73 | [0.47; 1.14] | 21.1% |
| Ershoff 1999                    | 133 257   | | 0.73 | [0.47; 1.14] | 21.1% |
| Prediction interval             | -        | -              | -          | -    | -      | --     |
| Heterogeneity: not applicable   | | | |

| intervention_subtype = smartphone app | 11 31 4 30 | | 2.66 | [0.95; 7.44] | 12.0% |
| Kurti 2020                       | 31 30    | | 2.66 | [0.95; 7.44] | 12.0% |
| Prediction interval              | -        | -              | -          | -    | -      | --     |
| Heterogeneity: not applicable    | | | |

| Random effects model 881 977 |  |  | 1.39 | [0.85; 2.26] | 100.0% |
| Prediction interval         |         | | | [0.34; 5.72] | |

Figure 3  Effect size of biochemically validated digital health interventions to assist pregnant smokers achieve point prevalence abstinence* in late pregnancy. *include point prevalence abstinence of various points in time but not continuous abstinence.
et al and De Vries et al reported a significant association with CA in late pregnancy and during the postpartum period, respectively.

The P-curve test results for publication bias of NoMC intervention studies indicated that publication bias and p-hacking for this type of intervention may be less pronounced and a true value is more likely. These results can be found in online supplemental file 2.

Table 2 presents the overall statistical heterogeneity (I²) for each type of intervention. The results suggest low heterogeneity between studies for DH type interventions, but substantial heterogeneity between studies for BF and NoMC type interventions.

Certainty of evidence
The GRADE summary of findings tables (tables 3–5) show that the confidence in evidence ranged between very low to moderate depending on type of outcome, intervention and timepoint for that intervention.

DISCUSSION
This review evaluates the impact of three types of interventions on smoking abstinence among pregnant smokers at clinically relevant timepoints. The evidence indicates that NoMC interventions had moderate certainty evidence to increase pregnant smokers achieve PPA by 54% (95% CI 16% to 206%, p<0.01) in late pregnancy compared with usual care. However, there is low certainty evidence that NoMC interventions increase PPA among pregnant smokers by 79% (95% CI 14% to 283%, p=0.01) during the postpartum period. NoMC interventions did not assist pregnant smokers in achieving CA in late pregnancy (206% (95% CI −10% to 471%, p=0.09)) or during postpartum (43% (95%CI −16% to 245%, p=0.19)).

The results of this review show that DH interventions did not increase PPA among pregnant smokers in late pregnancy (37% (95% CI −10% to 207%, p=0.14) but had low certainty evidence to increase PPA by 46% (95% CI 5% to 202%, p=0.02) during the postpartum period. DH interventions had moderate certainty evidence to increase CA by 98% (95% CI 8% to 364%, p=0.03) in late pregnancy. On the other hand, BF interventions did not increase PPA among pregnant smokers in late pregnancy (32% (95% CI −25% to 232%, p=0.34)) nor CA during postpartum (5% (95%CI −16% to 30%, p=0.66)).

This review did not analyse the effect estimates of specific subtypes of intervention but instead pooled the effect estimates of overall intervention types, limiting the ability to distinguish between the different subtypes. However, for DH type interventions, short text message, computer and mobile application programmes that include contingency management (ie, financial reward for abstinence), 5As-based counselling, TTM-based counselling or gamified type behavioural interventions appeared to be more effective for promoting abstinence compared with usual care or information-only comparators. These findings
are consistent with previous research, including a review by Griffiths et al which found that digital interventions, particularly text message and computer-based interventions, were effective. Contingency management has also been shown to improve abstinence in pregnant smokers, as demonstrated in a review by Wilson et al. This review also highlights the continued effectiveness of behavioural interventions when delivered or communicated digitally.

The evidence around some outcome measures for DH interventions in this review is low or very low which is in line with findings from a review by Hussain et al on mobile phone-based interventions. This review more specifically indicates that DH interventions have an overall limited evidence they assist pregnant smokers quit. As the field of DH continues to evolve, further evaluation of such interventions is recommended (similar conclusion reached by Iyawa et al). Challenges related to DH,
Figure 7  Effect size of biochemically validated nurse or midwife-led counselling interventions to assist pregnant smokers achieve point prevalence abstinence* in late pregnancy. *include point prevalence abstinence of various points in time but not continuous abstinence.
such as fidelity, and a relatively new mode of intervention delivery need to be further explored and overcome.

The review found that BF interventions may improve abstinence when combined to other interventions but there was low evidence it could achieve abstinence on its own. Qualitative evidence (eg, by Koller et al) also suggests that BF may be less helpful in motivating postpartum women to quit but might inspire them to cut back or quit. However, there was limited or insufficient evidence for most outcomes related to BF in this review.

NoMC interventions had the highest number of studies and data compared with DH or BF, and the evidence

**Figure 8** Effect size of biochemically validated nurse or midwife-led counselling interventions to assist pregnant smokers achieve point prevalence abstinence* at postpartum. *Include point prevalence abstinence of various points in time but not continuous abstinence.

**Figure 9** Effect size of biochemically validated nurse or midwife-led counselling interventions to assist pregnant smokers achieve continuous abstinence in late pregnancy.
suggests they are effective in increasing abstinence rates of pregnant smokers. This is consistent with the Chamberlain Cochrane review15 which found that psychological interventions including counselling, had moderate to high-quality evidence to assist pregnant smokers quit. Other reviews have also confirmed the benefit of counseling by trained professionals, which may include nurses or midwives, in pregnant smokers2 21 140 and the general population.14

The narrative review of the results suggests that NoMC interventions, such as face-to-face, the 5As, TTM and CBT-based counselling, are more effective in achieving abstinence compared with nurse home visitation programmes or motivational interviewing. The effectiveness of counselling is observed to increase with increased frequency (eg, those who attend more sessions of counseling are more likely to achieve abstinence) and are more effective when added to other components such as self-help or information material, peer counselling, further support or other types of intervention such as DH or BF. The increased effect of counselling due to higher intensity was also demonstrated by the Chamberlain Cochrane review and Siddiqui et al.14 15 Furthermore, two studies have shown that a multi-component intervention approach to assist pregnant smokers quit is effective, feasible and acceptable.24 141 Self-help and social support are also effective behavioural change techniques to improve abstinence rates, as demonstrated by two reviews.140 142

Table 2 Quantitative estimate of overall statistical heterogeneity for all outcomes by intervention type

<table>
<thead>
<tr>
<th>Intervention type</th>
<th>Q-value</th>
<th>Df (Q)</th>
<th>P value</th>
<th>$\hat{\tau}^2$</th>
<th>95% CI ($\hat{\tau}^2$)%</th>
<th>$\hat{I}^2$ %</th>
<th>95% CI ($\hat{I}^2$)%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Digital health intervention</td>
<td>62.26</td>
<td>41</td>
<td>0.0177</td>
<td>0.22</td>
<td>0.003 to 3.321</td>
<td>34</td>
<td>3.8 to 54.9</td>
</tr>
<tr>
<td>Biomarker feedback Intervention</td>
<td>23.48</td>
<td>9</td>
<td>0.0052</td>
<td>0.56</td>
<td>0.013 to 2.613</td>
<td>62</td>
<td>23.7 to 80.7</td>
</tr>
<tr>
<td>Nurse or midwife-led counselling intervention</td>
<td>268.29</td>
<td>85</td>
<td>&lt;0.0001</td>
<td>0.99</td>
<td>0.242 to 0.825</td>
<td>68</td>
<td>60.5 to 74.6</td>
</tr>
</tbody>
</table>
Brown et al concluded that counselling in combination with behavioural change techniques have demonstrated effectiveness on quitting during the postpartum period. In comparison, the meta-analysis in our review provides only low-quality evidence for NoMC interventions on various abstinence types (ie, PPA or CA) during postpartum. Furthermore, the Patnode Cochrane review found that behavioural interventions (which include clinician advice) were associated with greater abstinence during late pregnancy (RR=1.35). However, the meta-analysis in this review only assessed counselling (by nurses or midwives) as interventions to stop smoking and moderate level evidence was established for the effect on PPA in late pregnancy.

To improve the confidence in the pooled estimate, we applied stringent inclusion criteria to the study selection process. This systematic review included only RCTs or quasi-randomised studies and excluded studies without a comparator. For the meta-analysis, we included measures of abstinence that were biochemically verified, which may have excluded other self-reported measures and limited the amount of data used to estimate the overall effects. In addition, rigorous and consistent evaluation of risk of bias and application of the GRADE assessment across all three intervention types (DH, BF and NoMC) allowed for a comparative approach to evaluating the confidence in the evidence and ensured conservative findings. Where ambiguity existed, we downgraded the quality of the evidence.
In addition to estimating the effect of the three types of interventions on point prevalence and CA, this review determines the quality of evidence associated with each type at clinically relevant timepoints for the two abstinence types. The review demonstrates that based on available evidence, while NoMC interventions assist pregnant smokers achieve PPA during pregnancy and postpartum, these interventions do not assist with CA at any timepoint. Also, this review showed that DH interventions increase PPA during postpartum and CA in late pregnancy. Furthermore, BF interventions alone do not assist pregnant smokers achieve any type of abstinence at any relevant timepoint.

**Limitations**

Due to the range of interventions, abstinence and time points for measuring outcomes, the meta-analysis in our review was deliberately not specific but rather focused on utility for practice, policy and further research. Consequently, this review did not focus on outcomes for specific subtypes of the three major types of interventions (DH, BF and NoMC) and did not report on pooled effect estimates for discrete points in time (eg, late pregnancy, at delivery, 3 months postpartum and 6 months postpartum). Therefore, effect estimates and related confidence in these estimates for more specific outcomes were not determined. Furthermore, meta-analysis studies have limited sensitivity and specificity and may not predict significant results for potentially a significant proportion of included studies where such results may actually exist. Another limitation with applying the GRADE is due to the considerate heterogeneity displayed by some of the outcome measures and the high risk of bias for several of the assessed studies which reduced the confidence in the evidence.

Our review is also limited by the range and type of studies included and did not include studies that were published but were inaccessible, such as those from the grey literature, non-English language, unpublished or not peer reviewed. Most studies were from high-income or middle-income countries. In addition, this review did not investigate how the effect of the interventions may be influenced by the appropriateness of the cultural, social, structural, economic or other contextually relevant aspects to pregnant smokers. It is well established that those deterministic aspects can significantly impact the effect of such interventions and several other studies have considered those factors.46 143 144
Further, assessment of the quality of evidence including the risk of bias was mostly based on information found in published articles. Requests for additional information from authors where it was possible to find their contact details did not lead to significant amount of responses.

### Impact on policy, practice and future research

In our review we summarised and quantified the estimated effects of three types of interventions to assist pregnant smokers achieve a point in time abstinence or abstinence for an extended period of time toward the end of pregnancy and during the postpartum period.

For public health practitioners, programme planners, policy-makers or decision-makers, it is clear that counselling interventions by nurses or midwives are evidence based and will assist pregnant smokers achieve PPA at the late stage or the end of pregnancy. However, there is less confidence NoMC interventions will assist in achieving PPA during the postpartum period and CA in late pregnancy and during the postpartum period. Furthermore, there is some confidence that DH interventions, although influenced by the type of technology and content of the intervention subtype, will assist pregnant smokers achieve CA in late pregnancy, but with less confidence that PPA and CA during the postpartum period will be achieved, and with even less confidence that PPA will be achieved in late pregnancy. However, due to the rapidly evolving area of DH and the rising popularity and influence of handheld smart devices, further research on design, feasibility, and economic positions.

### Table 5  Summary of evidence table for nurse or midwife-led counselling intervention studies to assist pregnant smokers achieve abstinence

<table>
<thead>
<tr>
<th>Population: Pregnant smokers</th>
<th>Setting: Any setting*</th>
<th>Intervention: Nurse or midwife led counselling†</th>
<th>Comparison: Usual care or control‡</th>
<th>Outcome: Anticipated absolute effects (95% CI)</th>
<th>Effect with usual care or control group</th>
<th>Effect with intervention</th>
<th>Relative effect (95% CI)§</th>
<th>No of participants (studies)</th>
<th>Certainty of evidence (Grading of Recommendations Assessment, Development and Evaluation)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurse or midwife-led counselling interventions (biochemically validated) on point prevalence abstinence¶ in late pregnancy</td>
<td>104 per 1000</td>
<td>155 per 1000</td>
<td>1.56 (1.16 to 2.08)</td>
<td>1623.4 (15)</td>
<td>Moderate</td>
<td>Low certainty in evidence due to high risk of bias and mostly impacted by one study††</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurse or midwife-led counselling interventions (biochemically validated) on point prevalence abstinence at postpartum (1–3 months, 4–6 months and 7–18 months and unspecified)</td>
<td>60 per 1000</td>
<td>146 per 1000</td>
<td>1.79 (1.14 to 2.83)</td>
<td>5468 (13)</td>
<td>Low certainty in evidence due to high risk of bias in two studies and some concern in risk of bias to moderate to high heterogeneity and low overlap of CIs. Certainty in evidence was upgraded due to a large effect size.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurse or midwife-led counselling interventions (biochemically validated) on continuous abstinence‖ in late pregnancy</td>
<td>14 per 1000</td>
<td>29 per 1000</td>
<td>2.06 (0.90 to 4.71)</td>
<td>918 (1)</td>
<td>Low certainty in evidence due to high risk of bias in 6 out of 12 studies and some concern in risk of bias in four other studies, imprecision due to large CIs as well as publication bias. Certainty in evidence was upgraded due to a large effect size.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurse or midwife-led counselling interventions (biochemically validated) on continuous abstinence at postpartum (1–3 months, 4–6 months and 7–18 months and unspecified)</td>
<td>132 per 1000</td>
<td>143 per 1000</td>
<td>1.43 (0.84 to 2.45)</td>
<td>7646 (6)</td>
<td>Low certainty in evidence due to high risk of bias in two studies and some concern in risk of bias in 3 out of the six included studies, inconsistency due to significant moderate heterogeneity and limited overlap in CI, imprecision caused by CI crossing value of 1 and publication bias. Certainty of evidence was upgraded due to large effect size.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Included studies were conducted in a variety of countries (ie, low, middle or high income countries), included English and non-English speaking populations, and recruitment occurred mainly through antenatal or maternity clinics and/or hospitals and community general/primary care practices. Included studies may have involved pregnant smokers of various socio-economic positions.
†Nurse or midwife-led counselling interventions included studies where nurses or midwives were or could be delivering the smoking cessation counselling intervention. Such interventions predominantly involved counselling or coaching as part of the antenatal or nursing/midwifery care services. The nurse or midwife-led counselling included brief or more comprehensive types counselling, including the 5As (ie, ask, advice, assess, assist and arrange), trans-theoretical model and cognitive behavioural therapy approaches and were measured alongside other interventions such as self-help or smoking cessation material, social support, follow-up, Digital Health, as part of a nurse visitation programme or a combination of those interventions.
‡Usual care often included no specific intervention, very brief smoking cessation counselling or advice, provision of printed or similar information.
¶Relative effect was calculated as relative risk where risk is treated as effect rather than risk and CI is for this calculated relative effect.
‖Point prevalence abstinence was either defined as point prevalence abstinence of various time periods or was abstinence at a point in time that was biochemically validated but was not specifically defined. This type of abstinence did not include continuous abstinence which is understood as abstinence for a period of time rather than a point in time.
§Moderate certainty in evidence due to high risk of bias in 4 of the 15 studies and some concern in risk of bias to seven other studies, inconsistency due to significant moderate to high heterogeneity and low overlap of CIs. Certainty in evidence was upgraded due to a large effect size.
§§Low certainty in evidence due to high risk of bias in 6 out of 12 studies and some concern in risk of bias in four other studies, imprecision due to large CIs as well as publication bias. Certainty in evidence was upgraded due to a large effect size.
††Continuous abstinence was defined as abstinence for a period of time rather than at a point time. This definition included both undefined and defined time periods.
§§§Low certainty in evidence due to high risk of bias in two studies and some concern in risk of bias in 3 out of the six included studies, inconsistency due to significant moderate heterogeneity and limited overlap in CI, imprecision caused by CI crossing value of 1 and publication bias. Certainty of evidence was upgraded due to large effect size.
acceptability and effectiveness of this type of interventions is warranted and likely to occur in the near future.

There is less confidence that BF interventions will assist pregnant smokers achieve PPA in late pregnancy or CA in postpartum. Evidence for effectiveness for this type of intervention is limited and further research is necessary, particularly if feedback is also possible through a handheld device. Research based on a multi-component intervention based on the three types of interventions (DH, BF and NoMC) which has been investigated in this review is warranted as there is evidence that multi-component interventions leads to positive outcomes in relation to smoking cessation among pregnant women.

CONCLUSION

We conclude that based on moderate certainty evidence, NoMC interventions may assist pregnant smokers achieve PPA and DH interventions achieve CA in late pregnancy.

We also conclude that based on low certainty evidence, NoMC interventions may assist pregnant smokers achieve PPA during the postpartum period and DH interventions achieve PPA during the postpartum period.

Additionally, based on very low and low certainty evidence, respectively, DH and BF interventions may not assist pregnant smokers achieve PPA in late pregnancy. Finally, there was insufficient evidence to determine if DH or BF interventions assist pregnant smokers achieve CA during the postpartum period, NoMC and BF interventions achieve CA in late pregnancy or BF interventions achieve PPA during the postpartum period.

Contributors    RR and CT conceptualised this research. TD and CT conceptualised the related analysis. CT carried out the database search and exclusion. CT and FH independently screened and extracted the data. Discrepancies were resolved by discussion and consensus among RR, CT and FH. CT drafted the initial manuscript. RR, CT, TD, RL and FH read, extensively edited and commented on the manuscript and approved the final manuscript. RL has reviewed manuscript and advised on edits. CT is responsible for the overall content as the guarantor.

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Provenance and peer review    Not commissioned; externally peer reviewed.

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ORCID iD    Chadi Tahan http://orcid.org/0000-0002-5850-7897

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