Do interventions containing risk messages increase risk appraisal and the subsequent vaccination intentions and uptake? A systematic review and meta-analysis

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Abstract

Purpose: There is good evidence that for many behaviours, increasing risk appraisal can lead to a change in behaviour, heightened when efficacy appraisals are also increased. The present systematic review addressed whether interventions presenting a risk message, increase risk appraisal and an increase in vaccination intentions and uptake.

Method: A systematic search identified Randomised Controlled Trials of interventions presenting a risk message and measuring risk appraisal and intentions and uptake post-intervention. Random effects meta-analyses investigated the size of the effect that interventions had on vaccination risk appraisal, and on vaccination behaviour or intention to vaccinate, and the size of the relationship between vaccination risk appraisal and vaccination intentions and uptake.

Results: Eighteen studies were included and 16 meta-analysed. Interventions overall had small significant effects on risk appraisal (d= 0.161, p= .047) and perceptions of susceptibility (d= 0.195, p= .025), but no effect on perceptions of severity (d= -0.036, p= .828). Interventions showed no effect on intention to vaccinate (d= 0.138, p= .195) and no effect on vaccination behaviour (d= 0.043, p= .826). Interventions typically did not include many Behaviour Change Techniques (BCTs), with the most common BCT unique to intervention conditions being ‘Information about Health Consequences’. Few of the included studies attempted to, or successfully increased, efficacy appraisals.

Conclusions: Overall, there is a lack of good quality primary studies, and existing interventions are suboptimal. The inclusion of additional BCTs, including those to

target efficacy appraisals, could increase intervention effectiveness. Protocol (CRD42015029365) available from http://www.crd.york.ac.uk/PROSPERO/

Keywords; Vaccination, Randomised Controlled Trial, Uptake, Risk Appraisal

Many infectious diseases are preventable through vaccination. Vaccinations are responsible for preventing two to three million deaths per year globally (WHO, 2016). The efficacy of vaccination can be demonstrated by the eradication of Smallpox worldwide over the last 40 years (Miller & Sentx 2006). Furthermore, in the UK, vaccination has led to a 99% reduction in Meningitis C cases in those under 20 years old since its introduction in 1999 (NHS Choices 2016).

Despite benefits to health at the individual and societal levels, uptake of vaccination does not reach targets set by the World Health Organisation (WHO). It is estimated that 18.7 million children worldwide do not receive the recommended, routine vaccinations against preventable diseases (WHO, 2016). In developed countries, programmes routinely include vaccination of major childhood illnesses and vaccination against seasonal illnesses for groups at higher risk. In the UK, although free routine vaccinations are available for groups at higher risk, national uptake targets of these vaccinations are not met (WHO, 2016). Uptake levels of some vaccinations remain poor, e.g. only 45.1% of adults under 65 years in a clinical risk group (i.e. those that are considered to be more at risk of the illness being vaccinated against,excluding pregnancy) in the UK received the flu vaccination in the 2015- 16 season. (www.gov.uk).

Individual factors contribute to vaccination decisions, notably risk appraisal, defined as individuals' beliefs about personal susceptibility associated with a disease and the severity of that disease (Wright, 2010). In a recent systematic review, vaccination uptake was lower amongst people who believed that they were unlikely to contract the disease, or those that believed that the disease was not severe (Bish, Yardley, Nicoll & Michie, 2011). Vaccination uptake was also lower when individuals believed that the vaccine was ineffective.

There is now good systematic review evidence that increasing risk appraisal can have a small effect on increasing behaviour, and that interventions increasing risk appraisal have a greater effect on intention when elements of efficacy appraisals (comprised of self-efficacy and response-efficacy) are simultaneously increased (Peters, Ruiter & Kok, 2013; Sheeran, Harris & Epton, 2014; Tannenbaum, Hepler, Zimmerman, Saul, Jacobs, Wilson, et al 2015). In line with this, one way of increasing vaccination uptake would therefore be to increase individuals' beliefs about the risk of infectious diseases, and the efficacy of vaccinations in reducing that risk.

Existing meta-analyses of experimental studies examining the effect of changing risk appraisals on behaviour, have typically examined effects across a number of health-related behaviours (Sheeran et al, 2014, Tannenbaum et al, 2015). This approach increases the number of studies analysed, and thereby increases the strength of confidence in the effect size reported. By contrast, studies examining only one behaviour are considered more informative for developing future interventions, as estimates of effect can be reliably attributable to the one behaviour (Wright, 2010). In line with this, the systematic review of Brewer, Chapman, Gibbons, Gerrard, McCaul, & Weinstein (2007) included only studies of vaccination. This review however included cross-sectional and prospective studies, which are not as

informative for intervention design as experimental designs, as correlation alone does not allow causal relationships to necessarily be inferred (Weinstein, Rothman & Nicolich, 1998).

A further meta-analysis by Sheeran and colleagues (2014) examined the effect of heightening risk appraisal on intentions and behaviour. The overall effect (intention; d= 0.31, behaviour; d= 0.23), and the effect by behaviour type (including for vaccination: intention; d= 0.38, behaviour; d= 0.33), was reported. This meta-analysis however only included Randomised Controlled Trials that were successful in changing risk appraisals; if there was no change in risk appraisals, then they were not included in the review. This decision was taken by the authors because they specifically wanted to examine the relationship between risk and behaviour, necessitating that only studies where the manipulation of risk was successful be included. This however means that the success of existing interventions in changing risk appraisals cannot be inferred from the findings.

The primary aim of the present systematic review was to examine interventions reported in the literature to see whether those that include risk messages have been successful in influencing risk appraisals and the subsequent intentions and uptake of vaccination. To further add to the body of evidence about the relationship between risk appraisal and vaccination uptake, secondary aims of the current systematic review were to examine the size of the relationship between these variables, and also to examine whether changes to risk appraisal are enhanced by experimentally induced increases in efficacy appraisal. It is the first systematic review to examine if risk messages influence risk appraisal and vaccination using only experimental studies. This will enable firmer conclusions to be drawn about success of existing intervention strategies in changing risk and subsequent vaccination behaviour. The present systematic review also aimed to establish which BCTs were present in

interventions used to increase risk appraisal and vaccination intention and uptake in the included studies, and how these were associated with changes in risk appraisal and vaccination intention and uptake.

Method

This systematic review was conducted in accordance with the protocol (CRD42015029365) published on the International Prospective Register of Systematic Reviews (PROSPERO). http://www.crd.york.ac.uk/PROSPERO/

Inclusion and Exclusion Criteria

Studies were required to be randomised controlled trials, with random assignment of participants to experimental conditions. At least one control condition was required; this could have been either no intervention or usual practice. No date restrictions or limitations on country of study were set but studies had to have been published in the English language.

Studies were included in the systematic review if they described an intervention aiming to increase vaccination intention or uptake that included a risk message. Whether an intervention had targeted an increase in risk appraisal was determined by whether this construct (namely susceptibility and/or severity) was measured and reported post-intervention. Studies were also required to have measured vaccination uptake, or intention to have a vaccination, at least once following the intervention, where vaccination was the participant's own decision, not a decision made on the behalf of someone else e.g. a child.

To be included, studies had to include all of the necessary statistical information to calculate an effect size for changes in risk appraisal and vaccination intention or behaviour

following the intervention. Where this information was not available, attempts were made to contact authors for appropriate data. If this was unsuccessful, then the study was included in the systematic review, but excluded from the meta-analysis. Studies included in the systematic review were required to provide a description of the intervention (which could be any type or length of exposure). Where there was no description, or the information provided was not sufficiently reported, then attempts were made to contact authors for this information. In cases where no further intervention information was available, the available information was coded. Where no information on the intervention was available, the study was excluded from the systematic review.

Search Strategy

Peer-reviewed publications were searched using CINAHL, Medline, PsycINFO, Scopus (including Science Direct) and Web of Science. Reference sections of included papers were examined to identify any relevant studies that were not identified by the initial search. Forward citation searches were conducted on included articles and major systematic reviews in this area (namely Brewer, Chapman, Gibbons, Gerrard, McCaul, & Weinstein, 2007; Sheeran, Harris & Epton, 2014; Tannenbaum, Hepler, Zimmerman, Saul, Jacobs, Wilson & Albarracín, 2015). Last searches were completed in September 2017. Full search terms can be found in the online supplemental materials (supplemental material 1).

To identify unpublished studies the Ethos database was used to search for relevant PhD theses using combinations of the same search terms. Additionally, authors of included studies were contacted to identify any other unpublished, relevant studies (contact details for authors of eight studies were available, and of those, three responses were received). Furthermore, requests were distributed electronically via affiliated groups (namely European

Association of Social Psychology, European Health Psychology Society, Midlands Health Psychology Network, Social, Personality and Health Network and Society for Personality and Social Psychology) asking members if they were aware of any unpublished papers meeting the inclusion criteria.

Screening

Titles and abstracts of papers identified from database searches were initially screened by the lead author. A second stage of screening was undertaken using the full text of all studies that had not yet been excluded. This led to a sample of studies which met all inclusion criteria and which would provisionally be included in the meta-analysis (see Figure 1). All studies considered eligible for inclusion, including any studies where inclusion was not clear, or where queries arose, were examined by the second author. A small number of minor discrepancies were resolved by discussion and a consensus reached on included studies.

Figure 1 here.

Extraction and Coding

Information required for the calculation effect sizes was extracted. In all studies except one (Prati Pietrantoni and Zani 2012), outcome data for susceptibility or severity or both was reported separately. In the study by Prati and colleagues (2012) a combined risk outcome measure was reported. All of this information was extracted. In addition, information was extracted for vaccination behaviour and intention to vaccinate. In studies that used multiple follow-up measures, the first measure of risk and intention following intervention, and the last measure of behaviour reported, was used.

A number of study and sample characteristics were coded including: the illness type under examination, whether participants were pregnant, and the age group of participants.

Whether interventions had successfully increased efficacy appraisals was also extracted. Please note, whilst it was originally planned that analysis would differentiate between increases in self and response-efficacy, this was not possible. Of the three studies that successfully manipulated efficacy appraisals, only two measured self-efficacy, and the other measured response and self-efficacy as a combined measure. For this reason efficacy appraisals were analysed as a combined measure. Age group was categorised as follows: Adolescent: 16-18, Adults: 19-64 and Older Adults: 65+. In cases where the age groups of participants in any one study crossed these boundaries, the age group was deemed to fall into the category where the majority of the participants resided). The nature of questions used to measure risk was also extracted to identify whether conditional or unconditional questions were used. Conditional questions refer to the likelihood of the event occurring according to whether action is taken to prevent it. Unconditional questions on the other hand refer to the likelihood of the event occurring regardless of action, and take into account any subjective factors that influence the individual (Van Der Velde, Hooykaas & Van Der Pligt, 1996). Unconditional questions have been described as being methodologically inferior because they allow for the behavioural intentions of participants to influence risk appraisals (Weinstein, Rothman, & Nicolich, 1998).

Coding of BCTs within interventions was completed using the 93-item Behaviour Change Technique Taxonomy v1 (Michie, Richardson, Johnston, Abraham, Francis, Hardeman, Eccles, Cane & Wood, 2013). Full interventions were coded where available, with authors being contacted for full interventions when these were not present within the paper. When no further information was provided, descriptions within the papers were coded. BCTs within both experimental and control group interventions were coded. Any BCTs that were present in both of the conditions were excluded to ensure that only unique intervention

content was isolated. BCT coding was completed independently by both the lead author (who has previous experience in coding behaviour change techniques), and the second author (who has more extensive behaviour change technique coding experience). Any disagreements were discussed and a consensus was reached where required.

In addition, the lead author coded: the dose of each BCT (dose was derived from information available within intervention descriptions and was calculated by counting the number of times the BCT was delivered, either using the same intervention strategy or a something different), practical applications (Bartholemew, 2016) used to deliver each BCT, and the mode of intervention delivery (in line with the Mode of Delivery of Behaviour Change Interventions Taxonomy version 0; Carey, Evans, Horan, Johnston, West and Michie 2016). Categorised modes included: printed material ('Delivery through information produced on paper; can be hand-delivered or posted to the participant; materials can include diagrams, pictures and text.'), Digital; Computer/Television ('Delivery through a computing device or television set'), and Human; face-to-face ('Delivery through human contact in which the participant meets a person in real-time, face-to-face'). See supplemental material 2.

Assessment of Study Risk of Bias

A risk of bias assessment is designed to assess the validity of included studies, and to examine whether any bias exists (whereby the true effect of the intervention is overestimated or underestimated). The Cochrane Risk of Bias Tool was used to assess the risk of bias in the included studies, and to assess the quality of the randomised controlled trials (Higgins & Green, 2011). Risk of bias assessment was completed by the lead author, and independently assessed by a second coder. Any disagreements in scoring were discussed and a consensus was reached.

Publication Bias (the tendency for studies reporting significant or positive findings to be published more commonly than those without statistical significant findings, leading to meta-analyses missing some studies) was assessed using Funnel Plots and Trim and Fill analysis conducted in line with Duval and Tweedie (2000).

Statistical Methods

Meta-analysis software Comprehensive Meta-Analysis (CMA) version 3 was used to calculate Standardised Mean Difference for each intervention using a Random Effects model. Where separate outcome measures for risk were provided (i.e. susceptibility and severity), these were entered separately into CMA and their mean used within effect size calculations. A pooled and weighted Standardised Mean Difference was thus calculated for risk (susceptibility and severity combined), intention to vaccinate, and behaviour (having the vaccination). Effect size estimates were however also calculated separately for measures of susceptibility and severity where studies provided the necessary information. Where studies included multiple interventions containing different types of risk messages, all of these interventions were included separately and the sample size of the control group was reduced to control for multiple comparisons. The relationship between risk appraisal and vaccination intention was assessed using a pooled, within-study Pearson Correlation Coefficient. It was originally planned that the relationship between risk appraisal and vaccination uptake, and between risk appraisal and intention to vaccinate, would be examined. There were however insufficient studies reporting the relationship between risk appraisal and behaviour for the effects to be pooled. For this reason, only the relationship between risk appraisal and intention to vaccinate is reported. The heterogeneity of the results was calculated using the I^2 statistic (Higgin, Thompson, Deeks & Altman, 2003).

A number of pre-specified meta regression analyses were conducted. Moderators were only tested when they contained a sufficient range of values, that is, they had to be present or absent in at least three studies. Between groups heterogeneity was assessed using the Q statistic to determine which moderators accounted for significantly different effect size estimates. Meta regression analysis was conducted to establish whether effect sizes for risk differed as a function of: whether efficacy appraisal was also increased and whether conditional or unconditional questions of risk were used. Additionally, they were conducted to establish whether effect sizes for risk appraisal or vaccination intention or uptake differed as a function of: the illness being vaccinated against, the age group of participants, and whether study participants were pregnant or not.

A further pre-specified meta regression analysis was also conducted to explore whether there was a difference in the size of effect (risk, intention, and behaviour) as a function of BCTs most commonly coded within the included interventions: Information about Health Consequences, Information about Social and Environmental Consequences or Credible Source.

Two further meta regression analyses were performed that were not pre-specified in the review protocol. These established whether there was a difference in the size of effect when more than two BCTs were included in the intervention, and according to the mode of delivery employed.

Moderators were only tested when they were present or absent in at least three studies. Accordingly, meta-regression was not conducted for the following moderators:

credible source for the outcome variable risk, and, credible source and number of BCTs for the outcome variable intention to vaccinate. No moderators were run for the outcome variable behaviour. The limited number of studies measuring behaviour meant that there were always too few studies with the moderator either present or absent..

Results

Of 10,379 potential studies initially identified (after duplicates were removed), 18 satisfied all inclusion criteria. A table listing all included studies and summary characteristics can be found in the online supplemental materials (supplemental material 3). The majority of studies had a high percentage of female participants, with six studies involving female participants only, in part attributable to the nature of some studies examining vaccination intention or uptake in pregnancy. Only three studies recruited only men. Nine of the 18 included studies reported the mean age of participants, or the age range of participants, as being under 26 years. Seventeen of the 18 included studies were conducted in community settings. Community settings included participant's own homes, health centres and churches. The remaining study (Gerend and Sheperd 2012) was conducted in a laboratory within a university. Four studies used conditional risk questions, whereas 14 used unconditional risk questions (an example of a conditional risk question used is 'What is the likelihood that you will get the flu this year if you don't get a flu shot?' (Prati et al 2012)).

Table 1 here

Results of Main Outcomes

On the whole, studies reported a statistically significant increase in risk appraisal following intervention. Of the 18 included studies, thirteen did not measure or manipulate efficacy appraisals. Of the five that did attempt to manipulate efficacy appraisals, three showed a statistically significant increase. Thirteen of the included studies measured intention as the

primary outcome variable, whilst five studies measured behaviour as the primary outcome variable. Thirteen studies reported a statistically significant increase in vaccination uptake or intention to vaccinate post intervention. Five reported no increase in intention or uptake as a result of the intervention.

Meta-analysis. Sixteen studies, reporting on the effect of 29 interventions, were able to be included in the meta-analysis (Bennett, Patel, Carlos, Zochowski, Pennewell, Chi & Dalton, 2015, and Dabbs and Leventhal 1966 contained insufficient statistical information to be included in the meta-analysis). A full table of effect sizes can be found in Supplemental material 4.

Study interventions had a small but significant pooled effect on risk appraisal (d= 0.161, CI 95% .002 to .320, n= 7,914, k= 29, p= .047, I^2 = 76.855). By contrast, there was no significant pooled effect on intention (d= 0.138, CI 95% -.071 to .346, n= 5,905, k= 19, p = .195, I^2= 72.613), or on behaviour (d= 0.043, CI 95% -.343 to .429, n= 2009, k=9, p= .826, I^2= 79.468). Interventions had a small significant pooled effect on susceptibility (d= 0.195, CI 95% .024 to .366, n= 6722, k= 27 , p= .025) but no pooled effect on severity (d= -0.036, CI 95% -.366 to .293, n= 5390, k= 15, p= .828). There was a small significant relationship (r= .114, CI 95% = .031 to .196, n= 1017 k= 8, p= .007, I^2= 80.303) between risk appraisals and intention to vaccinate. Six studies reported this relationship, consisting of eight interventions. Forest plots for risk, intention, behaviour, susceptibility, severity, and the relationship between risk and intention can be found in the online supplemental materials (supplemental material 5).

The most common BCT, unique to the intervention condition, was 'Information about Health Consequences' which was included in interventions reported by thirteen of the included interventions. Other BCTs included Credible Source (k= 5), and Information about Social and Environmental Consequences (k= 6). On the whole, there were very few unique BCTs used within interventions compared to controls. Three studies had no unique BCTs in the intervention condition compared to the control condition (de Wit, Das and Vet 2008; Frew, Owens, Saint-Victor, Benedict, Zhang & Omer, 2014 and Godinho, Yardley, Marcu, Mowbray, Beard and Michie 2016).

Study Risk of Bias

Of the 18 studies included in the review, three had a moderate risk of bias (Bennett et al, 2015, Hopfer, 2009 and Vet, de Wit and Das 2011), and 15 had a high risk of bias (Higgins & Green, 2011). Plots of the risk of bias assessment per domain, and by study can be found in the online supplemental material (supplemental material 6). The domain contributing most frequently to an overall high risk of bias rating was 'Random Sequence Generation' (unclear descriptions of how participants were randomised to conditions was often not specified, resulting in a rating of 'unclear') and 'Selective Reporting (Protocols were often unavailable or not mentioned, so there was insufficient information to establish whether all of the intended outcomes had been reported).

Assessment of Heterogeneity

Considerable heterogeneity was present in measures of risk appraisal $I^2 = 76.855$, Intention $I^2 = 72.613$ and Behaviour $I^2 = 79.468$. As substantial heterogeneity was present, a random effects model was used.

Publication Bias

There was evidence of Publication Bias for the outcome variable Behaviour. Trim and Fill analysis made two adjustments, and no change in behaviour was observed. (Adjusted values can be found in supplemental material 7). There was no evidence of Publication Bias for the outcomes of risk or Intention and therefore no adjustments were made.

Meta Regression Results

All meta-regression results can be found in table 2.

Table 2 here.

Efficacy Appraisals. Efficacy appraisals had no significant association with risk (Δd= 0.242, Q= 0.92, p= .339). Interventions that included efficacy had a higher effect size (d= 0.372, k= 3) than interventions that did not (d= 0.130, k= 14).

Type of Risk Question Used. The type of risk question used (conditional or unconditional) had no significant association with risk (Δd= -0.218, Q= 1.61, p= .205). Interventions that used unconditional questions had a higher effect on risk (d= 0.237, k= 12) than interventions that used conditional questions (d= 0.019, k= 4).

Illness type: Flu. Illness type had no significant association with risk when flu was the illness being vaccinated against (Δd= -0,122, Q= 0.57, p= 452). Interventions for flu vaccination had a higher effect on risk (d= 0.228, k= 9) than when interventions were for other illnesses (d= 0.106, k= 8).

Illness type had no significant association with intention when flu was the illness being vaccinated against (Δd= 0.034, Q= 0.02, p= .876). Interventions for flu vaccination had

a higher effect on risk (d= 0.152, k= 8) than when interventions were for other illnesses (d= 0.117, k= 4).

HPV. Illness type had no significant association with risk when HPV was the illness being vaccinated against (Δd= 0.139, Q= 0.45, p= .500). Interventions for HPV vaccination had a lower effect on risk (d= 0.049, k= 3) then when interventions were for other illnesses (d= 0.188, k= 13).

Age Group: Adult. Age Group of participants had no significant association with risk when participants were Adults (Δd= -0.239, Q= 1.92, p= 0.166). Interventions had a higher effect on risk when participants were adult (d= 0.250, k= 10) than when they were other age groups (d= 0.011, k= 6).

Age group of participants had no significant association with intention when participants were Adult (Δd= 0.078, Q= 0.10, p= .751). Interventions had a lower effect on intention when participants were adults (d= 0.112, k= 80 than when they were other age groups (d= 0.190, k= 4).

Older Adult. Age group of participants had no significant association with risk when participants were older adults (Δd= 0.245, Q= 1.94, p= .163). Interventions had a higher effect on risk when participants were other age groups (d= 0.244, k= 11) than when they were older adults (d= -0.000, k= 5).

Pregnancy. Whether participants were pregnant had no significant association with risk (Δd= 0.269, Q= 1.19, p= .276). Interventions had a higher effect on risk when participants were pregnant (d= 0.396, k= 3) than when they were not pregnant (d= 0.127, k= 13).

Whether participants were pregnant had no significant association with intention (Δd= -0.110, Q= 0.14, p= .704). Interventions had a lower effect on intention when participants were pregnant (d= 0.045, k= 3) than when they were not pregnant (d= 0.155, k= 9).

BCTs: Information about Health Consequences. Including the BCT information about health consequences had no significant association with risk (Δd= -0.238, Q= 2.02, p= .155). Interventions that included Information about Health Consequences had a lower effect on risk (d= 0.033, k= 6) than interventions that did not 9d= 0.271, k= 10).

Including the BCT Information about Health Consequences had no significant association with intention (Δd=-0.007, Q= 0.00, p= .970). Interventions that included Information about Health Consequences had a lower effect on intention (d= 0.128, k= 40 than interventions that did not (d= 0.135, k= 8).

Information about Social and Environmental Consequences. Including the BCT information about social and environmental consequences had a small, significant negative association with risk (Δd= -0.431, *Q*=4.58, p=.032*). Interventions with this BCT had a lower effect size (d= -0.179, k= 3) than interventions without this BCT (d=0.252, k=13).

Number of BCTs in intervention (less than two, or two or more). The number of BCTs had a significant negative association with risk (Δd= -0.431, *Q*= 8.25, p=.0004**). Interventions with less than two BCTs had a higher effect size (d=0.344, k=10) than interventions with two or more BCTs (d=-0.088, k= 6).

Mode of Delivery: Digital. Digital methods of delivery had no significant association with risk (Δd= -0.201, Q= 1.54, p= .215). Interventions that used a digital mode of delivery had a higher effect on risk (d= 0.243, k= 8) than other modes of delivery (d= 0.042, k= 8).

Digital methods of delivery had no significant association with intention (Δd= 0.052, Q= 0.01, p= .913). Interventions that used a digital mode of delivery had a lower effect on intention (d= 0.126, k= 6) than other modes of delivery (d= 0.151, k= 6).

Human. The mode of delivery had a small significant association with risk (Δd= 0.514, Q= 7.21, p= .007**). Interventions delivered by humans had a significantly larger negative effect on risk (d= -0.252, k= 3) compared to those where other methods of delivery were used (d= 0.262, k= 13).

Printed Material. Printed materials had no significant association with risk (Δd= -0.201, Q= 0.98, p= .323). Interventions that used printed materials had a higher effect on risk (d= 0.319, k= 5) than other modes of delivery (d= 0.118, k= 11).

Where sub-groups within a moderator contained insufficient studies (e.g. for illness type within studies measuring intention, there were only two studies that examined Hepatitis B and two that examined HPV), but there was at least one reference group with three or more studies (e.g. flu had eight studies), the other sub-groups were combined (e.g. Hepatitis and HPV combined to create an 'other illness category') and compared to the reference group (e.g. flu).

Discussion

Principal Findings

Overall, whilst interventions containing risk messages did not increase intention to vaccinate or vaccination behaviour, they did have a small effect on risk appraisal. There was a small relationship between vaccination risk appraisal and intention to vaccinate. There was a small but significant pooled effect of interventions on susceptibility, but no pooled effect on severity. Interventions with higher numbers of BCTs and those delivered in person (as

446 opposed to via digital or printed material) had smaller effects on risk appraisals. The majority
447 of studies had high risk of bias, often due to multiple indicators being unclear.
448
449 Interventions in the present review were found to include few Behaviour Change
450 Techniques (BCTs), with the most commonly used being Information about Consequences,
451 Credible Source and Information about Social and Environmental Consequences. The
452 presence of Information about Social and Environmental Consequences had a negative effect
453 on vaccination risk appraisal, suggesting that the presence of this BCT within interventions
454 reduced individuals' appraisals of risk. Interestingly, of the three studies that included this
455 BCT, only one successfully increased efficacy appraisal. It is possible therefore that this
456 finding reflects an element of defensive processing (see Wright, 2010). In other words,
457 intervention content that triggers individuals to appraise the risk of illness without also
458 ensuring that they feel able to perform a behaviour perceived as effective, may lead them to
459 adopt coping strategies such as denial or avoidance.
460
461 Meta regression analysis showed that the number of BCTs included in an intervention
462 had a small, significant negative effect on risk. Specifically, interventions that had three or
463 more unique BCTs decreased risk appraisal. This unexpected finding is in contrast to other
464 reviews which have found that including more BCTs has a greater effect on behaviour change
465 (Craddock, ÓLaighin, Finucane, Gainforth, Quinlan and Ginis 2017; Webb, Joseph, Yardley
466 and Michie 2010). One possible explanation for this, may be that brief information on
467 vaccination is preferable. Shorter, more concise material may increase engagement, and
468 therefore may be more effective in increasing risk appraisal.
469 Meta regression analysis also showed that there was a difference in the effect of
470 interventions delivered by people, compared to those delivered digitally or using printed

material. Specifically, those delivered by people had a negative effect on risk (whilst interventions delivered digitally or with printed materials had a positive effect). This may be explained in a number of ways; firstly, research suggests that risk information is often communicated less effectively when done so verbally. Furthermore, interventions delivered face-to-face may be more at risk of variation in the way they are delivered, compared to more standardised paper digital materials. Finally, some medical professionals may demonstrate a preference to promote informed choices of individuals, thus tempering messages that actively promote vaccination uptake (French and Marteau 2007).

Strengths and Weaknesses

Review-level strengths include that the present review was conducted and reported in line with PRISMA guidelines, and the Meta-Analysis Reporting Methods (MARS). Stringent inclusion criteria ensured that only studies that could contribute to understanding about the impact of interventions on risk appraisal on vaccination intention or uptake were included. This however also introduced a weakness in the ability of the review to draw conclusions, in that few studies met the inclusion criteria and could therefore be included in the review. This indicates the paucity of experimental studies that exist in this field and the need for more to further increase knowledge in this area. Grey literature was searched for and included, so authors are confident that all appropriate studies were found and included in the review. However, due to limited resources, only studies in the English language were included in the review. This may have excluded other potentially useful contributions to the topic.

A strength of the present systematic review is the thorough risk of bias assessment it was subject to, using the Cochrane Risk of Bias Assessment Tool, which identified the frequent unclear reporting leading to unclear risk of bias assessments.

Study-level weaknesses include that the majority of studies were conducted in the United States. International differences in healthcare systems and vaccination programmes may mean that studies conducted in the United States may not be generalisable to populations within the United Kingdom or other European countries, nor to low-middle income countries. A further weakness lies with the failure of most studies to measure vaccination behaviour, with studies largely measuring intention to vaccinate instead.

The illness being vaccinated against varied greatly amongst studies in this review. There is the potential that differences in appraisals of risk may exist between illnesses, meaning that the effect of risk on vaccination differs accordingly. For example, appraisals of Hepatitis B risk may be higher than for influenza risk due to the belief that the former causes serious liver damage, whereas the latter has few serious consequences. This means it is potentially problematic to directly compare interventions, as different risk appraisal processes may be present. Equally, how common an illness is may influence the success of the intervention, as less common illnesses may be perceived as more threatening and associated with higher appraisals of risk. Additionally, some illnesses examined in the included studies required one dose of vaccine (such as flu), whereas for other illnesses (such as HPV), required up to three doses. These behaviours are not directly comparable, with the latter being more difficult to perform. There were too few studies in the present review to compare the effect of risk appraisal on vaccination behaviour according to illness type or frequency of doses. Meta regression was often not possible due to there being insufficient studies in each sub-group, again highlighting the need for additional experimental studies in this field.

One strength of the included studies themselves was the use of composite measures of risk rather than single measures of risk, which was coded in 12 of the 18 included studies. Risk is a complex construct, which is better measured using composite measures due to the increased validity of multiple measures (Van Der Velde et al, 1996).

A further strength of the included studies, is the study setting. Of the 18 included studies, 17 were conducted in a community rather than a laboratory setting. This is advantageous as it reduces the chance of bias as a result of artificial settings, and reflects real behavioural decisions, rather than a hypothetical decision.

The present review highlighted a number of weaknesses in the existing literature on risk appraisal and vaccination uptake. First, the majority of included studies were rated as demonstrating an overall high risk of bias, largely attributable to the fact that a large proportion of domains across all studies were rated as 'unclear'. A rating of unclear reflects limitations in the reporting of the study rather than necessarily being a weakness in methodology. However, a high risk of bias suggests that it is unclear whether results of the study reflect a true effect of the intervention and therefore a degree of caution should be employed when interpreting the results. The presence of high risk of bias ratings reduces confidence in the findings, and makes it difficult to conclude whether interventions that include risk messages are indeed successful in increasing risk appraisal or the uptake of vaccination. Once again, this leads to calls for better conducted and reported studies on this topic.

Second, it should be noted that in a number of the included studies, a similar level of intervention content was delivered in the control groups, as in the intervention groups. One

explanation for this may be that detailed intervention descriptions were often unavailable in the papers and contact with authors for further details was met with limited response. Therefore, BCT coding was often only possible on the information within the paper itself, and it is acknowledged that full interventions may have included more BCTs in their entirety.

The BCT 'Information about Health Consequences' was coded within the control group of six included studies. Whilst only BCTs unique to the intervention group were included when examining the moderating effect of BCTs, the presence of BCTs within control groups that would be expected to have an impact of risk appraisal means that the relationship between risk and vaccination behaviour may be underestimated by our analysis. It is also important to examine the dose of BCTs in both the intervention and the control groups, as although a BCT may be present in both (and therefore not coded as a BCT unique to the intervention condition), it may appear more frequently, or may be a stronger influence in the intervention condition, than in the control condition (this can be seen in the practical application table, in Supplemental material 2 where BCT and dose of both intervention and control condition are detailed for each included study). This is supported by previous findings that intervention effects can be reduced in situations where the level of care received by the control group is higher (de Bruin, Viechtbauer, Schaalma, Kok, Abraham & Hospers, 2010). Furthrmore, only including those BCTs that are unique to the intervention group, may mean that clusters of BCTs working together to change behaviour may be ignored.

It is important to consider that the primary aim of the included studies was often not to examine the effectiveness of an intervention involving a risk message, and so the interventions were often not specifically aiming to increase risk appraisal alone. The decision to include all interventions that targeted risk, regardless of whether they also targeted a

change in other variables, means that the effect of interventions on intentions and behaviour is confounded. The overall number of studies included in the review was too small to enable a number of planed analyses to be performed and therefore requiring included studies to only be examining risk appraisal would have reduced the pool further. Consequently, there is a need for more studies which aim to manipulate risk and efficacy exclusively (ideally with factorial design so that the independent and interaction effects of each can be examined). Also, the studies often tested methods of delivery, for example examining the effect of gain versus loss framing of risk information. Increases in risk appraisal found in included studies may therefore be attributable to other factors that are unrelated to the content of the intervention.

Finally, limitations exist relating to how risk was measured. For example not all included studies measured levels of risk pre-intervention. This makes it unclear whether differences in risk between conditions existed at baseline, thus influencing differences between conditions post-interventions. Furthermore, the majority of studies included in this review measured risk using unconditional risk questions. To correctly assess appraisals of risk, participants should be asked about how likely they are to become ill if they don't have the vaccination. By asking unconditional questions, participants may be taking into account their good intention. In this situation, risk appraisals are based on the perceived likelihood of becoming ill after having the vaccination, rather than the likelihood of becoming ill without it (Weinstein et al 1998). This makes it difficult to draw firm conclusions about the influence that risk messages have on risk appraisal and vaccination uptake. Finally, the way risk was measured varied greatly between studies, with some measuring risk in terms of likelihood, some measuring severity and some measuring both likelihood and severity. It is acknowledged that these ways of measuring risk are theoretically different and depending on

the measurement choices made may have impacted upon the ability of studies to capture any intervention effects.

What This Study Adds

This is the first systematic review to examine the effect of interventions on risk appraisal and vaccination intentions or uptake using only experimental studies. It builds on a previous meta-analysis in this area (Brewer et al, 2007) which included not only experimental studies, but also prospective and cross-sectional studies. Including only experimental studies is important because it increases the strength of conclusions which can be drawn about the effect of interventions on risk and behaviour. The findings of this review are however inconclusive. The lack of unique BCT content within intervention conditions, along with the high risk of bias and almost total reliance on unconditional measures of risk by studies examining those interventions, means that we cannot be confident in the findings. Consequently the potential value of this type of review in better understanding how to increase risk in order to increase vaccination behaviour is lost. Instead its value is in shining a light on the paucity of experimental studies in this area, and the quality of methods and reporting used. It should be noted that eight of the 18 included studies were conducted in the past five years. This is encouraging as it indicates increasing use of experimental designs.

A secondary aim of the present review was to examine the relationship between risk and vaccination intention and uptake. Earlier work by Sheeran and colleagues found that risk appraisal had a small but significant effect on vaccination intention (d= 0.38) and behaviour (d= 0.33). Whilst the review by Sheeran and colleagues only included studies that had a significant effect on susceptibility or severity in order to enable this relationship to be observed (pooled effects being d= 0.75 and d= 0.56 respectively), the inclusion of all studies

in the present review regardless of their success in changing risk appraisal reduced the size of the overall effect. Given the small pooled effect on risk appraisal, the possible reasons for which have been discussed above, it is unsurprising then that no relationship between risk and vaccination intentions or uptake was observed. The present review is therefore unable to contribute new knowledge about the relationship between risk and vaccination intentions or uptake.

This systematic review builds on work conducted by Sheeran, Harris and Epton (2014) as it adds to evidence more broadly about the relationship between risk appraisal and behaviour. The current review included studies that would have been omitted by Sheeran and colleagues which only included RCTs that were successful in changing risk appraisals. Restricting studies to those examining single health behaviour controls for factors relating to the nature of the behaviour itself which may confound results.

Implications for Practice

The present review demonstrates that interventions in included studies utilise relatively few BCTs. For this reason, specific recommendations regarding which BCTs should be included in interventions to successfully increase vaccination intention or uptake cannot be made. There is compelling evidence that providing information about the risk of health, or the risk of failing to carry out the health behaviour alone is not sufficient to elicit behaviour change (French, Cameron, Benton, Deaton & Harvie, 2017). Additional BCTs may improve the effectiveness of interventions in increasing risk appraisal and subsequent uptake of vaccination.

Recent research suggests that simultaneously increasing efficacy appraisals with risk appraisals is an important parameter for having an overall effect on behaviour. Evidence suggests that the effect of increasing risk appraisal on intention or behaviour is further increased when efficacy appraisals are also high (Kok, Gottlieb, Peters, Mullen, Parcel, Ruiter et al, 2015; Sheeran et al, 2014). Unfortunately, because only three studies within this review significantly increased efficacy appraisals, conclusions could not be drawn about the interaction between risk appraisals and efficacy appraisals. This highlights the need for future research to examine the effect of increasing both risk and efficacy appraisals, ideally using full factorial designs that enable individual and interaction effects to be observed. In the meantime, interventions should aim to target an increase in self-efficacy and response efficacy simultaneously with risk appraisal in order to prevent defensive processing. The present review found that interventions delivered by people, as opposed to those delivered digitally or via printed materials, were less effective at increasing risk appraisals. This maybe because risk information communicated verbally is more difficult to absorb and understand. This concurs with other work which has found that interventions utilising images or visual components have been found to be successful predictors of changing risk appraisal (French, Cameron, Benton, Deaton & Harvie, 2017). Accordingly it is advised that future interventions aiming to communicate risk incorporate images into their design. .

Implications for Research

The present review highlights the need for robust, well reported experimental studies examining the effect of interventions on risk and vaccination behaviour. Reporting of methods by included studies was often vague and incomplete, and future studies would benefit from clearer more transparent reporting. As previously highlighted, the reporting of methods and intervention content by authors is currently inadequate. This makes assessing

the quality of experimental studies, their risk of bias, and accurately coding the presence of BCTs difficult. We acknowledge that journal restrictions may prevent detailed reporting of intervention content within the paper itself. As an alternative, we urge authors to use supplementary files where permitted, publish intervention content separately, or to make content descriptions available via the web.

Risk of bias assessment revealed that the main potential source of bias was 'Random Sequence Generation' and of the 18 studies assessed, eight were allocated an unclear rating, and three a high rating. In addition to this, 13 studies were allocated an unclear rating for 'Selective Reporting', reflecting a need for better reporting.

Future research would benefit from exploring potential reasons why interventions using digital or printed methods may be more effective in increasing risk appraisals, than those delivered fact-to-face. This may include difficulties communicating risk verbally, and the reluctance of medical professionals to actively recommend vaccination. Furthermore, it would be beneficial for future research to explore whether briefer interventions are more successful in increasing risk appraisal than longer, more in-depth interventions.

Conclusion

This systematic review is the first to explore the influence that interventions containing risk messages have on risk appraisal and vaccination intention and uptake using only experimental studies. Weaknesses in the included studies mean that it is not possible to draw firm conclusions about effect of interventions on risk, nor to examine the relationship between risk appraisal and vaccination behaviour. Successful interventions might benefit

from using more BCTs, and from targeting increases in self-efficacy and response efficacy, in addition to risk appraisal.

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Competing Interests

The authors declare that they have no competing interests.

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(References marked with * indicate they were included in the systematic Review, references marked with ** indicate they were included in the Meta-analysis).

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Figure 1:
Flowchart of included studies

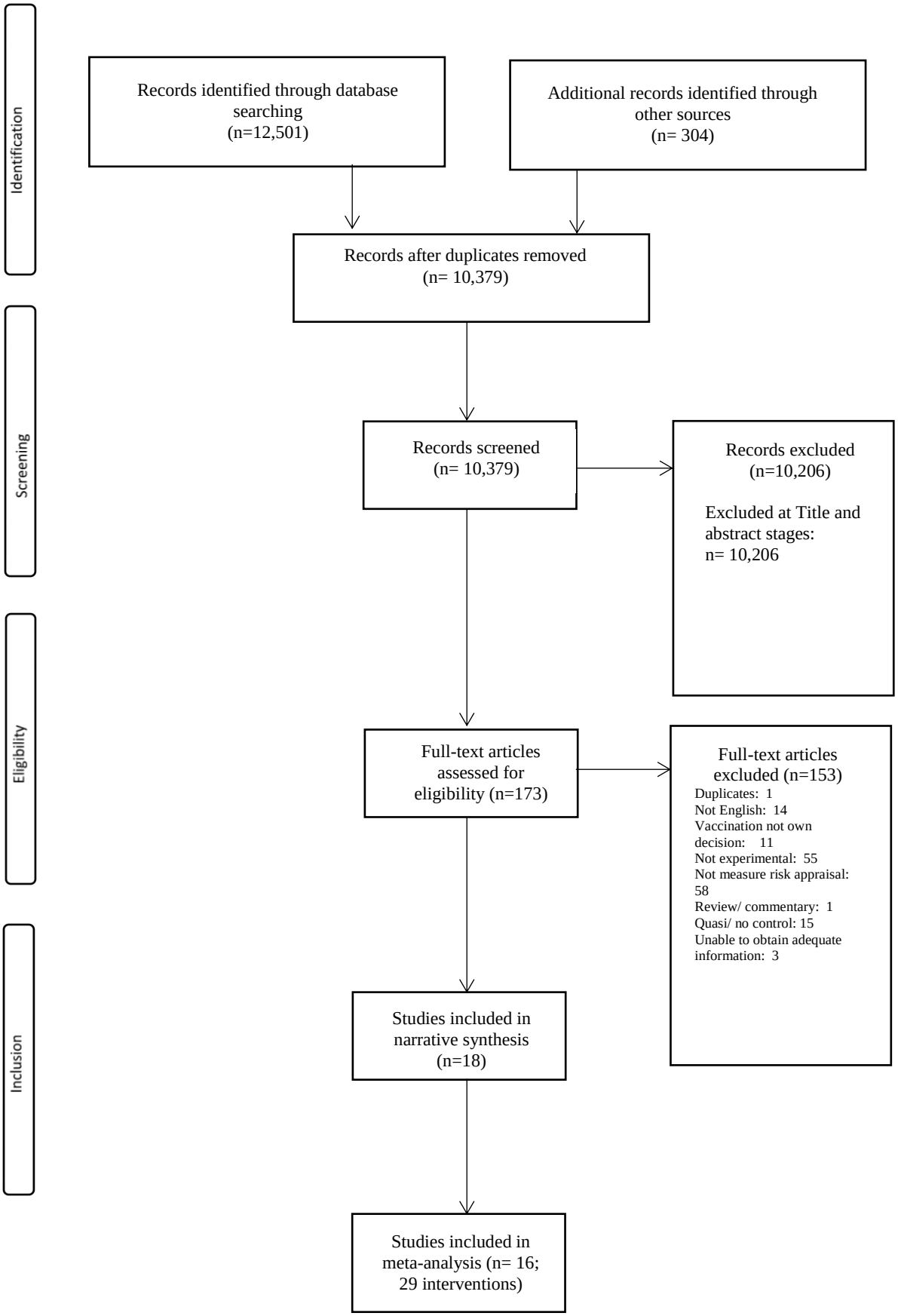

Table 1:
Summary table of frequency of characteristics of included studies

Characteristic		Number of studies
Study Country	US	11
	Other (non US country)	7
Illness being vaccinated against	Flu	8
	HPV	6
	Hepatitis B	2
	Flu and pneumococcal	1
	Tetanus	1
Participants pregnant or not	Pregnant	5
	Not pregnant	13
Measure of risk	Composite	12
	Single	6

Table 2:
Effects of risk appraisals, intention and behaviours, according to potential moderators.

Outcome variable	Moderator	Sub group	Number of studies/ total sample size	d	Δd	*Q*	Standard error	Confidence intervals (95%)	Reference Group	Number of studies/ total sample size (of reference group)	d (of reference group)
Risk											
	Efficacy Appraisal also increased	Increased	3/449	0.372	0.242	0.92	0.253	(-0.254, 0.738)	Not increased	14/6584	0.130
	Type of risk question used	Conditional question	4/1083	0.019	-0.218	1.61	0.172	(-0.554, 0.119)	Unconditional question	12/5950	0.237

Outcome variable	Moderator	Sub group	Number of studies/ total sample size	d	Δd	*Q*	Standard error	Confidence intervals (95%)	Reference Group	Number of studies/ total sample size (of reference group)	d (of reference group)
	Illness type	Flu	9/5023	0.228	-0.122	0.57	0.162	(-0.439, 0.196)	Other	8/2125	0.106
		HPV	3/1490	0.049	0.139	0.45	0.207	(-0.207, 0.545)	Other	13/5543	0.188
	Age Group	Adult	10/2105	0.250	-0.239	1.92	0.174	(-0.577, 0.099)	Other	6/4928	0.011
		Older adult	5/4177	-0.000	0.245	1.94	0.175	(-0.099, 0.589)	Other	11/2856	0.244

Outcome variable	Moderator	Sub group	Number of studies/ total sample size	d	Δd	*Q*	Standard error	Confidence intervals (95%)	Reference Group	Number of studies/ total sample size (of reference group)	d (of reference group)
	Pregnancy	Pregnant	3/645	0.396	0.269	1.19	0.247	(-0.215, 0.752)	Not pregnant	13/6395	0.127
	BCT Information about Health Consequences	Included	6/3449	0.033	-0.238	2.02	0.168	(-0.567, 0.090)	Not included	10/3584	0.271
	BCT Information	Included	3/694	-0.179	-0.431*	4.58	0.201	(-0.826,-0.036)	Not included	13/6339	0.252

Outcome variable	Moderator	Sub group	Number of studies/ total sample size	d	Δd	*Q*	Standard error	Confidence intervals (95%)	Reference Group	Number of studies/ total sample size (of reference group)	d (of reference group)
	about Social and Environmental Consequences										
	BCT Credible Source	Included	2/561	0.005							
		Not included	14/6472	0.204							
	Number of BCTs used	Less than two	10/5137	0.344	-0.431**	8.25	0.150	(-0.726, -0.137)	Two or more	6/1896	-0.088

Outcome variable	Moderator	Sub group	Number of studies/ total sample size	d	Δd	*Q*	Standard error	Confidence intervals (95%)	Reference Group	Number of studies/ total sample size (of reference group)	d (of reference group)
	Mode of Delivery	Digital	8/5123	0.243	-0.201	1.54	0.162	(-0.517, 0.116)	Other	8/1910	0.042
		Human	3/956	-0.252	-0.514**	7.21	0.191	(0.139, 0.890)	Other	13/6077	0.262
		Printed Materials	5/954	0.319	-0.201	0.98	0.203	(0.560, 0.198)	Other	11/6079	0.118
Intention											

Outcome variable	Moderator	Sub group	Number of studies/ total sample size	d	Δd	*Q*	Standard error	Confidence intervals (95%)	Reference Group	Number of studies/ total sample size (of reference group)	d (of reference group)
	Illness Type	Flu	8/4602	0.152	0.034	0.02	0.220	(-0.396, 0.465)	Other	4/520	0.117
	Age Group	Adults	8/1366	0.112	0.078	0.10	0.246	(-0.404, 0.559)	Other	4/3909	0.190
	Pregnancy	Pregnant	3/645	0.045	-0.110	0.14	0.289	(-0.675, 0.456)	Not pregnant	9/4630	0.155
	BCT Information	Included	4/3047	0.128	-0.007	0.00	0.247	(-0.491, 0.477)	Not included	8/2228	0.135

Outcome variable	Moderator	Sub group	Number of studies/ total sample size	d	Δd	*Q*	Standard error	Confidence intervals (95%)	Reference Group	Number of studies/ total sample size (of reference group)	d (of reference group)
	about Health Consequences										
	BCT Credible Source	Included	1/158	0.062							
		Not included	11/5117	0.140							
	Number of BCTs used	Less than two	10/4984	0.103							
		Two or more	2/291	0.372							

Outcome variable	Moderator	Sub group	Number of studies/ total sample size	d	Δd	*Q*	Standard error	Confidence intervals (95%)	Reference Group	Number of studies/ total sample size (of reference group)	d (of reference group)
	Mode of Delivery	Digital	6/4384	0.126	0.052	0.01	0.230	(-0.426, 0.476)	Other	6/684	0.151
Behaviour											
	Illness Type	Flu	1/115	0.375							
		HPV	3/1490	-0.333							
		Pneumonia	1/115	2.000							
	Age Group	Adolescent	1/751	-0.045							
		Adult	2/739	-0.482							

Outcome variable	Moderator	Sub group	Number of studies/ total sample size	d	Δd	*Q*	Standard error	Confidence intervals (95%)	Reference Group	Number of studies/ total sample size (of reference group)	d (of reference group)
		Older adult	1/115	0.871							
	BCT Information about Health Consequences	Included	3/1116	0.081							
		Not included	1/489	-0.033							
	BCT Credible Source	Included	2/1001	-0.471							
		Not included	2/604	0.605							
		Included	2/604	0.605							

Outcome variable	Moderator	Sub group	Number of studies/ total sample size	d	Δd	*Q*	Standard error	Confidence intervals (95%)	Reference Group	Number of studies/ total sample size (of reference group)	d (of reference group)
	BCT Information about Social and Environmental Consequences	Not included	2/1001	-0.471							
	Mode of Delivery	Digital	2/1200	-0.487							
		Human	2/866	0.589							

Notes: Blank cells indicate that there was insufficient variability in the moderator to conduct the analysis (less than three studies).

*p<.05; **p<.01; ***p<.001