

**Women's and Children's Health Policy Center
Johns Hopkins University**

**Strengthen the Evidence for
Maternal and Child Health Programs**

**National Performance Measure 5 Safe Sleep
Evidence Review**

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EXECUTIVE SUMMARY

Safe sleep is one of fifteen Maternal and Child Health National Performance Measures (NPMs) for the State Title V Block Grant program. The goal is to increase the number of infants placed to sleep on their backs. The purpose of this evidence review is to identify evidence-informed strategies that State Title V programs might consider implementing to address NPM 5 Safe Sleep.

Twenty-three peer-reviewed sources and one gray literature source met study inclusion criteria and informed the review. These sources discussed interventions that targeted caregivers only, child care providers only, health care providers only; interventions implemented at the caregiver, health care provider, and hospital levels with and without quality improvement initiatives; and national campaigns. Examples of each type of intervention and its evidence rating are shown below:

Intervention Category	Example	Evidence Rating
Caregiver Only	Caregiver education	Emerging Evidence
Child Care Provider Only	Child care provider education	—
Health Care Provider Only	Health care provider education	—
Caregiver + Health Care Provider + Hospital without Quality Improvement	Caregiver education + Health care provider education + Hospital safe sleep policy	Moderate Evidence
Caregiver + Health Care Provider + Hospital with Quality Improvement	Caregiver education + Health care provider education + Hospital safe sleep policy + Quality improvement	Emerging Evidence
National Campaign	Mass media	Moderate Evidence

— indicates insufficient number of studies to assign evidence rating

Five key findings emerged:

1. Interventions targeting caregivers only appear to be somewhat effective.
2. Interventions implemented at the caregiver, health care provider, and hospital levels without quality improvement initiatives appear to be effective.
3. Interventions implemented at the caregiver, health care provider, and hospital levels

with quality improvement appear to be somewhat effective.

4. National campaigns appear to be effective.
5. Due to the limited scope of included studies, there is less clear evidence of the effectiveness for interventions focusing on health care providers or child care providers only.

The evidence review categorized safe sleep interventions along an evidence continuum from *Evidence Against* (least favorable) to *Scientifically Rigorous* (most favorable). *Moderate Evidence* was identified for interventions implemented at the caregiver, health care provider, and hospital levels without quality improvement as well as for national campaigns. *Emerging Evidence* was found for interventions targeting caregivers only as well as those implemented at the caregiver, health care provider, and hospital levels with quality improvement. The lower evidence rating for interventions with quality improvement components reflects, in part, that many existing studies report high baseline rates of infants placed to sleep on their backs. This makes it difficult to observe increases in favorable outcomes.

Interventions targeting health care providers only or child care providers only were unable to be categorized due to the limited number of studies.

Interventions implemented at the caregiver, health care provider, and hospital levels without quality improvement and national campaigns appear to be most effective in increasing the percentage of infants placed to sleep on their backs. It is important to note that this evidence review focused only on sleep position among numerous safe sleep practices. In addition to exclusive supine positioning (on the back), a safe sleep environment includes the use of a firm sleep surface, room-sharing without bed-sharing, and avoidance of soft bedding and overheating. Additional recommendations include avoidance of exposure to smoke, alcohol, and illicit drugs;

breastfeeding; routine immunization; and the use of a pacifier.* It is critical to avoid all modifiable risk factors and adhere to the most recent recommendations to reduce the risk for sleep-related infant deaths.

* Moon RY, Task Force on Sudden Infant Death Syndrome. SIDS and other sleep-related infant deaths: Evidence base for 2016 updated recommendations for a safe infant sleeping environment. *Pediatrics*. 2016:e20162940.

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INTRODUCTION†

Strengthen the Evidence Base for Maternal and Child Health (MCH) Programs is a Health Resources and Services Administration (HRSA)-funded initiative that aims to support states in their development of evidence-based or evidence-informed strategies to promote the health and well-being of MCH populations in the United States. This initiative, carried out through a partnership among Johns Hopkins Women's and Children's Health Policy Center, the Association of Maternal and Child Health Programs, and Welch Library at Johns Hopkins, was undertaken to facilitate the transformation of the MCH Title V Block Grant Program.

A goal of the Strengthen the Evidence project is to conduct reviews that provide evidence of the effectiveness of possible strategies to address the National Performance Measures (NPMs) selected for the 5-year cycle of the Title V MCH Services Block Grant, beginning in fiscal year 2016. States are charged to select eight NPMs and incorporate evidence-based or evidence-informed strategies in order to achieve improvement for each NPM selected.

BACKGROUND

Safe sleep is one of the fifteen maternal and child health (MCH) National Performance Measures (NPMs). Thirty-three states and jurisdictions selected NPM 5 Safe Sleep, including Alabama, Alaska, Arkansas, Florida, Hawaii, Idaho, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Mississippi, Montana, Nebraska, New Hampshire, New Jersey, New York, North Dakota, Northern Mariana Islands, Ohio, Oklahoma, Palau, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Virginia, Virgin Islands, Washington, West Virginia, and Wisconsin.¹

The goal for NPM 5 is to increase the number of infants placed to sleep on their backs.^{2,3}

† The language used in the Introduction section was crafted by the Strengthen the Evidence team and is consistent across all evidence reviews within this project.

The Pregnancy Risk Assessment Monitoring System (PRAMS) is used to monitor the progress toward achieving this goal. According to the most recent PRAMS data on Maternal and Child Health Indicators from 2013, 78.5% of mothers report laying their babies down to sleep on their backs most often.⁴ According to the National Infant Sleep Position Study, data from 1993 through 2007 showed that during the 15-year period, supine sleep (on their backs) increased from 16.9% in 1993 to 71.7% in 2007, while prone sleep (on their stomachs) decreased for all infants, with no significant difference in trend by race.⁵ Recent data from the National Infant Sleep Position Study in 2010 showed that the prevalence of supine sleep was 75%. However, racial disparities were observed in infant sleep position. The prevalence of supine sleep position in 2010 was 75% among white infants, compared with 53% among black infants. The prevalence was 73% and 80% for Hispanic and Asian infants, respectively.⁶

Infant sleep position is a serious public health concern as it is strongly related to sudden unexpected infant deaths (SUIDs).⁶ In 2015, about 3,700 infants in the United States died suddenly and unexpectedly.⁷ SUIDs are reported as one of three types of infant deaths: sudden infant death syndrome (SIDS), unknown cause, or accidental suffocation and strangulation in bed. SIDS is defined as “the sudden death of an infant under 1 year of age that cannot be explained after a thorough investigation is conducted, including a complete autopsy, examination of the death scene, and a review of the clinical history.”⁸ In the United States, SIDS is the leading cause of death in infants 1 to 12 months old, contributing to nearly half of all post-neonatal deaths. Placing infants to sleep in prone position is a major risk factor for SIDS.⁹ Compared with supine position, prone position has a 2.3 to 13.1 times the risk of SIDS. Recent studies have also demonstrated that the side position carries a similar magnitude of SIDS risk compared with prone position.⁶ However, the mechanisms by which prone position might lead to

SIDS are not entirely clear. Studies suggest that prone position may increase the risk of SIDS through rebreathing expired gas, overheating, and decreasing cerebral oxygenation.⁶

Due to the concern over sleep-related infant deaths, studies have been conducted to examine factors related to sleep position in infants. Receiving advice from a physician or a nurse and having infants exclusively placed to sleep in the supine position while in the hospital are strongly associated with supine sleep position.^{5,10,11} A study of primarily low-income, black mothers of infants revealed that advice from female friends and relatives appeared to be a stronger predictor of sleep position than advice from a health care provider. The study concluded that barriers to placing infants in the supine sleep position include insufficient or inaccurate advice, lack of trust in providers, knowledge, and concerns about safety and comfort in this population.¹² These findings were confirmed by two more recent qualitative studies with African American and American Indian parents.^{13,14} Counseling strategies should provide greater detailed rationale for recommendations and incorporate or acknowledge familial and cultural preferences.¹⁵

In order to bring public attention to SIDS, several national initiatives have been established. The Safe to Sleep[®] campaign, formerly known as the Back to Sleep Campaign, is an ongoing campaign launched by the National Institute of Child Health and Human Development in 1994 to educate parents and caregivers on ways to reduce the risk of SIDS and other sleep-related causes of infant death.¹⁶ The National Action Partnership to Promote Safe Sleep (NAPSS) is a more recent initiative that engages a coalition of over 50 partners to develop and implement the National Action Plan to increase safe infant sleep and breastfeeding through tailored strategies.¹⁷ The Bright Futures Guidelines for Health Supervision highlight the importance of safe sleep practices and the role of related anticipatory guidance during well child

visits.¹⁸ Additional national initiatives in the US with a focus on safe sleep include: the Collaborative Improvement and Innovation Network to Reduce Infant Mortality,¹⁹ the CDC Sudden Unexpected Infant Death and Sudden Death in the Young Case Registries,²⁰ and the National Center for the Review and Prevention of Child Deaths.²¹

Given the consequences of improper sleep position among infants, in addition to national efforts to combat SIDS, the American Academy of Pediatrics (AAP) released policy statements regarding this topic in 1992, 2005, 2011, and 2016.²²⁻²⁵ The most recent 2016 policy statement “SIDS and Other Sleep-Related Infant Deaths: Updated 2016 Recommendations for a Safe Infant Sleeping Environment,” provides a comprehensive list of recommendations regarding infant safe sleep practices, including practices related to sleep environment, breastfeeding, and immunizations in addition to sleep position. The policy statement clearly states that infants should be placed to sleep in a supine position for every sleep by every caregiver until 1 year of age. Preterm infants should be placed supine as soon as possible. Prone positioning during sleep should only be considered in infants with upper airway disorders, such as those with anatomic abnormalities who have not undergone antireflux surgery. However, once an infant can roll from supine to prone and vice versa, the infant can be allowed to remain in the sleep position assumed.²⁵

Since the AAP released recommendations for supine sleep position in infants in 1992, the incidence of SIDS has significantly decreased by over 50%. However, this decline has plateaued in recent years.^{24,26} Thus, it is critical to continue to invest in efforts to increase safe sleep practices in infants. In supporting states and jurisdictions in their work related to safe sleep, the current review synthesizes the evidence regarding interventions to promote supine sleep position in infants. Relevant previously published reviews about infant safe sleep synthesized evidence

regarding a wide variety of safe sleep practices in addition to sleep position.^{27,28} To our knowledge, this is the first review that focuses exclusively on interventions to increase safe sleep position among various infant safe sleep practices.

METHODS

Studies were identified for review by searching through the PubMed, Cochrane Library, and CINAHL Plus databases. Search strategies varied depending on the database due to differences in controlled vocabulary, indexing, and syntax. Table 1 provides detailed search strategies used for each database. The same three concepts informed search strategies in each database: infant, safe sleep, and intervention/evaluation. A library specialist (informationist) at Welch Medical Library was consulted in selecting appropriate databases and ensuring the adequacy of the search strategies. There were no restrictions on dates of publication. The following inclusion criteria were used:

1. The study evaluated the effectiveness of an intervention aimed to increase the uptake of safe sleep practices in infants 0-12 months of age and clearly indicated that the change in exclusive supine sleep position was included as an outcome measure. The components of the intervention and the results were clearly described.
2. The study described interventions that fall within the scope of Title V as deemed by the authors and reviewers.
3. Sleep position was measured using reported or observed behavior. Studies measuring only the intention of behavior or knowledge about sleep position were excluded.
4. At a minimum, the study included a control and intervention group, an appropriate comparison group, or a pretest-posttest design to assess intervention effectiveness.
5. The study was published in the English language.

6. The study was published in a peer-reviewed journal.

The results of each database search were systematically evaluated for relevant studies. Duplicates were removed before beginning title screening. Each article's title was reviewed and if the title appeared related to the NPM, the abstract was then screened. If the abstract did not indicate whether the study met the inclusion criteria or the abstract was not available, full-text of the article was reviewed. All articles remaining after title and abstract screening were retrieved for detailed full-text review to assess their eligibility for inclusion. In addition, reference lists of relevant previously published review articles were reviewed to identify potential articles to be included in the current review.^{27,28} In addition to peer-reviewed literature, the 2016 Technical Report, *SIDS and Other Sleep-Related Infant Deaths: Evidence Base for 2016 Updated Recommendations for a Safe Sleep Environment*, released by the American Academy of Pediatrics, was included as a gray literature source.⁶

The lead author (YL) extracted data pertaining to the study characteristics (setting, sample, and design); intervention (components, implementation, data collection); data sources and outcome measures for assessing safe sleep; and results. The study team met regularly to review interim extractions and resolve items in question. Interventions were characterized by target audience: caregiver, child care provider, health care provider, inpatient hospital, community, and national.

Studies were categorized into six groups based on intervention components: "Caregiver Only," "Child Care Provider Only," "Health Care Provider Only," "Caregiver + Provider + Hospital without Quality Improvement," "Caregiver + Provider + Hospital with Quality Improvement," and "National Campaign." Studies were considered as "Quality Improvement" if

they stated a quality improvement model (e.g., Plan-Do-Study-Act cycles) was used and/or routine auditing/monitoring was performed as part of the intervention. The “Hospital” level referred to inpatient hospital only.

An evidence continuum was created to assess evidence-informed strategies, along with criteria for each category along the continuum. The Robert Wood Johnson *What Works for Health* evidence ratings were adapted to create an evidence continuum tailored toward the Strengthen the Evidence project.²⁹ The evidence rating categories include: *Evidence Against*, *Mixed Evidence*, *Emerging Evidence*, *Expert Opinion*, *Moderate Evidence*, and *Scientifically Rigorous*. Strategies that are characterized by *Emerging Evidence* or more favorable ratings are considered evidence-informed. Table 2 shows the detailed evidence rating criteria for both study type and study results for each rating.

Interventions identified through assessment of both peer-reviewed and gray literature were placed along the evidence continuum. Assignment to the continuum required that interventions or intervention categories be evaluated in 4 or more peer-reviewed studies or in the gray literature selected for the evidence review. However, interventions or intervention categories that were evaluated in 3 peer-reviewed studies with expert opinion from gray literature were also assigned an evidence rating and placed on the evidence continuum. Interventions or intervention categories that were evaluated in 3 peer-reviewed studies without expert opinion from gray literature were not assigned an evidence rating, nor placed on the evidence continuum. A team of two project members independently assigned ratings to the interventions or intervention categories. The members then compared their assessments and discrepancies were discussed by the full project team until a consensus was reached.

RESULTS

Search Results

Searches in the PubMed, Cochrane Library, and CINAHL Plus databases were performed on September 23, 2016. In total, the systematic search identified 5374 records. The search in PubMed, Cochrane Library, and CINAHL Plus yielded 4209, 254, and 911 records respectively. A total of 27 records were also identified from searching through previously published review articles prior to duplicate removal.^{27,28}

Title and abstract screening was conducted for 4644 records after 757 duplicates were removed from the total records. During title and abstract review, 4580 were excluded due to failure to meet inclusion criteria. The most common reason for not meeting the inclusion criteria was that studies were irrelevant to the purpose of this review, namely, that they were not evaluations of interventions aimed to increase supine sleep position in infants. Full-text articles were assessed for eligibility for 64 records, and 41 were excluded due to failure to meet all inclusion criteria. Major reasons for excluding studies included: not evaluations of interventions; did not measure the outcome of interest; did not include an appropriate comparison group; and did not describe results clearly. Twenty-three records were included in the current review. A total of 24 sources were included in this review after combining 23 peer-reviewed studies with 1 source of gray literature. Figure 1 displays the flow chart for the study selection process.

Characteristics of Studies Reviewed

The 23 articles included in this review varied in study setting and design, intervention type and duration, and data source. The detailed characteristics of the studies are reported in Table 3. Of the 23 studies, 5 studies were randomized controlled trials³⁰⁻³⁴; 1 study was a cluster randomized controlled trial³⁵; and 17 studies were quasi-experimental studies (16 pretest-posttest design³⁶⁻⁵¹ and 1 non-equivalent control group design⁵²). In terms of the setting, 18 studies were

conducted in the United States^{30,33-38,41-45,47-52} and 5 in various other countries (1 in Argentina,⁴⁶ 1 in Brazil,³² 1 in France,³¹ 1 in Norway,⁴⁰ and 1 in the United Kingdom³⁹). Although all studies reported sleep position as an outcome, the data source used to measure the level of compliance of safe sleep practices varied. The data sources used included caregiver/parent/mother report,^{30,31,33,34,36,37,39,40,44,46,48,50,52} crib audit/infant observation,^{35-38,41-43,45,47-49,51} and mother/doll observation.³² Table 4 provides details regarding data sources and outcome measures.

Intervention Components

Table 5 includes a detailed description of the intervention implemented in each study. The nature of the comparison group varied by study design. Table 6 summarizes the intervention components each study contained. The groups “Caregiver Only,” “Child Care Provider Only,” “Health Care Provider Only,” “Caregiver + Provider + Hospital without Quality Improvement,” “Caregiver + Provider + Hospital with Quality Improvement,” and “National Campaign,” included 6, 1, 1, 8, 4, and 3 studies respectively.

Examples of caregiver level intervention components included education, educational material, assessment, note-taking, and provision of safe sleep item (e.g., wearable blanket, baby undergarment). An example of a child care provider level intervention component was education. Examples of health care provider level intervention components included education, assessment, and attestation. Examples of hospital level intervention components included quality improvement, policy/guidelines, crib cards, visual displays, sleep environment modifications, and promotional events. Among the three studies categorized as “National Campaign,” Hiley & Morley (1994) assessed the UK Department of Health’s Back to Sleep Campaign³⁹; McCulloch et al. (2000) examined the effectiveness of the National Institute of Child Health and Human Development’s Back to Sleep Campaign in North Dakota, which is furthered described online (<https://www.nichd.nih.gov/sts/Pages/default.aspx>)⁴⁴; Hill et al. (2004) described the impact of a

national campaign in Norway that included mass media and the provision of education, educational material, and safe sleep items to caregivers.⁴⁰

Summary of Study Results

Study results organized by groups are presented in detail in Table 7. Table 8 summarizes study findings. Tables 7 and 8 display studies organized by the Intervention Components groups described previously. The results presented in Table 8 for supine sleep position demonstrate a mix of favorable and non-significant findings.

Studies categorized as “Caregiver Only” appear to be somewhat effective in increasing exclusive supine sleep position in infants as they demonstrate a mix of favorable and non-significant findings. Studies categorized as “Caregiver + Provider + Hospital without Quality Improvement” appear to be effective as the majority of the studies had favorable results. Studies categorized as “Caregiver + Provider + Hospital with Quality Improvement” appear to be somewhat effective, as they demonstrate a mix of favorable and non-significant findings with most results being non-significant. Studies categorized as “National Campaign” also appear to be effective since all three studies had favorable results. The “Child Care Provider Only” and “Health Care Provider Only” intervention categories each contained only one study. Due to the limited number of studies focusing exclusively on interventions addressing the behaviors of child care providers or health care providers, conclusions cannot be drawn for either category.

The addition of quality improvement to interventions implemented at the caregiver, health care provider, and hospital levels did not appear to increase the effectiveness of these interventions. Issues related to sample size and study results could potentially contribute to this finding. Of the 8 studies that included quality improvement, 2 studies had a sample size smaller than 40 at both the baseline and follow-up.^{38,51} Of these 8 studies, 5 had a higher baseline rate of supine sleep position than the most recent national estimate of 78.5%.^{38,43,48,49,51} The remaining 3

studies also had relatively high baseline rates.^{37,45,47}

The interventions in the “Caregiver,” “Health Care Provider,” and “Hospital” categories focused on a variety of components. The most common caregiver level components included education (n=15), educational material (n=13), and provision of safe sleep item (n=6). Caregiver education and educational material contained information regarding SIDS and safe sleep practices. Examples of safe sleep items included wearable blankets with safe sleep messages and “this-side-up” baby undergarments. The most common health care provider level component was education (n=13). The nature of the provider education was similar to caregiver education. The most common hospital level components included safe sleep policy/guideline (n=9), quality improvement (n=8), and sleep environment modification (n=7). Examples of sleep environment modification included designated storage for crib items and the replacement of loose blankets with sleep sacks.

The one gray literature source included in the review, the 2016 AAP Technical Report, *SIDS and Other Sleep-Related Infant Deaths: Evidence Base for 2016 Updated Recommendations for a Safe Sleep Environment*, recommended national campaigns as well as primary care-based educational interventions and quality improvement initiatives as effective strategies to increase safe sleep practices.⁶

Evidence Rating & Evidence Continuum

Assignments of evidence ratings were based on the synthesis of study results for the 23 studies (Tables 7 and 8) in combination with gray literature recommendations. The intervention categories “Child Care Provider Only” and “Health Care Provider Only” each contained only one peer-reviewed study, and therefore were not assigned evidence ratings, nor placed on the evidence continuum. The intervention category “National Campaign” was placed on the

Evidence Continuum as it received support from the gray literature source in addition to the three peer-reviewed studies. Based on the evidence rating criteria (Table 2), *Moderate Evidence* was identified for the intervention categories “Caregiver + Provider + Hospital without Quality Improvement” and “National Campaigns.” *Emerging Evidence* was found for the intervention categories “Caregiver Only” and “Caregiver + Provider + Hospital with Quality Improvement.” Figure 2 displays the evidence-informed interventions and intervention categories along the evidence continuum for NPM 5.

IMPLICATIONS

A substantial number of states and jurisdictions selected the Safe Sleep National Performance Measure as one of their foci for the current 5-year cycle of the Title V MCH Services Block Grant beginning in fiscal year 2016. The purpose of this review was to provide evidence-based and evidence-informed strategies for how to best achieve the desired outcome of increasing safe sleep practices in infants.

From this review, interventions implemented at the caregiver, health care provider, and hospital levels without quality improvement appear to be most effective in increasing exclusive supine sleep position in infants. National campaigns also appear to be as effective. Interventions targeting caregivers only as well as those implemented at the caregiver, health care provider, and hospital levels with quality improvement appear to be somewhat effective. The lower evidence rating for interventions with quality improvement components reflects, in part, that many existing studies report high baseline rates of supine sleep position, making it difficult to observe increases in favorable outcomes. It was not possible to draw conclusions about interventions targeting health care providers only or child care providers only due to a limited number of studies.

The major strength of this evidence review is that it is the first to focus exclusively on sleep position among various safe sleep practices. There are, however, several limitations. First, only 23 peer-reviewed studies and 1 gray literature source met inclusion criteria. The relatively small number of sources limits the conclusions that may be drawn regarding effective interventions. Second, a single source of gray literature was included, which may have omitted evidence regarding safe sleep interventions from other sources. Third, search results were screened and interpreted by one reviewer; nevertheless, a consistent protocol was followed and issues that arose during this process were addressed with a team of experts. Lastly, comparing and synthesizing studies was limited due to variations in study setting, sample, and design. Intervention components included in each study varied; while components could be articulated for each study, interventions were assessed broadly and summarized where possible by groups of target audience and/or components.

Since research has shown substantial variation in adherence to safe sleep recommendations among racial/ethnic groups,⁶ future evaluations should assess the effectiveness of evidence-informed interventions by subgroups. With a deeper understanding of the effectiveness by subgroups, safe sleep interventions could be tailored toward the specific composition of target populations and focus on the most vulnerable subgroups at disproportionate risk of sleep-related infant deaths.

It is important to note that this evidence review focused only on sleep position among numerous safe sleep practices. In addition to exclusive supine positioning, a safe sleep environment includes the use of a firm sleep surface, room-sharing without bed-sharing, and avoidance of soft bedding and overheating. Additional recommendations include avoidance of exposure to smoke, alcohol and illicit drugs; breastfeeding; routine immunization; and the use of

a pacifier. It is critical to avoid all modifiable risk factors and adhere to the most recent recommendations to reduce the risk for sleep-related infant deaths.⁶

FIGURES AND TABLES

Figure 1. Flow Chart of the Review Process and Results.

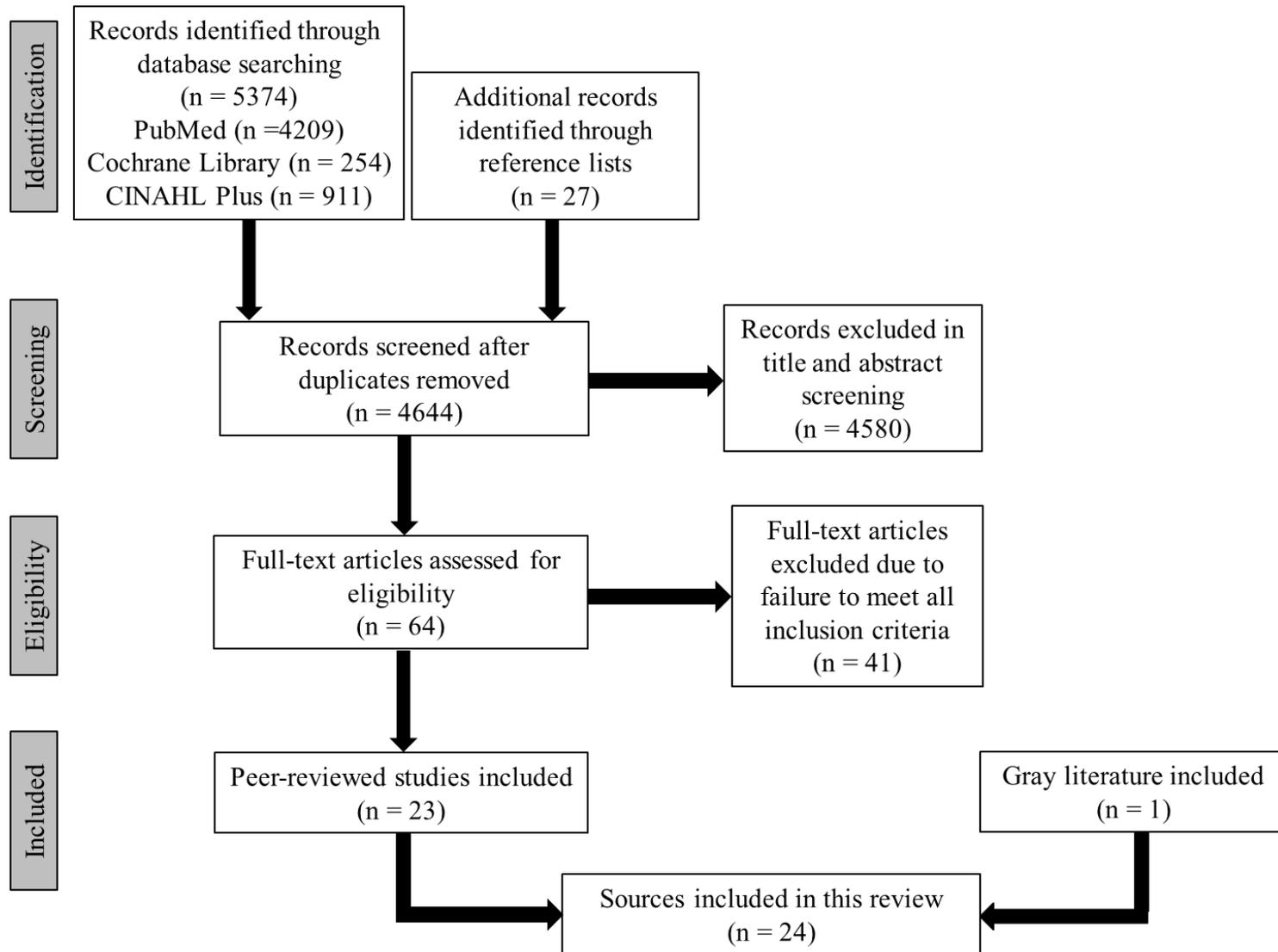


Figure 2. Evidence Continuum.

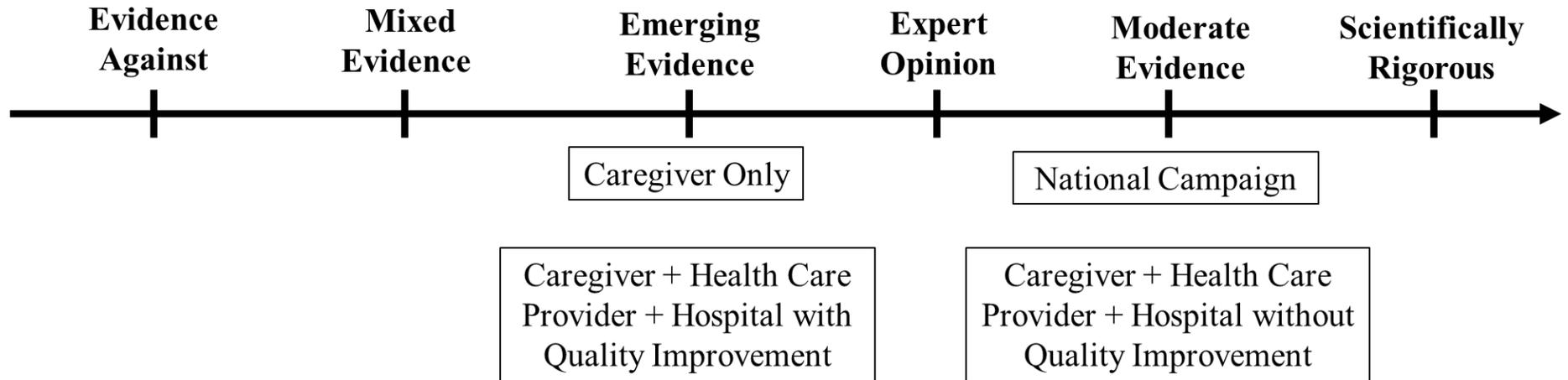


Table 1. Detailed Search Strategies.

Database	Search Strategies
PubMed	#1: "Infant"[Mesh] OR infant[tw] OR infants[tw] OR infancy [tw] OR newborn*[tw] OR new born*[tw] OR neonat*[tw] OR baby[tw] OR babies[tw]
	#2: "Supine Position"[Mesh] OR "Prone Position"[Mesh] OR "Sudden Infant Death"[Mesh] OR supine[tw] OR back position*[tw] OR back to sleep[tw] OR prone[tw] OR sleep position*[tw] OR sleeping position*[tw] OR safe sleep*[tw] OR sudden infant death*[tw] OR SIDS[tw] OR infant death syndrome*[tw] OR SUID[tw] OR unexpected infant death*[tw] OR sleep death*[tw] OR crib death*[tw]
	#3: "Program Evaluation"[Mesh] OR "Health Promotion"[Mesh] OR "Quality Improvement"[Mesh] OR "Education"[Mesh] OR health promotion*[tw] OR quality improvement*[tw] OR education*[tw] OR evaluation*[tw] OR effective*[tw] OR intervention*[tw] OR prevention*[tw] OR campaign*[tw] OR strateg*[tw]
	#4: #1 AND #2 AND #3
Cochrane Library	#1: MeSH descriptor: [Infant] explode all trees
	#2: infant* OR infancy OR newborn* OR (new NEXT born*) OR neonat* OR baby OR babies
	#3: #1 OR #2
	#4: MeSH descriptor: [Supine Position] explode all trees
	#5: MeSH descriptor: [Prone Position] explode all trees
	#6: MeSH descriptor: [Sudden Infant Death] explode all trees
	#7: supine OR (back NEXT position*) OR (back NEAR/2 sleep*) OR prone OR (sleep* NEXT position*) OR (safe NEXT sleep*) OR ("sudden infant" NEXT death*) OR SIDS OR ("infant death" NEXT syndrome*) OR SUID OR ("unexpected infant" NEXT death*) OR (sleep* NEAR/2 death*) OR (crib* NEAR/2 death*)
	#8: #4 OR #5 OR #6 OR #7
	#9: MeSH descriptor: [Program Evaluation] explode all trees
	#10: MeSH descriptor: [Health Promotion] explode all trees
	#11: MeSH descriptor: [Quality Improvement] explode all trees
	#12: MeSH descriptor: [Education] explode all trees
	#13: (health NEXT promotion*) OR (quality NEXT improvement*) OR education* OR evaluation* OR effective* OR intervention* OR prevention* OR campaign* OR strateg*
	#14: #8 OR #9 OR #10 OR #11 OR #12
	#15: #3 AND #8 AND #14
CINAHL Plus	S1: (MH "Infant+") OR TI (infant* OR newborn* OR (new W0 born*) OR baby OR babies) OR AB (infant* OR newborn* OR (new W0 born*) OR baby OR babies)
	S2: ((MH "Supine Position") OR (MH "Prone Position") OR (MH "Sudden Infant Death")) OR TI (supine OR (back W0 position*) OR (back N2 sleep*) OR prone OR (sleep* W0 position*) OR (safe W0 sleep*) OR ("sudden infant" W0 death*) OR SIDS OR ("infant death" W0 syndrome*) OR SUID OR ("unexpected infant" W0 death*) OR (sleep* N2 death*) OR (crib* N2 death*)) OR AB (supine OR (back W0 position*) OR (back N2 sleep*) OR prone OR (sleep* W0 position*) OR (safe W0 sleep*) OR ("sudden infant" W0 death*) OR SIDS OR ("infant death" W0 syndrome*) OR SUID OR ("unexpected infant" W0 death*) OR (sleep* N2 death*) OR (crib* N2 death*))
	S3: ((MH "Program Evaluation") OR (MH "Health Promotion+") OR (MH "Quality Improvement+") OR (MH "Education+")) OR TI ((health W0 promotion*) OR (quality W0 improvement*) OR education* OR evaluation* OR effective* OR intervention* OR prevention* OR campaign* OR strateg*) OR AB ((health W0 promotion*) OR (quality W0 improvement*) OR education* OR evaluation* OR effective* OR intervention* OR prevention* OR campaign* OR strateg*)
	S1 AND S2 AND S3

Table 2. Evidence Rating Criteria.

Evidence Rating	Evidence Criteria: Type	Evidence Criteria: Study Results
Scientifically Rigorous	<ul style="list-style-type: none"> • Peer-reviewed study results are drawn only from: <ul style="list-style-type: none"> ○ Randomized controlled trials, and/ or ○ Quasi-experimental studies with pre-post measures and control groups 	<ul style="list-style-type: none"> • Preponderance of studies have statistically significant favorable findings
Moderate Evidence	<ul style="list-style-type: none"> • Peer-reviewed study results are drawn from a mix of: <ul style="list-style-type: none"> ○ Randomized controlled trials ○ Quasi-experimental studies with pre-post measures and control groups ○ Quasi-experimental studies with pre-post measures without control groups ○ Time trend analyses 	<ul style="list-style-type: none"> • Preponderance of studies have statistically significant favorable findings
Expert Opinion	<ul style="list-style-type: none"> • Gray literature 	<ul style="list-style-type: none"> • Experts deem the intervention as favorable based on scientific review
Emerging Evidence	<ul style="list-style-type: none"> • Peer-reviewed study results are drawn from a mix of: <ul style="list-style-type: none"> ○ Randomized controlled trials ○ Quasi-experimental studies with pre-post measures and control groups ○ Quasi-experimental studies with pre-post measures without control groups ○ Time trend analyses ○ Cohort studies 	<ul style="list-style-type: none"> • Studies with a close-to-evenly distributed mix of statistically significant favorable and non-significant findings • Only cohort studies with preponderance of statistically significant favorable findings
	<ul style="list-style-type: none"> • Gray literature 	<ul style="list-style-type: none"> • Experts deem the intervention as favorable
Mixed Evidence	<ul style="list-style-type: none"> • Peer-reviewed study results are drawn from a mix of: <ul style="list-style-type: none"> ○ Randomized controlled trials ○ Quasi-experimental studies with pre-post measures and control groups ○ Quasi-experimental studies with pre-post measures without control groups ○ Time trend analyses ○ Cohort studies 	<ul style="list-style-type: none"> • Studies with a close-to-evenly distributed mix of statistically significant favorable, unfavorable, and non-significant findings
	<ul style="list-style-type: none"> • Gray literature 	<ul style="list-style-type: none"> • Experts deem the intervention as having mixed evidence
Evidence Against	<ul style="list-style-type: none"> • Peer-reviewed study results are drawn from a mix of: <ul style="list-style-type: none"> ○ Randomized controlled trials ○ Quasi-experimental studies with pre-post measures and control groups ○ Quasi-experimental studies with pre-post measures without control groups ○ Time trend analyses ○ Cohort studies 	<ul style="list-style-type: none"> • Preponderance of studies have statistically significant unfavorable or non-significant findings
	<ul style="list-style-type: none"> • Gray literature 	<ul style="list-style-type: none"> • Experts deem the intervention as being ineffective or unfavorable

Table 3. Study Characteristics.¹

Study	Country	Setting	Study Sample		Study Design
			Target Sample	Sample Size	
Ahlers-Schmidt et al. (2015)	US	University of Kansas Pediatric Clinic	Caregivers of patients in the waiting room at the 1-month well-baby visit and the 2-month well-baby visit	Baseline <ul style="list-style-type: none"> • Intervention (n=75) • Control (n=77) Follow-up (Analysis) <ul style="list-style-type: none"> • Intervention (n=57) • Control (n=58) 	RCT
Colson & Joslin (2002)	US	Yale-New Haven Hospital (New Haven, CT)	Infants in the well-newborn nursery during the postpartum stay	Baseline (n=100) Follow-up (n=100)	QE: pretest-posttest
		Pediatric Primary Care center of the Yale-New Haven Hospital	Parents of infants at the infants' 2-week health supervision visit	Baseline (n=100) Follow-up (n=100)	
D'Halluin et al. (2011)	France	Maternity department of the Rennes University Hospital	Mothers hospitalized during the immediate postpartum period between Jun 19 and Aug 28, 2005 who were not hospitalized for abnormal or high-risk pregnancies and did not have newborns hospitalized in neonatology	Baseline (n=320) Follow-up (n=292) <ul style="list-style-type: none"> • Intervention (n=148) • Control (n=144) 	RCT
Gelfer et al. (2013)	US	Children's Memorial Hermann Hospital NICU in Houston, TX	Infants in open cribs eligible for safe sleep practices	Baseline (n=62) Follow-up (n=79)	QE: pretest-posttest
			Parents of infants after discharge	Baseline (n=66) Follow-up (n=98)	
Geyer et al. (2016)	US	University of Iowa Children's Hospital	Infants less than 1 year of age developmentally ready for a crib and asleep	Baseline (n=22) Follow-up 1 (not reported) Follow-up 2 (n=37) Follow-up 3 (n=18)	QE: pretest-posttest
Goetter & Stepan (2005)	US	Rural, western, mountain community hospital	Newly delivered primiparas between 18 and 35 years of age unacquainted with the researcher, whose infants did not require more than the usual newborn care	Intervention (n=32) Control (n=29)	RCT
Hiley & Morley (1994)	UK	Cambridge, Huntingdon, and Bury St Edmunds	Random selection of mothers of normal term babies who gave birth at least 8 months before the campaign and those who gave birth after the campaign when their children were 6 months old	Baseline (n=385) Follow-up (n=399)	QE: pretest-posttest
Hill et al. (2004)	Norway	N/A	All mothers registered with the Medical Birth Registry of Norway as having given birth between Oct and Nov 1998 and Oct and Nov 1999 without a pathological condition	Baseline (n=5539) Follow-up (n=4143)	QE: pretest-posttest
Hwang et al. (2015)	US	Two level III NICUs at South Shore Hospital and St Elizabeth's Medical Center in MA	Infants eligible for safe sleep practices as determined by an algorithm and clinical status of the infant	Baseline (n=112) Follow-up (n=118)	QE: pretest-posttest
Issler et al. (2009) ²	Brazil	Maternity ward of the Hospital de Clínicas in Porto Alegre	Mothers of infants in an area of Porto Alegre born between Sep 2005 and Sep 2006	Intervention (n=112/91) Control (n=116/100)	RCT
Kistin et al. (2012) ²	US	Postpartum ward of an urban safety-net hospital	Mothers on the postpartum ward (infant gestational age >35 weeks, no prolonged hospitalization of the mother or the infant, expecting to retain custody of the infant)	Intervention (n=61/48) Control (n=65/58)	RCT

Kuhlmann et al. (2016)	US	Eight children's hospitals	Infants aged 0 to 6 months admitted to the general pediatric unit (excluding infants in the NICUs, PICUs, and maternal fetal units)	Baseline (n=234) Follow-up (n=210)	QE: pretest-posttest
Macklin et al. (2016)	US	Six children's hospitals without internal maternity centers or well-baby nurseries (academic tertiary or quaternary care institutions) in OH	Infants ≤ 1 year of age admitted to the general medical/surgical units who were not awake during the audit (excluding those in the ICUs, with tracheostomies, ventilator or noninvasive ventilator dependence, recent spinal surgeries, or upper airway anatomic abnormalities)	Baseline (n=856) Follow-up (n=189)	QE: pretest-posttest
McCulloch et al. (2000)	US	North Dakota	Caretakers of infants ≤ 6 months of age	Baseline (n=324) Follow-up (n=273)	QE: pretest-posttest
McMullen et al. (2016)	US	Golisano Children's Hospital at the University of Rochester in NY	Hemodynamically stable infants less than 1 year of age in the mother-baby unit and nine pediatric units	Baseline (n=65) Follow-up (n=60)	QE: pretest-posttest
Moon et al. (2004)	US	WIC Clinic at Children's National Medical Center in Washington, DC	Current and prospective caregivers of young infants	Intervention- Follow-Up (n=76) Comparison (n=113)	QE: nonequivalent control group
Moon et al. (2008)	US	California, Louisiana, Montana, and Pennsylvania	Child care professionals (child care facility directors and child care providers)	Intervention <ul style="list-style-type: none"> • Initial (n=328) • Follow-up (n=282) Control <ul style="list-style-type: none"> • Initial (n=285) • Follow-up (n=253) 	Cluster RCT
Rocca Rivarola et al. (2016)	Argentina	Hospital Municipal Comodoro Meisner and Hospital Universitario Austral	Live newborns with >36 gestation weeks born in two hospitals whose mothers lived in the District of Pilar without major congenital malformations and/or hospitalization in the NICU for more than 10 days	Baseline (n=251) Follow-up (n=248)	QE: pretest-posttest
Rowe et al. (2016)	US	A tertiary care children's hospital in AR	Infants 0-12 months in intensive care and medical-surgical units caring asleep at the time of the audit	Baseline (n=398) Follow-up (n=498)	QE: pretest-posttest
Shadman et al. (2016)	US	American Family Children's Hospital in WI	Infants <12 months admitted to medical and surgical units	Baseline (n=59) Follow-up (n=257)	QE: pretest-posttest
			Caregivers of infants <6 months after hospital discharge	Baseline (n=56) Follow-up (n=48)	
Shaefer et al. (2010)	US	Seven urban hospitals in MI	Healthy newborn infants in cribs at the time of the audit	Baseline (n=579) Follow-up (n=692)	QE: pretest-posttest
Srivasta et al. (1999)	US	Pediatric ambulatory care center of Wyckoff Heights Medical Center in NY	Mothers of healthy term infants 6 months and younger born in the hospital and attending the pediatric outpatient clinics	Baseline (n=250) Follow-up (n=250)	QE: pretest-posttest
Voos et al. (2015)	US	The Children's Mercy Hospital NICU in MO	Safe sleep eligible infants (medically stable and transitioned to open cribs)	Baseline (n=28) Follow-up (n=26)	QE: pretest-posttest

¹ Abbreviations used in this table: RCT (randomized controlled trial); QE (quasi-experimental study)

² Sample size format (n=x/x) indicates the allocation and analysis sample sizes respectively

Table 4. Data Sources & Outcome Measures.

Study	Data Source	Outcome Measure
Ahlers-Schmidt et al. (2015)	Caregiver report	Percent of infants placed to sleep on their backs
Colson & Joslin (2002)	Infant observation	Percent of infants placed in supine sleeping position in the well-newborn nursery
	Parent report	Percent of nursing staff exclusively placing infants in the supine sleep position
	Parent report	Percent of infants usually placed to sleep in the supine position at home
D'Halluin et al. (2011)	Mother report	Right answer rate to the observance questionnaire on sleeping position recommendation (back to sleep)
Gelfer et al. (2013)	Crib audit/infant observation	Rate of supine positioning
	Parent report	Percent of infants always placed to sleep on their backs
Geyer et al. (2016)	Crib audit/infant observation	Percent of sleeping infants in safe position (supine)
Goetter & Stepan (2005)	Mother report	Percent of mothers choosing supine sleep position for their infants
Hiley & Morley (1994)	Mother report	Percent of infants placed to sleep on their backs
Hill et al. (2004)	Mother report	Prevalence of non-supine sleeping position just after birth
Hwang et al. (2015)	Crib audit/infant observation	Percent of infants positioned in supine sleep position
Issler et al. (2009)	Mother/doll observation	Percent of baby doll models placed in supine position (favorite position to put infant to sleep)
Kistin et al. (2012)	Mother report	Percent of infants placed to sleep on their backs
Kuhlmann et al. (2016)	Crib audit/infant observation	Percent of sleeping infants in safe position (supine)
Macklin et al. (2016)	Crib audit/infant observation	Percent of infants sleeping on their backs
McCulloch et al. (2000)	Caregiver report	Percent of infants positioned in supine sleep position on the previous night
McMullen et al. (2016)	Crib audit/infant observation	Percent of infants positioned in supine sleep position
Moon et al. (2004)	Caregiver report	Percent of infants usually placed to sleep on their backs
Moon et al. (2008)	Infant observation	Percent of infants positioned in supine sleep position
Rocca Rivarola et al. (2016)	Caregiver report	Percent of infants positioned in supine sleep position
Rowe et al. (2016)	Crib audit/infant observation	Percent of infants positioned in supine sleep position
Shadman et al. (2016)	Crib audit/infant observation	Percent of infants positioned in supine sleep position
	Caregiver report	Percent of infants positioned in supine sleep position
Shaefer et al. (2010)	Crib audit/infant observation	Percent of infants placed to sleep on their backs
Srivasta et al. (1999)	Mother report	Percent of infants positioned in supine sleep position
Voos et al. (2015)	Crib audit/infant observation	Percent of infants not positioned on their backs to sleep

Table 5. Intervention Description.

Study	Comparison Group ¹	Description of Intervention	Intervention Implementation	Data Collection
Ahlers-Schmidt et al. (2015)	Reusable water bottle without safe sleep message	Wearable blanket with safe sleep message to use at home	Between the 1-month and 2-month well-baby visits	Baseline: at the 1-month well-baby visit Follow-up: at the 2-month well-baby visit
Colson & Joslin (2002)	N/A	30-minute training of nursing staff led by a physician and clinical nurse specialist <ul style="list-style-type: none"> • SIDS update, AAP recommendations for infant sleep position, concerns with supine position • Emphasis on the importance of giving appropriate advice about infant sleep position and of modeling the advice for families 	Between Mar and Jul 2000	Infant observations <ul style="list-style-type: none"> • Baseline: 1 month prior to intervention • Follow-up: 3 months after intervention Parent interviews <ul style="list-style-type: none"> • Baseline: between Dec 1999 and Mar 2000 • Follow-up: between Jul 2000 and Jan 2001
D'Halluin et al. (2011)	<ul style="list-style-type: none"> • Information package about SIDS prevention: oral advice by pediatrician; leaflet about SIDS prevention • Questionnaire on socioeconomic and medical background 	<ul style="list-style-type: none"> • Same information package as the control group • Questionnaire on socioeconomic and medical background • Questionnaire on recommendations for SIDS prevention (educative questionnaire with 10 items regarding risk factors for SIDS listed in the leaflet) prior to receiving information about SIDS 	3 days after birth before discharge (between Jun 19, and Aug 28, 2005)	3 months after birth
Gelfer et al. (2013)	N/A	<ul style="list-style-type: none"> • Quality improvement (QI) model • Development of NICU guideline on safe sleep practice (SSP) • Continuing education for nurses on SIDS risk reduction • Testing of safe sleep role modeling during nurses' annual skills evaluation • Q&A sessions with nurses to educate them on issues regarding implementation strategies for the NICU • "Back to Sleep" crib cards in open cribs with the appropriate side up (SSP or NICU therapeutic positioning) • SIDS education for parents at discharge <ul style="list-style-type: none"> ○ "Back to Sleep" crib cards for parents with SSP recommendations on one side and cardiopulmonary resuscitation tips on the other side ○ DVD on safe sleep education ○ Written parent discharge instruction sheet- reviewed with nurses 	Jul-Sep 2010	Baseline: May-Jun 2010 Follow-up: Oct-Nov 2010

		<ul style="list-style-type: none"> ○ Inclusion of SSP strategies in the discharge educational class for parents ● Methods of evaluation and monitoring of compliance <ul style="list-style-type: none"> ○ Routine crib audits ○ Parental surveys- parents were asked about SSPs and provided with counseling if incorrect practices were identified ○ Display of results of crib audits and parental surveys in nursing lounges for review and feedback 		
Geyer et al. (2016)	N/A	<ul style="list-style-type: none"> ● QI: Plan-Do-Study-Act (PDSA) cycle model ● Review and revision of hospital policy ● Staff education <ul style="list-style-type: none"> ○ Presentation about current practice and audit findings, description of SUID and SIDS, safe sleep environment, and the importance of in-hospital modeling ○ Posters for continued presence on units ○ Computer-based program ● Products <ul style="list-style-type: none"> ○ Replacement of blankets with HALO® sleep sacks ○ Auditing of objects left in cribs ○ Diaper caddies for organization of items ○ Fitted crib sheets ● Parent education <ul style="list-style-type: none"> ○ Crib cards for the bedside- reviewed with families ○ Encouragement of viewing of SIDS education video ○ Printed educational material ● Presentation for nurses at Nursing Grand Rounds ● Hospital computer displays of safe sleep information ● Information posted on UI Children’s Hospital Facebook page ● Promotional event in the hospital lobby- display of “safe” and “unsafe” cribs and giveaway of HALO® sleep sacks ● Safety displays at the local Children’s Museum, county fair, and the UI Staff Health Fair 	Aug 2013-Aug 2014	Baseline: Aug 2013 Follow-up 1: Nov 2013 (1 month after staff education) Follow-up 2: Aug 2014 (1 year after workgroup was formed) Follow-up 3: Aug 2015 (1 year following the intervention)
Goetter & Stepan (2005)	Usual care: maternal education by a nurse without emphasis on SIDS and sleep position	Maternal education provided by a nurse, with emphasis on SIDS, sleep position, AAP recommendations	Oct 2002-Feb 2003	Follow-up 1: 6-7 weeks postpartum; 1 week after discharge Follow-up 2: 6-7 weeks post-intervention
Hiley & Morley (1994)	N/A	UK Department of Health’s “Back to Sleep” campaign advising babies not to be placed to sleep on their stomach, be exposed to cigarette smoke, or be overheated	Dec 1991	Baseline: before the campaign (births at least 8 months prior) Follow-up: after the campaign (births after at 6 months old)

Hill et al. (2004)	N/A	<p>Campaign launched by Norwegian SIDS society at lowering the prevalence of risk factors for SIDS</p> <ul style="list-style-type: none"> • Television, newspapers, magazines for the general public • Parents at the maternity wards were provided with verbal and written information from the midwives and baby undergarment with “this-side-up” printed on the front 	Sep 1999	<p>Baseline: before the campaign (births between Oct and Nov 1998; ~9 months after birth)</p> <p>Follow-up: after the campaign (births between Oct and Nov 1999; ~9 months after birth)</p>
Hwang et al. (2015)	N/A	<ul style="list-style-type: none"> • QI initiative • Nursing education <ul style="list-style-type: none"> ○ Web-based continuing education ○ In-person teaching sessions/beside education • Double-sided cribs cards (SSP or NICU therapeutic positioning)- assisted nurses in teaching parents about SSP • Posters in the staff lounge, near the provider work area, and entrance to units • Refresher sessions to reinforce guidelines 	<p>South Shore Hospital: between Oct 2013 and Jan 2014</p> <p>St. Elizabeth’s Medical Center: between Jan 2014 and Apr 2014</p>	<p>South Shore Hospital</p> <ul style="list-style-type: none"> • Baseline: Aug-Oct 2013 • Follow-up: Jan-Jun 2014 <p>St. Elizabeth’s Medical Center</p> <ul style="list-style-type: none"> • Baseline: Dec 2013-Jan 2014 • Follow-up: Apr 2014
Issler et al. (2009)	Routine orientation	<ul style="list-style-type: none"> • Routine orientation • One-on-one bedside education • Folder with information 	~Sep 2005-Sep 2006	<p>Baseline: at discharge</p> <p>Follow-up 1: ~3 months after discharge</p> <p>Follow-up 2: ~ 6 months after discharge</p>
Kistin et al. (2012)	Standard-of-care newborn teaching: verbal and written instructions on ‘back to sleep,’ breastfeeding, car seat safety, signs of illness and daily care at postpartum	<ul style="list-style-type: none"> • Same instruction as the control group • Encouragement of note-taking with pen and paper while receiving the instruction 	~2009-2010	Follow-up: 2009-2010 (2 days after discharge prior to the newborn’s first outpatient appointment)
Kuhlmann et al. (2016)	N/A	<ul style="list-style-type: none"> • Development of infant safe sleep policy • Safe sleep training for staff with written declaration of committing to practice safe sleep in patient care • Designated storage for extraneous supplies • Education for caregivers <ul style="list-style-type: none"> ○ Viewing of 10-minute video on the hospital’s televised educational system ○ Instructions on watching the video and using the designated storage carts for supplies ○ Provision of a safe sleep door hanger from the NICHD to take home as a reminder • Use of infant wearable blankets (2 sites) 	Mar 2012-Dec 2013	<p>Site 1</p> <ul style="list-style-type: none"> • Baseline: Apr-May 2013 • Follow-up: Aug-Oct 2013 <p>Site 2</p> <ul style="list-style-type: none"> • Baseline: Feb-Mar 2013 • Follow-up: Aug-Dec 2013 <p>Site 3</p> <ul style="list-style-type: none"> • Baseline: Nov-Dec 2012 • Follow-up: Jun-Nov 2013 <p>Site 4</p> <ul style="list-style-type: none"> • Baseline: Feb-Apr 2013 • Follow-up: May-Aug 2013 <p>Site 5</p> <ul style="list-style-type: none"> • Baseline: Feb 2013 • Follow-up: Nov-Dec 2013 <p>Site 6</p>

				<ul style="list-style-type: none"> • Baseline: Feb 2013 • Follow-up: Sep-Dec 2013 Site 7 <ul style="list-style-type: none"> • Baseline: Oct-Nov 2012 • Follow-up: Mar 2013 Site 8 <ul style="list-style-type: none"> • Baseline: Mar-Apr 2012 • Follow-up: May-Jun 2012
Macklin et al. (2016)	N/A	<ul style="list-style-type: none"> • QI: PDSA cycles (3 cycles) • 2-hour onsite/online learning session <ul style="list-style-type: none"> ○ Safe sleep guidelines, local statistics, QI principles, utilization of PDSA cycles ○ Collaborative work on key driver diagrams • Physician and nursing staff education through online modules, Grand Rounds, or lectures • Acquisition of sleep sacks to replace loose blankets • Policy creation or revisions • Parental support and education • Monthly conference calls to assess progress, share best practices, identify problems, and provide education on SSP, infant mortality, injury prevention, QI, and resources to promote safe sleep behaviors • Weekly audits 	Jan 24, 2014-Jan 30, 2015 (“action phase”: 10 months beginning on Apr 1, 2014)	Baseline: Feb 3-Mar 31, 2014 Follow-up: Apr 1, 2014-Jan 30, 2015 (data was collected weekly after the baseline period for 10 additional months)
McCulloch et al. (2000)	N/A	“Back to Sleep” campaign in North Dakota	1994	Baseline: 1991 Follow-up: 1998
McMullen et al. (2016)	N/A	<ul style="list-style-type: none"> • QI project: PDSA framework • Education for nurses and resident physicians <ul style="list-style-type: none"> ○ Continuing education program on SIDS Risk Reduction ○ Computer-based instruction specific for NICU nurses ○ Documentation of education to parents by nursing staff ○ YouTube video on correct swaddling ○ Education about the attestation form for parents to verify the receipt of safe sleep education ○ Reference articles ○ Safe sleep discussion on daily rounds and reminder emails • Development and revision of safe sleep guidelines • Parent education materials and video on hospital network • Parents requested to sign an attestation form to verify the receipt of safe sleep education • Safe sleep posters throughout the hospital • Safe sleep crib cards used on pediatric units • “Safe sleep week”: meetings, display in the hallway, initiation 	Initiated in Spring 2013	Baseline: 3 months before the intervention Follow-up: 3 months after the intervention

		<ul style="list-style-type: none"> of sleep sack use • Use of sleep sacks to eliminate loose bedding • Provision of sleep sacks to NICU infants at discharge • Nurse role modeling of correct swaddling procedures for parents to learn and practice • Monthly monitoring of observation of clinical practice (routine audits) 		
Moon et al. (2004)	N/A	<ul style="list-style-type: none"> • 15-minute educational intervention for current and prospective caregivers led by a health educator <ul style="list-style-type: none"> ○ Small group discussions regarding SSP (sleep position, bed sharing/co-sleeping, smoke avoidance) ○ Emphasis placed on a culturally sensitive curriculum 	Oct 2001-Jul 2002	Follow-up: 6 months after the infant's birth
Moon et al. (2008)	No intervention	<ul style="list-style-type: none"> • State-level formation of a team of trainers/observers (health care professionals, child care health consultants, and health educators) <ul style="list-style-type: none"> ○ Training session coordinated by the AAP and led by an experienced pediatrician or health educator ○ Familiarization with the AAP Reducing the Risk of SIDS in Child Care Speaker's Kit: SIDS diagnosis and statistics, risk factors, safe sleep practices, barriers to safe sleep practices, and suggestions for developing policies ○ Training for conducting observations and recording findings • Child care provider training on safe sleep practices using the AAP Speaker's Kit by team of trainers/observers 	May 2006-Mar 2007	Baseline: initial visit Follow-up: ~3 months after the initial observation or training
Rocca Rivarola et al. (2016)	Hospital's usual oral recommendations	<ul style="list-style-type: none"> • Caregiver education- group/individual lessons • Written educational material for caregivers • Crib cards • Posters in hallways and waiting rooms • Training for health care staff- courses, workshops 	May 1-Jun 30, 2014	Baseline: Feb 1-Apr 30, 2014 (60 days after discharge) Follow-up: Jul 1-Sep 30, 2014 (60 days after discharge)
Rowe et al. (2016)	N/A	<ul style="list-style-type: none"> • QI: Define, Measure, Analyze, Improve, Control • Education for staff: online training for registered nurses (components of the 2011 AAP Safe Sleep Guidelines, national and state level data on SIDS, components of SSP, hospital policy on SSP, and documentation requirements) • Education for licensed independent providers: face-to-face education, online training modules discussing components of 2011 AAP Safe Sleep Guidelines • Educational materials for families: handouts and videos • Sleep sacks for infants facility-wide • Updated hospital policy change • Documentation in electronic medical record- care of infants 	Planning: Jul-Sep 2013 Provider education: Oct 2013 Implementation of SSP (policy, documentation changes, sleep sacks, family educational materials): early Jan 2014	Baseline: Jun 2013 Follow-up: Jan-Jun 2014

		<p>following SSP guidelines and family education on SSP</p> <ul style="list-style-type: none"> • Routine audits 		
Shadman et al. (2016)	N/A	<ul style="list-style-type: none"> • Hospital policy statement for SSP • Elimination of extraneous items in cribs and excessive linens • Computer-based education outlining SSP for nursing staff • QI activities: PDSA cycles <ul style="list-style-type: none"> ○ Weekly auditing & feedback ○ Incorporation of visual cue in infant rooms ○ Distribution of sleep sacks to units and families ○ Designation of space for the infants' personal care items 	<p>Pre-intervention: Jul-Dec 2013</p> <p>Intervention: Jan-Dec 2014</p>	<p>SSP room audits</p> <p>Baseline: Oct-Nov 2013</p> <p>Follow-up: weekly audits through Dec 2014</p> <p>Caregiver reports</p> <p>Baseline: Oct 2013-Jan 2014</p> <p>Follow-up: Feb-Apr 2014</p>
Shaefer et al. (2010)	N/A	<ul style="list-style-type: none"> • QI model • Review and revision of hospital nursing practice policies and information on infant safe sleep in patient education materials • Development of in-service training materials for nurse education, materials for patients, and a tool for auditing cribs during regular visits by nurses 	2004-2007 (Phase 1 & Phase 2)	<p>Baseline: N/A</p> <p>Follow-up: 6-12 months after baseline</p>
Srivasta et al. (1999)	N/A	<ul style="list-style-type: none"> • In-service education for medical and paramedical personnel • Back to Sleep video played daily in the well-baby nursery • Advice against prone positioning incorporated in the bedside rounds to the parents • Pamphlet about sleep position and SIDS along with an educational poem and advice given to mothers by nurse 	May-Jul 1997	<p>Baseline: Jan-Apr 1997</p> <p>Follow-up: 3 months after intervention implementation</p>
Voos et al. (2015)	N/A	<ul style="list-style-type: none"> • QI: PDSA cycles • Revision of NICU Safe Sleep policy • Educational sessions and reinforcing emails for nursing staff and physicians • Nurse yearly competency assessment • Parent education by the bedside nurse, reinforced by a packet with written and video materials • Availability of wearable blankets • Routine monitoring- results shared via email and monitor displays 	Between Apr 2012 and Oct 2013	<p>Baseline: Apr 13, 2012</p> <p>Follow-up: Oct 2, 2013</p>

¹ “No intervention” refers to the comparison group not having received an intervention. “N/A” (not applicable) refers to quasi-experimental studies with pretest-posttest designs.

Table 6. Intervention Components.

Study	Caregiver						Child Care Provider	Health Care Provider			Inpatient Hospital						Community			National	
	Training/Education	Educational material	Assessment	Note-taking	Provision of safe sleep	Attestation	Training/Education	Training/Education	Assessment	Attestation	Quality improvement	Policy/guideline	Crib card	Visual display	Sleep environment modification	Promotional event	Presentation	Visual display	Social media	Campaign	Mass media
Caregiver Only (n=6)																					
Ahlers-Schmidt et al. (2015)					X																
D'Halluin et al. (2011)	X	X	X																		
Goetter & Sepans (2005)	X																				
Issler et al. (2009)	X	X																			
Kistin et al. (2012)	X	X		X																	
Moon et al. (2004)	X																				
Child Care Provider Only (n=1)																					
Moon et al. (2008)							X														
Health Care Provider Only (n=1)																					
Colson & Joslin (2002)								X													
Caregiver + Provider + Hospital without Quality Improvement (n=4)																					
Hwang et al. (2015)	X							X				X	X								
Kuhlmann et al. (2016)	X	X			X			X		X				X							
Rocca Rivarola et al. (2016)	X	X						X				X	X								
Srivasta et al. (1999)	X	X						X					X								
Caregiver + Provider + Hospital with Quality Improvement (n=8)																					
Gelfer et al. (2013)	X	X			X			X	X		X	X	X								
Geyer et al. (2016)	X	X						X			X	X	X	X	X	X		X	X		
Macklin et al. (2016)	X							X			X	X			X						
McMullen et al. (2016)	X	X			X	X		X		X	X	X	X	X	X						
Rowe et al. (2016)		X						X		X	X			X	X						
Shadman et al. (2016)					X			X			X	X		X	X						
Shaefer et al. (2010)		X						X			X	X									
Voos et al. (2015)	X	X						X	X		X	X			X						
National Campaign (n=3)																					
Hiley & Morley (1994)																				X	
Hill et al. (2004)	X	X			X															X	X
McCulloch et al. (2000)																				X	

Table 7. Study Results.

Study	Results
Caregiver Only	
Ahlers-Schmidt et al. (2015)	At baseline, 83% of the caregivers in the control group and 89% in the intervention group reported placing their infants to sleep on their backs. At follow-up, the control group increased to 88% while the intervention group remained at 89%. No significant difference was observed between the two groups at post-intervention.
D'Halluin et al. (2011)	At follow-up, 91.9% and 86.8% of the mothers reported practicing supine sleep position in the intervention and control group respectively (p=0.16; OR=1.7, 95% CI: 0.7-4.0).
Goetter & Sepans (2005)	At the first follow-up (6 to 7 weeks postpartum; 1 week after discharge), mothers in the experimental group reported choosing supine position more often than mothers in the control group (p=0.034). At the second follow-up (6 to 7 weeks after the intervention), responses were mixed. In regard to the current infant sleep position, no significant difference was observed between the two groups (p=0.276). In terms of the sleep position in the previous night, no significant difference was observed (p=0.592). However, on sleep position for naptime on the day of follow-up, the experimental group reported an increased selection of supine position compared to the control group (p=0.028).
Issler et al. (2009)	In the third postpartum month, 42.9% of the mothers in the intervention group indicated that they put their infants to sleep in the supine position, compared with 24% in the control group (p=0.009). In the sixth postpartum month, these values were 41.8% and 19.1% respectively (p=0.001).
Kistin et al. (2012)	Mothers in the intervention group were more likely than those in the control group to report placing their infant on their back for sleep (88% vs. 78%), but the difference was not statistically significant (RR=1.13, 95% CI: 0.95-1.34). However, first-time mothers were significantly more likely to report placing their infant on the back for sleep (95% vs. 65%, RR=1.46, 95% CI: 1.06-2.00).
Moon et al. (2004)	At the 6-month follow-up, 75% of the infants in the intervention group were usually placed to sleep on their backs compared with 45.1% in the comparison group (p=0.0005).
Child Care Provider Only	
Moon et al. (2008)	At baseline, 51.8% of the child care providers in the control group and 50.9% in the intervention group reported placing infants to sleep on their backs. At follow-up, the control group increased to 57.1% and the intervention group increased to 62.1%. No significant difference was observed between the two groups at post-intervention.
Health Care Provider Only	
Colson & Joslin (2002)	<ul style="list-style-type: none"> • Infant observations showed that 20% and 99% of the infants in the well-newborn nursery were placed in the supine position before and after the intervention respectively (p<0.05). • Parents reported that 37% and 88% of nursery staff exclusively placed infants to sleep in the supine position before and after the intervention respectively (OR=12.5, 95% CI: 5.7-27.7). • Parent report showed that 42% and 75% of parents usually placed infants to sleep in the supine position at home before and after the intervention respectively (OR=4.2, 95% CI: 2.1-7.9).
Caregiver + Provider + Hospital without Quality Improvement	
Hwang et al. (2015)	For both sites combined, from the pre- to post-intervention period, there was a significant increase in compliance with supine positioning from 80.4% to 95.8% (p<0.001).
Kuhlmann et al. (2016)	Across all 8 sites, safe sleep position increased from 85.0% at baseline to 96.2% at follow-up (p<0.001).
Rocca Rivarola et al. (2016)	Caregiver report showed that 42% and 77% of infants were asleep supine at baseline and follow-up respectively (p<0.0001).

Srivasta et al. (1999)	Comparing baseline to follow-up, there was no significant change in supine sleep position (20.4% vs. 22.4%) ($p>0.05$).
Caregiver + Provider + Hospital with Quality Improvement	
Gelfer et al. (2013)	<ul style="list-style-type: none"> • Audit data showed that there was a significant increase in the rate of supine positioning from 39% at baseline to 83% at follow-up ($p<0.001$). • Parental surveys showed that there was a significant increase in the rate of supine position from 73% at baseline to 93% at follow-up ($p<0.05$).
Geyer et al. (2016)	Between baseline and a year after the initiation of the intervention, the rate of supine positioning increased from 82% to 95%, but the increase was not statistically significant ($p=0.183$). From baseline to a year following the intervention, the rate of supine positioning remained stable at 83% ($p=1.000$).
Macklin et al. (2016)	Comparing baseline to the last follow-up, there was no significant change in supine sleep position (84.0% to 84.7%) ($p=0.913$).
McMullen et al. (2016)	Prior to the intervention, 70% of infants were found in the supine sleep position; after the intervention, 90% were found supine ($p<0.01$).
Rowe et al. (2016)	Audit data showed that 72% and 77% of infants were asleep supine at baseline and follow-up respectively ($p=0.07$).
Shadman et al. (2016)	<ul style="list-style-type: none"> • Audit data showed that there was a non-significant increase in supine position from 81.0% to 84.3% from baseline to follow-up ($p=0.54$). • Caregiver report showed that there was a non-significant increase in supine position from 89.3% to 93.8% ($p=0.42$).
Shaefer et al. (2010)	Across all 7 sites, among infants in cribs at the time of the audits, there was a significant increase in the percentage on their backs from 80.7% to 91.9% ($p<0.05$).
Voos et al. (2015)	Comparing baseline to follow-up, there was no significant change in infants not positioned on back (21% vs. 12%) ($p>0.05$).
National Campaign	
Hiley & Morley (1994)	Comparing before and after the campaign, there was a significant increase in supine position for newborns from 9% to 40% ($p<0.0001$), for 3 month olds from 14% to 54% ($p<0.0001$), and for 6 months old from 30% to 64% ($p<0.0001$).
Hill et al. (2004)	The prevalence of non-supine sleep position decreased significantly from 33.7% before the campaign to 13.6% after (RR=0.40, 95% CI: 0.37-0.44). The decrease was significant by maternal education, cohabitation, birth order, and maternal age.
McCulloch et al. (2000)	Comparing before and after the campaign, combining American Indian and Caucasian infants, there was a significant increase in supine position from 17.3% to 67.0% (OR=0.103, 95% CI: 0.070-0.151). The increase was significant among Caucasian infants from 12.0% to 68.6% (OR=0.603, 95% CI: 0.059-0.099). For American Indian infants, there was a non-significant increase from 37.9% to 54.8% (OR: 0.502, 95% CI: 0.212-1.19).

Table 8. Summary of Study Results.¹

Study	Supine Sleep Position
Caregiver Only	
Ahlers-Schmidt et al. (2015)	ns
D'Halluin et al. (2011)	ns
Goetter & Sepans (2005) ²	+, ns
Issler et al. (2009)	+
Kistin et al. (2012)	ns
Moon et al. (2004)	+
Child Care Provider Only	
Moon et al. (2008) ³	ns
Health Care Provider Only	
Colson & Joslin (2002)	+
Caregiver + Provider + Hospital without Quality Improvement	
Hwang et al. (2015)	+
Kuhlmann et al. (2016)	+
Rocca Rivarola et al. (2016)	+
Srivasta et al. (1999)	ns
Caregiver + Provider + Hospital with Quality Improvement	
Gelfer et al. (2013)	+
Geyer et al. (2016)	ns
Macklin et al. (2016)	ns
McMullen et al. (2016)	+
Rowe et al. (2016)	ns
Shadman et al. (2016)	ns
Shaefer et al. (2010)	+
Voos et al. (2015)	ns
National Campaign	
Hiley & Morley (1994)	+
Hill et al. (2004)	+
McCulloch et al. (2000) ⁴	+

¹ The symbol “+” refers to a statistically significant favorable outcome on a p=0.05 level; “ns” refers to a non-significant outcome.

² Results were statistically significant favorable for the first follow-up as well as naptime at the second follow-up. Results were non-significant for the usual sleep position and the previous night at the second follow-up.

³ The study reported significance levels between baseline and follow-up for the control and intervention groups separately. The study did not compare the control and intervention groups. A chi-square test of the follow-up data between the control and intervention group was performed by lead author (YL).

⁴ Results were reported for the overall sample.

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