Review protocol for review question: What are the benefits and harms of co-sleeping?

Table 3: Review Protocol

Field (based on PRISMA-P)	Content
Review question	What are the benefits and harms of co-sleeping?
Type of review question	Intervention
Objective of the review	This review aims to determine what are the benefits and harms of co-sleeping. By co-sleeping, we mean mother and baby sharing a sleep surface, whether intentional or unintentional.
Eligibility criteria – population/disease/condition/issue/domain	Parents or carers who have a healthy baby Exclude studies with a specific population of babies who were born pre-term. This means babies born before 37 weeks since 'term' is considered to be between 37 and 42 weeks of pregnancy. For studies with a mixed population, they will be included if at least 66% of babies are born at term.
Eligibility criteria – intervention(s)	Co-sleeping with the baby on a shared sleep surface within the first 8 weeks after birth, whether intentional or unintentional. Shared sleep surfaces include but are not limited to the parents' bed, the use of a side-car cot or crib, a pepi-pod, a sofa or armchair.
Eligibility criteria – comparator(s)	Baby sleeps in a cot or Moses style basket in the same room or separate room One of the other interventions

Outcomes and prioritisation	**Critical outcomes:** • infant mortality within the first year (MIDs: any statistically significant difference) • proportion of women breastfeeding (exclusively or partially) at 6 weeks, 12 weeks and 6 months after the birth ((MIDs: any statistically significant difference)) • emotional attachment between parent and baby when the baby is 12 to 18 months of age (MIDs: default). **Important outcomes:** • mother's satisfaction with own sleep in the first 8 weeks after the birth (MIDs: default) • serious illness in the baby, for example infection within the first 3 months (MIDs: default) • parental emotional health and wellbeing in the first 8 weeks after the birth (MIDs: default) • parental satisfaction (MIDs: default).
Eligibility criteria – study design	• Published full text papers only • RCTs • Systematic reviews of RCTs • Only if RCTs unavailable to inform decision making: prospective or retrospective comparative cohort studies or case control studies of at least 50 mother-infant pairs in each arm • Cohort studies will be prioritised over case-control studies • Prospective study designs will be prioritised over retrospective study designs • Conference abstracts will not be considered Studies of co-sleeping within the first 8 weeks will be prioritised and if none are available then analyses of co-sleeping beyond 8 weeks (e.g. 3 months) will be included. **Addendum**: Following agreement with the guideline committee after the protocol had been signed off, a post hoc restriction was applied to include only studies that reported adjusted data for the outcomes of interest. Adjusting data attempts to take into account and adjust estimates of effect for methodological limitations (i.e. likely biases) associated with the studies.
Other inclusion exclusion criteria	Studies from low- and middle-income countries, as defined by the World Bank, will be excluded, as the configuration of antenatal and postnatal services in these countries might not be representative of that in the UK. Date: Studies conducted post 1990 will be considered for this review question, as there was a big change in 1991 with the 'back to sleep campaign', after which fashions in co-sleeping changed markedly.

Proposed sensitivity/sub-group analysis, or meta-regression	Groups that will be reviewed and analysed separately: • singletons versus twins • young women (19 years or under) • women sleeping separately from a partner • women with physical and cognitive disabilities • women with severe mental health illness • nature of the sleep surface, for example shared bed or sofa/armchair • smoking, alcohol, drugs (prescribed or recreational) • sleeping with other siblings • intentional and unintentional co-sleeping • co-sleeping all night, every night and co-sleeping some of the time. In the presence of heterogeneity, the following subgroups will be considered for sensitivity analysis: • low-income population versus the general population • cultural practicing population versus the general population. Potential confounders: • Characteristics defining the groups above
Selection process – duplicate screening/selection/analysis	Sifting, data extraction and appraisal of methodological quality will be performed by the systematic reviewer. Any disputes will be resolved in discussion with the senior systematic reviewer and the Topic Advisor. Quality control will be performed by the senior systematic reviewer. Review questions selected as high priorities for health economic analysis (and those selected as medium priorities and where health economic analysis could influence recommendations) will be subject to dual weeding and study selection; any discrepancies above 10% of the dual weeded resources will be resolved through discussion between the first and second reviewers or by reference to a third person. This review question was not prioritised for health economic analysis and so no formal dual weeding, study selection (inclusion/exclusion) or data extraction into evidence tables will be undertaken. (However, internal (NGA) quality assurance processes will include consideration of the outcomes of weeding, study selection and data extraction and the committee will review the results of study selection and data extraction).

Data management (software)	Pairwise meta-analyses will be performed using Cochrane Review Manager (RevMan5). 'GRADEpro' was used to assess the quality of evidence for each outcome.
Information sources – databases and dates	The following databases will be searched: • CCRCT • CDSR • DARE • Embase • EMCare • HTA Database • MEDLINE and MEDLINE IN-PROCESS Searches will be restricted by: • Date limitations: 1990 to 10th May 2019 • English language • Human studies Other searches: • Inclusion lists of systematic reviews
Identify if an update	Not an update, but linked to the review question from the 2014 addendum 'What is the risk of co-sleeping in relation to sudden infant death syndrome (SIDS)?'
Author contacts	National Guideline Alliance https://www.nice.org.uk/guidance/indevelopment/gid-ng10070
Highlight if amendment to previous protocol	For details please see section 4.5 of Developing NICE guidelines: the manual 2014

Search strategy – for one database	For details please see appendix B
Data collection process – forms/duplicate	A standardised evidence table format will be used, and published as appendix D (clinical evidence tables) or H (economic evidence tables).
Data items – define all variables to be collected	For details please see evidence tables in appendix D (clinical evidence tables) or H (economic evidence tables).
Methods for assessing bias at outcome/study level	Standard study checklists will be used to critically appraise individual studies. For details please see section 6.2 of Developing NICE guidelines: the manual The risk of bias across all available evidence will be evaluated for each outcome using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group http://www.gradeworkinggroup.org/
Criteria for quantitative synthesis (where suitable)	For details please see section 6.4 of Developing NICE guidelines: the manual 2014
Methods for analysis – combining studies and exploring (in)consistency	For a full description of the methods see Supplement 1.
Meta-bias assessment – publication bias,	For details please see section 6.2 of Developing NICE guidelines: the manual 2014

selective reporting bias	
Assessment of confidence in cumulative evidence	For details please see sections 6.4 and 9.1 of Developing NICE guidelines: the manual 2014
Rationale/context – Current management	For details please see the introduction to the evidence review
Describe contributions of authors and guarantor	A multidisciplinary committee developed the guideline. The committee was convened by the National Guideline Alliance and chaired by Dr David Jewell in line with section 3 of Developing NICE guidelines: the manual 2014. Staff from the National Guidelines Alliance undertook systematic literature searches, appraised the evidence, conducted meta-analysis and cost-effectiveness analysis where appropriate, and drafted the guideline in collaboration with the committee. For a full description of the methods see Supplement 1.
Sources of funding/support	The National Guideline Alliance is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists
Name of sponsor	The National Guideline Alliance is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists
Roles of sponsor	NICE funds the National Guideline Alliance to develop guidelines for those working in the NHS, public health, and social care in England
PROSPERO registration number	This protocol has not been registered in PROSPERO

BMI: body mass index; CDSR: Cochrane Database of Systematic Reviews; CINAHL: Cumulative Index of Nursing and Allied Health Literature; CCRT:: Cochrane Central Register of Controlled Trials; DARE: Database of Abstracts of Reviews of Effects; GRADE: Grading of Recommendations Assessment, Development and Evaluation; HTA: Health Technology Assessment; MID: minimally important difference; NGA: National Guideline Alliance; NHS EED: National Health Service Economic Evaluation Database; NICE: National Institute for Health and Care Excellence; PROSPERO: Prospective Register of Systematic Review Protocols on health related topics; RCT: randomised controlled trial