

Appendix D

Review protocols

Faltering growth in children

Recognition and management

April 2017

Draft for Consultation

*Developed by the National Guideline Alliance,
hosted by the Royal College of Obstetricians
and Gynaecologists*

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1 Key area A: Recognition of faltering growth (question A.1)

Item	Details
Area in the scope	Recognition of faltering growth, including defining growth thresholds for concern (including, early weight loss after birth).
Review question in the scope	What are the growth thresholds for enhanced monitoring or intervention for suspected or confirmed faltering growth in infants and preschool children?
Review question for the guideline	Are current definitions (thresholds) effectively identifying children with faltering growth who require interventions? In infants and children with growth concerns defined by one particular criterion (see below) what are the adverse outcomes compared to those who do not have that growth concern by that definition?
Objective	To determine how to recognise and define (diagnose) faltering growth.
Population and directness	Infants and children suspected of having faltering growth (including neonates with early weight loss) Exclude infants with complex, severe malnutrition in World Bank low and middle income group countries, and infants and children in intensive care settings
Definition of criteria, i.e. thresholds	Criteria based on weight and length/height measures individually and in combination: <u>Children meeting the following criteria:</u> Low weight for age, for example: <ul style="list-style-type: none"> • weight below the 0.4 percentile, • weight below the 2nd percentile, <ul style="list-style-type: none"> • downward crossing of weight over two or more main percentile spaces • conditional weight gain (current weight compared with that predicted from previous weight) • low weight for length/height (according to WHO growth charts) • low BMI (< 2nd percentile UK-WHO) • discrepant family pattern: length low and low in relation to weight and parental length/weight (child's length and weight centiles compared to mid parental centile calculations) <u>Babies with excessive early weight loss</u> <ul style="list-style-type: none"> • 10 – 12.5 % weight loss at 5 days • greater than 12.5 % at 5 days
Comparison of definitions	Those who do not fulfil the specific growth criterion used (for example whose weight is above the chose threshold)
Outcomes	Rate of adverse outcomes, such as <ul style="list-style-type: none"> • persisting slow growth • progression to stunted growth • impaired cognitive development (IQ) • specific morbidities and mortality • child protection instances / unrecognised underlying medical condition
Importance of outcomes	Critical outcomes for decision making: <ul style="list-style-type: none"> • stunted growth • cognitive development

Item	Details
Setting	Any setting where a child is suspected of having faltering growth in World Bank high income group countries except intensive care settings.
Stratified, subgroup and adjusted analyses	<p>Stratified analyses: Groups that will be reviewed and analysed separately: Infants and preschool children who:</p> <ul style="list-style-type: none"> • were born prematurely • were born with intrauterine growth restriction (IUGR) • small for gestational age (SGA) • with a specific disorder known to cause faltering growth • early weight loss after birth <p>Sub-group analyses, e.g. in the presence of heterogeneity, the following subgroups will be considered for sensitivity analysis: Population subgroups</p> <ul style="list-style-type: none"> • weight /length at first measurement (regression toward the mean) • severity of faltering growth <p>Intervention subgroups (e.g. route of administration, drugs within drug classes, high/low dose):</p> <ul style="list-style-type: none"> • type of growth chart <p>Important confounders (when comparative observational studies are included for interventional reviews) – these may be similar to the subgroups above:</p> <ul style="list-style-type: none"> • severity • age • interventions for faltering growth • length of follow-up
Language	English
Study design	<p>Prospective population based cohort studies (multivariable analysis, including the confounders listed above) Minimum of 500 children in the population considered</p>
Search strategy	<p>Sources to be searched: Limits (e.g. date, study design): Supplementary search techniques: No supplementary search techniques were used. See appendix E for full search strategies.</p>
Review strategy	<p>Dual weeding of the literature search results will be performed on 10% of records because this is a prognostic review; Any disagreements will be resolved through discussion and consultation with senior staff where necessary.</p> <p>Appraisal of methodological quality: For prognostic studies predicting of future outcome (e.g. cognitive development or future growth) a prognostic checklist (e.g. CASP clinical prediction rule checklist) will be used. Methodological quality will be summarised using modified GRADE.</p> <p>Appropriate other checklists will be used if the studies are of a different type.</p>
Equalities	Effective interventions to address should take into consideration parents' and carers' socioeconomic, cultural, religious and ethnic environment, and potential language barriers. Access to appropriate nutrition may also differ across socioeconomic groups. Certain groups may be at greater risk of developing faltering growth, including preterm infants and children, children and infants with intrauterine growth restriction, those with learning-disabled parents or carers, asylum seekers, and looked-after children.
Notes/additional	n/a

Item	Details
information	

2 Key area A: Recognition of faltering growth (question A.2)

Item	Details
Area in the scope	A) Recognition of faltering growth, including defining growth thresholds for concern (including, early weight loss after birth).
Review question in the scope	A.2 What are the growth thresholds for enhanced monitoring or intervention for suspected or confirmed faltering growth in infants and preschool children?
Review question for the guideline	In infants under 4 weeks what percentage of weight loss is associated with adverse outcomes?
Objective	To determine the degree and timing of weight loss that should cause concern.
Population and directness	Infants under 4 weeks of age Exclude infants with complex, severe malnutrition in World Bank low and middle income group countries, and infants and children in intensive care settings
Prognostic factors and thresholds	<ul style="list-style-type: none"> weight loss of greater than 10% at the specified time point (age in days)
Confounders	<ul style="list-style-type: none"> mode of delivery (caesarean vs vaginal delivery) intra uterine growth restriction (IUGR) small for gestational age (SGA) ethnicity <p>Prematurity and method of feeding (breast versus other) will be analysed as separate subgroups.</p>
Outcomes	<ul style="list-style-type: none"> dehydration (including hypernatremic dehydration) mortality subsequent weight change impaired cognitive development (IQ) jaundice
Importance of outcomes	<p>Preliminary classification of the outcomes for decision making:</p> <ul style="list-style-type: none"> dehydration (including hypernatremic dehydration) mortality
Setting	Any setting where a child is suspected of having faltering growth in World Bank high income group countries apart from ICU settings
Stratified, subgroup and adjusted analyses	<p>Stratified analyses: Groups that will be reviewed and analysed separately: infants who:</p> <ul style="list-style-type: none"> were born at term or those born prematurely method of feeding (breast-feeding vs not breast-feeding) <p>Sub-group analyses, e.g. In the presence of heterogeneity, the following subgroups will be considered for sensitivity analysis:</p> <ul style="list-style-type: none"> n/a <p>Important confounders (when comparative observational studies are included for interventional reviews) – these may be similar to the subgroups above:</p> <ul style="list-style-type: none"> n/a
Language	English
Study design	<p>Prospective population based studies</p> <p>Minimum of 100 children in the population considered</p>

Item	Details
Search strategy	<p>Sources to be searched:</p> <p>Limits (e.g. date, study design):</p> <p>Supplementary search techniques: No supplementary search techniques were used.</p> <p>See appendix E for full search strategies.</p>
Review strategy	<p>Dual weeding of the literature search results will be performed on 10% of records because this is a prognostic review; Any disagreements will be resolved through discussion and consultation with senior staff where necessary.</p> <p>Appraisal of methodological quality:</p> <p>For prognostic studies a prognostic checklist (e.g. CASP clinical prediction rule checklist) will be used. For each outcome the range of odds ratios associated with 10% weight loss will be reported. Results from multivariate analyses incorporating the stated confounders will be prioritised. Methodological quality will be summarised using modified GRADE.</p> <p>For comparative studies (comparing the use of different thresholds):</p> <ul style="list-style-type: none"> • The methodological quality of each study should be assessed using quality checklists and the quality of the evidence for an outcome (i.e. across studies) will be assessed using GRADE. • Synthesis of data: • Meta-analysis will be conducted where appropriate. • Default MIDs will be used: 0.75 and 1.25 for dichotomous outcomes; 0.5 times SD for continuous outcomes to assess imprecision <p>If studies only report p-values, this information will be plotted in GRADE tables without an assessment of imprecision possible to be made.</p>
Equalities	<p>Effective interventions to address should take into consideration parents' and carers' socioeconomic, cultural, religious and ethnic environment, and potential language barriers. Access to appropriate nutrition may also differ across socioeconomic groups. Certain groups may be at greater risk of developing faltering growth, including preterm infants and children, children and infants with intrauterine growth restriction, those with learning-disabled parents or carers, asylum seekers, and looked-after children.</p>
Notes/additional information	n/a

3 Key area A: Recognition of faltering growth (question A.3)

Item	Details
Area in the scope	Recognition of faltering growth, including defining growth thresholds for concern (including, early weight loss after birth).
Review question in the scope	What are the growth thresholds for enhanced monitoring or intervention for suspected or confirmed faltering growth in infants and preschool children?
Review question for the guideline	What are the normal limits of maximal weight loss in the first two weeks of life?
Objective	<p>To determine the normal range of weight loss in the first weeks of life and when it is at its maximum.</p> <p>From the answer of the review we will then be able to determine what would be the weight loss that would be above the normal range and would therefore cause concern.</p>
Population and directness	<p>Infants under 4 weeks of age</p> <p>Exclude infants with complex, severe malnutrition in World Bank low and middle income group countries, and infants and children in intensive care settings</p>
Definition of criteria, i.e. thresholds	<p>Weight loss from birth weight: this could be measured in different ways:</p> <ul style="list-style-type: none"> • % weight loss from birth • absolute weight loss • conditional weight loss from birth (current weight compared with that predicted from previous weight)
Outcomes	<ul style="list-style-type: none"> • average weight loss and confidence intervals • timing of maximal weight loss
Importance of outcomes	<p>Preliminary classification of the outcomes for decision making:</p> <ul style="list-style-type: none"> • average weight loss and confidence intervals • timing of maximal weight loss
Setting	Any setting where a child is suspected of having faltering growth in World Bank high income group countries except intensive care settings.
Stratified, subgroup and adjusted analyses	<p>Stratified analyses:</p> <p>Groups that will be reviewed and analysed separately:</p> <p>babies who:</p> <ul style="list-style-type: none"> • mode of delivery (caesarean vs vaginal delivery) • method of feeding (breast-feeding vs not breast-feeding) • day of measurement in three categories (3-7 days, 7-14 days and 14-28 days) • preterm babies • IUGR • SGA <p>Sub-group analyses, e.g. In the presence of heterogeneity, the following subgroups will be considered for sensitivity analysis:</p> <ul style="list-style-type: none"> • n/a <p>Important confounders (when comparative observational studies are included for interventional reviews) – these may be similar to the subgroups above:</p> <ul style="list-style-type: none"> • ethnicity • inpatient / outpatient

Item	Details
Language	English
Study design	<p>Ideally prospective population based prevalence studies, but retrospective studies will also be considered for inclusion as long as they provide normative data.</p> <p>Ideally a minimum of 1000 children, but populations between 500 to 1000 children will be considered for inclusion.</p> <p>Exclusions studies <500 participants will not be included in the review (not robust enough sample size to generalise to all babies in the UK)</p>
Search strategy	<p>Sources to be searched:</p> <p>Limits (e.g. date, study design):</p> <p>Supplementary search techniques: No supplementary search techniques were used.</p> <p>See appendix E for full search strategies.</p>
Review strategy	<p>Dual weeding of the literature search results will be performed on 10% of records because this is not a straightforward intervention review. Any disagreements will be resolved through discussion and consultation with senior staff where necessary.</p> <p>Appraisal of methodological quality: A standard checklist for prevalence studies will be applied. Even though it is not covering exactly this topic many of the same criteria will apply (for example representativeness of population):</p> <ul style="list-style-type: none"> • The JBI Critical Appraisal Checklist for Studies Reporting Prevalence Data (Munn et al. 2014) assesses critical issues of internal and external validity that must be considered when addressing validity of such data. The JBI checklist is not included in the NICE manual: although cohort and cross-sectional study checklist in the manual identify important criteria, this checklist was more suited to assessment of quality of prevalence studies <p>Overall methodological quality will be summarised on a per study basis.</p> <p>The evidence will be reported narratively. Mean weight loss and standard deviations will be extracted and a range of weight loss will be reported grouped into the days at which their weight was measured.</p>
Equalities	<p>Assessments should take into consideration parents' and carers' socioeconomic, cultural, religious and ethnic environment, and potential language barriers. Access to appropriate nutrition may also differ across socioeconomic groups. Certain groups may be at greater risk of developing faltering growth, including preterm infants and children, children and infants with intrauterine growth restriction, those with learning-disabled parents or carers, asylum seekers, and looked-after children.</p>
Notes/additional information	n/a

4 Key area B: Risk factors for faltering growth (question B.1)

Item	Details
Area in the scope	Identification of risk factors for faltering growth.
Review question in the scope	What are the risk factors for faltering growth that could inform recognition and management?
Review question for the guideline	What are the risk factors for faltering growth?
Objective	To determine factors that improve recognition and identify management strategies for faltering growth. These may assist in recognition and management.
Population and directness	Infants and preschool children Excluding infants and children with a pre-existing underlying specific condition that limits energy intake and/or increases the child's energy requirements.
Risk factors / variables under consideration	<p>Factors related to recognition:</p> <p>Infant or preschool child variables:</p> <ul style="list-style-type: none"> • born preterm • family history of faltering growth • intrauterine growth restriction • small for gestational age • developmental and developmental delay <p>Family/social factors:</p> <ul style="list-style-type: none"> • maternal mental health (including depression, eating disorders) • parental substance misuse, including postnatal smoking • socioeconomic status • parental educational status (particularly maternal) • physical, emotional, sexual abuse and neglect (safeguarding issues) <p>Common to both categories above:</p> <ul style="list-style-type: none"> • restricted intake (for example restricted diet) <p>Risk factors related to early weight loss (under 4 weeks):</p> <ul style="list-style-type: none"> • breast-feeding • parity • birth complications including caesarean section (neonate only) • mother-child relationship/ attachment
Confounders	<p>Multivariate analyses of the above risk factors should also adjust for the following confounders</p> <p>Critical:</p> <ul style="list-style-type: none"> • age • severity of faltering growth • definition (including consideration of birthweight) of faltering growth • treatment • if the evidence is looking at small for gestational age (SGA), then the analysis should adjust for gestation.
Outcomes	<ul style="list-style-type: none"> • confirmed diagnosis of faltering growth (studies may vary on their criteria for faltering growth, but this is noted as a confounder) • measurements of growth for age (weight, length/height centile, head

Item	Details
	circumference, mid-arm circumference, BMI z-scores)
Importance of outcomes	Preliminary classification of the outcomes for decision making: <ul style="list-style-type: none"> • confirmed diagnosis of faltering growth • measurement of growth
Setting	Studies from the UK or other World Bank high income group countries Exclude studies in ICU settings.
Stratified, subgroup and adjusted analyses	<ul style="list-style-type: none"> • None specified (subgroups are covered as different risk factors)
Language	English
Study design	Cohort studies using multivariable analyses at least accounting for age, severity and treatment Population-based studies (where all infants and children within a geographically defined region are included), ideally prospective cohort studies. Minimum sample size = 100 participants
Search strategy	Sources to be searched: Medline, Medline In-Process, CCTR, CDSR, DARE, HTA, Embase, CINAHL Limits (e.g. date, study design): Standard English language and animal restrictions to be applied Supplementary search techniques: No supplementary search techniques will be used. See appendix E for full search strategies.
Review strategy	Dual weeding of the literature search results will be performed on 10% of records because this is a prognostic review. Any disagreements will be resolved through discussion and consultation with senior staff where necessary. Appraisal of methodological quality: The methodological quality of each study should be assessed using NICE checklists for prognostic studies and the quality of the evidence for an outcome (i.e. across studies for each risk factor) will be summarised on a per study basis. Synthesis of data: If there is sufficient prognostic data available and studies are sufficiently similar then it may be possible to conduct a meta-analysis. Otherwise it may be necessary to report the evidence for each risk factor narratively or to report ranges.
Equalities	Effective interventions to address should take into consideration parents' and carers' socioeconomic, cultural, religious and ethnic environment, and potential language barriers. Access to appropriate nutrition may also differ across socioeconomic groups. Certain groups may be at greater risk of developing faltering growth, including preterm infants and children, children and infants with intrauterine growth restriction, those with learning-disabled parents or carers, asylum seekers, and looked-after children. For this particular topic there are also specific equality considerations with regards to women's mental health postnatally (e.g. postnatal depression).
Notes/additional information	n/a

5 Key area C: Assessment of infants and preschool children with faltering growth (question C.1)

Item	Details
Area in the scope	Assessment of infants and preschool children with faltering growth. This includes identifying possible causes of faltering growth and, in the absence of any other symptoms or signs, deciding on appropriate investigations.
Review question in the scope	What is the prevalence of specific conditions in infants and preschool children who present with faltering growth and no other symptoms or signs, to help determine appropriate investigations?
Review question for the guideline	What is the prevalence of the specific causative conditions (and of no causative condition) identified in infants and preschool children who present with faltering growth who have no other symptoms or signs pointing to such a condition?
Objective	The answer to this question may help determine what investigations and or referrals, if any, are appropriate in primary care settings
Population and directness	Infants and preschool children who present with borderline or definite faltering growth. Exclude infants from low and middle income group countries, and infants and children in intensive care settings
Specific causative conditions	<ul style="list-style-type: none"> • coeliac disease • urinary tract infections • hypothyroidism • chronic renal disease • no causative conditions
Outcomes	<ul style="list-style-type: none"> • Percentage/proportion of children with a causative condition (coeliac disease, urinary tract infection, hypothyroidism or chronic renal disease) and with no identified causative condition.
Importance of outcomes	<p>Critical outcomes:</p> <ul style="list-style-type: none"> • Percentage/proportion of children with a causative condition (coeliac disease, urinary tract infection, hypothyroidism or chronic renal disease) and with no identified causative condition.
Setting	Primary care settings in World Bank high income group countries.
Stratified, subgroup and adjusted analyses	<p>Groups that will be reviewed and analysed separately:</p> <ul style="list-style-type: none"> • each specific condition will be analysed separately • children with faltering growth who do not present with symptoms or signs pointing to a causative organic disorder <p>Sub-group analyses, the following subgroups will be considered for sensitivity analysis:</p> <p>population subgroups:</p> <ul style="list-style-type: none"> • age – early weight loss after birth (first two weeks), infants (under 1 year), preschool children <p>Important confounders – see subgroups</p>
Language	English
Study design	<p>Systematic reviews of observational studies</p> <p>Prospective cohort studies</p> <p>Retrospective cohort studies</p> <p>Cross sectional studies</p> <p>Registry data (if available)</p> <p>Only observational studies above sample size of 500 participants will be included (due to the relatively low prevalence of underlying causative</p>

Item	Details
	conditions). If no studies available will consider studies over 200
Search strategy	<p>Sources to be searched: Medline, Medline In-Process, CENTRAL, CDSR, DARE, HTA, Embase</p> <p>Limits (e.g. date, study design): Apply standard animal/non-English language exclusions</p> <p>Supplementary search techniques: No supplementary search techniques will be used</p> <p>See appendix E for full search strategies.</p>
Review strategy	<p>This question is not prioritised for dual weeding as it should be clear whether studies are in a primary care setting. A list of excluded studies will be provided to the GC following full text screening</p> <p>Appraisal of methodological quality: The JBI Critical Appraisal Checklist for Studies Reporting Prevalence Data (Munn et al. 2014) will be used. Methodological quality will be summarised on a per study basis</p> <p>Synthesis of data: Ranges of prevalence and overall quality will be presented narratively. Evidence tables by condition will be used to summarise the quality of the body of the evidence (on a per study basis) for a particular condition</p>
Equalities	Effective interventions to address should take into consideration parents' and carers' socioeconomic, cultural, religious and ethnic environment, and potential language barriers. Access to appropriate nutrition may also differ across socioeconomic groups. Certain groups may be at greater risk of developing faltering growth, including preterm infants and children, children and infants with intrauterine growth restriction, those with learning-disabled parents or carers, asylum seekers, and looked-after children.
Notes/additional information	n/a

6 Key area C: Assessment of infants and preschool children with faltering growth (question C.2)

Item	Details
Area in the scope	Assessment of infants and preschool children with faltering growth. This includes identifying possible causes of faltering growth and, in the absence of any other symptoms or signs, deciding on appropriate investigations.
Review question in the scope	None
Review question for the guideline	What approaches are useful in assessing feeding and eating in faltering growth in individual children, including formal feeding observations and assessment?
Objective	To identify the most useful approaches and tools to identify mechanisms contributing to faltering growth in individual children.
Population and directness	<p>Infants and preschool children in whom weight gain concerns have been raised through either routine monitoring (defined in recommendation 17 of the NICE guideline on maternal and child nutrition) or concern by professionals parents or carers</p> <p>Exclude complex, severe malnutrition in World Bank low and middle income group countries, and infants and children in intensive care settings</p>
Assessment methods	<ul style="list-style-type: none"> • history taking of <ul style="list-style-type: none"> ○ feeding (milk feeding) ○ age of weaning ○ range and types of food now taken • food diary • meal observation • video observation • assessment of breastfeeding and/or bottle feeding • validated feeding or eating assessment tools <p>Individually or in combination</p>
Comparison	<p>The following possible comparisons will be included:</p> <ul style="list-style-type: none"> • assessment without any of the above • any comparison of any of the above
Outcomes	<ul style="list-style-type: none"> • fluid and nutritional intake • milk transfer • rates of feeding behavioural problems (e.g. refusal) • oromotor function • parent-child interaction during feeding/mealtimes • health-related quality of life • parent or carer satisfaction <p>Only to include measurements by validated methods</p>
Importance of outcomes	<p>Preliminary classification of the outcomes for decision making:</p> <p>Critical outcomes</p> <ul style="list-style-type: none"> • measurement of fluid and nutritional intake • behavioural problems (e.g. refusal)
Setting	Any setting where a child is suspected of having faltering growth in World Bank

Item	Details
	high income group countries except intensive care settings.
Stratified, subgroup and adjusted analyses	<p>Stratified analyses:</p> <ul style="list-style-type: none"> • neonates • age / stage of feeding - (1 - 6 months, 6 months and older) <p>Subgroups</p> <ul style="list-style-type: none"> • premature birth, including degree of prematurity • IUGR • type of intervention • children with a previous condition that caused the faltering growth but who are still not thriving once the condition has been controlled (e.g. treated cardiac condition that may have led to faltering growth but even after treatment growth is still not catching up) • breastfed babies <p>Sensitivity analysis: including and excluding studies with a high risk of bias.</p> <p>Confounders (for cohort studies):</p> <ul style="list-style-type: none"> • age • prematurity • baseline severity of faltering growth • socio-economic factors • parental height • maternal cognition
Language	English
Study design	<p>For comparative studies</p> <p>Systematic reviews of RCTs or systematic reviews of comparative observational studies (if no RCT evidence for each comparison is found).</p> <p>Randomised controlled trials (RCTs).</p> <p>If no RCTs are available we will look for abstracts of RCTs and comparative cohort studies. If non-randomised studies are included we would prioritise studies using multivariable analysis over univariate methods.</p> <p>Minimum sample size for RCT studies would be 10 participants in each arm and for cohort studies 30 participants or at least 10 per outcome variable.</p> <p>If no comparative studies are available cohort studies reporting the predictive accuracy of assessment methods will be included.</p>
Search strategy	<p>Sources to be searched:</p> <p>Limits (e.g. date, study design):</p> <p>Supplementary search techniques: No supplementary search techniques were used.</p> <p>See appendix E for full search strategies.</p>
Review strategy	<p>This question is not prioritised for dual weeding as the interventions of interest should be readily apparent in the study abstracts.</p> <p>Appraisal of methodological quality:</p> <ul style="list-style-type: none"> • The methodological quality of each study should be assessed using quality checklists and the quality of the evidence for an outcome (i.e. across studies) will be assessed using GRADE. • Synthesis of data:

Item	Details
	<ul style="list-style-type: none"> • Meta-analysis will be conducted where appropriate. • Default MIDs will be used: 0.75 and 1.25 for dichotomous outcomes; 0.5 times SD for continuous outcomes to assess imprecision • If studies only report p-values, this information will be plotted in GRADE tables without an assessment of imprecision possible to be made. <p>In the absence of studies comparing alternative assessment methods, studies of the predictive accuracy of assessment methods will be appraised using the CASP checklist for clinical prediction tools and methodological quality summarised using modified GRADE.</p>
Equalities	<p>Effective interventions to address should take into consideration parents' and carers' socioeconomic, cultural, religious and ethnic environment, and potential language barriers. Access to appropriate nutrition may also differ across socioeconomic groups. Certain groups may be at greater risk of developing faltering growth, including preterm infants and children, children and infants with intrauterine growth restriction, those with learning-disabled parents or carers, asylum seekers, and looked-after children.</p>
Notes/additional information	n/a

7 Key area C: Assessment of infants and preschool children with faltering growth (question C.3)

Item	Details
Area in the scope	Assessment of infants and preschool children with faltering growth. This includes identifying possible causes of faltering growth and, in the absence of any other symptoms or signs, deciding on appropriate investigations.
Review question in the scope	None
Review question for the guideline	What are the differences in feeding and eating behaviour and practices in children with faltering growth compared to those without?
Objective	To identify possible behaviour and practices that may adversely affect feeding and eating and may thus contribute to faltering growth. This information could contribute to management strategies.
Population and directness	Infants and preschool children with faltering growth Exclude complex, severe malnutrition in World Bank low and middle income group countries, and infants and children in intensive care settings
Assessment methods	<ul style="list-style-type: none"> • prospectively completed food diaries • direct observation of feeding (including breastfeeding) and mealtime • video observation • validated feeding or eating assessment tools <p>Any of the above individually or in combination</p>
Comparison	Infants and preschool children with faltering growth Compared to: Matched infants and preschool children without faltering growth
Outcomes / differences	<ul style="list-style-type: none"> • fluid and nutritional intake • milk transfer (using a validated tool such as the baby friendly initiative breast feeding assessment tool) • feeding eating and appetite behaviour and problems (e.g. refusal) • oromotor and swallow function • parent-child interaction during feeding/mealtimes (such as mellow parenting tool) • environmental factors (such as meal settings etc) • health-related quality of life • parent or carer satisfaction <p>Only to include measurements by validated methods</p>
Importance of outcomes	Preliminary classification of the outcomes for decision making: Critical outcomes <ul style="list-style-type: none"> • measurement of fluid and nutritional intake • feeding eating and appetite behaviour and problems (e.g. refusal) • parent-child interaction during feeding/mealtimes
Setting	Any setting where a child is suspected of having faltering growth in World Bank high income group countries except intensive care settings.

Item	Details
Stratified, subgroup and adjusted analyses	<p>Stratified analyses:</p> <ul style="list-style-type: none"> • age / stage of feeding • neonates (28 days or less) • age - (1 - 6 months, 6 months and older) • method of feeding <p>Subgroups</p> <ul style="list-style-type: none"> • premature birth, including degree of prematurity • IUGR • type of assessment • children with a previous condition that caused the faltering growth but who are still not thriving once the condition has been controlled (e.g. treated cardiac condition that may have led to faltering growth but even after treatment growth is still not catching up) <p>Sensitivity analysis: including and excluding studies with a high risk of bias.</p> <p>Confounders (for cohort studies):</p> <ul style="list-style-type: none"> • age • prematurity • baseline severity of faltering growth • socio-economic factors • parental height • maternal cognition
Language	English
Study design	<p>Systematic reviews of prospective cohort studies</p> <p>Prospective comparative cohort studies of no less than 50 participants</p> <p>If there are no prospective comparative cohort studies of no less than 50 participants we might consider prospective comparative cohort studies of less than 50</p> <p>Case control studies</p>
Search strategy	<p>Sources to be searched:</p> <p>Limits (e.g. date, study design):</p> <p>Supplementary search techniques: No supplementary search techniques were used.</p> <p>See appendix E for full search strategies.</p>
Review strategy	<p>This review is not prioritised for dual weeding.</p> <p>Appraisal of methodological quality:</p> <ul style="list-style-type: none"> • The methodological quality of each study should be assessed using quality checklists appropriate to the study design (for example the case-control study checklist, Appendix E NICE guidelines manual 2012) and the quality of the evidence for an outcome (i.e. across studies) will be assessed on a per study basis <p>Synthesis of data:</p> <ul style="list-style-type: none"> • Meta-analysis will be conducted where appropriate.
Equalities	<p>Effective interventions to address should take into consideration parents' and carers' socioeconomic, cultural, religious and ethnic environment, and potential language barriers. Access to appropriate nutrition may also differ across socioeconomic groups. Certain groups may be at greater risk of developing faltering growth, including preterm infants and children, children</p>

Item	Details
	and infants with intrauterine growth restriction, those with learning-disabled parents or carers, asylum seekers, and looked-after children.
Notes/additional information	n/a

8 Key are D: Growth monitoring (question number D.1)

Item	Details
Area in the scope	Growth monitoring in infants and preschool children with suspected or confirmed faltering growth.
Review question in the scope	What growth monitoring should be carried out in infants and preschool children with suspected or confirmed faltering growth?
Review question for the guideline	In children with suspected or confirmed faltering growth is an increased frequency of monitoring more effective compared to routine monitoring to improve outcome?
Objective	The aim of this review is to identify whether an increased frequency of monitoring is necessary for faltering growth compared to routine monitoring.
Population and directness	<p>Infants and preschool children in whom weight gain concerns have been raised through either routine monitoring (defined in recommendation 17 of the NICE guideline on maternal and child nutrition) or concern by professionals, parents or carers.</p> <p>Exclude complex, severe malnutrition in World Bank low and middle income group countries, and infants and children in intensive care settings</p>
Intervention	<p>Growth monitoring:</p> <ul style="list-style-type: none"> • monitoring of weight • monitoring of length • other components of monitoring • over and above routine monitoring frequency as described below <p>Routine monitoring (defined in recommendation 17 of the NICE guideline on maternal and child nutrition) - <i>As a minimum, ensure babies are weighed at birth and in the first week, as part of an overall assessment of feeding. Thereafter, healthy babies should usually be weighed at 8, 12 and 16 weeks and at 1 year, at the time of routine immunisations. If there is concern, weigh more often, but no more than once a month up to 6 months of age, once every 2 months from 6–12 months of age and once every 3 months over the age of 1 year</i></p>
Comparison	<ul style="list-style-type: none"> • frequent growth monitoring compared to routine growth monitoring • one frequency of monitoring compared to another
Outcomes	<ul style="list-style-type: none"> • measurements of growth (weight gain, length/height, head circumference, mid-arm circumference) • health-related quality of life • parent or carer satisfaction • adherence to treatment (missing appointments etc.)
Importance of outcomes	<p>Preliminary classification of the outcomes for decision making:</p> <ul style="list-style-type: none"> • measurements of growth (weight gain, length/height, head circumference, mid-arm circumference) • health-related quality of life • parent or carer satisfaction
Setting	Primary care setting and secondary care setting (World Bank high income group countries excluding ICU)
Stratified, subgroup and adjusted analyses	<p>Groups that will be reviewed and analysed separately:</p> <ul style="list-style-type: none"> • were born at term or preterm babies • method of feeding (breast-feeding vs not breast-feeding) • small for gestational age • IUGR

Item	Details
	<p>Sub-group analyses, e.g. In the presence of heterogeneity, the following subgroups will be considered for sensitivity analysis:</p> <ul style="list-style-type: none"> • age: under 2 weeks of age (early weight loss) and under 28 days (establishing feeding) then >6 months or after introduction of solids. <p>Important confounders (when comparative observational studies are included for interventional reviews) – these may be similar to the subgroups above:</p> <ul style="list-style-type: none"> • severity of faltering growth • treatment received
Language	English
Study design	<p>Systematic reviews of RCTs or systematic reviews of comparative observational cohort studies (if no RCT evidence for each comparison is found). Randomised controlled trials (RCTs).</p> <p>If no RCTs are available we will look for abstracts of RCTs and cohort studies. If non-randomised studies are included we would prioritise studies using multivariable analysis over univariate methods.</p> <p>Minimum sample size for RCT studies would be 30 participants in each arm (this threshold was chosen based on GC knowledge of the evidence base) and for cohort studies we will look for prospective multivariable studies in the first instance (with at least 30 participants per outcome variable). If not we will consider retrospective cohort studies.</p>
Search strategy	<p>Sources to be searched: Limits (e.g. date, study design): Supplementary search techniques: No supplementary search techniques were used. See appendix E for full search strategies.</p>
Review strategy	<p>Dual weeding of the literature search results will be performed on 10% of records. Any disagreements will be resolved through discussion and consultation with senior staff where necessary.</p> <p>Appraisal of methodological quality:</p> <ul style="list-style-type: none"> • The methodological quality of each study should be assessed using quality checklists and the quality of the evidence for an outcome (i.e. across studies) will be assessed using GRADE. • Synthesis of data: • Meta-analysis will be conducted where appropriate. <p>Default MIDs will be used: 0.75 and 1.25 for dichotomous outcomes; 0.5 times SD for continuous outcomes to assess imprecision. If studies only report p-values, this information will be plotted in GRADE tables without an assessment of imprecision possible to be made.</p>
Equalities	<p>Monitoring should take into consideration parents' and carers' socioeconomic, cultural, religious and ethnic environment, and potential language barriers. Access to appropriate nutrition may also differ across socioeconomic groups. Certain groups may be at greater risk of developing faltering growth, including preterm infants and children, children and infants with intrauterine growth restriction, those with learning-disabled parents or carers, asylum seekers, and looked-after children.</p>
Notes/additional information	n/a

9 Key area E: Referral to secondary care (question number E.1)

Item	Details
Area in the scope	Referral to secondary care
Review question in the scope	What factors determine the need for referral to secondary care for infants and preschool children with suspected or confirmed faltering growth?
Review question for the guideline	Does the use of specific criteria or protocols for the referral of infants and preschool children with suspected or confirmed faltering growth to secondary care improve outcome?
Objective	The aim of this review is to provide guidance on criteria that may indicate that a child with faltering growth may need specialist services.
Population and directness	<p>Infants and preschool children in whom weight gain concerns have been raised through either routine monitoring (defined in recommendation 17 of the NICE guideline on maternal and child nutrition) or concern by professionals parents or carers</p> <p>Exclude complex, severe malnutrition in World Bank low and middle income group countries, and infants and children in intensive care settings.</p>
Criteria	<p>Potential criteria for referral from primary to secondary services:</p> <ul style="list-style-type: none"> • diagnostic uncertainty • severe faltering growth • persistent faltering growth despite primary care interventions • persistent parental concerns
Comparison	Referral vs. non-referral in relation to specified criteria
Outcomes	<ul style="list-style-type: none"> • measurements of growth (weight gain, length/height, head circumference, mid-arm circumference) • health-related quality of life • parent or carer satisfaction • adherence to interventions • adverse effects of not being referred (for instance, mortality) • admission and re-admission to hospital • number of referrals
Importance of outcomes	<p>Preliminary classification of the critical and important outcomes for decision making:</p> <p>Critical:</p> <ol style="list-style-type: none"> 1. measurements of growth 2. health-related quality of life 3. parent or carer satisfaction <p>Important:</p> <p>All other specified outcomes</p>
Setting	Primary care setting in World Bank high income group countries except intensive care settings.
Stratified, subgroup and adjusted analyses	<p>Stratified analyses:</p> <ul style="list-style-type: none"> • age / stage of feeding • neonates • age - (1 - 6 months, 6 months and older) <p>Subgroups</p> <ul style="list-style-type: none"> • premature birth, including degree of prematurity

Item	Details
	<ul style="list-style-type: none"> • IUGR • type of intervention • children with a previous condition that caused the faltering growth but who are still not thriving once the condition has been controlled (e.g. treated cardiac condition that may have led to faltering growth but even after treatment growth is still not catching up) • method of feeding <p>Sensitivity analysis: including and excluding studies with a high risk of bias.</p> <p>Confounders (for cohort studies):</p> <ul style="list-style-type: none"> • age • prematurity • baseline severity of faltering growth • socio-economic factors • parental height • maternal cognition
Language	English
Study design	Systematic reviews of prospective comparative cohort studies Prospective comparative cohort studies of no less than 10 participants in each arm
Search strategy	Sources to be searched: Limits (e.g. date, study design): Supplementary search techniques: No supplementary search techniques were used. See appendix E for full search strategies.
Review strategy	Dual weeding of the literature search results will be performed on 10% of records. Any disagreements will be resolved through discussion and consultation with senior staff where necessary.
	<p>Appraisal of methodological quality:</p> <ul style="list-style-type: none"> • The methodological quality of each study should be assessed using quality checklists and the quality of the evidence for an outcome (i.e. across studies) will be assessed using GRADE. • Synthesis of data: • Meta-analysis will be conducted where appropriate. • Default MIDs will be used: 0.75 and 1.25 for dichotomous outcomes; 0.5 times SD for continuous outcomes to assess imprecision <p>If studies only report p-values, this information will be plotted in GRADE tables without an assessment of imprecision possible to be made.</p>
Equalities	Effective interventions to address should take into consideration parents' and carers' socioeconomic, cultural, religious and ethnic environment, and potential language barriers. Access to appropriate nutrition may also differ across socioeconomic groups. Certain groups may be at greater risk of developing faltering growth, including preterm infants and children, children and infants with intrauterine growth restriction, those with learning-disabled parents or carers, asylum seekers, and looked-after children.
Notes/additional information	n/a

10 Key are F: Interventions to manage faltering growth – nutritional (question number F.1)

Item	Details
Area in the scope	Interventions to manage faltering growth, including: <ul style="list-style-type: none"> breastfeeding support
Review question in the scope	What interventions related to breastfeeding are effective in the management of faltering growth?
Review question for the guideline	What forms of breastfeeding support are effective in the management of faltering growth?
Objective	The aim of this review is to identify effective interventions to support breastfeeding: <ul style="list-style-type: none"> in the context of suspected or confirmed faltering growth.
Population and directness	<p>Infants and preschool children in whom weight gain concerns have been raised through either routine monitoring (defined in recommendation 17 of the NICE guideline on maternal and child nutrition) or concern by professionals parents or carers</p> <p>Exclude complex, severe malnutrition in World Bank low and middle income group countries, and infants and children in intensive care settings.</p>
Intervention	<p>Health education interventions (parental education and support):</p> <ul style="list-style-type: none"> factual or technical information about breastfeeding (hospital or community setting; to individuals or groups). <p>Peer or professional support</p> <ul style="list-style-type: none"> advice or support given by a trained individual (professional or non-professional). This could include one-to-one, groups or helplines. <p>Physical, pharmacological, psychological or behavioural interventions (related to either the mother the baby or both)</p> <ul style="list-style-type: none"> behavioural changes for instance positioning and attachment, breast milk expression, frequency of feeds (feeding cues/responsive/baby led/demand vs. scheduling). division of tongue tie / tethered oral tissue / lip tie / frenotomy or frenulotomy / ankyloglossia domperidone, metoclopramide, fenugreek, galactogogues supplementation with artificial feed / expressed breast milk interventions to adjust maternal diet interventions related to maternal mental health / emotional family / partner support (e.g. stress or postnatal depression) <p>Multifaceted interventions</p> <ul style="list-style-type: none"> any of the above interventions used in combination <p>Exclude:</p> <ul style="list-style-type: none"> studies with fewer than 10 participants in each arm
Comparison	<p>The following possible comparisons will be included:</p> <ul style="list-style-type: none"> any of above interventions versus no intervention (no support) any of above interventions versus placebo any of above intervention versus any other of the above interventions (individually or in combination or in different routes)

Item	Details
	<p>Exclude:</p> <ul style="list-style-type: none"> • Comparisons of interventions for breastfeeding with non-breastfeeding interventions.
Outcomes	<ul style="list-style-type: none"> • resolution of borderline or definite faltering growth concerns: based on measurements of growth (weight change, length/height, head circumference, mid-arm circumference) • continuation of breastfeeding (for instance duration of breastfeeding)? • health-related quality of life (parent/carer) • parent or carer satisfaction • adverse effects of interventions (psychological and physical effects, allergies)?
Importance of outcomes	<p>Preliminary classification of the critical and important outcomes for decision making:</p> <ul style="list-style-type: none"> • Critical: <ol style="list-style-type: none"> 1. continuation of breastfeeding 2. measurements of growth 3. health related quality of life (parental) • Important: <p>all other specified outcomes including adverse effects of interventions (related to mother and baby)</p>
Setting	Any setting where a child is suspected of having faltering growth in World Bank high income group countries except intensive care settings.
Stratified, subgroup and adjusted analyses	<p>Stratified analyses:</p> <p>Borderline or definite faltering growth:</p> <p>Groups that will be reviewed and analysed separately:</p> <p>Infants and preschool children who:</p> <ul style="list-style-type: none"> • were born prematurely • were born small for gestational age • were born after intrauterine growth restriction (IUGR) • excessive early weight loss after birth • Intervention categories <p>Sub-group analyses, e.g. In the presence of heterogeneity, the following subgroups will be considered for sensitivity analysis:</p> <ul style="list-style-type: none"> • socio-economic, cultural, ethnic background • age (maternal and infant) • severity of growth concern <p>Intervention subgroups:</p> <ul style="list-style-type: none"> • setting in which the intervention is conducted (community or healthcare setting) • group or individual intervention
Language	English
Study design	<p>Only published full text papers – state if conference abstracts are being considered only of RCT studies and only if insufficient fully published data is identified</p> <p>Systematic reviews of RCTs</p>
Search strategy	<p>Sources to be searched: Medline, Medline In-Process, CCTR, CDSR, DARE, HTA, Embase, CINAHL</p> <p>Limits (e.g. date, study design): Standard English language and animal restrictions to be applied. Limit to RCTs in first instance.</p>

Item	Details
	<p>Supplementary search techniques: No supplementary search techniques will be used.</p> <p>See appendix E for full search strategies.</p>
Review strategy	<p>Appraisal of methodological quality: The methodological quality of each study should be assessed using checklists suggested in the NICE manual and the quality of the evidence for an outcome (i.e. across studies) will be assessed using GRADE.</p> <p>Synthesis of data: A meta-analysis will be conducted where appropriate. State the MIDs, e.g. default MIDs will be used: 0.75 and 1.25 for dichotomous outcomes; 0.5 times SD for continuous outcomes. The Committee agreed that default MIDs would be used for the protocol outcomes. For continuous data final and change scores will be pooled together and if any study reports both, the method used in the majority of studies will be analysed. If studies only report p-values, this information will be entered into GRADE tables without an assessment of imprecision possible to be made.</p>
Equalities	<p>Effective interventions to address should take into consideration parents' and carers' socioeconomic, cultural, religious and ethnic environment, and potential language barriers. Access to appropriate nutrition may also differ across socioeconomic groups. Certain groups may be at greater risk of developing faltering growth, including preterm infants and children, children and infants with intrauterine growth restriction, those with learning-disabled parents or carers, asylum seekers, and looked-after children.</p>
Notes/additional information	n/a

11 Key area F: Interventions to manage faltering growth – nutritional (question number F.2)

Item	Details
Area in the scope	Interventions to manage faltering growth, including: <ul style="list-style-type: none"> • breastfeeding support • support for other types of feeding • <u>dietary advice and supplementation</u> • <u>family support</u>.
Review question in the scope	What interventions related to dietary advice or supplementation are effective in the management of faltering growth?
Review question for the guideline	What is the effectiveness of providing dietary advice or supplementation to families or carers in the management of infants and preschool children with suspected or confirmed faltering growth when compared to no intervention or compared to advice on feeding practices other than breastfeeding, or family support?
Objective	The aim of this review is to identify what interventions are clinically and cost effective for improving nutritional status in children with concerns regarding possible or actual faltering growth.
Population and directness	<p>Infants and preschool children in whom weight gain concerns have been raised through either routine monitoring (defined in recommendation 17 of the NICE guideline on maternal and child nutrition) or concern by professionals parents or carers</p> <p>Exclude complex, severe malnutrition in World Bank low and middle income group countries, and infants and children in intensive care settings.</p>
Intervention	<p>This review will consider the following interventions:</p> <p>Supplements and combinations of supplementations and the infant's and preschool child's regular food:</p> <ul style="list-style-type: none"> • milk feeding only • complementary solids (e.g. milk feeding plus additional solids) • high energy supplements (specialised medical formulas or other supplements) • change of supplement (e.g. change in formula milk or other solid or fluid supplements) • tube feeding, Sip feeds (oral nutrition support) Therapeutic foods (older children), • over the counter supplements <p>Dietary advice (practical feeding advice), for example:</p> <ul style="list-style-type: none"> • increase type and variety of food offered • increase energy density (i.e. increase in protein and carbohydrate content) of usual foods – food fortification, food first , increased energy density, concentrated feeds, • increase volume and frequency of meals • family foods <p>Individual or in combination with each other</p>

Item	Details
	Exclude vitamin and micronutrient supplementation unless used as part of a particular supplementation
Comparison	<p>The following possible comparisons will be included:</p> <ul style="list-style-type: none"> • any of above interventions versus no intervention • any of above interventions versus placebo • any of above intervention versus any other of the above interventions • any of above intervention versus other non-nutritional interventions
Outcomes	<ul style="list-style-type: none"> • measurements of growth (weight gain, length/height, head circumference, mid-arm circumference) • health-related quality of life • parent or carer satisfaction • adherence to interventions • adverse effects of interventions (for instance, gastrointestinal symptoms, discontinuation of breastfeeding, disordered appetite and feeding behaviour) <p>Cognition and neurodevelopment - only restricted to IQ at school age if reported</p> <p>If none of the above outcomes are identified in studies we would consider looking at nutrient intake compared to estimated nutritional requirements</p>
Importance of outcomes	<p>Preliminary classification of the critical and important outcomes for decision making:</p> <ul style="list-style-type: none"> • Critical: <ol style="list-style-type: none"> 1. measurements of growth 2. adverse effects of interventions (for instance, gastrointestinal symptoms) • Important: <p>All other specified outcomes</p>
Setting	Any setting where a child is suspected of having faltering growth in World Bank high income group countries except intensive care settings.
Stratified, subgroup and adjusted analyses	<p>Stratified analyses:</p> <ul style="list-style-type: none"> • age / stage of feeding • neonates • age - (1 – 6 months, 6 months and older) <p>Subgroups</p> <ul style="list-style-type: none"> • premature birth, including degree of prematurity • IUGR • type of intervention • children with a previous condition that caused the faltering growth but who are still not growing once the condition has been controlled (e.g. treated cardiac condition that may have led to faltering growth but even after treatment growth is still not catching up) <p>Sensitivity analysis: including and excluding studies with a high risk of bias.</p> <p>Confounders (for cohort studies):</p> <ul style="list-style-type: none"> • age • prematurity • baseline severity of faltering growth

Item	Details
	<ul style="list-style-type: none"> • socio-economic factors • parental height • maternal educational attainment
Language	English
Study design	<ul style="list-style-type: none"> • Systematic reviews of RCTs or systematic reviews of comparative observational studies (if no RCT evidence for each comparison is found). • Randomised controlled trials (RCTs). • If sufficient evidence from RCTs from developed countries is identified then evidence from developing countries would be considered for inclusions <p>Minimum sample size for RCT studies would be 10 participants in each arm and for cohort studies 30 participants or at least 10 per outcome variable.</p>
Search strategy	<p>Sources to be searched: Medline, Medline In-Process, CCTR, CDSR, DARE, HTA, Embase</p> <p>Limits (e.g. date, study design): Standard English language/animal studies exclusions will be applied where possible. RCT/SR filters will be applied where possible.</p> <p>Supplementary search techniques: No supplementary search techniques will be used.</p> <p>See appendix E for full search strategies.</p>
Review strategy	<p>Appraisal of methodological quality:</p> <ul style="list-style-type: none"> • The methodological quality of each study should be assessed using quality checklists and the quality of the evidence for an outcome (i.e. across studies) will be assessed using GRADE. <p>Synthesis of data:</p> <ul style="list-style-type: none"> • Meta-analysis will be conducted where appropriate. • Default MIDs will be used: 0.75 and 1.25 for dichotomous outcomes; 0.5 times SD for continuous outcomes to assess imprecision • If studies only report p-values, this information will be plotted in GRADE tables without an assessment of imprecision possible to be made.
Equalities	Effective interventions to address should take into consideration parents' and carers' socioeconomic, cultural, religious and ethnic environment, and potential language barriers. Access to appropriate nutrition may also differ across socioeconomic groups. Certain groups may be at greater risk of developing faltering growth, including preterm infants and children, children and infants with intrauterine growth restriction, those with learning-disabled parents or carers, asylum seekers, and looked-after children.
Notes/additional information	Only tools that are externally validated will be assessed

12 Key area F: Interventions to manage faltering growth – non-nutritional (question number F.3)

Item	Details
Area in the scope	Interventions to manage faltering growth, including: <ul style="list-style-type: none"> • breastfeeding support • <u>support for other types of feeding</u> • dietary advice and supplementation • family support.
Review question in the scope	What is the effectiveness of non-nutritional interventions (including providing advice on, and practical support for feeding practices other than breastfeeding) to families or carers in the management of faltering growth when compared to no intervention or compared to dietary advice and supplementation?
Review question for the guideline	What is the effectiveness of providing advice on, and practical support for feeding practices other than breastfeeding to families or carers in the management of children with suspected or confirmed faltering growth when compared to no intervention or compared or dietary advice and supplementation?
Objective	The aim of this review is to identify what feeding practices interventions other than breastfeeding are clinically and cost effective for improving nutritional status for infants and preschool children in whom growth concerns have been raised, through either routine monitoring (defined in recommendation 17 of the NICE guideline on maternal and child nutrition) or professional or parental concern.
Population and directness	Infants and preschool children in whom weight gain concerns have been raised through either routine monitoring (defined in recommendation 17 of the NICE guideline on maternal and child nutrition) or concern by professionals parents or carers Exclude complex, severe malnutrition in World Bank low and middle income group countries, and infants and children in intensive care settings.
Intervention	This review will consider the following interventions: Parent based <ul style="list-style-type: none"> • behavioural and practical mealtime advice, for example, <ul style="list-style-type: none"> ◦ mealtime interventions (e.g. routine, setting, duration, frequency family meals, social modelling) models of parent – child interactions (e.g. promoting and avoiding certain feeding practices, e.g. persecutory/forced feeding, mechanistic feeding, praising good behaviour/ignoring undesired behaviour) • observation (including videoing) and support of mealtimes in the family home Child based <ul style="list-style-type: none"> • feeding therapies • sensory interventions (SOS) • behavioural interventions (e.g. ABA applied behavioural analysis) • oral motor therapy, chewing exercises • child-led feeding (finger food) • desensitisation

Item	Details
	<ul style="list-style-type: none"> • use of feeding cup • use of age appropriate feeding utensil • alternative care (e.g. nursery placement, pre-school, child minder)
Comparison	<p>The following possible comparisons will be included:</p> <ul style="list-style-type: none"> • any of above interventions versus no intervention • any of above interventions versus placebo • any of above intervention versus any other of the above interventions • any of above intervention versus other supportive interventions and dietary advice or supplementation.
Outcomes	<ul style="list-style-type: none"> • measurements of growth • other anthropometric measurements relating to nutritional status, including length/height, head circumference, mid-arm circumference • health-related quality of life • parent or carer satisfaction • adherence to interventions • adverse effects of interventions (for instance, gastrointestinal symptoms) • cognition and neurodevelopment - only restricted to IQ at school age if reported <p>If none of the above outcomes are identified in studies we would consider looking at calorie intake</p> <p>Only tools that are externally validated will be assessed</p>
Importance of outcomes	<p>Preliminary classification of the critical and important outcomes for decision making:</p> <p>Critical:</p> <ul style="list-style-type: none"> • measurements of growth • other anthropometric measurements relating to nutritional status, including length/height, head circumference, mid-arm circumference • adverse effects of interventions (for instance, gastrointestinal symptoms) <p>Important:</p> <ul style="list-style-type: none"> • all other specified outcomes
Setting	Any setting in World Bank high income group countries except intensive care settings.
Stratified, subgroup and adjusted analyses	<p>Stratified analyses:</p> <ul style="list-style-type: none"> • age / stage of feeding: • neonates (i.e. early weight loss after birth) • age - (1 - 6 months, 6 months and older), i.e. milk fed and after the introduction of solids <p>Subgroups</p> <ul style="list-style-type: none"> • premature birth, including degree of prematurity • IUGR • type of intervention • baseline severity of faltering growth • children with a previous condition that caused the faltering growth but who are still not thriving once the condition has been controlled (e.g. treated cardiac condition that may have led to faltering growth but even after treatment growth

Item	Details
	<p>is still not catching up)</p> <p>Sensitivity analysis: including and excluding studies with a high risk of bias.</p> <p>Confounders (for cohort studies):</p> <ul style="list-style-type: none"> • age • prematurity • baseline severity of faltering growth • socio-economic factors • parental height • maternal cognition
Language	English
Study design	<ul style="list-style-type: none"> • Systematic reviews of RCTs or systematic reviews of comparative observational studies (if no RCT evidence for each comparison is found). • Randomised controlled trials (RCTs). • If no RCTs are available we will look for abstracts of RCTs and comparative cohort studies. If non-randomised studies are included we would prioritise studies using multivariable analysis over univariate methods. <p>Minimum sample size for RCT studies would be 10 participants in each arm and for cohort studies 30 participants or at least 10 per outcome variable.</p>
Search strategy	<p>Sources to be searched: Medline, Medline In-Process, CCTR, CDSR, DARE, HTA, Embase, PsycINFO, AMED, CINAHL</p> <p>Limits (e.g. date, study design): Standard English language/animal studies exclusions will be applied where possible. RCT/SR filters will be applied where possible.</p> <p>Supplementary search techniques: No supplementary search techniques will be used.</p> <p>See appendix E for full search strategies.</p>
Review strategy	<p>Dual weeding of the literature search results will be performed on 10% of records, because relevant non-nutritional interventions may be difficult to recognise in study abstracts. Any disagreements will be resolved through discussion and consultation with senior staff where necessary.</p> <p>Appraisal of methodological quality:</p> <ul style="list-style-type: none"> • The methodological quality of each study should be assessed using quality checklists and the quality of the evidence for an outcome (i.e. across studies) will be assessed using GRADE. <p>Synthesis of data:</p> <ul style="list-style-type: none"> • Meta-analysis will be conducted where appropriate. • Default MIDs will be used: 0.75 and 1.25 for dichotomous outcomes; 0.5 times SD for continuous outcomes to assess imprecision. • If studies only report p-values, this information will be plotted in GRADE tables without an assessment of imprecision possible to be made. In this case we would downgrade the evidence because a p-value would create uncertainty and therefore impact on our confidence in this evidence.
Equalities	<p>Effective interventions to address should take into consideration parents' and carers' socioeconomic, cultural, religious and ethnic environment, and potential language barriers. Access to appropriate nutrition may also differ across socioeconomic groups. Certain groups may be at greater risk of developing faltering growth, including preterm infants and children, children and infants with</p>

Item	Details
	intrauterine growth restriction, those with learning-disabled parents or carers, asylum seekers, and looked-after children.
Notes/additional information	n/a

13 Key area G: Service configuration (question number G.1)

Item	Details
Area in the scope	Design of services for the management of faltering growth.
Review question in the scope	What service configurations are effective for the management of faltering growth in infants and preschool children?
Review question for the guideline	In the management of infants and preschool children what is the most effective service configuration with regard to the configuration and working arrangements of multidisciplinary teams?
Objective	To identify the most effective service with regards to: <ul style="list-style-type: none"> • how multidisciplinary teams are organised (including the role of midwives and health visitors) • the level of intensity and workload of the team with regards to the management and assessment of faltering growth (e.g. how many hours per week dedicated to this) • care in varied settings (including primary, secondary and tertiary but excluding neonatal intensive care units).
Population and directness	Infants and preschool children with borderline or definite faltering growth. Exclude complex, severe malnutrition in World Bank low and middle income group countries, and infants and children in intensive care settings.
Intervention	<ul style="list-style-type: none"> • multidisciplinary teams configuration (for example, including the role of midwives, health visitors, dieticians, community nurses and infant feeding specialists) • specialist services, for example, infant feeding teams or community teams • intensity and workload of the team with regards to the management and assessment of faltering growth (e.g. how many hours per week dedicated to this) • settings: primary care, community paediatric services, and secondary and tertiary care services • specialist packages of care (including combinations of settings, staff and approaches or mobile (i.e. roaming service without a fixed location))
Comparison	The following possible comparisons will be included: <ul style="list-style-type: none"> • any of above interventions versus usual care • any of above intervention versus any other of the above interventions (individually or in combination or in different settings)
Outcomes	<ul style="list-style-type: none"> • measurements of growth (weight gain, length/height, head circumference, mid-arm circumference) – resolution of faltering growth • health-related quality of life • parent or carer satisfaction • adherence to interventions • adverse effects of interventions (for instance, family dissatisfaction) • cognition and neurodevelopment - only restricted to IQ at school age if reported • admission and re-admission to hospital • resource use outcomes reported in studies included in the clinical evidence, will be extracted and presented in the health economic part of the review.
Importance of outcomes	Preliminary classification of the critical and important outcomes for decision making: <ul style="list-style-type: none"> • Critical: <ol style="list-style-type: none"> 1. measurements of growth (resolution of faltering growth)

Item	Details
	2. health-related quality of life 3. resource use • Important: All other specified outcomes
Setting	All settings in World Bank high income group countries excluding intensive care units. Primary care, community paediatric services, secondary and tertiary care service models will be compared, if there is available evidence.
Stratified, subgroup and adjusted analyses	Stratified analyses: <ul style="list-style-type: none"> • age / stage of feeding • neonates • age - (1 – 6 months, 6 months and older) Subgroups (in case of heterogeneity) <ul style="list-style-type: none"> • premature birth, including degree of prematurity • IUGR • type of intervention • children with a previous condition that caused the faltering growth but who are still not thriving once the condition has been controlled (e.g. treated cardiac condition that may have led to faltering growth but even after treatment growth is still not catching up) • different health care models/systems • baseline severity of faltering growth • socio-economic factors (parental income, parental education) Sensitivity analysis: (in the presence of heterogeneity) including and excluding studies with a high risk of bias.
Language	English
Study design	<ul style="list-style-type: none"> • Systematic reviews of RCTs or systematic reviews of comparative observational studies (if no RCT evidence for each comparison is found). It may be possible to incorporate the results of high quality systematic reviews (according to CASP SR checklist) into the evidence review (updating them if necessary). • Randomised controlled trials (RCTs). <ul style="list-style-type: none"> • If no RCTs are available we will look for abstracts of RCTs and cohort studies. If non-randomised studies are included we would prioritise studies using multivariable analysis over univariate methods.
Search strategy	Sources to be searched: Medline, Medline In-Process, CCTR, CDSR, DARE, HTA, Embase Limits (e.g. date, study design): Standard English language/animal studies exclusions will be applied where possible. RCT/SR filters will be applied where possible. Supplementary search techniques: No supplementary search techniques will be

Item	Details
	<p>used.</p> <p>See appendix E for full search strategies.</p>
Review strategy	<p>This review is not prioritised for dual weeding, as the GC are aware of relevant randomised trial evidence which should be straight forward to identify in the search results.</p> <p>Appraisal of methodological quality:</p> <ul style="list-style-type: none"> • The methodological quality of each study will be assessed using quality checklists and the quality of the evidence for an outcome (i.e. across studies) will be assessed using GRADE. <p>Synthesis of data:</p> <ul style="list-style-type: none"> • Meta-analysis will be conducted where appropriate (if there are RCTs). Otherwise ranges of values will be reported. • Default MIDAs will be used: 0.75 and 1.25 for dichotomous outcomes; 0.5 times SD for continuous outcomes to assess imprecision • If studies only report p-values, they may still be downgraded one level due to unclear risk of imprecision.
Equalities	<p>Effective interventions to address should take into consideration parents' and carers' socioeconomic, cultural, religious and ethnic environment, and potential language barriers. Access to appropriate nutrition may also differ across socioeconomic groups. Certain groups may be at greater risk of developing faltering growth, including preterm infants and children, children and infants with intrauterine growth restriction, those with learning-disabled parents or carers, asylum seekers, and looked-after children.</p>
Notes/additional information	n/a

14 Key area H: Information and support (question H.1)

Item	Details
Area in the scope	Information and support for parents and carers of infants and preschool children with suspected or confirmed faltering growth.
Review question in the scope	What information and support should be provided for parents and carers of infants and preschool children with suspected or confirmed faltering growth?
Review question for the guideline	What is the effectiveness of information and support interventions for parents and carers of infants and preschool children with suspected or confirmed faltering growth? What are the barriers and facilitators in the provision of information and support to successfully address the needs of families with an infant or preschool child in whom concerns about growth have been raised?
Objective	To discover what information and support interventions are effective or perceived as making a positive difference to families with infants or preschool children in whom concerns about growth have been raised. Two objectives have been set up: <ol style="list-style-type: none"> 1. To explore the areas of information and support that families find helpful. 2. To test the effectiveness of information or support interventions as compared to usual care. 3. To see how they would like to receive this information or support.
Population and directness	Families of infants and preschool children in whom growth concerns have been raised, through either routine monitoring (defined in recommendation 17 of the NICE guideline on maternal and child nutrition) or professional or parental concern. Exclude complex, severe malnutrition in World Bank low and middle income group countries, and infants and children in intensive care settings.
Intervention – information and support (quantitative)	<ul style="list-style-type: none"> • mode of information provision (written, oral, online) • peer support within faltering growth including online forums • group meetings/support • family support including emotional support (health visiting, children’s centres/nurseries/education setting qualitative)
Comparison	Compare the above interventions with each other
Context and likely themes (qualitative)	<p>Context:</p> <ul style="list-style-type: none"> • perspectives on information and support that parents perceive as helpful <p>Themes will be identified from the literature, but expected themes are:</p> <ul style="list-style-type: none"> • stigma of having a child with faltering growth • difficulties in the recognition of faltering growth • experience with healthcare professionals • lack of support • condition specific information • treatment related information • communication with staff • how service is delivered and what to expect • care planning • how the information is delivered – individual or group • peer support

Item	Details
	<ul style="list-style-type: none"> • internet information (pros and cons) • parental and HCP perception of what is important • cultural and religious factors • parental emotional well-being • parents and carers feeling isolated • family diet (e.g. vegan) • cognition (knowledge about and attitudes to faltering growth)
Outcomes (quantitative)	<ul style="list-style-type: none"> • resolution of borderline or definite faltering growth: based on measurements of growth (weight change, length/height, head circumference, mid-arm circumference) • health-related quality of life • parent or carer satisfaction and preferences • adherence to information / support intervention • hospital admissions (of the infant or child)
Importance of outcomes (quantitative)	<p>Preliminary classification of the critical and important outcomes for decision making:</p> <ul style="list-style-type: none"> • Critical: <ol style="list-style-type: none"> 1. measurements of growth 2. health related quality of life (parental?)
Setting	<p>Any setting where a child is suspected of having faltering growth in World Bank high income group countries except intensive care settings.</p>
Stratified, subgroup and adjusted analyses	<p>Stratified analyses:</p> <p>Borderline or definite faltering growth:</p> <p>Groups that will be reviewed and analysed separately:</p> <p>Infants and preschool children who:</p> <ul style="list-style-type: none"> • were born prematurely • were born with intrauterine growth restriction (IUGR) • early weight loss after birth • Intervention categories <p>Sub-group analyses, e.g. In the presence of heterogeneity, the following subgroups will be considered for sensitivity analysis:</p> <ul style="list-style-type: none"> • socio-economic background • severity of growth concern • age of infants or children <ul style="list-style-type: none"> • setting in which the intervention is conducted (community or healthcare setting) • group versus individual interventions
Language	English
Study design	<p>Quantitative: Systematic reviews of RCTs or RCTs for effectiveness</p> <p>Qualitative: Systematic reviews of qualitative evidence or qualitative studies (interviews, focus groups, blogs). It may be possible to incorporate the results of high quality systematic reviews (according to CASP SR checklist) into the evidence review (updating them if necessary).</p>
Search strategy	<p>Sources to be searched: Medline, Medline In-Process, CCTR, CDSR, DARE, HTA, Embase, PsycINFO</p> <p>Limits (e.g. date, study design): Apply English language and human only limits where appropriate</p>

Item	Details
	<p>Supplementary search techniques: No supplementary search techniques will be used. See appendix E for full search strategies.</p>
Review strategy	<p>This review was not prioritised for dual weeding.</p> <p>Appraisal of methodological quality: Quantitative studies</p> <ul style="list-style-type: none"> • The methodological quality of each study will be assessed using quality checklists and the quality of the evidence for an outcome (i.e. across studies) will be assessed using GRADE. <p>Synthesis of data:</p> <ul style="list-style-type: none"> • Meta-analysis will be conducted where appropriate. • Default MIDs will be used: 0.75 and 1.25 for dichotomous outcomes; 0.5 times SD for continuous outcomes to assess imprecision • If studies only report p-values, this information will be plotted in GRADE tables without an assessment of imprecision possible to be made. <p>Qualitative studies Study quality will be assessed using the CASP qualitative study checklist The GRADE-CERQual approach will be used to assess the quality of the evidence by theme. Themes themselves will be summarised narratively.</p>
Equalities	<p>Effective interventions to address should take into consideration parents' and carers' socioeconomic, cultural, religious and ethnic environment, and potential language barriers. Access to appropriate nutrition may also differ across socioeconomic groups. Certain groups may be at greater risk of developing faltering growth, including preterm infants and children, children and infants with intrauterine growth restriction, those with learning-disabled parents or carers, asylum seekers, and looked-after children.</p>
Notes/additional information	n/a