Appendix 19

Data extraction form for adverse effects of weight management interventions in pregnancy

A) Comparative experimental studies 1. Study characteristics Methods/methodological quality Study design	Reviewer ID Study title First author Publication year Source of publication Journal yy;vol.(issue):pp Language Publication type	
Study title First author Publication year Source of publication Journal yy;vol.(issue):pp Language Publication type	Study title First author Publication year Source of publication Journal yy;vol.(issue):pp Language Publication type	Study ID
First author Publication year Source of publication Journal yy;vol.(issue):pp Language Publication type	First author Publication year Source of publication Journal yy;vol.(issue):pp Language Publication type	
Publication year Source of publication Journal yy;vol.(issue):pp Language Publication type	Publication year Source of publication Journal yy;vol.(issue):pp Language Publication type	
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Journal yy;vol.(issue):pp Language Publication type	Journal yy;vol.(issue):pp Language Publication type	
Language Publication type	Language Publication type	
Publication type	Publication type Journal Abstract If included study is a comparative experimental study (randomis lf included study is a comparative observational study (case–co	
If included study is a comparative experimental study (randomised or non-randomised controlled trial), then go to point A in Part II If included study is a comparative observational study (case—control or cohort), then go to point B in Part II If included study is a non-comparative study, then go to point C in Part II Part II A) Comparative experimental studies 1. Study characteristics Methods/methodological quality Study design RCT NRS RCT Population indirectness Very Serious Not serious Difficult to assess Was the eligible population representative of the source? Were important groups under-represented?	If included study is a comparative experimental study (randomis If included study is a comparative observational study (case–co	
If included study is a comparative observational study (case–control or cohort), then go to point B in Part II If included study is a non-comparative study, then go to point C in Part II Part II A) Comparative experimental studies 1. Study characteristics Methods/methodological quality Study design RCT NRS RCT Population indirectness Very Serious Not serious Difficult to assess Was the eligible population Describe	If included study is a comparative observational study (case-co	Other (specify):
If included study is a comparative observational study (case–control or cohort), then go to point B in Part II If included study is a non-comparative study, then go to point C in Part II Part II A) Comparative experimental studies 1. Study characteristics Methods/methodological quality Study design RCT NRS RCT Population indirectness Very Serious Not serious Difficult to assess Was the eligible population Describe	If included study is a comparative observational study (case-co	
Part II A) Comparative experimental studies 1. Study characteristics Methods/methodological quality Study design		sed or non-randomised controlled trial), then go to point A in Part II
Part II A) Comparative experimental studies 1. Study characteristics Methods/methodological quality Study design	If included study is a non-comparative study, then go to point C	ntrol or cohort), then go to point B in Part II
A) Comparative experimental studies 1. Study characteristics Methods/methodological quality Study design		in Part II
A) Comparative experimental studies 1. Study characteristics Methods/methodological quality Study design		
1. Study characteristics Methods/methodological quality Study design	Part II	
1. Study characteristics Methods/methodological quality Study design	A) Commonstive communicated attacks	
Methods/methodological quality Study design		
Study design	1. Study characteristics	
RCT Population indirectness	Methods/methodological quality	
Population indirectness	Study design RCT NRS	
Was the eligible population Describe	RCT	
representative of the source? Were important groups under-represented?	Population indirectness	☐ Not serious ☐ Difficult to assess
important groups under-represented?		
	important groups under-represented?	
Method of randomisation Specify and assess the method:		ha mathad:
	, ,	ne memoo.
☐ Adequate ☐ Inadequate ☐ Unclear ☐ Not reported	☐ Adequate ☐ Ir	
Allocation concealment	Allocation concealment Adequate Ir	
Describe	Describe	nadequate □ Unclear □ Not reported

Blinding	Select blinded subjects: Patients Investigators/clinicians Outcome assessors No blinding used assess the method: Adequate Inadequate Unclear Not reported				
Information about drop-outs	 Precise information (number of patients and reasons) Inaccurate information Lack of information 				
Rate of loss to follow-up					
Patients lost to follow-up analysed for adverse events					
Was the follow-up adequate to ascertain adverse effects?	☐ Yes ☐ No ☐ Unclear If 'yes', specify				
Statistical technique used					
Was adequate statistical analysis of potential confounders performed?	□ Yes □ No □ Unclear				
Intention-to-treat analysis	☐ Implemented ☐ Not implemented				
What was the definition of ITT in the study?					
Sample size calculation					
Was sensitivity analysis performed?	☐ Yes ☐ No ☐ Not applicable				
How problem with missing data was resolved?					
Were missing data accounted for in the analyses?	□ Yes □ No				
Post hoc analysis					
Funding source					
NRS					
Population indirectness Was the eligible population representative of the source? Were important groups under-represented?	□ Very □ Serious □ Not serious □ Difficult to assess Describe				
Control group selection	Specify and assess the method:				
Allocation concealment	□ Adequate □ Inadequate □ Unclear □ Not reported				
7 Modelion Concealment	□ Adequate □ Inadequate □ Unclear □ Not reported Describe				
Blinding	Select blinded subjects:				
	□ Patients □ Investigators/clinicians				
	☐ Outcome assessors ☐ No blinding used Assess the method:				
	☐ Adequate ☐ Inadequate ☐ Unclear ☐ Not reported				
Information about drop-outs □ Precise information (number of patients and reasons) □ Inaccurate information					
					□ Lack of information
Rate of loss to follow-up					

Patients lost to follow-up analysed for adverse events		
Was the follow-up adequate to ascertain adverse effects?	☐ Yes ☐ No ☐ Unclear If 'yes', specify	
Statistical technique used		
Was adequate statistical analysis of potential confounders performed?	☐ Yes ☐ No ☐ Unclear	
Intention-to-treat analysis What was the definition of ITT in the study?	□ Implemented □ Not implemented	
Sample size calculation		
Was sensitivity analysis performed?	☐ Yes ☐ No ☐ Not applicable	
How problem with missing data was resolved?	The The The applicable	
Were missing data accounted for in the analyses?	☐ Yes ☐ No	
Post hoc analysis		
Funding source		
Population		
Trial inclusion criteria		
	•	
	•	
Trial exclusion criteria	•	
mai exclusion chiena		
	•	
	Intervention group	Control group
Number of enrolled patients	intervention group	Control group
·		
Number of patients randomised, $N_{R(RCT)}$ Number of patients included, $N_{(NRS)}$		
Number of patients who completed treatment, <i>n</i> (%)		
Number of patients available for follow-up, n (%)		
Age in years		
Specify the measure:		
Ethnicity, <i>n</i> (%)		
BMI at baseline (mean, SD)		
Normal (18.5–24.9 kg/m²)	□ Normal	□ Normal
Overweight (25–29.9 kg/m²)	☐ Overweight	□ Overweight
Obese (≥ 30 kg/m²)	□ Obese	□ Obese
Weight at baseline (mean, SD)		
Singleton pregnancy only (if no give percentage)	Yes/no/unclear ()	Yes/no/unclear ()

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Primiparas only (if no give percentage)	Yes/no/unclear ()	Yes/no/unclear ()
Gestational age (week; SD; SE)		
Other baseline characteristics		
Are the treatment groups comparable	☐ Yes ☐ No	
at baseline?	If 'no' please specify the reasons:	
Intervention		
Type of dietary or lifestyle intervention with description		
How was intervention delivered		
Intervention duration		
Intervention provider		
Duration of follow-up		
Comparator		
Comparator	☐ No intervention	
	☐ Other intervention (specify)	
Outcomes (harms)		
Definition of outcomes	□ Any published definition	
	□ No definition	
Adequacy of data source	□ Reliable	
	□ Non-reliable	
Approach to ascertain the cause of	☐ Adequate	
harm	□ Non-adequate	
Proportion of cases with attributable	······(%)	
cause of harm established	☐ Unclassified	
Adverse effects occurred in	☐ Mother	
	□ Fetus/baby/child	
	□ Both	
Outcomes (adverse effects) related with	☐ Weight change in pregnancy	
Will I	□ Dietary intervention type□ Not clear	
	☐ Others (specify)	
Maternal ternal outcomes (adverse		
effects)	*Outcome assessment	
	•	
	*Outcome assessment	
	*Outcome assessment	

Child outcomes (adverse effects)	*Outcome assessment		
	*Outcome assessment.		
	*Outcome assessment		
*Outcome assessm	ent:		
1. Self-reported 2. Hospital record 3. Trained assesso 4. Other 5. Blinded 6. Unblinded 2. Results Dichotomous data Outcome:	r a		. Follow up:
Intervention group $N_R/N =$		Control group $N_R/N =$	
N' n (%	6)	N	n (%)
Effect estimate	R (95% CI □ SE	□ <i>p</i>)	
□ □ As:	Outcome assessors csess the method:	☐ Investigators/clinicial☐ No blinding used☐ unclear ☐	ns Not reported
Incomplete outcome data addressed			
M' number of evaluated nationts: n r	number of nationts with ou	tcome	

N, number of evaluated patients; n, number of patients with outcome.

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1111100-1	U-GVGIII U	ala

Outcome	e:		Category:		Follo	ow up:	
Intervent	tion group		Control group				
$N_R/N =$				N_R/N =	=		
N'		Median		N'		Median	
Effect es	stimate 🔲	RR □ OR (99	5% CI □ SE □	p)			
Blinding		Select blir	nded subjects:				
		Patient	s 💷 l	nvestig	ators/clinicians		
		Outcom	ne assessors 🔲 I	No blind	ling used		
		Assess th					
		□ Adequa	ate 🛘 Inadequat	e □l	Jnclear □ Not re	eported	
Incomple	ete outcome dat	a addressed					
N', numb	per of evaluated	d patients.					
	Continuo	uis data					
Outcome			Category:		Foll	ow up:	
	tion group				ol group		
N _R /N =				N _R /N =			
	lean value at aseline	Mean end-point value	Mean change from baseline	N	Mean value at baseline	Mean end-point value	Mean change from baseline
	SD/	(□ SD/	(□ SD/		(□ SD/	(□ SD/	(□ SD/
`	SE/	□ SE/	□ SE/		SE/	SE/	SE/
	other)	□ other)	□ other)		□ other)	□ other)	□ other)
Blinding			Select blinded s	ubjects	:		
_			Patients	•	■ Investigators	/clinicians	
			☐ Outcome asset		No blinding υ	ised	
					guate 🛚 Unclea	r Not reported	i
Incomple	ete outcome d	ata addressed	-1				
moompie	ete outcome u	ala addressed					

N', number of evaluated patients.

Reviewers' comme	

B) Comparative observational studies 1. Study characteristics

Methods/methodological quality			
Study design	□ Case–control □ Cohort		
Case-control			
Population indirectness	□ Very □ Serious □ Not serious □ Difficult to assess		
Was the eligible population representative of the source? Were important groups under-represented?	Describe		
Is case definition adequate?	□ Independent validation □ Record linkage □ Self-reported □ None		
Are the cases representative?	☐ All cases arising from same population or group ☐ Not known		
Selection of controls	☐ Same population as cases ☐ Not known or no		
Definition of controls	Outcome of interest not present in historyNo mention of history of outcome		
Comparability of cases and controls	☐ Yes ☐ No ☐ Unclear		
Ascertainment of exposure to intervention	□ Secure record		
	 □ Structured interview where blind to case/control status □ Interview not blinded to case/control status □ Written self-report of medical record only □ No description 		
Was the method of acceptainment of	□ No description		
Was the method of ascertainment of exposure for cases and controls the same?	☐ Yes ☐ No ☐ Unclear		
Non-response rate	□ Same for both groups□ Non-respondents described□ Rate different and no designation		
Cohort			
Population indirectness	☐ Very ☐ Serious ☐ Not serious ☐ Difficult to assess		
Was the eligible population representative of the source? Were important groups under-represented?	Describe		
Is the cohort representative	☐ Yes ☐ No ☐ Unclear		
Selection of non-exposed cohort	☐ Same population as exposed cohort ☐ Not known or no		
Ascertainment of exposure	□ Secure record		
	□ Structured interview		
	☐ Written self-report		
	□ No description		
Demonstration that outcome of interest wasn't present at start of study?	☐ Yes ☐ No ☐ Unclear		
Assessment of outcome	Independent or blind assessment Record linkage Self-report No description		
Was follow-up long enough for outcomes to occur?	☐ Yes ☐ No ☐ Unclear If 'yes', specify		
Was follow-up of cohorts adequate?	 □ Complete follow-up □ Subjects lost to follow-up unlikely to introduce bias, small number lost (%) □ Follow-up rate%, and no description of this lost □ No statement 		

Are the objectives or the hypothesis of the study stated?	☐ Yes	□ No	☐ Unclear	
Method of allocation to groups				
For patients who were not eligible for study, are the reasons why stated?	□ Yes	□ No		
Information about drop-outs	□ Preci	se informa	ation (number of patie	nts and reasons)
		urate info		,
	□ Lack	of informa	ation	
Statistical technique used				
Sample size calculation				
Was loss to follow-up taken into account in the analysis?	□ Yes	□ No		
Were any confounders mentioned?	☐ Yes,	please de	scribe	
Were confounders accounted for in analyses?	☐ Yes	□ No		
Were missing data accounted for in the analyses?	☐ Yes	□ No		
Was the impact of biases assessed?	☐ Yes	□ No	□ Not clearly asses	sed
Funding source				
Population				
Trial inclusion criteria	•			
Trial exclusion criteria				
	•			
Is target population defined?	□ Yes	□ No		
N. I. C. F. H	Interve	ntion gro	up	Control group
Number of eligible patients				
Number of included patients, N				
Number of patients who completed treatment, n (%)				
Age in years				
Specify the measure:				
Ethnicity, n (%)				
BMI at baseline (mean, SD) Normal (18.5–24.9 kg/m²)	□ Norm	ıal		□ Normal
 Normal (18.5–24.9 kg/m²) Overweight (25–29.9 kg/m²) 		weight		□ Overweight
 Obese (≥ 30 kg/m²) 		e		□ Obese
Weight at baseline (mean, SD)				
Singleton pregnancy only (if no give percentage) Yes/no/ι	unclear ()	Yes/no/unclear ()
Primiparas only (if no give percentage)	Yes/no/u	unclear ()	Yes/no/unclear ()

Gestational age (week; SD; SE)	
Other baseline characteristics	
Are the treatment groups comparable at baseline?	☐ Yes ☐ No If 'no' please specify the reasons:
Intervention	
Type of dietary intervention with description	
How was intervention delivered	
Intervention duration	
Intervention provider	
Duration of follow-up	
Comparator	
Comparator	□ No intervention □ Other intervention (specify)
Outcomes (harms)	
Adverse effects occurred in	□ Mother□ Fetus/baby/child□ Both
Outcomes (adverse effects) related with	 □ Weight change in pregnancy □ Dietary intervention type □ Not clear □ Others (specify)
Maternal outcomes (adverse effects)	*Outcome assessment
	*Outcome assessment *Outcome assessment
Child outcomes (adverse effects)	*Outcome assessment *Outcome assessment *Outcome assessment
Definition of outcomes	□ Any published definition□ No definition
Adequacy of data source	□ Reliable □ Non-reliable
Approach to ascertain the cause of harm	□ Adequate□ Non-adequate
Proportion of cases with attributable cause of harm established	□(%) □ Unclassified

*Outcome assessment:						
 Self-report Hospital re Trained as Other Blinded 	ecords sessor					
6. Unblinded						
2. Results Dichotomous	s data					
Outcome:	Category:		Follow up:			
Intervention group $N_R/N =$		Control group $N_R/N =$				
N'	n (%)	N'	n (%)			
Effect estimate	□ OR (95% CI □ SE	□ <i>p</i>)				
Blinding	Select blinded subjects: ☐ Patients ☐ Outcome assessors Assess the method: ☐ Adequate ☐ Inade	☐ Investigators/clinicial☐ No blinding used				
Incomplete outcome data addressed						
N', number of evaluated patients; n, number of patients with outcome.						
Time-to-even						
Outcome: Intervention group	Category:	Control group	Follow up:			
N _R /N =		$N_{\rm R}/N =$				
N'	Median	N'	Median			
Effect estimate	□ OR (95% CI □ SE	□ <i>p</i>)				
Blinding	Select blinded subjects:					
	□ Patients□ Outcome assessors	Investigators/cliniciaNo blinding used	ans			
	Assess the method:	- 140 billialing asea				
	☐ Adequate ☐ Inade	equate 🗆 Unclear 🗅	Not reported			
Incomplete outcome data addressed						
N', number of evaluated patie	ents.					

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	Continuo	ous data							
Outc	ome:		Category:			Follow up:			
Inter	vention group			Contro	ontrol group				
N _R /N =				N _R /N =					
N	Mean value at baseline	Mean end-point value	Mean change from baseline	N	Mean value at baseline	Mean end-point value	Mean change from baseline		
	(S D/	(□ SD/	(D SD/		(□ SD/	(□ SD/	(□ SD/		
	SE/	□ SE/	□ SE/		□ SE/	□ SE/	SE/		
	□ other)	□ other)	□ other)		□ other)	□ other)	□ other)		
Blind	ing		Select blinded s □ Patients	subjects	s: Investigators	/clinicians			
			Assess the meth	nod:	☐ No blinding u	ısed			
			☐ Adequate □	□ Inade	equate 🔲 Uncle	ear 🔲 Not report	ed		
	nplete outcome d								
√, n	umber of evaluate	ed patients.							
	Review	ers' comments							

C) Non-comparative studies								
Quality assessment according to checklist from <i>Methods for the Development of NICE Public Health Guidance (second edition)</i>								
Type of study, methodology description								
Population								
Trial inclusion criteria								
Trial exclusion criteria								
Number of enrolled patients								
Number of patients who completed treatment, n (%)								
Number of patients available for follow-up, n (%)								
Age in years								
Specify the measure:								
Other baseline characteristics								
Treatment								
Type of treatment used (technique, no. of sessions) Treatment duration Duration of follow-up								
Outcomes Definition and unit of measurement								
Reviewers' comments								

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