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Are digital interventions for smoking cessation in pregnancy effective? A systematic review and meta-analysis

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Abstract

Smoking in pregnancy remains a global public health issue due to foetal health risks and potential maternal complications. The aims of this systematic review and meta-analysis were to explore: (1) whether digital interventions for pregnancy smoking cessation are effective, (2) the impact of intervention platform on smoking cessation, (3) the associations between specific Behaviour Change Techniques (BCTs) delivered within interventions and smoking cessation, and (4) the association between the total number of BCTs delivered and smoking cessation. Systematic searches of nine databases resulted in the inclusion of 12 published articles (n = 2970). The primary meta-analysis produced a sample-weighted odds ratio (OR) of 1.44 (95% CI 1.04–2.00, p=0.03) in favour of digital interventions compared with comparison groups. Computer-based (OR=3.06, 95% CI 1.28 – 7.33) and text-message interventions (OR=1.59, 95% CI 1.07 – 2.38) were the most effective digital platform. Moderator analyses revealed seven BCTs associated with smoking cessation: *information about antecedents; action planning; problem solving; goal setting (behaviour); review behaviour goals; social support (unspecified);* and *pros and cons.* A meta-regression suggested that interventions using larger numbers of BCTs produced the greatest effects. This paper highlights the potential for digital interventions to improve rates of smoking cessation in pregnancy.

Systematic review registration: PROSPERO CRD42016036201

Keywords: Systematic review; Smoking; Pregnancy; Digital interventions; Behaviour Change Techniques

Background

Smoking in pregnancy increases the risks of harm to the developing foetus, including miscarriage, low birth weight, and an increased risk of Sudden Infant Death Syndrome (SIDS) (Einarson & Riordan, 2009). Asthma, certain brain tumours, learning difficulties and behavioural issues, including hyperactivity, may be higher in children born to mothers that smoked during pregnancy (Batstra, Neeleman, & Hadders-Algra, 2003; Heck et al., 2016; Silvestri, Franchi, Pistorio, Petecchia, & Rusconi, 2015). Benefits of smoking cessation for the mother include reduced risk of coronary heart disease, stroke and various cancers, and increased life expectancy (Novello, 1990; D. H. Taylor, Hasselblad, Henley, Thun, & Sloan, 2002). Given that smoking in pregnancy is a modifiable risk factor for poor birth outcomes and childhood health, it is important that women are encouraged to stop smoking and provided with support to enable them to do so.

Despite declining rates of smoking in pregnancy in high-income countries, such as the USA, Sweden and Denmark, (Cnattingius, 2004), social inequalities remain. Women who continue to smoke in pregnancy are more likely to have lower socioeconomic status, represented by low income, low level of education and low occupational status (Greaves et al., 2011). Barriers to smoking cessation in pregnancy are more common amongst disadvantaged smokers, including perceptions that prenatal smoking provides a source of stress relief (Flemming, McCaughan, Angus, & Graham, 2015). Further barriers to cessation include increased nicotine metabolism during pregnancy, leading to more frequent sensations of nicotine withdrawal (Ebert, van der Riet, & Fahy, 2009), and women often experience low self-efficacy in achieving total abstinence (Tod, 2003). Services providing stop smoking support are not utilised by the majority of pregnant smokers. In England, for example, uptake of *free to access* Stop Smoking Services by pregnant smokers is approximately 15% (NHS, 2017). Barriers, including fear of stigma and being judged, accessibility issues and lack of

knowledge of the benefits of this support, can have an impact on attendance (Borland, Babayan, Irfan, & Schwartz, 2013; Butterworth, Sparkes, Trout, & Brown, 2014; Ussher, Etter, & West, 2006).

Interventions demonstrating some effectiveness for smoking cessation in pregnancy include counselling, feedback and financial incentives (Chamberlain et al., 2017), self-help aids (Naughton, Prevost, & Sutton, 2008), and telephone support programmes (Dennis & Kingston, 2008). However, there is insufficient evidence at present regarding the efficacy and safety of nicotine replacement therapy for this population (Coleman, Chamberlain, Davey, Cooper & Leonardi-Bee, 2015). Interventions using a digital platform, including telephone, video, internet or mobile application technologies (O'Brien, McCarthy, Gibney, & McAuliffe, 2014), show promise for smoking cessation in pregnancy as they can provide anonymity and are available on demand (Tombor, Neale, Shahab, Ruiz, & West, 2015). Whilst a review of mobile phone based smoking cessation interventions in pregnancy has been undertaken (Heminger, Schindler-Ruwisch, & Abroms, 2016), the timing of this review meant that only one randomised trial could be included. No review has yet assessed the overall effectiveness of both mobile phone and other digital interventions for cessation in pregnancy. There remains a need to collate current research delivered across all digital platforms, including websites and video messages.

In addition, it is important to understand the Behaviour Change Techniques (BCTs) used within interventions (Abraham & Michie, 2008), which are the smallest replicable components of an intervention that can be used individually or in combination to alter or redirect the processes of behaviour change (Michie et al., 2013). Identifying and reporting BCTs is essential for accurate replication of effective interventions (Michie et al., 2013). The BCT Taxonomy v1 was developed by international experts, and it includes 93 distinct BCTs hierarchically clustered into 16 groups (Michie et al., 2013). Reporting the use of BCTs

across the studies evaluated in systematic reviews can provide a systematic and comprehensive examination of which components are likely or unlikely to have an effect.

Lorencatto, West and Michie (2012) explored BCT use in seven psychosocial interventions which increased pregnancy smoking cessation. Using the Smoking Cessation Taxonomy (Michie, Hyder, Walia, & West, 2011), they found that BCTs including *facilitate goal setting* and *facilitate action planning/develop a treatment plan* were present in the majority of effective interventions. To date, this appears to be the only published exploration of the BCT content of interventions aimed at increasing smoking cessation amongst pregnant women.

Exploring whether there is an optimum number of BCTs for interventions can provide a useful guide for intervention developers. Current behaviour change research shows contrasting evidence regarding the ideal number of BCTs. A review of internet-based health promotion interventions reported that interventions using more BCTs achieved larger effects (Webb, Joseph, Yardley, & Michie, 2010), whilst a review of interventions addressing smoking, healthy eating and physical activity in low-income groups found that interventions using fewer BCTs were more effective (Michie, Jochelson, Markham, & Bridle, 2009). Further reviews on dietary and physical activity interventions could not conclude that using a larger number of BCTs improved effectiveness (Dombrowski et al., 2012; N. Taylor, Conner, & Lawton, 2012). Additional research is required to ascertain whether there is an optimum number of BCTs for inclusion in digital interventions addressing pregnancy smoking.

This review aimed to resolve current research shortfalls by providing a synthesis of the range of digital interventions implemented for smoking cessation in pregnancy and evaluating their effectiveness. To meet the need for further research examining the mechanisms of these interventions, the BCT content of included interventions was explored,

where content allowed, using the most up-to-date taxonomy: BCT Taxonomy v1 (Michie et al., 2013). The findings will provide a benchmark for future trials in this area.

Objectives

This review aimed to answer the following research questions relating to digital interventions for smoking cessation in pregnancy:

Primary focus:

1. Are digital interventions more effective in increasing smoking cessation rates in pregnancy than usual care/other control groups?

Secondary focus:

2. Is the platform of delivery of digital interventions associated with smoking cessation in pregnancy?
3. Which BCTs/combinations of BCTs, when included in digital interventions, are associated with smoking cessation in pregnancy?
4. Are the number of BCTs used in digital interventions associated with smoking cessation in pregnancy?

Method

The methodology for this review complies with the PRISMA guidelines for systematic reviews (Liberati et al., 2009) (see Supplementary File 1) and MARS guidelines for meta-analysis (American Psychological Association, 2008). It follows the published protocol (Griffiths, Brown, Fulton, Tombor, & Naughton, 2016), PROSPERO registration CRD42016036201. The second research objective, regarding the relationship between

platform of digital intervention and smoking cessation, was added as an amendment to the published protocol before data-extraction, as it became clear that a range of digital platforms were represented in the data.

Eligibility criteria

Study Requirements

Randomised and quasi-randomised controlled trials were included. Articles were included if they were written in English. No restrictions on publication date were applied in the initial search in September 2016. For the updated search carried out in May 2017, parameters were added to include research from 2016 - 2017 only.

Participants

Participants were women at any stage of pregnancy, reporting to be current cigarette smokers. Interventions explicitly targeting participants under the age of 16 were excluded as digital interventions aimed specifically at pregnant adolescents are likely to be designed around the particular needs of this age group. Studies with only ex-smokers or post-natal participants were excluded.

Interventions

For the purposes of this review, digital interventions included any intervention delivered largely through a computer (PC or laptop), video or DVD, mobile telephone or portable handheld device (e.g. tablet or iPad). This included email, video, DVDs, websites or web-based games, mobile or tablet applications and SMS text messages or MMS multimedia messages. Standard usual care for smoking cessation in pregnancy typically consists of brief cessation advice delivered by a healthcare professional. For this review, any method of usual

care or other comparison group was acceptable. Trials using the same method for the comparison group, e.g. usual care, were pooled into a subgroup meta-analysis. Trials with more than one comparator arm were included only if at least one of the experimental arms met the inclusion criteria for a digital intervention, as specified below. Where a study reported results for more than one digital intervention, the most intensive digital arm, or that judged to be most intensive, was entered into the meta-analysis.

Outcome measures

Only trials reporting smoking abstinence were included. The preferred primary outcome was latest available point prevalence abstinence taken towards the end of pregnancy, biochemically verified where possible by measurement of either exhaled carbon monoxide or urinary/salivary cotinine. Prolonged abstinence from a set time point, e.g. quit date, was also acceptable, again biochemically verified if available. Point prevalence abstinence was selected as this measure is more commonly reported in smoking cessation literature (Naughton et al., 2008).

BCT content of both interventions and control groups were assessed. If insufficient information was provided in the text or appendices of manuscripts in order to identify BCTs, authors of included texts were contacted by the review team to determine whether this information was available, or for permission to code the relevant manuals for BCT content. If authors could not be contacted or did not give permission, intervention description sections in the original manuscripts were coded independently by two reviewers.

Information sources

The following electronic bibliographic databases were searched in September 2016 and May 2017: Academic Search Complete, ASSIA, CINAHL, The Cochrane Library, EMBASE,

Medline, PsycINFO, Scopus and Web of Science. Key words and database-specific subject headings relating to the terms ‘pregnancy’, ‘smoking’, ‘randomised control trial’, and various words encompassing the term ‘digital’, including computer, video, internet, app, telephone and mobile phone were searched. Boolean logic using AND, OR was employed to provide an exhaustive list of all research covering these combinations. The following research registers were also searched using the inclusion criteria for recently completed, unpublished clinical trials: National Institute for Health Research UK Clinical Trials Gateway, ClinicalTrials.gov, and Current Controlled Trials through the ISRCTN registry. Lead investigators were contacted where necessary to ask whether trial results were available or near completion. Reference lists of screened studies meeting the inclusion criteria and relevant published reviews were searched by hand. Reference lists of papers citing included studies were also examined.

Search strategy

An information specialist provided support for this work to ensure that the most exhaustive search terms were employed. Supplementary File 2 provides an example of the full CINAHL database search strategy, which was amended for other databases using database specific subject headings where available, and keywords in both titles and abstracts.

Data management, screening process and data extraction

Data was managed using EndNote software. Original search results were combined and duplicates removed. One reviewer (SG) screened all abstracts and/or titles. To check for inclusion agreement, a second reviewer (KB) carried out a calibration exercise, screening the first 100 titles/abstracts using a checklist. Any discrepancies were resolved by discussion. A Kappa value (κ) of 0.82 was produced for inter-rater agreement, total agreement = 97%. As a

Kappa coefficient above 0.80 indicates strong agreement (McHugh, 2012), no further calibration was required.

For the second phase, full-text reports of studies identified as potentially suitable were obtained and checked against the inclusion criteria checklist by two independent reviewers (SG and KB) (κ 0.84; 92% total agreement), with any uncertainties discussed with a third reviewer until consensus was reached. For the third phase, two reviewers (SG and JP) independently extracted the following data (where available) using a data extraction sheet, including: date, year and country of study; sample size, ethnicity and socio-demographic details; mean age and gestation at enrolment; duration of intervention and data collection time points; mode and details of intervention; mode and details of control; primary smoking outcome measures; secondary smoking outcome measures; other outcome measures; effect size (OR and adjusted OR). Inter-rater agreement for this phase was κ 0.81; 90% total agreement. Any discrepancies were discussed further with referral back to the paper until consensus was reached. BCT coding was carried out by two reviewers (SG and JP), who independently coded all interventions where possible.

Quality assessment

The Cochrane Collaboration's tool for assessing risk of bias in randomised trials was used independently by two reviewers (SG and JP) to assess the validity of included studies (Higgins et al., 2011) (κ 0.80, 91.5% overall agreement). To assess for possible detection bias for primary outcomes, biochemical validation of abstinence was considered low risk and self-reported outcome measures only were high risk (Chamberlain et al., 2017). Risk of bias was also assessed across trials for the meta-analyses. Further details can be found in the published protocol (Griffiths et al., 2016).

Data analyses

Measures of treatment effect

Rates of abstinence were extracted and presented as odds ratios, as is commonly reported in the smoking cessation literature. Whilst not specified in the published protocol (Griffiths et al., 2016), in order to maximise data similarity between studies, crude rather than adjusted odds ratios (ORs) were the preferred outcome measure as all trials were expected to at least provide the data from which this could be calculated. An intention-to-treat (ITT) approach was applied, whereby any individuals with missing follow up data were assumed to still be smoking.

Statistical analysis

To address the primary objective relating to the effectiveness of digital interventions for smoking cessation in pregnancy, a meta-analysis was carried out to create an overall effect size. A single moderator analysis was carried out to examine whether a relationship existed between platform of intervention delivery and smoking cessation for the second research objective. A further moderator analysis was carried out to explore whether the platform of the control group had any impact on intervention effectiveness. To address the third research objective regarding which BCTs or categories of BCTs were associated with effectiveness, exploratory subgroup meta-analyses were carried out pooling BCTs coded as unique to the intervention alone within four or more papers – any less than this was seen as too few for an exploratory meta-analysis (see Fu et al., 2011; Michie, Abraham, Whittington, McAteer & Gupta, 2009; N. Taylor et al., 2012). Addressing the fourth research objective, a meta-regression explored whether the number of BCTs used in interventions had an impact on effect size. Comprehensive Meta-Analysis (CMA) software, version 3.3 was used to conduct all statistical analyses (Borenstein, Hedges, Higgins & Rothstein, 2005).

Heterogeneity

A random effects model was adopted for all meta-analyses, estimating intervention effects with 95% confidence intervals (CI) and significance at the 5% level. This model was adopted because interventions differed in content and levels of success, leading to the assumption that effects would fall on a distribution of effect sizes. Cohen's Q test following a chi-squared distribution (χ^2), and inconsistency index (I^2) were implemented to test for how much variance across studies was a result of heterogeneity rather than chance (Higgins, Thompson, Deeks, & Altman, 2003). An I^2 of more than 50% indicated significant heterogeneity.

Publication bias

Visual inspection of funnel plot asymmetry was used to assess publication bias.

Sensitivity analyses

Separate sensitivity analyses were carried out excluding trials providing only self-reported outcomes, with a high risk of bias, with high attrition rates, and using quasi randomised allocation.

Summary of findings table

GRADE system principles were used to assess the quality of evidence for each digital platform of intervention, using GRADEpro software (GRADEpro Guideline Development Tool, 2015) and the GRADE handbook (Schünermann, Brozek, Guyatt & Oxman, 2013).

Results

Study selection

<FIGURE 1 HERE>

Figure 1 summarises the screening process results. For the first phase of screening, 962 records were excluded. Twenty-six records underwent full-text screening, wherein a further 14 full-text articles were excluded. This left twelve papers for inclusion in the review.

Study characteristics

<TABLE 1 HERE>

Table 1 shows study characteristics for included papers. Trials took place in the USA (k = 8) or UK (k = 4) between 1991 and 2017. The oldest studies were videotape interventions (Cinciripini et al., 2000; Price et al., 1991; Secker-Walker et al., 1997), and the most recent were text-message interventions (Abroms et al., 2017; Naughton et al., 2017).

Digital Interventions

Four studies delivered digital content through text messages: 'Quit4Baby' (Abroms et al., 2017), 'MiQuit' (Naughton et al., 2017; Naughton, Prevost, Gilbert, & Sutton, 2012), and 'Scheduled Gradual Reduction' (SGR) (Pollak et al., 2013). Three studies used videotapes (Cinciripini et al., 2000; Price et al., 1991; Secker-Walker et al., 1997), and one study used telephone Interactive Voice Response Technology (IVR) (Ershoff et al., 1999). Two trials used websites, including a contingency management programme (Harris & Reynolds, 2015), and an interactive and personalised website, 'MumsQuit' (Herbec, Brown, Tombor, Michie, & West, 2014). The remaining two trials were computer programmes. Ondersma et al. (2012) used a computer programme following the 5 A guidelines for clinical practice from Fiore et al., (2008): Ask, advise, assess, assist, arrange, combined with a computer assisted contingency management programme. Lawrence, Aveyard, Evans and Cheng (2003) used a computer programme in addition to stage of change leaflets. The shortest intervention

duration was 10.5 minutes (two brief videotapes) (Price et al., 1991), and the longest was a three-month intervention (Abroms et al., 2017). The majority of digital interventions were accessed by women at home, or wherever women may be when receiving text-messages (k = 9). Exceptions to this were both computer interventions (Lawrence et al., 2003; Ondersma et al., 2012), and one of the video interventions (Price et al., 1991); these were all accessed in clinical settings.

Comparator groups

Three trials used self-help manuals in the control group arm (Cinciripini et al., 2000; Ershoff et al., 1999; Naughton et al., 2012). Five control arms used usual care, which was described as standard physician, obstetrician or nurse-midwife/midwife advice (Lawrence et al., 2003; Naughton et al., 2017; Ondersma et al., 2012; Price et al., 1991; Secker-Walker et al., 1997). Three trials used digitalised interventions as the comparator group: text-message comparison groups (Abroms et al., 2017; Pollak et al., 2012) and a static website providing brief smoking cessation advice (Herbec et al., 2014). One intervention used a nurse-led telephone counselling system (Harris & Reynolds, 2015).

Participant details

The total number of participants across all trials was 2970 (range of n = 17 – 918). The mean age at enrolment was 27.0 years (standard deviation (SD) = 2.3). Six trials reported mean gestation at enrolment, the average of which was 14.6 weeks (SD = 2.5). Seven trials reported the average number of cigarettes smoked per day at enrolment or in pregnancy, averaging 10.2 (SD = 3.0) across the trials with a median of 11.4. An average of 77.6 % of participants from 11 of the 12 included studies were of white ethnicity. Data regarding participants socio-economic status was varied, with only one study reporting socio-economic status (Herbec et

al., 2014) and one reporting index of deprivation (Naughton et al., 2017). Ten studies reported level of education; this ranged from 26.3% - 87% having less than a high school education, and 30.2% - 49.8% having GCSEs/O-Level qualifications.

Primary smoking cessation outcomes

Eleven of the 12 trials reported biochemically-verified abstinence using either salivary cotinine or exhaled carbon monoxide readings (see Table 1). The majority of studies reported 7-day point-prevalence smoking abstinence towards the end of pregnancy, with four further studies reporting continuous abstinence towards the end of pregnancy, and one reporting self-reported abstinence at 8 weeks post-intervention (Herbec et al., 2014). All included studies provided intention to treat (ITT) data, which were used for the primary meta-analysis.

Behaviour Change Techniques

The authors of seven included studies provided access to further intervention and/or control details; this ranged from full access (e.g. of all text-messages content and control leaflets) to partial access (e.g. a one-page summary of the intervention only). As this did not provide enough consistency to enable systematic coding of full manuals and controls, only the coding of descriptions provided within each published paper, including any supplementary files where these were available with the published papers, was included for analysis. Two review authors (SG and JP), both trained in BCT coding, independently coded all intervention and control descriptions using the BCT Taxonomy v1 (Michie et al., 2013). Overall inter-rater coding agreement was 93%%, $\kappa = 0.82$, indicating a strong level of agreement (McHugh, 2012).

<TABLE 2 HERE>

Fifty-four BCTs were identified across 15 BCT groups (Michie et al., 2013) (see Table 2). BCTs present in the most interventions were*: Problem solving* (*k* = 6); *goal setting (behaviour); action planning*; *self-monitoring of behaviour*; *social support (unspecified)*; and *information about antecedents* (*k* = 5); *review behaviour goals; demonstration of the behaviour; pros and cons*; and *adding objects to the environment* (*k* = 4). The number of BCTs used in each study ranged from 4 (Ershoff et al., 1999) to 15 (Secker-Walker et al, 1997), with a mean of 10 (SD = 3.52) and median of 10.5. The group of covert learning was not coded, and the groups most frequently coded were: *goals and planning* (*n* = 25); *feedback and monitoring* (*n* = 13); *reward and threat* (*n* = 12); *antecedents* (*n* = 12); *shaping knowledge* (*n* = 9); *and social support* (*n* = 8).

Risk of bias in included studies

<FIGURE 2 HERE>

A summary of the quality assessments can be found in Figure 2. The majority of studies had a high risk of bias on one or more key domains (*k* = 7), with high risk most commonly assigned for incomplete intervention implementation. One study was found to have a low risk of bias across all domains (Naughton et al., 2017), whilst four studies had an overall unclear risk of bias. All videotape interventions were classified as high-risk due to incomplete implementation. For example, videos were not watched in the experimental arm by 63% (Secker-Walker et al., 1997) and 47% of participants (Cinciripini et al., 2000). Similarly, almost 80% of participants in the interactive voice response group made no calls to the service (Ershoff et al., 1997). Other reasons suggesting incomplete implementation included high drop-out rates before the intervention was complete (Price et al., 1991), and inadequate breath samples at follow-up in the control group (Harris & Reynolds, 2015). Further sources of bias included lack of randomisation of medical practices recruited late in the study

(Lawrence et al., 2003), and only reporting self-reported abstinence, which may have led to an inflation in observed quit rates (Herbec et al., 2014).

Statistical analyses

<FIGURE 3 HERE>

A primary meta-analysis including 12 trial arms from 12 studies was performed (n = 2306). The sample weighted OR indicated that digital interventions significantly increased the odds of quitting smoking during pregnancy compared to control groups (OR = 1.44, 95% CI 1.04 – 2.00, p = 0.03) (see Figure 3). The effect estimate favoured the control group in three trials (Ciniciripini et al, 2000; Ershoff et al., 1999; Harris & Reynolds, 2015).

<FIGURE 4 HERE>

Examination of the funnel plot revealed some asymmetry across studies suggesting possible publication bias and missing unpublished trials with negative effects, although analysis of funnel plots is difficult and subjective (see Figure 4). Heterogeneity statistics indicated low heterogeneity (Higgins et al., 2003): Q = 13.37, df = 11, p = 0.27, I^2 = 17.7%.

<FIGURES 5 AND 6 HERE>

A moderator analysis examining the influence of intervention platform revealed that computer-based interventions produced a significant effect (k = 2, OR = 3.06, 95% CI 1.28 – 7.33, p = 0.01), as did text message interventions (k = 4, OR = 1.59, 95% CI 1.07 – 2.38, p = 0.02) (see Figure 5). To avoid running analyses on a small number of studies within groups, comparator groups were classified as either ‘usual care’ for interventions compared to usual care, or ‘active control’ for studies using a more active component for the control group, such as self-help leaflets or text messages. A moderator analysis found that interventions compared to usual care were more effective (k = 5, OR = 2.45, 95% CI 1.38 – 4.36, p =

<0.01) than those compared to a more active control group (k = 7, OR = 1.19, 95% CI 0.86 – 1.66, p = 0.29) (see Figure 6).

<TABLE 3 HERE>

Exploratory subgroup analyses performed on the 10 BCTs coded as unique to the intervention alone in at least four studies (see Table 3) revealed seven BCTs significantly associated with the effectiveness of digital interventions for smoking cessation in pregnancy: *information about antecedents; action planning; problem solving; goal setting (behaviour); review behaviour goals; social support (unspecified);* and *pros and cons.* No studies used all seven effective BCTs in the intervention condition only.

<FIGURE 7 HERE>

A meta-regression on the number of BCTs as a continuous variable was carried out, providing a coefficient of 0.11 (SE 0.05), 95% CI -0.02 – 0.19, $p = 0.02$ (see Figure 7), suggesting that interventions using a larger number of BCTs produced a greater effect.

Sensitivity Analyses

The sensitivity analyses can be seen in Supplementary File 3. Removing the study which reported self-reported outcome measures for smoking abstinence (Herbec et al., 2014) did not affect the findings ($k = 11$, OR = 1.45, 95% CI 0.98 – 2.15, $p = 0.07$), although heterogeneity increased slightly to 25%. Removing all studies classified as having a high risk of bias increased the pooled effect size ($k = 5$, OR = 1.63, 95% CI 1.11 – 2.41, $p = 0.01$), and appeared to remove any heterogeneity ($I^2 = 0.0\%$). A post-hoc sensitivity analysis was carried out removing the study with high attrition rates in the control group compared to the intervention group (Secker-Walker et al., 1997). This had no meaningful impact on the findings ($k = 11$, OR = 1.39, 95% CI 1.03 – 1.87, p = 0.03). The I^2 measure of heterogeneity dropped to 7.4% for this sensitivity analysis. A final post-hoc sensitivity analysis was carried

out removing the trial with quasi-randomised condition allocation (Lawrence et al., 2003). This also had little impact on the overall results (k = 11, OR = 1.32, 95% CI 0.98 – 1.79, p = 0.07), with heterogeneity reducing to 4.6%.

Summary of Findings

The GRADE summary of findings table (see Supplementary File 4) shows that the quality of evidence ranged across platforms, with the highest quality evidence provided by text-message and computer-based interventions, and the lowest quality evidence provided by video messages.

Discussion

This review is the first to assess the effectiveness of digital interventions across a range of platforms to aid smoking cessation during pregnancy. Of those platforms used in the included trials, computer-based and text message based interventions appear to be the most effective. Seven BCTs were found to be associated with effect size: *information about antecedents; action planning; problem solving; goal setting (behaviour); review behaviour goals; social support (unspecified); pros and cons*. This review found some evidence that interventions using a larger number of BCTs produced increased rates of smoking cessation in pregnancy.

Effectiveness of digital interventions

The research synthesised in this review highlights a general shift over time in the delivery of technological interventions aimed at increasing smoking cessation in pregnancy, evolving with advances in technology, with the exception of one of the included computer interventions (Lawrence et al., 2003). The body of knowledge within behavioural science has also developed in-line with digital improvements, and this is likely to have improved both the

quality of recent research for this population and the quality of usual care offered to pregnant smokers.

The text message interventions included within this review produced a significant effect upon smoking cessation. Text messages can also increase abstinence in the general population when compared to other non-tailored text messages or internet or written material (Whittaker, McRobbie, Bullen, Rodgers, & Gu, 2016). The effect size in the Whittaker Cochrane review (RR 1.67) is close to the effect size in the moderator analysis for text messages in the current review, suggesting that effects may be similar across populations or pregnant and non-pregnant smokers.

In the review presented here, trials evaluating computer-based interventions were carried out as an addition to usual prenatal care, and the computer programmes were accessed on laptops in midwifery clinics (Lawrence et al, 2003), or touch screen tablet PCs in private rooms of a prenatal care clinic (Ondersma et al., 2012). Whilst fulfilling the eligibility criteria of 'digital interventions' for the purpose of this review, as women were left to complete these programmes alone, these studies may not be fully comparable to other forms of digital intervention such as text-messages, which are designed to be flexible and easily accessible, and potentially could be less cost-effective. The strengths of computer-based interventions for smoking cessation in adults has been reported in a meta-analysis (Myung, McDonnell, Kazinets, Seo, & Moskowitz, 2009), where significant effects for smoking cessation were found across 13 trials of computer-based interventions when compared to control groups (RR = 1.88, 95% CI 1.25-1.76). However, information on where these computer programmes were accessed by participants is not clear. Further exploration of the accessibility and appeal of computer programmes for smoking cessation in pregnancy away from clinical settings is warranted. This would be of particular benefit given the small number of computer-based studies included within this review, which limit the generalisability of these findings.

All of the studies in this review were from high-income countries (USA or UK based), where access to digital technology is high; a median of 87% of adults across 11 advanced economies have access to the internet or own a smartphone, compared to 54% across 21 low-middle income countries (Pew Research Centre, 2017). Existing evidence suggests that certain modes of digital intervention may have international scope for behaviour change. A meta-analysis exploring the global impact of SMS text messages on health behaviours, including medication adherence and smoking cessation, found that included interventions had a small but significant impact upon a diverse range of participants from differing social and economic regions (Orr & King, 2015). Further research on the use of text message and other digital interventions in lower income countries where smoking in pregnancy remains an issue could ascertain whether digital techniques are likely to have global reach for this complex health behaviour.

It is important to determine who accesses digital interventions, as even within developed countries digital divides can exist. For example, in Canada, higher education and higher household income are associated with increased internet access and activity (Haight, Quan-Haase, & Corbett, 2014), yet rates of smoking in pregnancy are higher amongst women with low socio-economic status (Cui, Shooshtari, Forget, Clara, & Cheung, 2014). If digital interventions are not as easily accessed by pregnant women with more disadvantaged backgrounds, they run the risk of increasing social inequalities. Designing digital interventions with the support and approval of smokers of lower socio-economic status may alleviate these issues (Brown et al., 2014), making them more effective for smoking cessation for pregnant women from these populations. In the current review, only one included study specifically recruited women of lower socio-economic status (Price et al., 1991), meaning that accessibility of digital interventions across socio-economic groups could not be ascertained.

BCTs used in digital interventions

Of the BCTs associated with effectiveness, *action planning; problem solving; goal setting (behaviour)* and *review behaviour goals* are from the group 'Goals and planning', the first group from the BCTv1 Taxonomy (Michie et al., 2013). This suggests the importance of setting goals and considering how the barriers and facilitators to smoking cessation in pregnancy may be overcome. Although limitations of BCT coding in this review, particularly of control groups, mean these results should be treated with caution, the presence of these BCTs has also been found to be associated with effectiveness in non-digital behavioural support interventions for smoking cessation in pregnancy (Lorencatto et al., 2012). An evaluation of the BCTs used in NHS Stop Smoking Service treatment manuals also reported that 98% included action planning and goal setting (West, Walia, Hyder, Shahab, & Michie, 2010). Whilst setting a quit date is a requirement of the Service, action planning provides important preparation for a successful quit.

Providing information about antecedents, or understanding circumstances which are likely to lead to smoking, can also help women avoid tempting situations, resulting in increased self-efficacy in their ability to quit (Abrahamsson, Springett, Karlsson, & Ottosson, 2004). Combining these BCTs with others which focus on overcoming barriers to smoking cessation may be beneficial for pregnancy. For example, if women are given opportunities to think about situations where avoiding smoking will be most difficult, they will be better prepared for these eventualities.

An interesting observation regarding BCT inclusion is that no included studies within this review used all seven effective BCTs in the intervention arm only. It is possible that using a suite of complementary BCTs could enhance the effect of digital interventions which

aim to increase smoking cessation in pregnancy. However, this is a potential avenue for exploration within future work based on more robust BCT coding.

This review found a significant effect for the use of a larger number of BCTs within digital interventions to aid smoking cessation, suggesting that interventions using only a small number of BCTs may be less effective than more complex interventions. This supports further work on the use of BCTs in behaviour change interventions (Webb et al., 2010), and research on the effectiveness of interventions to improve type 2 diabetes control and treatment efficacy (Cradock et al., 2017). Due to the limited number of included studies within this review, and sparse intervention and control descriptions from which review authors could code BCTs, these results are exploratory rather than definitive, providing the groundworks for future research. As mentioned by Michie, Jochelson and colleagues (2009), using multiple BCTs may lead to a dilution in the effect of otherwise prominent BCTs. It may yet prove more important and cost-effective to focus on including specific BCTs in interventions, rather than making interventions increasingly complex with the hope of making them more effective.

Control conditions

Within this review, a significant effect was found for interventions comparing a digital intervention to usual care, but not for other more active control groups. This was perhaps not surprising, as usual care conditions would not be expected to be as effective as more active controls. However, usual care and other comparison conditions can also vary in quality. As identified in previous work, meta analyses of behaviour change interventions would benefit from controlling for these discrepancies (de Bruin, Viechtbauer, Hospers, Schaalma & Kok, 2009; de Bruin et al., 2010). In the current review, this was not entirely possible due to limited descriptions of control conditions provided by the majority of included papers,

although it is clear that variations in the level of 'usual care' offered to participants within and across trials would have been inevitable. For example, in the study by Lawrence et al. (2003), the only standardised element of the usual care arm was the provision of a leaflet; midwives delivering usual care were known to have variable skills and training, and therefore there could be no guarantee that the same set of BCTs were delivered to all participants in this condition.

Strengths

This review followed a rigorous review process with stringent inclusion criteria. Including only experimental studies allowed for causal conclusions to be made, and implementing a thorough risk of bias assessment acknowledges the quality of research that any findings are based on. The majority of reviewed literature used biochemically validated outcome measures, providing an accurate assessment of smoking cessation. By pooling the weighted effect sizes of digital interventions, it was possible to conclude that such interventions show promise for initiating smoking cessation. This review has also analysed the BCT content of included interventions, providing greater understanding about the active components of interventions to enable better transparency and future replication.

Limitations

There are a number of limitations which should be discussed. Coding for BCTs from papers rather than full intervention manuals reduces reliability, and a lack of information regarding the presence of a BCT does not guarantee that one was not delivered in the intervention. This problem has been discussed in behaviour change literature, as reports may fail to provide adequate detail or precision to allow for robust BCT coding (Dombrowski et al., 2012; N. Taylor et al., 2012). In the current review, coding of control groups was especially limited

due to incomplete descriptions given in the text of the majority of included studies. There is the possibility that incorrect labelling of the presence of a BCT in the intervention alone may have introduced Type 1 error. It is also not possible to guarantee that it is the inclusion of certain BCTs that are causing an effect, or lack of effect, as other factors may be more influential. For example, within this review the lack of significance produced by Secker Walker et al.'s study (1997), which used a large number of BCTs, may have been a result of low intervention uptake, rather than low efficacy of included BCTs. Nevertheless, this is currently the only known method for describing the content of interventions and, whilst not flawless, systematically exploring the BCT content of digital interventions can still elicit valuable insight into which content is associated with smoking cessation in pregnancy.

There is some evidence of potential publication bias in this review, indicated by forest plot asymmetry, possibly due to the inclusion of several pilot studies with small sample sizes. Given the rapid advance in technology over the last decade, it is likely that the addition of trials which are currently in progress, for example the development of SmokeFree Baby (Tombor et al., 2016), will decrease any uncertainty about the effectiveness of digital interventions. It remains important, however, to explore the content of older, more dated technological interventions to assess what can be improved upon with the use of the latest technology.

Over half of included studies were classified as having a high risk of bias, which can influence the effect sizes estimated when pooling trial data. This included the three studies which favoured the control group, which had issues with implementation of the intervention (Cinciripini et al., 2000; Ershoff et al., 1999) and the control group (Harris & Reynolds, 2015). However, as the majority of bias recorded was due to incomplete intervention implementation, this would most likely have led to reduced effectiveness of the intervention rather than an inflation of effect size or methodological flaws. Indeed, when studies with a

high risk of bias were removed as part of a sensitivity analysis, the pooled effect size increased.

Future directions

Future research would benefit from aiming digital interventions at pregnant women from disadvantaged backgrounds, to ascertain whether such interventions are able to reach women where rates of smoking in pregnancy are at their highest. As the current review did not identify any published trials on the use of smartphone apps for smoking cessation in pregnancy, it would be beneficial for forthcoming studies to explore their effectiveness. This would be especially useful as research has shown that apps are acceptable and engaging for this population due to their flexibility and potential for cost-effectiveness (Abroms et al., 2015; Wu, Tombor, Shahab, & West, 2017). It would also be advantageous to explore whether the BCTs found to be effective for other digital platforms in this review, particularly those focused on goals and planning, are also likely to be effective for smartphone apps.

Conclusion

The findings of this review indicate that digital interventions, particularly those delivered by text-message or computer, can be effective for smoking cessation in pregnancy. Digital interventions containing BCTs focused around goals and planning, such as goal setting, problem solving and action planning, may be more successful. Further work is required to ascertain whether using more rather than fewer BCTs has a significant impact upon smoking cessation in pregnancy.

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Figure 1: Flow diagram of searches

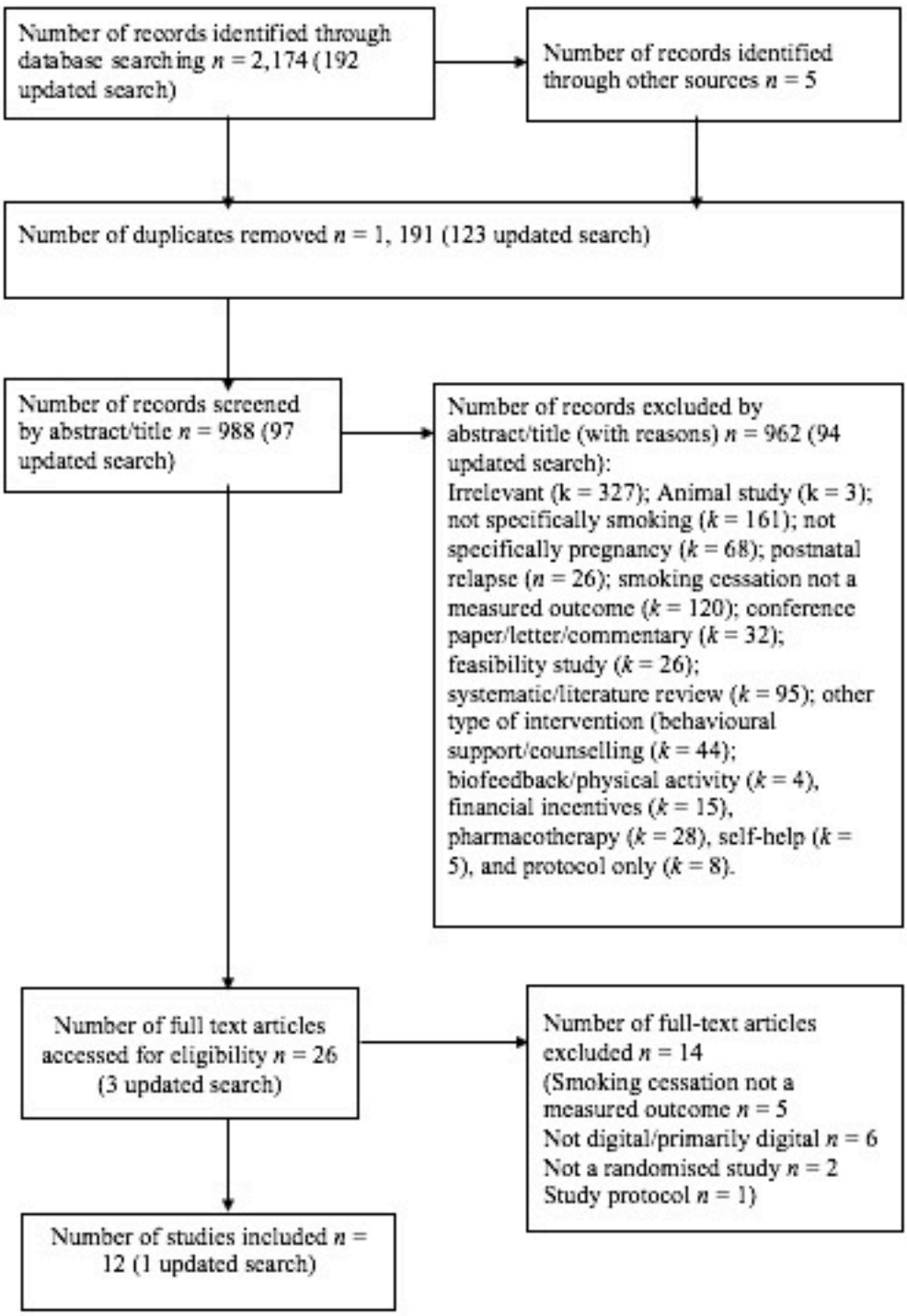


Figure 2: Risk of Bias Summary

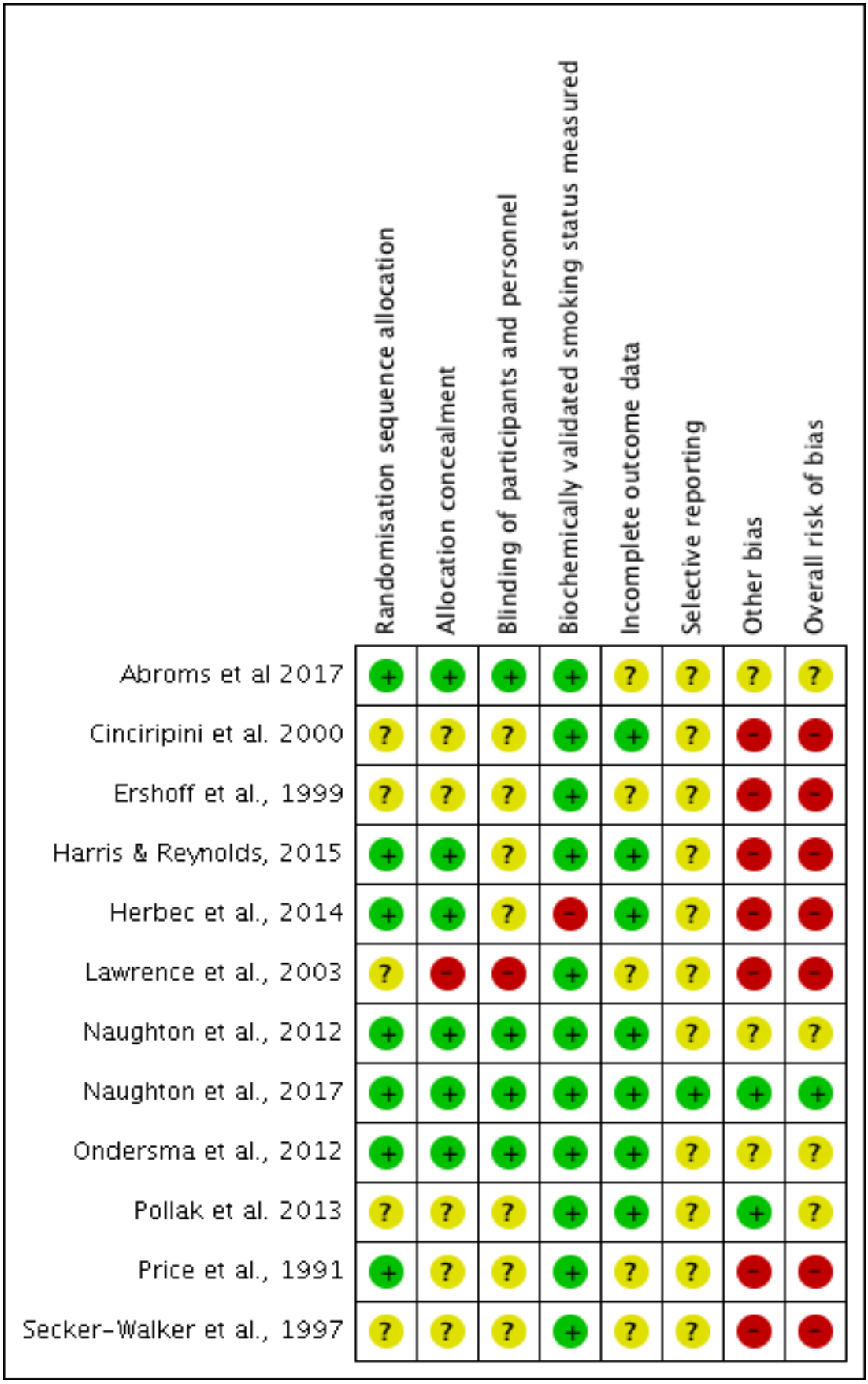
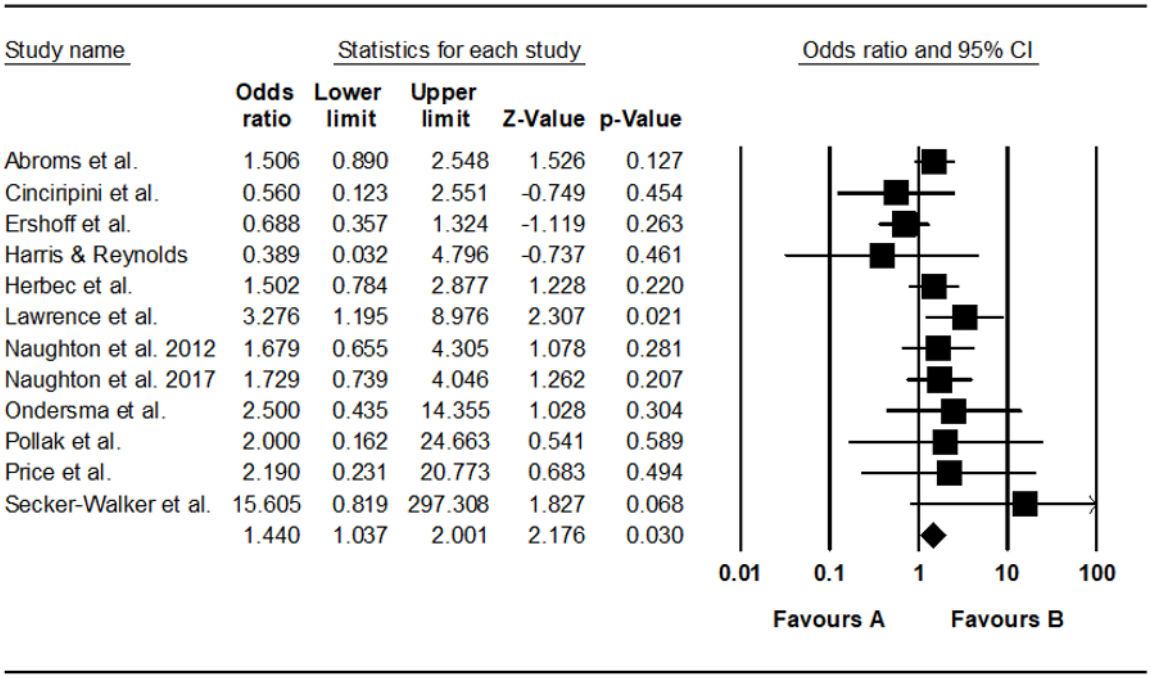


Figure 3. The effectiveness of digital interventions for smoking in pregnancy



	Q-Value	Df (Q)	P-value	I-squared %
Random effects model	13.37	11	0.27	17.73

Figure 4. Funnel Plot assessing publication bias

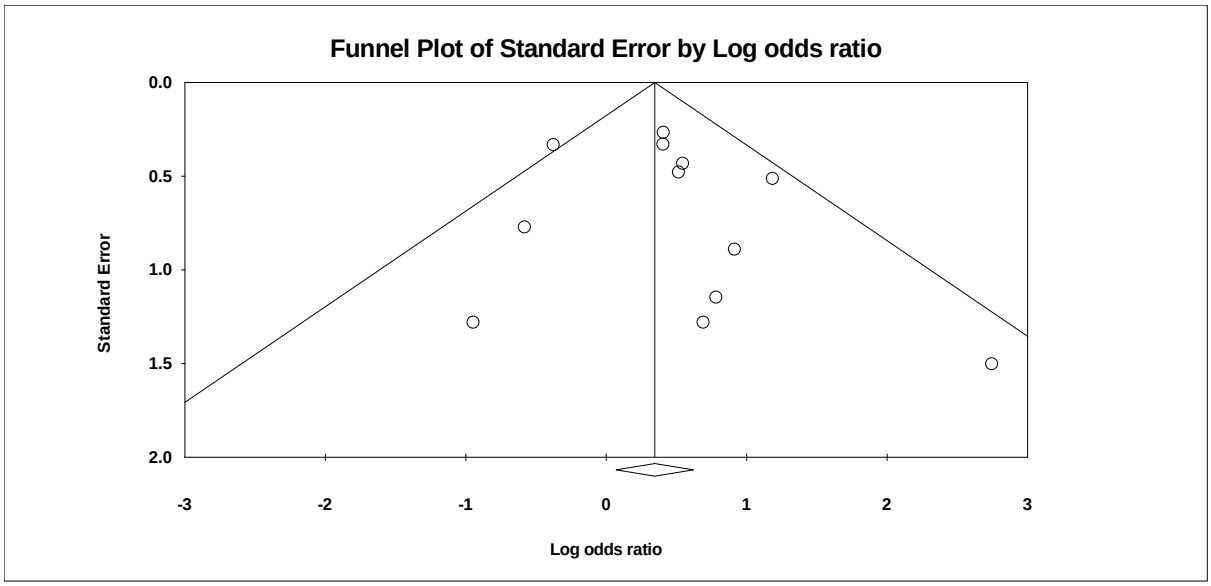
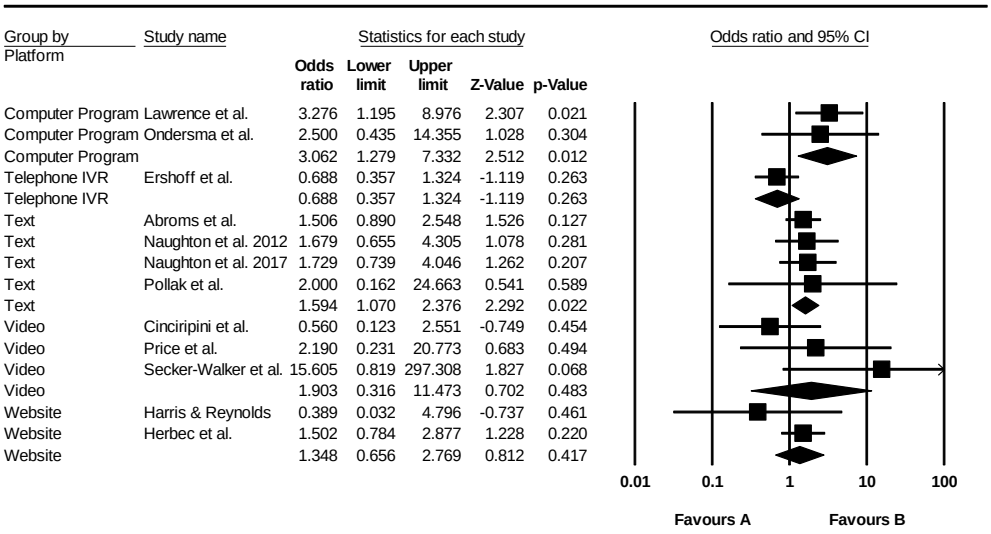
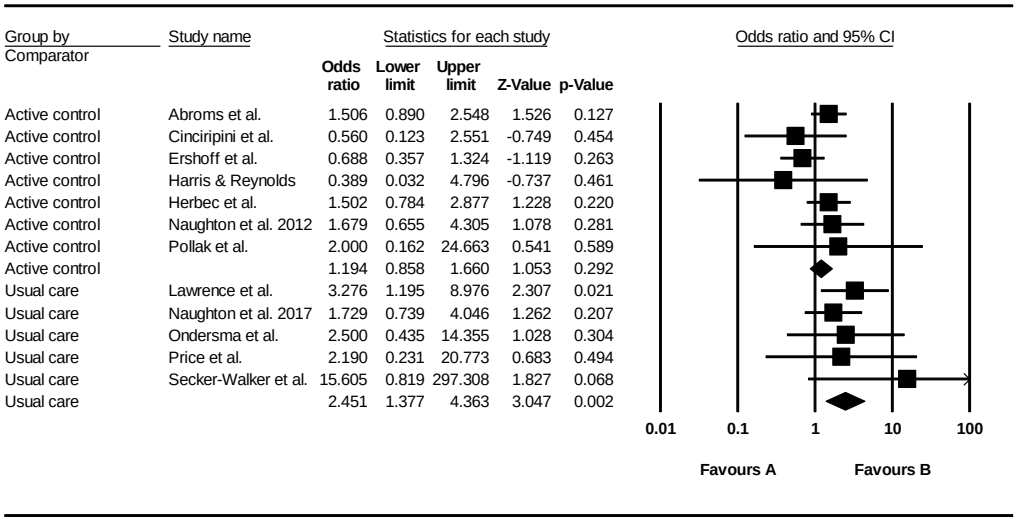


Figure 5. Effectiveness of intervention by platform



Random effects model	Q-Value	Df (Q)	P-value	I-squared %
Computer	0.07	1	0.80	0.00
Telephone	0.00	0	1.00	0.00
Text	0.12	3	0.99	0.00
Video	4.12	2	0.13	51.54
Website	1.04	1	0.31	4.04

Figure 6. Effectiveness by Control Group



Group by Comparator	Study name	Odds ratio	Lower limit	Upper limit	Z-Value	p-Value
Active control	Abroms et al.	1.506	0.890	2.548	1.526	0.127
Active control	Cinciripini et al.	0.560	0.123	2.551	-0.749	0.454
Active control	Ershoff et al.	0.688	0.357	1.324	-1.119	0.263
Active control	Harris & Reynolds	0.389	0.032	4.796	-0.737	0.461
Active control	Herbec et al.	1.502	0.784	2.877	1.228	0.220
Active control	Naughton et al. 2012	1.679	0.655	4.305	1.078	0.281
Active control	Pollak et al.	2.000	0.162	24.663	0.541	0.589
Active control		1.194	0.858	1.660	1.053	0.292
Usual care	Lawrence et al.	3.276	1.195	8.976	2.307	0.021
Usual care	Naughton et al. 2017	1.729	0.739	4.046	1.262	0.207
Usual care	Ondersma et al.	2.500	0.435	14.355	1.028	0.304
Usual care	Price et al.	2.190	0.231	20.773	0.683	0.494
Usual care	Secker-Walker et al.	15.605	0.819	297.308	1.827	0.068
Usual care		2.451	1.377	4.363	3.047	0.002

Random effects model	Q-Value	Df (Q)	P-value	I-squared %
Active control	6.34	6	0.39	5.3
Usual care	2.49	4	0.65	0.0

Figure 7a). Meta Regression on Number of BCTs

Main results for Model 1, Random effects (MM), Z-Distribution, Log odds ratio

Covariate	Coefficient	Standard Error	95% Lower	95% Upper	Z-value	2-sided P-value
Intercept	-0.6357	0.4445	-1.5069	0.2354	-1.43	0.1526
No. of BCTs	0.1057	0.0454	0.0167	0.1948	2.33	0.0200

Statistics for Model 1

Test of the model: Simultaneous test that all coefficients (excluding intercept) are zero
$Q = 5.41$, $df = 1$, $p = 0.0200$
Goodness of fit: Test that unexplained variance is zero
$Tau^2 = 0.0000$, $Tau = 0.0000$, $I^2 = 0.00\%$, $Q = 7.96$, $df = 10$, $p = 0.6329$

Comparison of Model 1 with the null model

Total between-study variance (intercept only)
$Tau^2 = 0.0559$, $Tau = 0.2365$, $I^2 = 17.73\%$, $Q = 13.37$, $df = 11$, $p = 0.2698$
Proportion of total between-study variance explained by Model 1
R^2 analog $= 1.00$

Number of studies in the analysis 12

Figure 7b). Meta Regression Scatterplot

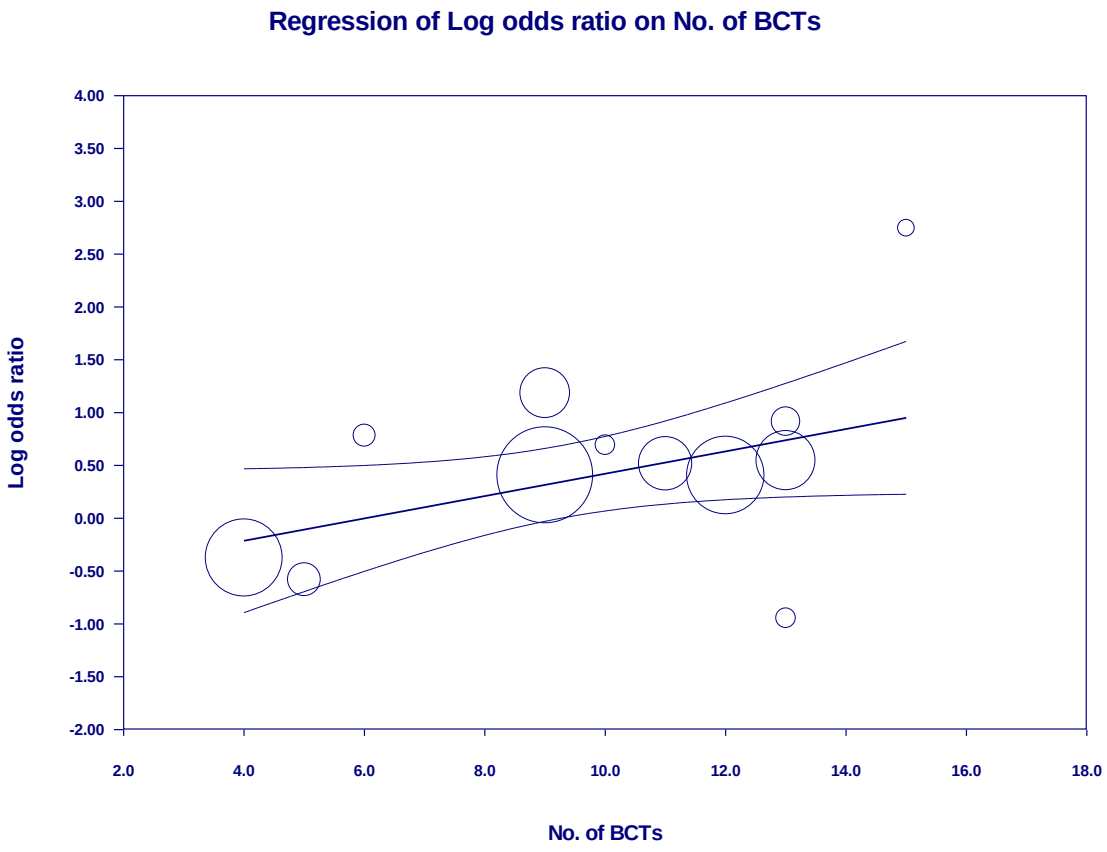


Table 1: Summary of Included Studies

Authors	Country	Total sample size	Mean age at enrolment (years)	Mean gestation at enrolment (weeks)	Control	Digital intervention	Primary Smoking Outcome Measure
Abroms et al., 2017	USA	497	26.31	17.8	Text4Baby text messages: messages on health issues, plus 6/150 on smoking cessation	Quit4Baby – 3 months of text messages aimed at increasing self-efficacy for quitting smoking	7-day PPA at 3-month follow-up, salivary cotinine verified (≤ 13 ng/ml)
Cinciripini et al., 2000	USA	82	30.5	15.2	Very Important Pregnant Smokers (VIPS) self-help quit calendar and cessation tip-guide providing daily information on risks of smoking and tips for quitting	Six 25-30 minute videotapes covering items from quitting strategies to relapse prevention	7-day PPA at end of pregnancy, salivary cotinine verified (< 30 ng/ml)
Ershoff et al., 1999	USA	332	29.4	Not reported	'Living Smoke Free' – 32-page tailored self-help booklet tailored to stage-of-change	Interactive Voice response (IVR)- access to computerised interactive telephone support 24 hours a day throughout pregnancy, stage appropriate customised messages	Smoking abstinence at end of pregnancy (34 weeks), urinary cotinine verified (< 30 ng/ml)

(ctd) Authors	Country	Total sample size	Mean age at enrolment (years)	Mean gestation at enrolment (weeks)	Control	Digital Intervention	Primary Smoking Outcome Measure
Harris & Reynolds, 2015	USA	17	24.1	10.8	'Smoking Cessation for Healthy Births' - Telephone delivered counselling system, 5 calls throughout pregnancy	Web-based contingency management program lasting 6 weeks	Abstinence throughout pregnancy (latest measure taken during 8th month of pregnancy) urinary cotinine verified (no cut-off given)
Herbec et al., 2014	UK	200	27.8	Not reported	One-page static, non-personalised website providing brief advice for users. Content based on widely used manual for smoking cessation support for practitioners	'MumsQuit' website lasting 8 weeks: provided an interactive, personalised and structured quit plan, replicating support from expert through NHS stop Smoking Services	Continuous, self-reported 4-week abstinence at 8-week follow-up
Lawrence et al., 2003	UK	918	26.1 (median)	12.2 (median)	Usual care: Smoking cessation advice as usual from midwife, plus Health Education Authority leaflet ‘Thinking about Stopping’, already routinely used by midwives.	6 self-help manuals, plus use of computer programme interventions for 20-minutes on 3 occasions in clinic - questions to stage women followed by on-screen and audio feedback of stage and meaning.	PPA at 28-30 weeks of pregnancy, urinary cotinine verified, < 1.5 μg/ml

(ctd) Authors	Country	Total sample size	Mean age at enrolment (years)	Mean gestation at enrolment (weeks)	Control	Digital Intervention	Primary Smoking Outcome Measure
Naughton et al., 2012	UK	207	26.9	12.75	Self help leaflet: Non-tailored leaflet in similar style to tailored version, and same assessment texts as experimental group. Plus access to routine smoking cessation support and advice.	'MiQuit' Tailored, 4-page colour leaflet plus 11-week tailored text messages - smoking beliefs, motivation, confidence, nicotine dependence, reasons for quitting, barriers. On demand support/ distraction game.	7-day PPA at 3-month follow-up, salivary cotinine verified (<13 ng/ml)
Naughton et al., 2017	UK	407	26.5	14.7	Usual care: Participants were given a standard NHS booklet on smoking cessation for pregnant women, plus access to routine smoking cessation support and advice.	‘MiQuit’: As control plus 12-week tailored text messages - smoking beliefs, motivation, confidence, nicotine dependence, reasons for quitting, barriers. On demand support/ distraction game.	7-day PPA at late pregnancy (approx. 36-weeks), salivary cotinine and/or CO verified (< 10 ng/ml or < 9 ppm)

(ctd) Authors	Country	Total sample size	Mean age at enrolment (years)	Mean gestation at enrolment (weeks)	Control	Digital Intervention	Primary Smoking Outcome Measure
Ondersma et al., 2012	USA	110	27.9	Not reported, <27 weeks	Treatment as usual from prenatal care advisors, with no influence from research team.	Combination of CD 5As (Computer-delivered 5 As-based brief motivational intervention: tailored 4-6 minute videos, e.g. 'advise' with obstetrician and 3 testimonials) and CM-Lite (computer-assisted low-intensity Contingency Management).	7-day PPA at 10-week follow-up, CO verified (< 4 ppm)
Pollak et al., 2013	USA	31	28	16.5	SMS text-based support: up to 5 messages a day for 5 weeks new theme each week based around stopping smoking, e.g. reasons for quitting, preparing for quit date, partner smoking and relapse handling.	Scheduled Gradual Reduction: Participants were sent messages for 5 weeks to help them gradually cut down to zero cigarettes by week 4. women texted when they smoked, algorithm calculated number of cigarettes per day in weeks 2-4.	7-day PPA at 6-week follow-up, salivary cotinine verified (< 10 ng/ml)

(ctd) Authors	Country	Total sample size	Mean age at enrolment (years)	Mean gestation at enrolment (weeks)	Control	Digital Intervention	Primary Smoking Outcome Measure
Price et al., 1991	USA	109	22.6	Not reported, <28 weeks	Usual physician's advice: received usual information on importance of not smoking in pregnancy, usually discussed at one or more prenatal visits.	Educational videotape: 6.5 minute videotape in clinic focusing on potential smoking risks and benefits of quitting. Also given pamphlet on how to quit. One month later viewed 2nd videotape (4 mins) focusing on quitting strategies - tailored to needs of the group.	Smoking cessation at end of pregnancy (37-38 weeks), CO verified (< 7 ppm)
Secker-Walker et al., 1997	USA	60	23	Not reported, all recruited at first prenatal visit	Usual care: Smoking cessation advice from obstetrician or nurse-midwife, plus tip-sheet (designed to commit to setting a quit date/date by which to cut down by half).	One 29-minute videotape for women to watch at home, showing real women going through the process of quitting smoking. Only the women's voices were heard on the video.	Smoking abstinence at 36-weeks of pregnancy, CO verified (< 8ppm)

PPA: Point prevalence abstinence
CO: Carbon Monoxide
Ppm: parts per million