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## Review title

The effectiveness of weight management, smoking cessation, and alcohol reduction interventions on changing behaviors during pregnancy: an umbrella review protocol.

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## Review objective/question

The objective of this umbrella review is to examine the effectiveness of different types of weight management, smoking cessation, and alcohol reduction interventions on producing explicitly measured behavior change, or proxy measures of behavior change in pregnant women..

The question of this review is: Are weight management, smoking cessation and alcohol reduction interventions effective in producing behavior change in pregnant women?

## Background

Teachable moments are described as “naturally occurring events thought to motivate individuals to spontaneously adopt risk-reducing health behaviours”.<sup>1</sup> Pregnancy itself is argued as a prime teachable moment, with women undergoing a life transition whilst in frequent contact with healthcare professionals.<sup>2</sup> For many, this may be their first encounter with healthcare services. NICE guidance on behavior change emphasizes the importance of intervening at ‘key life stages or times’, including pregnancy.<sup>3</sup> An underlying assumption is that behaviors change due both to women prioritizing fetal health and also responding to social norms on the acceptability of certain behaviors in pregnancy. A major question is whether or not there are similarities or differences across health behaviors in women’s propensity for positive change.

Behaviors and conditions associated with a greater risk to the mother and fetus include maternal obesity and weight, smoking and alcohol use. These behaviors form the focus of this umbrella review, enabling comparison of: a behavior/condition that is gaining in prevalence (maternal obesity); a behavior generally in decline (smoking); and a behavior where safe levels are contested (alcohol use). Maternal obesity is increasing in prevalence, carries associated health risks to mother and infant (including gestational diabetes, pre-eclampsia, and pre-term birth), and has implications for healthcare resources.<sup>4-7</sup> Prevalence of smoking among pregnant women in high income countries is decreasing; however, a different picture is evident amongst socially disadvantaged women and among women in the developing world.<sup>8-11</sup> Health risks of smoking in pregnancy include spontaneous abortions, ectopic pregnancies, placenta previa, and babies being small for gestation age.<sup>12-14</sup> Prevalence of alcohol use in pregnancy varies by country, and is associated with preterm birth, low birth weight and Fetal Alcohol Spectrum Disorders.<sup>10, 15-18</sup>

National and international guidelines exist for weight management,<sup>19-21</sup> and smoking cessation.<sup>22-26</sup> Guidance on alcohol consumption is variable, with advice ranging from abstinence to light consumption.<sup>23,27</sup> The extent of adoption of changed behaviors among pregnant women is, however, unclear.<sup>28</sup> Research into smoking in pregnancy shows a number of 'spontaneous quitters', though many do not continue to abstain beyond pregnancy, arguably due to a newly defined self-concept, and perceived social stigmatisation.<sup>1, 29</sup> Weight management research shows some women make dietary changes due to prioritizing the health of their unborn baby.<sup>30</sup> Others report pregnant women showing vigilance in making changes to a range of health behaviors, under pressure from societal norms.<sup>31</sup>

There is clear emphasis on pregnant women as a target for intervention across different behavior types. Preliminary searching was undertaken for reviews/umbrella reviews addressing weight management, smoking cessation, and alcohol reduction in pregnancy simultaneously, to enable a 'look across' effective interventions. Searches were carried out using: PROSPERO (Centre for reviews and dissemination); EPISTIMINEKOS; The JBI Database of Systematic Reviews and Implementation Reports and JBI registered titles; and a brief search of the grey literature via Google Scholar. Retrieved reviews mainly focused on behavior specific interventions in pregnancy, with no attempt to synthesize across behaviors. Reviews considering multiple target behaviors focused on school children,<sup>32</sup> or on internet-based interventions among a general population.<sup>33</sup> One review focused on the general population, but included pregnant women for some behaviors, yet little depth was given to this aspect.<sup>34</sup> Another recent review considered the effectiveness of a range of lifestyle interventions among pre-conceptual women. A relatively short list of interventions with substantial evidence for effectiveness was reported.<sup>35</sup> Perhaps most closely related to the focus of this umbrella review were two UK systematic reviews of reviews, which looked specifically at midwifery-based interventions.<sup>36, 37</sup> Alderdice et al.<sup>36</sup> focused on interventions to improve maternal mental health and wellbeing, finding a lack of conclusive evidence around the role of midwives in maternal mental health interventions. McNeill et al.<sup>37</sup> carried out a wider review of reviews considering a broad range of midwifery-based public health interventions, including (but not limited to) smoking cessation and weight management interventions. The review highlighted that a number of reviews presented statistically significant positive findings. However, there were also noted gaps in getting evidence into practice. These reviews differ from this proposal in that their focus was solely on midwifery-based interventions, and their target behaviors were different. Furthermore, the searches for the McNeill et al.<sup>37</sup> review of reviews were last carried out in 2010, and there is likely to be updated evidence now available.

The increasing focus of multiple interventions, and development of a plethora of referral systems, pathways and guidelines, can ultimately present a significant burden to women, healthcare professionals and services trying to manage complex pregnancies. An umbrella review focusing on effective interventions across these three different behavior types will enable enhanced understanding of mechanisms and what types of intervention are effective and for whom, as well as identification of similarities or differences across different target behaviors. Such information will be of value for the development and delivery of cost effective interventions that have the potential to impact on short term and long term health outcomes for women and children.

## Keywords

Alcohol; interventions; pregnancy; smoking; weight.

## Methods

### Inclusion criteria

#### Types of participants

This umbrella review will consider existing research syntheses/reviews that include pregnant women at any gestational age. There will be no restrictions based on socio demographic factors; such as age, ethnicity, parity, socioeconomic status, or disease status (e.g. gestational diabetes). The umbrella review will not include studies specifically focusing on preconception or postnatal periods.

#### Types of intervention(s)/phenomena of interest

This umbrella review will consider research syntheses that evaluate interventions during pregnancy that are in one of the following public health areas of interest: weight management interventions, smoking cessation interventions, and alcohol reduction interventions. In the case of weight management interventions, this will include interventions aiming to improve weight management-related behaviors (i.e. diet and physical activity) even if they do not specifically target weight management as an outcome.

Interventions that are targeted (e.g. to overweight women), as well as those delivered universally to all pregnant women will be included to provide as broad an overview as possible.

#### Types of outcomes

We will explore the effectiveness of interventions in changing behaviors as the broad specified outcome. This will encompass both 'explicit' behavior change outcomes, and 'proxy' behavior change outcomes, relating to the three target behaviors of the interventions. Examples of behavior change (explicit) and behavior change (proxy) outcomes for each target behavior are provided below. Please note that due to the broad nature of this review this is not an exhaustive list, but is provided for illustrative purposes.

#### Target behavior of intervention: weight management (including diet and physical activity interventions):

- Behavior change (explicit) i.e. change in diet, change in physical activity levels etc.
- Behavior change (proxy)
  - o Determinants of behavior i.e. intentions to change, self-efficacy etc.
  - o Health outcomes i.e. gestational weight gain, gestational diabetes etc.

#### Target behavior of intervention: smoking cessation:

- Behavior change (explicit) i.e. quit rates, smoking reduction rates, quantity of cigarettes etc. (self-report or bio medically validated i.e. urinary analysis or CO levels)
- Behavior change (proxy)
  - o Determinants of behavior i.e. intentions to change, self-efficacy, stage of change etc.
  - o Health outcomes i.e. birth weight, preterm delivery etc.

#### Target behavior of intervention: alcohol reduction:

- Behavior change (explicit) i.e. abstinence, change in units of alcohol consumed etc.
- Behavior change (proxy)
  - o Determinants of behavior i.e. intentions to change, self-efficacy etc.
  - o Health outcomes i.e. birth weight, fetal alcohol syndrome etc.

The effectiveness data reported in the systematic reviews and included in the umbrella review will be grouped and summarized using a number of a-priori decisions.

- A comparison of the effectiveness of all interventions in pregnancy will be carried out (i.e. not target behavior specific), with sub-group comparison of explicit and proxy measures of behavior change for all types of intervention
- A comparison of the effectiveness of target behavior interventions will be carried out (i.e. weight management, smoking cessation, alcohol reduction), with sub group comparison of explicit and proxy measures of behavior change for each target behavior
- Where enough data is provided in the systematic reviews included in the umbrella review, further comparisons will be carried out exploring the effectiveness of interventions according to pre-defined subgroups listed below.
  - o Whether or not behavior change theory was explicitly used as the basis for the intervention
  - o Methods of intervention delivery (e.g. internet-based, peer-group delivered, individual patient/health professional, intensity of intervention etc.)
  - o Description of the intervention (e.g. educational, psychological, information provision, motivational interviewing etc.)

### **Types of studies**

The review will aim to identify relevant international scientific evidence synthesized in systematic reviews that has been summarized narratively or via meta-analyses. The umbrella review will not include primary research studies, or reviews where the primary sources of evidence are theoretical studies, qualitative data, or opinion. Mixed methods reviews will not be excluded, however due to the focus of this umbrella review on effectiveness, only quantitative elements of mixed methods reviews will be included.

### **Search strategy**

The search strategy will aim to find both published and unpublished studies. A three-step search strategy will be utilized in this review. An initial limited search of the review databases: The Cochrane Library, and the Database of Abstracts of Reviews of Effectiveness (DARE) will be undertaken followed by analysis of the text words contained in the title and abstract, and of the index terms used to describe the article.

Initial keywords to be used will be:

Pregnancy OR Pregnant OR Maternal OR Maternity OR Antenatal

AND

Weight management OR Obesity, OR Body Mass Index OR Diet OR Physical Activity OR

Smoke OR, Smoking OR, Tobacco OR, Cigarette OR, Alcohol OR Drinking

The search strategy will be developed including identified keywords and index terms which will be tailored for each resource including key terms “systematic” and “meta-analysis”. Where filters for review

articles exist within databases these will be applied.

A second search using all identified keywords and index terms will then be undertaken across several databases (refer to list below). Thirdly, the reference list of all studies selected for critical appraisal will be screened for additional studies. Fourthly, and citation records of these eligible reviews will also be considered. Only reviews published in English will be considered for inclusion in this review. Reviews published since 2005 until the present date will be considered for inclusion in this umbrella review. This date has been selected following JBI guidance that research syntheses<sup>38</sup> published in the last 10 years will yield primary research conducted 30+ years prior.

Where grey literature is identified this does not have to be solely in published reviews: for example reviews within government reports, or student dissertations that are relevant will be included. If conference abstracts are identified an attempt will be made to contact the authors for any peer reviewed papers or unpublished full reports, due to limited information within the abstract itself.

### **Information Sources**

*The major repositories of systematic reviews to be searched include:*

Joanna Briggs Institute (JBI) Database of Systematic Reviews and Implementation Reports

The Cochrane Library: including Cochrane Database of Systematic Reviews

The Database of Abstracts of Reviews of Effectiveness (DARE)

PROSPERO

Epistemonikos

*The following databases will also be searched:*

EBSCOhost Medline

Ovid EMBASE

EBSCOhost CINAHL

EBSCOhost AMED

ProQuest ASSIA

Ovid Maternity and Infant Care

EBSCOhost PsycINFO, Science Direct

LILACS (<http://lilacs.bvsalud.org/en/>)

Social Care Online (<http://www.scie-socialcareonline.org.uk/>)

*The search for unpublished studies will include:*

Google Scholar

NICE Evidence Search (<http://www.evidence.nhs.uk>)

OpenGrey (<http://www.opengrey.eu/>)

The Grey Literature Report (<http://www.greylit.org>)

National Institute for Health Research (NIHR) Journals library

Health Technology Assessment Database (produced by the NIHR Centre for Reviews and Dissemination)

Ovid Health Management Information Centre Database (HMIC)

Cochrane Pregnancy and Childbirth Group (<http://pregnancy.cochrane.org/>)

**Screening:** All retrieved papers will be assessed for relevance using the title, abstract and index terms. Screening will be conducted by two reviewers. One reviewer will screen all of the abstracts for relevance. The other reviewer will screen only the excluded abstracts to ensure nothing of relevance has been missed. If relevance is unclear from the abstract the full text will be accessed.

Reviews selected for retrieval will be then be appraised using pre-defined inclusion criteria developed for this review (Appendix 1). This will ensure that only studies that meet the inclusion criteria of this umbrella review will be included. This will be carried out by two reviewers independently.

## Assessment of methodological quality

Retrieved research syntheses that meet the inclusion criteria will then be critically appraised by two independent reviewers prior to inclusion in the review using standardized JBI critical appraisal instruments for Systematic Reviews and Research Syntheses and supporting guidance (Appendix 2). The two reviewers will carry this process out for all included reviews. Reviewers will be blinded to each other's assessment and assessments will be compared once they have both completed the appraisal. Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer. Reviews will not be excluded based on the critical appraisal, however the results of critical appraisal will be reported in narrative form and in relevant tables. This information will be used to critically consider the conclusions of included reviews, and will inform the discussion of the umbrella review.

## Data extraction

Data will be extracted from research syntheses included in the umbrella review using the JBI data extraction tool for Systematic Reviews and Research Syntheses (Appendix 3) by two independent reviewers. All additions or modifications have been discussed in detail and submitted with the review protocol. In line with JBI guidance a period of piloting has been carried out by 3 members of the review team (SD, NH and LA) to ensure consistency and the likelihood of relevant results being identified and detailed sufficiently. The review team are aware that these changes require approval for publication in the JBI database of systematic reviews and implementation reports before being used by any reviewer.

The data extracted will be guided by the modified extraction tool and will include: objectives of the review; type of review; participants; setting; scope of database searching; dates of the search; date range of included studies; the number/types of studies/country of origin of primary research studies in the included research synthesis; details of critical appraisal and quality assessment; method of synthesis/analysis; outcomes of significance to the umbrella review question and objectives; and any comments or notes the umbrella review authors may have regarding included studies. Importantly, we will use the RE-AIM framework (R: Reach, E: Effectiveness, A: Adoption, I: Implementation, and M: Maintenance) to guide data extraction and presentation of narrative information on the type of interventions that are most effective during pregnancy.<sup>39</sup> This framework has previously been operationalized within an umbrella review of online behavior change interventions for multiple behaviors (including diet, physical activity, alcohol use, smoking, and condom use).<sup>33</sup> Within this pre-existing review the final three constructs (AIM) were combined and defined as Use. This adaptation was due to these latter constructs of the framework primarily being intended for organizational level intervention (e.g. maternity services),<sup>39</sup> therefore enabling a more useable definition at an individual level (e.g. pregnant women). It is anticipated that the data provided in the existing reviews will provide information on the RE constructs, with somewhat limited information on use. However, this information will be extracted and considered within the umbrella review where available.

## Reach

Data will be extracted and summarized to identify individual measure of participation and characteristics of participants as following:

- Total participant numbers: across all studies within the review; within intervention and control groups; and in interventions considering behavior change explicit outcomes vs. proxy measures of behavior change
- Percentage of individuals who received an intervention compared to potential audience (participant rate)
- The recruitment strategy used and effectiveness of this strategy (e.g. recruitment and retention rates)
- Characteristics of participants and non -participants. In particular considering the level of homogeneity/heterogeneity related to engagement with the intervention (e.g. socio-demographics of women recruited compared with those who decline participation, and for women retained compared with drop outs [maternal age, parity, socio-economic status, relationship status])
- Barriers and facilitators to participation described (i.e. reasons for choosing/declining to participate or for drop out [such as time, cost])
- Intervention delivered to a specific target group or universally to pregnant women.

## Use

Information about the Use will also be extracted from included systematic reviews according to the following topic areas:

- Fidelity to intervention delivery (extent to which program is delivered as intended/to which individuals engaged with the intervention as intended)
- Measures of adherence to the intervention
- Drop-out rates (considering both the intervention and control arms of study): number of withdrawals and characteristics of women retained compared with withdrawals [maternal age, parity, socio-economic status, relationship status])
- Maintenance: Extent to which any behavior change is maintained in the long term (if studies included follow up measures)

Data will be extracted via a custom built word table, or an online survey tool (such as Bristol Online Survey Software). This will be available to all data extractors, and will enable storage and collation of the data extracted.

## Data summary

Due to the expected heterogeneity of the reviews retrieved findings will be presented in a narrative form including tables and figures to aid in data presentation where appropriate. We will provide a clear indication of any overlaps of original research studies in each of the included systematic reviews.

Tabular presentation of quantitative findings will be provided for interventions addressing each of the three target behaviors. So for example, one table will summarize interventions addressing weight management, one will summarize interventions addressing smoking cessation, and one will summarize interventions addressing alcohol consumption. In this instance this will include: Reach (e.g. participation rate, characteristics of participants informing this target behavior); Effectiveness on explicit outcomes, and Effectiveness on proxy outcomes (e.g. overall effect estimates/other presented numerical data); Use (e.g. loss to follow up/participant retention). Heterogeneity of the results of the included reviews, and limitations and recommendations reported in the reviews will also be included where possible. Data may be presented by subgroups where possible/ where this is most intuitive, for example weight management interventions may be presented by interventions that target physical activity, interventions that target dietary behavior etc.



A narrative summary will consider each of the target behaviors for intervention in turn. This will summarize the interventions' reach and use (where data exists), and then consider their effectiveness using explicit and proxy outcomes as two subgroups for analysis, with a further comparison of the similarities or differences between the two subgroups. For example within weight management, the narrative summary will aim to consider:

1. How effective are interventions that target/ measure explicit behavior change measures (i.e. diet, physical activity levels)?
2. How effective are the interventions that target/measure the proxy outcomes (i.e. intentions to change, pregnancy outcomes etc.)?
3. Are there any similarities or differences between the two subgroups (explicit and proxy)?

These stages will be repeated for smoking cessation interventions, and for alcohol reduction interventions

Following this the narrative will look across the three target behaviors of the interventions, providing a summary of key findings, and a comparison of the similarities or differences across the reviews of the three different target behaviors. This will summarize reach and use of interventions, and then consider effectiveness of interventions considering explicit outcomes, and proxy outcomes. Following this any similarities or differences between the two subgroups (explicit and proxy) would be considered.

A 'Summary of Evidence' table will be produced to provide a simple visual indication of the findings of the review. This will include the target behavior of the intervention, a description of the intervention, the included research synthesis, and a simple visual indication of the results which will be done via a 'stop-light' indicator. A beneficial or effective intervention will be labelled green, a no effect or no difference in the investigated comparison (amber), and a detrimental intervention or less effect than a comparator (red).

Finally, the review team aim to involve a lay participant (e.g. a recent mother), a clinical expert (e.g. a public health midwife); and relevant stakeholder groups/ government organizations (e.g. Public Health England) who will be provided with the progress, give feedback, discuss issues aroused during the systematic reviews and guide the translation of the research results into policy and practice.

## Assessing confidence

The GRADE approach for assessing confidence in the quality of evidence will be used for this review to form an overall assessment of the quality of evidence for each intervention or phenomena of interest with the results presented in a summary of findings table created using GRADEPro.

## Conflicts of interest

No conflicts of interest have been declared.

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39. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health* 1999;89(9):1322-1327.

## Appendix I: Screening tool based on the inclusion criteria of this Umbrella review

<b>Author and Year</b>
<b>Journal</b>
<b>Title</b>
<b>Name/code of reviewer</b>
<b>Design:</b> This article is/ contains a systematic review or meta-analysis  <b>Yes</b>
<b>Language/Date:</b> The review is published in English and was published since 2005  <b>Yes</b>
<b>Review type:</b> The review is an effectiveness review considering quantitative evidence For mixed methods reviews: the review contains quantitative evidence focusing on effectiveness  <b>Yes</b>
<b>Participants:</b> Does the review include <b>any</b> types of pregnant women (regardless of socio demographic factors; such as age, ethnicity, parity, socioeconomic status and so forth), and NOT focus solely on women in the preconception/ postnatal phases.  <b>Yes</b>
<b>Interventions:</b>  Interventions of interest to the review focus on one of the following target behaviors; weight management interventions, smoking cessation interventions, and alcohol reduction interventions (or to behaviors that relate to these target behaviors i.e. physical activity or diet)  <b>Yes</b>
<b>Outcomes:</b>  Does the review report on any of the following outcomes: Effectiveness on behavior change (explicit), or behavior change (proxy), reach or usage of the intervention <b>Yes</b>
<b>If you have not answered YES to all of the above questions, you should exclude the study. If you answered yes to all, please continue.</b>

**Appendix 2: Appraisal instruments**

**JBI Critical Appraisal Checklist for Systematic Reviews and Research Syntheses**

Reviewer \_\_\_\_\_ Date \_\_\_\_\_

Author \_\_\_\_\_ Year \_\_\_\_\_ Record Number \_\_\_\_\_

	Yes	No	Unclear	Not applicable
1. Is the review question clearly and explicitly stated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Were the inclusion criteria appropriate for the review question?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Was the search strategy appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Were the sources and resources used to search for studies adequate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Were the criteria for appraising studies appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Was critical appraisal conducted by two or more reviewers independently?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Were there methods to minimize errors in data extraction?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Were the methods used to combine studies appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Was the likelihood of publication bias assessed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Were recommendations for policy and/or practice supported by the reported data?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Were the specific directives for new research appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Overall appraisal:    Include               Exclude               Seek further info  

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Appendix 3: Data extraction instrument

## Modified JBI Data Extraction Form for Review for Systematic Reviews and Research Syntheses

<b>Data Extraction carried out by (name/ institution):</b>									
<b>Date that data extraction was carried out</b>									
<b>Review study details (Include full reference for review paper):</b>									
<b>Aims and objectives/focus of the review:</b>									
Review type: (Please tick relevant box). NB: For Mixed methods reviews please only include the quantitative/ effectiveness data for data extraction.	Systematic review <b>with</b> meta-analysis <input type="checkbox"/> Systematic review <b>without</b> meta-analysis: <input type="checkbox"/> Mixed methods review: <input type="checkbox"/> <input type="checkbox"/> Other : <input type="checkbox"/> Please provide details: <input type="checkbox"/>								
Review Aims and Objectives: (As defined by the author. If the aims and objectives are unclear/not stated then state 'unclear')									
Target behavior of the intervention (Please tick the relevant box/ boxes if more than one. If weight management please identify which behavior is targeted.)	Weight management (or related behaviors i.e. physical activity/ diet) <input type="checkbox"/>  <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 70%;">If weight management</th> <th>Tick all that apply</th> </tr> </thead> <tbody> <tr> <td>Diet</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Physical Activity</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Other (Please state)</td> <td><input type="checkbox"/></td> </tr> </tbody> </table> Smoking <input type="checkbox"/>  Alcohol use <input type="checkbox"/>	If weight management	Tick all that apply	Diet	<input type="checkbox"/>	Physical Activity	<input type="checkbox"/>	Other (Please state)	<input type="checkbox"/>
If weight management	Tick all that apply								
Diet	<input type="checkbox"/>								
Physical Activity	<input type="checkbox"/>								
Other (Please state)	<input type="checkbox"/>								
<b>Methodology used in the review</b>									

Inclusion/exclusion criteria (i.e. the inclusion/exclusion criteria for the systematic review, not the inclusion/exclusion criteria of the individual studies included in the review)	
<p>Inclusion/exclusion criteria: <b>Participants.</b>                      Did the review take a Universal approach/targeted approach to participant inclusion criteria (i.e. were all women included or did they stipulate that they only included studies with a certain population e.g. women with a BMI&gt;30, women with a pre-existing health condition)</p>	<p><b>Universal</b> <input type="checkbox"/></p> <p>Details:</p> <p><b>Targeted</b> <input type="checkbox"/></p> <p>Details:</p>
<p>Inclusion/exclusion criteria: <b>Type of Interventions included in the review.</b>                      (For example were there any specific inclusion criteria for intervention duration, type of delivery (e.g. HCP), content etc.)</p>	
<p><b>Inclusion Criteria: Setting/context of the included interventions.</b>                      (For example did they only look at interventions in healthcare settings etc. Only include if stated by authors of the review)</p>	
<p>Inclusion/exclusion criteria: <b>Study designs to be included in the review.</b>                      E.g. Did they include just RCTs/ non-RCTs/ etc?</p>	
<p>Inclusion/ exclusion criteria: <b>Comparator.</b>                      What comparator types were included (e.g. usual care, true control)                      Were there any inclusion/exclusion</p>	



<p>criteria relating to the control group? Only include is stated by authors of the review.</p>				
<p>Inclusion/exclusion criteria: <b>Outcomes specifically looked at within the review</b> Please tick the relevant box AND THEN provide details of the outcomes considered in the review</p>	<p>Behavior change specific outcomes</p>	<input type="checkbox"/>		
	<p>Proxy outcomes</p>	<input type="checkbox"/>		
	<p>Both Behavior change and proxy outcomes</p>	<input type="checkbox"/>		
	<p>Description of outcomes included:</p>			
	<p><i>Behavior change specific:</i></p>			
	<p><i>Proxy outcomes:</i></p>			
<p>Methods: Search Details</p>				
<p>Databases searched for the review.</p>				
<p>Date range of search (for the review)</p>				
<p>Other restrictions applied to search (please tick if stated within the review and provide details):</p>	<p>Restriction</p>	<p>Tick if stated in review</p>	<p>Provide details</p>	
	<p>Language restrictions</p>			
	<p>Restrictions on type of articles included (e.g. Peer reviewed articles only/ is grey literature included).</p>			
	<p>Other restrictions to the search stated by review authors</p>			

Methods: Data extraction and analysis	
Data extraction: What information was extracted by the reviewers? (State if the details of data extraction are explicitly included within the review only)	
Appraisal instruments used	
Method of analysis/synthesis used. By authors of review- not within individual articles. i.e. narrative review, meta-analysis.	
Results: Details of included studies	
Range (years) of included studies (overall range of dates from earliest study to latest study: please base this on the year of publication stated for each included study.	
Number of studies included by outcome of interest.	<b>Explicit behavior change outcomes (number of studies):</b>  References of studies:
	<b>Proxy behavior change outcomes (number of studies):</b>  References of studies:
Types of studies included and number of each: (i.e. RCTs/ non-RCTs)	
Country of origin of incl. studies (if stated within the review)	
Language of included studies (only provide if	

authors of the review have)	
<b>Appraisal rating of included studies</b>	
Appraisal rating	
<b>Outcomes of specific interest to the review</b>	
<b>Reach:</b>	
Total Participant number In total across <b>all</b> studies within the review – include if this information is provided. Please indicate if the total was stated by the review authors or has been added up by data extractor	Total number (if information available)..... Stated by review author? <input type="checkbox"/> Added up by extractor? <input type="checkbox"/>
Total Participant numbers in intervention and control groups (for whole review if available). Please indicate totals were stated by the review authors or added up by data extractor.	Total number in intervention group(s) (if information available).....  Total number in control group (If information available).....  Stated by review author? <input type="checkbox"/>  Added up by extractor? <input type="checkbox"/>
Total Participant numbers in interventions considering behavior change explicit outcomes, and in interventions	Total number in interventions considering behavior change explicit outcomes (if information available).....

<p>considering proxy outcomes. (for whole review if available). Please indicate totals were stated by the review authors or added up by data extractor.</p>	<p>Total number in interventions considering proxy outcomes (if information available).....</p> <p>Stated by review author? <input type="checkbox"/></p> <p>Added up by extractor? <input type="checkbox"/></p>
<p>Participation rates How many individuals were approached, and how many were recruited in total for the whole review (If available/ stated by the author) Please indicate totals were stated by the review authors or added up by data extractor.</p>	<p>Total number approached (if information available).....</p> <p>Total number recruited (If information available).....</p> <p>Stated by review author? <input type="checkbox"/></p> <p>Added up by extractor? <input type="checkbox"/></p>
<p>Recruitment strategies used</p>	
<p>Characteristics of participants (socio demographic)</p>	
<p>Characteristics of non-participants (socio demographic)</p>	
<p>Barriers and facilitators to participation</p>	
<p>Participants: Universal/ targeted Total Number of studies within the review that are targeted (i.e. focus on a set population, such as women with a pre-existing condition) and total number of studies within a review that are universal (i.e. focus on all women). If targeted please state what targeted on:</p>	<p>Targeted (number of studies, and details of what targeted on)</p> <p>Universal (number of studies)</p>

Effectiveness	
<p><u>Narrative data ONLY:</u> Please complete if data is only presented in a narrative format without meta-analysis. Please provide a summary of results per outcome type if possible, or as presented by the review authors.</p>	<p><u>Effectiveness of interventions at changing behavior: explicit outcomes</u></p>
	<p><u>Effectiveness of interventions at changing behavior: proxy outcomes</u></p>
<p>Narrative data: Significance/direction. Please provide a <b>summary</b> of significance as the authors have provided within the review</p>	

Please complete if a meta-analysis was carried out	Outcome assessed	Number of studies	Number of participants	Type of effect measured (e.g. odds, ratio, effect size, risk-ratio)	Result (numerical value e.g. effect size; standardized mean difference OR etc.) Include Standard Error or Standard Deviation if provided.	Significance (p value and or confidence interval)	heterogeneity of effect estimates (e.g. I <sup>2</sup> , and or Q)
<b>Delivery of intervention</b>							
Who delivered the intervention within included studies? Please include a numerical summary of the number of interventions led by different specialties (for example healthcare professional led= 5, peer led = 2)							
How were interventions delivered? E.g. one to one/group/online/face to face/other (Please include number of studies for each)							
Frequency of intervention delivery for included studies. How often was the intervention delivered? (as described in the review)							
Duration of intervention delivery in included studies. How long did the intervention(s) last for (as described in the review)							
Context/setting of included studies (for example were they set							

<p>in clinics/ the community: only provide information if authors of the review have)</p>	
<p>Have the authors identified any behavior change techniques (explicitly) i.e. motivational interviewing, CBT, educational. If yes please state which techniques and state the number of studies for each.</p>	
<p><b>Use</b></p>	
<p>Fidelity to intervention delivery Extent to which people engaged with as intended (e.g. if 6 sessions were planned were 6 sessions delivered to all participants)</p>	
<p>Adherence to the intervention (Were the individuals able to adhere to the intervention content, e.g. if the intervention recommended keeping a food diary every day as a form of self-monitoring, were participants able to complete them every day for the required duration?/ Or r if they recommended 30 mins physical activity each day did they complete the full 30 mins?</p>	
<p>Drop outs rates (total number of participants recruited compared with those who provided final outcome data, if reported by review authors)</p>	

<p>Characteristics of those who dropped out in comparison to those who stayed engaged.</p>	
<p>Post intervention</p>	
<p>Maintenance: long term/continued use of intervention. How many studies had follow up measures (after the intervention delivered) What were the findings of these?</p>	<p><u>Number of studies with follow up measures after the intervention</u>  <u>delivery ceased</u>  <u>Findings of follow ups</u></p>
<p><b>Comments</b></p> <ul style="list-style-type: none"> <li>• Consider conflict of interest</li> <li>• Strengths of the review</li> <li>• Major limitations of the review</li> <li>• Other</li> </ul>	