Appendix 19

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

Part I: General

Date	(dd/mm/yy)
Reviewer ID	Study ID

Study title	
First author	
Publication year	
Source of publication	
Journal yy;vol.(issue):pp	
Language	
Publication type	❑ Journal Abstract ❑ Other (*specify*):

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?	Describe..... ....
Method of randomisation	*Specify and assess the method:* ..... ❑ Adequate ❑ Inadequate ❑ Unclear ❑ Not reported
Allocation 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	❑ 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	❑ Very ❑ Serious ❑ Not serious ❑ Difficult to assess
Was the eligible population representative of the source? Were important groups under-represented?	Describe..... ....
Control group selection	*Specify and assess the method:* ..... ❑ Adequate ❑ Inadequate ❑ Unclear ❑ Not reported
Allocation 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	❑ 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	
Population	
Trial inclusion criteria	■ ■ ■ ■
Trial exclusion criteria	■ ■ ■ ■

	Intervention group	**Control group**
Number of enrolled patients		
Number of patients randomised, $N_{R\,(RCT)}$		
Number of patients included, $N_{(NRS)}$		
Number of patients who completed treatment, *n* (%)		
Number of patients available for follow-up, *n* (%)		
Age in years *Specify the measure*:		
Ethnicity, *n* (%)		
BMI at baseline (mean, SD)		
■ Normal (18.5–24.9 kg/m^2)	❑ Normal.....	❑ Normal.....
■ Overweight (25–29.9 kg/m^2)	❑ Overweight.....	❑ Overweight.....
■ Obese (≥ 30 kg/m^2)	❑ Obese.....	❑ Obese.....
Weight at baseline (mean, SD)		
Singleton pregnancy only (if no give percentage)	Yes/no/unclear (.....)	Yes/no/unclear (.....)

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 at baseline?	❑ Yes ❑ No *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 harm	❑ Adequate ❑ 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 ❑ 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 assessment:

1. Self-reported
2. Hospital records
3. Trained assessor
4. Other
5. Blinded
6. Unblinded

2. Results

Dichotomous data

Outcome:..... Category:..... Follow up: .....

Intervention group		Control group	
N_R/N =		N_R/N =	
N'	***n* (%)**	***N'***	***n* (%)**

Effect estimate ❑ RR ❑ OR (95% CI ❑ SE ❑ *p*)

Blinding *Select blinded subjects:*
❑ Patients ❑ Investigators/clinicians
❑ Outcome assessors ❑ No blinding used
Assess the method:
❑ Adequate ❑ Inadequate ❑ Unclear ❑ Not reported

Incomplete outcome data addressed

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

Time-to-event data

Outcome:..... Category:..... Follow up:.....

Intervention group
N_R/N =

N' Median

Control group
N_R/N =

N' Median

Effect estimate ❑ RR ❑ OR (95% CI ❑ SE ❑ *p*)

Blinding
Select blinded subjects:
❑ Patients ❑ Investigators/clinicians
❑ Outcome assessors ❑ No blinding used
Assess the method:
❑ Adequate ❑ Inadequate ❑ Unclear ❑ Not reported

Incomplete outcome data addressed

N', number of evaluated patients.

Continuous data

Outcome:..... Category:..... Follow up:.....

Intervention group N_R/N =				Control group N_R/N =			
N'	Mean value at baseline (❑ SD/ ❑ SE/ ❑ other)	Mean end-point value (❑ SD/ ❑ SE/ ❑ other)	Mean change from baseline (❑ SD/ ❑ SE/ ❑ other)	*N'*	Mean value at baseline (❑ SD/ ❑ SE/ ❑ other)	Mean end-point value (❑ SD/ ❑ SE/ ❑ other)	Mean change from baseline (❑ SD/ ❑ SE/ ❑ other)

Blinding
Select blinded subjects:
❑ Patients ❑ Investigators/clinicians
❑ Outcome assessors ❑ No blinding used
Assess the method:
❑ Adequate ❑ Inadequate ❑ Unclear ❑ Not reported

Incomplete outcome data addressed

N', number of evaluated patients.

Reviewers' comments

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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 history ❑ No 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 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	❑ Precise information (number of patients and reasons) ❑ Inaccurate information ❑ Lack of information
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 describe……..... ❑ No
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 assessed
Funding source	
Population	
Trial inclusion criteria	■ ■ ■ ■
Trial exclusion criteria	■ ■ ■ ■
Is target population defined?	❑ Yes ❑ No

	Intervention group	**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/m^2)	❑ Normal.....	❑ Normal.....
■ Overweight (25–29.9 kg/m^2)	❑ Overweight.....	❑ Overweight.....
■ Obese (≥ 30 kg/m^2)	❑ Obese.....	❑ Obese.....
Weight at baseline (mean, SD)		
Singleton pregnancy only (if no give percentage)	Yes/no/unclear (.....)	Yes/no/unclear (.....)
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 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:

1. Self-reported
2. Hospital records
3. Trained assessor
4. Other
5. Blinded
6. Unblinded

2. Results

Dichotomous data

Outcome:..... Category:..... Follow up:.....

Intervention group		Control group	
N_R/N =		N_R/N =	
N'	***n* (%)**	***N'***	***n* (%)**

Effect estimate ❑ RR ❑ OR (95% CI ❑ SE ❑ *p*)

Blinding *Select blinded subjects:*
❑ Patients ❑ Investigators/clinicians
❑ Outcome assessors ❑ No blinding used
Assess the method:
❑ Adequate ❑ Inadequate ❑ Unclear ❑ Not reported

Incomplete outcome data addressed

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

Time-to-event data

Outcome:..... Category:..... Follow up:.....

Intervention group		Control group	
N_R/N =		N_R/N =	
N'	Median	*N'*	Median

Effect estimate ❑ RR ❑ OR (95% CI ❑ SE ❑ *p*)

Blinding *Select blinded subjects*:
❑ Patients ❑ Investigators/clinicians
❑ Outcome assessors ❑ No blinding used
Assess the method:
❑ Adequate ❑ Inadequate ❑ Unclear ❑ Not reported

Incomplete outcome data addressed

N', number of evaluated patients.

Continuous data

Outcome:..... Category:..... Follow up:.....

Intervention group N_R/N =				Control group N_R/N =			
N'	Mean value at baseline (❑ SD/ ❑ SE/ ❑ other)	Mean end-point value (❑ SD/ ❑ SE/ ❑ other)	Mean change from baseline (❑ SD/ ❑ SE/ ❑ other)	*N'*	Mean value at baseline (❑ SD/ ❑ SE/ ❑ other)	Mean end-point value (❑ SD/ ❑ SE/ ❑ other)	Mean change from baseline (❑ SD/ ❑ SE/ ❑ other)

Blinding

Select blinded subjects:

❑ Patients ❑ Investigators/clinicians

❑ Outcome assessors ❑ No blinding used

Assess the method:

❑ Adequate ❑ Inadequate ❑ Unclear ❑ Not reported

Incomplete outcome data addressed

N', number of evaluated patients.

Reviewers' comments

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C) Non-comparative studies

Quality assessment according to checklist from *Methods for the Development of NICE Public Health Guidance (second edition)*

Type of study, methodology description

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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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