Author Manuscript

Author Manuscript

Author Manuscript

Author Manuscript

HHS Public Access

Author manuscript

JAMA. Author manuscript; available in PMC 2017 September 11.

Published in final edited form as:

JAMA. 2017 July 25; 318(4): 351–359. doi:10.1001/jama.2017.8982.

The Effect of Nursing Quality Improvement and Mobile Health Interventions on Infant Sleep Practices:

A Randomized Clinical Trial

Rachel Y. Moon, MD, **Fern R. Hauck, MD, MS**, **Eve R. Colson, MD, MHPE**, **Ann L. Kellams, MD**, **Nicole L. Geller, MPH**, **Timothy Heeren, PhD**, **Stephen M. Kerr, MPH**, **Emily E. Drake, PhD, RN**, **Kawai Tanabe, MPH**, **Mary McClain, RN, MS**, and **Michael J. Corwin, MD**

Department of Pediatrics, School of Medicine, University of Virginia, Charlottesville (Moon, Kellams); Department of Family Medicine, School of Medicine, University of Virginia, Charlottesville (Hauck, Tanabe); Department of Pediatrics, Yale University, New Haven, Connecticut (Colson); Slone Epidemiology Center, Boston University, Boston, Massachusetts (Geller, Kerr,McClain, Corwin); Department of Biostatistics, School of Public Health, Boston University, Boston, Massachusetts (Heeren); Department of Family, Community, and Mental Health Systems, School of Nursing, University of Virginia, Charlottesville (Drake)

Abstract

IMPORTANCE—Inadequate adherence to recommendations known to reduce the risk of sudden unexpected infant death has contributed to a slowing in the decline of these deaths.

OBJECTIVE—To assess the effectiveness of 2 interventions separately and combined to promote infant safe sleep practices compared with control interventions.

Corresponding Author: Rachel Y. Moon, MD, Division of General Pediatrics, Department of Pediatrics, University of Virginia, PO Box 800386, Charlottesville, VA 22908 (rym4z@virginia.edu).

Conflict of Interest Disclosures: The authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

Author Contributions: Drs Heeren and Corwin had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.
Concept and design: Moon, Hauck, Colson, Kellams, Geller, McClain, Corwin.
Acquisition, analysis, or interpretation of data: Moon, Hauck, Colson, Kellams, Geller, Heeren, Kerr, Drake, Tanabe, Corwin.
Drafting of the manuscript: Moon, Kellams, Geller. *Critical revision of the manuscript for important intellectual content:* All authors.
Statistical analysis: Heeren, Kerr, Corwin.
Obtained funding: Moon, Hauck, Colson, Kellams, Corwin.
Administrative, technical, or material support: Moon, Hauck, Kellams, Geller, Drake, Tanabe, Corwin.
Supervision: Moon, Hauck, Colson, Corwin.

Additional Contributions: We thank the staff at Slone Epidemiology Center, including Lisa Crowell, RN, Taylor Platt, BA, and Dena Margolis, BA, who assisted with study implementation and data collection. Their salaries were paid by the grants and they did not receive additional compensation. We also acknowledge the study staff at the 16 participating hospitals for their role in recruitment and data collection, which are listed by study group: (1) breastfeeding nursing quality improvement (NQI) and breastfeeding mobile health (mHealth) group: Delaware County Memorial Hospital, Drexel Hill, Pennsylvania; Medical Center of Arlington, Arlington, Texas; Saint Francis Hospital and Medical Center, Hartford, Connecticut; and Saint Joseph Hospital, Orange, California; (2) safe sleep NQI and breastfeeding mHealth group: Brookdale Hospital and Medical Center, Brooklyn, New York; Johns Hopkins Hospital and Medical Center, Baltimore, Maryland; Riverside County Regional Medical Center, Moreno Valley, California; and Rush Copley Medical Center, Aurora, Illinois; (3) breastfeeding NQI and safe sleep mHealth group: Jersey Shore University Medical Center, Neptune City, New Jersey; Moreno Valley Community Hospital, Moreno Valley, California; Riverside Regional Medical Center, Newport News, Virginia; Texas Health Presbyterian Hospital, Plano; and (4) safe sleep NQI and safe sleep mHealth group: Baystate Medical Center, Springfield, Massachusetts; Bethesda Memorial Hospital, Boynton Beach, Florida; Kaweah Delta Health Care District, Visalia, California; and Mount Carmel Health System, Columbus, Ohio.

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

DESIGN, SETTING, AND PARTICIPANTS—Four-group cluster randomized clinical trial of mothers of healthy term newborns who were recruited between March 2015 and May 2016 at 16 US hospitals with more than 100 births annually. Data collection ended in October 2016.

INTERVENTIONS—All participants were beneficiaries of a nursing quality improvement campaign in infant safe sleep practices (intervention) or breastfeeding (control), and then received a 60-day mobile health program, in which mothers received frequent emails or text messages containing short videos with educational content about infant safe sleep practices (intervention) or breastfeeding (control) and queries about infant care practices.

MAIN OUTCOMES AND MEASURES—The primary outcome was maternal self-reported adherence to 4 infant safe sleep practices of sleep position (supine), sleep location (room sharing without bed sharing), soft bedding use (none), and pacifier use (any); data were collected by maternal survey when the infant was aged 60 to 240 days.

RESULTS—Of the 1600 mothers who were randomized to 1 of 4 groups (400 per group), 1263 completed the survey (78.9%). The mean (SD) maternal age was 28.1 years (5.8 years) and 32.8% of respondents were non-Hispanic white, 32.3% Hispanic, 27.2% non-Hispanic black, and 7.7% other race/ethnicity. The mean (SD) infant age was 11.2 weeks (4.4 weeks) and 51.2% were female. In the adjusted analyses, mothers receiving the safe sleep mobile health intervention had higher prevalence of placing their infants supine compared with mothers receiving the control mobile health intervention (89.1% vs 80.2%, respectively; adjusted risk difference, 8.9% [95% CI, 5.3%–11.7%]), room sharing without bed sharing (82.8% vs 70.4%; adjusted risk difference, 12.4% [95% CI, 9.3%–15.1%]), no soft bedding use (79.4% vs 67.6%; adjusted risk difference, 11.8% [95% CI, 8.1%–15.2%]), and any pacifier use (68.5% vs 59.8%; adjusted risk difference, 8.7% [95% CI, 3.9%–13.1%]). The independent effect of the nursing quality improvement intervention was not significant for all outcomes. Interactions between the 2 interventions were only significant for the supine sleep position.

CONCLUSIONS AND RELEVANCE—Among mothers of healthy term newborns, a mobile health intervention, but not a nursing quality improvement intervention, improved adherence to infant safe sleep practices compared with control interventions. Whether widespread implementation is feasible or if it reduces sudden and unexpected infant death rates remains to be studied.

TRIAL REGISTRATION—clinicaltrials.gov Identifier: NCT01713868

A national public awareness campaign (Back to Sleep) to improve rates of supine infant sleep positioning to reduce the risk of sudden infant death syndrome (SIDS) was successful in halving the US SIDS rate; however, in 2014 there were still approximately 3500 infant deaths due to SIDS, accidental suffocation or strangulation in bed, or ill-defined causes.[1] The peak age incidence for these deaths to occur is at 1 to 4 months, and 90% occur before the age of 6 months.[2] Barriers to changing parental behavior regarding infant safe sleep environments include concerns that the infant will not sleep as well[3–6] or will be more likely to aspirate[3–7] when placed in the supine sleep position. Adherence to supine sleep recommendations plateaued between 2001 and 2010, never reaching target levels.[8] Furthermore, US public health efforts have been less successful in changing behaviors with regard to bed sharing[9] and soft bedding use.[10] Although pacifier use is associated with

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

reduced SIDS risk,[11] no interventions to increase pacifier use have been published. In addition, there are racial/ethnic disparities in adherence to infant safe sleep recommendations.[6,9,10,12]

To address these issues, 2 separate complementary interventions to promote infant safe sleep practices were developed. A nursing quality improvement (NQI) intervention targeted initial adherence,[13] and a mobile health (mHealth) messaging intervention was aimed at promoting continued adherence during the first 2 months of the infant's life.[14,15] These interventions were designed to use strategies that could be widely implemented in a cost-effective manner if they are proven effective. All interventions were branded with a name, logo, and tagline (TodaysBaby: Helping You Make the Best Choices for Your Baby).

The Social Media and Risk-Reduction Training (SMART) study, a 4-group cluster randomized clinical trial (RCT), was designed to assess these safe sleep interventions with similar breastfeeding interventions used as controls.

Methods

Study Population

Recruitment—Mothers of healthy term infants were recruited from 16 US hospitals that were selected from a nationally representative sample of 32 hospitals with more than 100 deliveries annually (the hospitals are listed at the end of this article). The hospitals were selected based on their history of successful recruitment for the Study of Attitudes and Factors Effecting Infant Care Practices (SAFE), a national study of infant care practices,[16–18] and their prestudy rates of parental adherence to infant care practice recommendations. The trial protocol appears in Supplement 1.

Due to the known racial/ethnic disparities in adherence to safe sleep recommendations,[19] hospitals were provided target recruitment numbers for Hispanic, non-Hispanic black, and mothers of all other race/ethnicities in a manner identical to the strategy used in the SAFE study.[16–18] Race/ethnicity was self-reported using fixed categories from which to select. Institutional review board approval was obtained from Boston University, Yale University, the University of Virginia, and all participating hospitals.

Randomization—A cluster randomized approach allowed hospitalwide implementation of the interventions. Sixteen hospitals were divided into 4 groups that were balanced based on prestudy rates of infant care (sleep and feeding) practices and geographic location. Each group of hospitals was randomly assigned by computer-generated random numbers using a blocked randomization scheme to 1 of the following 4 intervention combinations: (1) breastfeeding NQI and breastfeeding mHealth; (2) safe sleep NQI and breastfeeding mHealth; (3) breastfeeding NQI and safe sleep mHealth; or (4) safe sleep NQI and safe sleep mHealth.

Enrollment—Enrollment at each hospital began after a median of 86 days (range, 20–149 days) following NQI completion so that the hospitals could begin enrollment in a rolling fashion between March 2015 and May 2016. All mothers were enrolled during the

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

hospitalization for the birth. Mothers were excluded if they were non-English speaking, did not live in the United States, did not have custody of the infant, or could not receive daily email or text messages. Other exclusions included if the infant required hospitalization for more than 3 days, had contraindications to breast milk feeding (ie, feeding directly on the breast or drinking pumped breast milk) or following safe sleep guidelines, or was deceased.

Data Collection

After written informed consent was obtained, mothers provided demographic and contact information and were oriented to their preferred email or text message platform. Using procedures identical to those used in the SAFE study,[16–18] mothers completed a survey that asked about sleep and feeding practices when the infant was aged 60 days or older. Although there was an emphasis on study completion before the infant was aged 150 days, mothers received reminders to complete the survey until the infant was aged 240 days. Data collection ended in October 2016.

Description of Interventions

NQI Interventions—The NQI interventions were designed to ensure that mothers would hear key messages, and that there was appropriate role modeling by hospital personnel. Because randomization was at the hospital level, all mothers who delivered at a given hospital were exposed during routine postpartum care to education and role modeling resulting from the assigned NQI intervention, along with any preexisting educational practices performed at the hospital.

Mothers in all groups received basic information about breastfeeding and safe sleep per hospital protocols, including advice to bring the infant into the parental bed for feeding, but to move the infant back into a separate sleep space when the parent was ready for sleep, and to postpone pacifier use for directly breastfed infants until breastfeeding was well established.

Study investigators developed the safe sleep and breast-feeding control NQI interventions using prior successful interventions,[20–23] existing curricula,[24–26] prior research on barriers to adherence,[3–5,7,27] and qualitative data from focus groups with maternity unit staff at 2 large academic hospitals (Yale New Haven Hospital and University of Virginia Health System) as guides.

The NQI used a train-the-trainer model with local nurse champions as coordinators, evidence-based educational materials that provided strategies for addressing barriers to safe sleep[3–5,7,27] and breastfeeding,[28–32] and an emphasis on the importance of role modeling best practices. Each hospital team decided on and implemented NQI initiatives in plan-do-study-act cycles. Following each cycle, hospital staff conducted unannounced audits in which they observed maternal practices and asked mothers about information received from staff.

mHealth Interventions—The mHealth interventions provided ongoing messaging timed to anticipate likely adherence challenges. Study investigators developed health messages and educational videos to be delivered by email or text messages to parents. The health messages

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

and educational videos were reviewed by experts in safe sleep, breastfeeding, health education, and social marketing and by family caregivers of newborn infants (target audience). Videos contained parent testimonials, addressed common questions and barriers to safe sleep (intervention) or breastfeeding (control), and were delivered at times when these issues typically arise. For instance, because concern about aspiration while an infant is placed in the supine sleep position is a major reason for early prone placement, a video addressing this concern was among the first videos mothers were given. Video topics appear in eTable 1 in Supplement 2.

At enrollment while in the hospital, mothers answered questions about current infant feeding status and feeding plans after hospitalization and viewed the first 2 TodaysBaby videos (safe sleep or breastfeeding; each approximately 3 minutes long). Within 24 hours, participants began receiving email or text messages (based on participant preference) with TodaysBaby videos (lasting 60–90 seconds long). Messages were delivered centrally by the study data center using proprietary platforms (Mobile Commons for text messages; iContact for email). Mothers received daily messages and videos for the first 11 days and then every 3 to 4 days for 60 days.

Outcomes

The primary outcome was adherence to the following 4 infant safe sleep practice recommendations from the American Academy of Pediatrics: (1) infant sleep position (supine vs other), (2) infant sleep location (room sharing without bed sharing vs other), (3) pacifier use (any use vs no use), and (4) soft bedding use (no soft bedding use vs other). Adherence was measured by maternal responses to the survey, which asked about usual practice during the past 2 weeks. Prespecified secondary outcomes regarding breastfeeding behavior are not reported in this article.

Statistical Methods

Sample size was determined to provide adequate power of detecting the effect of an individual intervention in the presence of an interaction. To account for the cluster randomized design and generalized estimating equation logistic regression analysis, necessary sample size was determined through simulation. Based on results from the SAFE study, we assumed prestudy prevalence of a safe sleep practice ranging from 50% to 60% across hospitals.[18]

Because clinical trials have demonstrated modest improvements in infant safe sleep practices (increases ranging from 7%–30% in supine sleep positioning and decreases ranging from 12%–28% in bed sharing[14,33]), we powered the study to detect a 10 percentage point difference between 2 groups, and determined that a sample size of 1280 (320 per treatment group) was needed for 80% power (2-sided $P < .05$ with a Bonferroni adjustment for multiple comparisons). Allowing for an anticipated 20% loss to follow-up, this led to an enrollment sample size of 1600 (400 per group).

Survey respondent and nonrespondent demographic characteristics were compared using a χ^2 test. Prespecified statistical analyses evaluated the 2 study interventions (NQI and mHealth) on the sleep outcomes. Unadjusted and adjusted analyses, controlling for infant

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

age and sex; mother's age, parity, educational level, marital status, and household income; and the baseline between-group differences were performed using generalized estimating equation logistic regression models to account for within-hospital clustering and to allow both individual-level and hospital-level covariates.

Prevalence of safe sleep outcomes range from approximately 60% to 90%, and the usual interpretation of odds ratios may be misleading given these common outcomes. Therefore, we converted adjusted odds ratios and 95% CIs from the logistic regression models to adjusted risk differences and 95% CIs using the observed prevalence in the group that received the control for both the NQI and mHealth interventions as the control group prevalence.

We first report on the separate effects of the NQI and mHealth interventions based on the main effect models with indicator variables for the 2 interventions. We then fit multiplicative interaction models with indicator variables for the NQI intervention, mHealth intervention, and their interaction. When the interaction between the 2 interventions was not significant, only the main effect model is presented. When the interaction between the 2 interventions was significant, the results from the interaction model are also presented. To account for examining multiple outcome measures, our original protocol called for calculating Bonferroni-adjusted *P* values.

The Hochberg procedure also provides strong control of the family-wise error rate and is more powerful than the Bonferroni procedure; therefore, Hochberg-adjusted *P* values are presented to account for multiple comparisons. A secondary aim was to evaluate mediators of the intervention effects; however, these analyses are not included in this article.

Imputation was planned if loss to follow-up was greater than anticipated (ie, >20%). Even though the observed loss to follow-up was at the anticipated rate of approximately 20%, post hoc multiple imputation analyses were conducted. Based on the fraction of missing data, 20 imputed data sets were generated using fully conditional specification methods. The procedures described above were followed for the multiple imputation analyses.

Because previous data from the SAFE study showed that infant care practices vary by race/ethnicity,[18] and recruitment for SMART oversampled black and Hispanic mothers, post hoc exploratory safe sleep outcomes for black, Hispanic, and white mothers are also provided. Statistical analyses were performed using SAS version 9.3 (SAS Institute Inc). Two-sided *P* values less than .05 were considered statistically significant.

Results

Study Population

Of 3733 mothers assessed for eligibility, 2937 (78.7%) were found to be eligible based on chart review or interview with the mother. Of these, 387 were not approached for consent due to lack of ability to meet with the mother prior to hospital discharge. Therefore, 2550 (86.8%) were approached and 1600 (100 per hospital) provided written informed consent (62.7%). The mean (SD) time to complete enrollment was 200 days (76 days; range, 81–361

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

days) and was largely dependent on the annual number of births at each hospital. All hospitals achieved 90% adherence with all NQI measures except for encouragement of pacifier use before initiating mother recruitment. The mHealth messaging intervention was not correctly enabled on the cell phones of 20 women at enrollment (these women did not receive the videos or queries) and 337 were lost to follow-up.

The survey was completed by 1263 mothers (78.9% of those enrolled; Figure). The mean (SD) maternal age was 28.1 years (5.8 years) and 32.8% of respondents were non-Hispanic white, 32.3% Hispanic, 27.2% non-Hispanic black, and 7.7% other race/ethnicity. The mean (SD) infant age was 11.2 weeks (4.4 weeks) and 51.2% were female. Survey nonrespondents were more likely younger than 30 years, black, never married, and to not have attended college ($P < .001$ for all). The characteristics of the respondents appear in Table 1. The characteristics of both respondents and nonrespondents appear in eTable 2 in Supplement 2. The rates of opening and viewing messages were consistently higher than 50%.

Infant Safe Sleep Outcomes

The prestudy (from SAFE study participants) rates of parental adherence to infant safe sleep practices that were used as baseline rates appear in Table 2. The demographic characteristics of prior SAFE study participants used to calculate baseline rates appear in eTable 3 in Supplement 2.

Safe sleep outcomes by group assignment appear in Table 3. Mothers who received both the NQI and mHealth safe sleep interventions had the highest rates of adherence to all 4 recommended outcomes (92.5% for supine sleep position, 85.9% for room sharing without bed sharing, 81.9% for no soft bedding use, and 76.2% for any pacifier use), followed by mothers who received the breastfeeding NQI and the safe sleep mHealth intervention (88.3% for supine sleep position, 79.9% for room sharing without bed sharing, 77.8% for no soft bedding use, and 69.3% for any pacifier use).

In the prespecified adjusted analysis for supine sleep position, the main effect model showed significantly greater adherence to the safe sleep recommendation for those given the mHealth intervention (adjusted prevalence in the intervention and control group of 89.1% and 80.2%, respectively; adjusted risk difference, 8.9% [95% CI, 5.3%–11.7%]) and no significant effect for the NQI intervention. The interaction model showed a significant interaction between the 2 interventions, suggesting that mothers receiving both the NQI and mHealth interventions had better adherence to supine sleep recommendations than mothers receiving the mHealth intervention alone.

Because a significant interaction was not observed between the 2 interventions for the other 3 safe sleep outcomes, the separate effects of each individual intervention are reported. In each case, the adjusted independent effect of the mHealth intervention was significantly greater adherence to the recommended sleep practice (adjusted prevalence for usual room sharing without bed sharing was 82.8% in the intervention group and 70.4% in the control group [adjusted risk difference, 12.4%; 95% CI, 9.3%–15.1%]; no soft bedding use: 79.4% and 67.6%, respectively [adjusted risk difference, 11.8%; 95% CI, 8.1%–15.2%], and any pacifier use: 68.5% and 59.8% [adjusted risk difference, 8.7%; 95% CI, 3.9%–59.8%]). The

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

adjusted independent effect of the NQI intervention did not show improved adherence for any of these outcomes.

Post hoc Analyses

Post hoc sensitivity analyses that accounted for loss to follow-up through multiple imputation (eTable 4 in Supplement 2) showed that the interaction between the NQI and mHealth interventions was not significant for supine sleep position. Although the effects for the mHealth intervention were somewhat attenuated, they remained consistent with the main analysis.

A post hoc analysis in which the data were stratified by race showed that even though control rates of the safe sleep outcomes varied widely depending on race, the rates of beneficial outcomes for the group receiving both the NQI and mHealth safe sleep interventions were similarly high regardless of race (eTable 5 and eFigure in Supplement 2).

Discussion

In this RCT of 2 complementary interventions to improve infant safe sleep practices, receiving a safe sleep mHealth intervention resulted in increases in supine sleep position placement, room sharing without bed sharing, no soft bedding use, and any pacifier use at 2 months of age compared with controls. The safe sleep NQI intervention alone did not significantly affect any of these outcomes, although the significant interaction for supine sleep position suggests that mothers receiving both the mHealth and NQI safe sleep interventions had the highest adherence to supine sleep position placement.

There have been few RCTs to improve infant safe sleep practices, and the rates of supine sleeping (92.5%) and room sharing without bed sharing (85.9%) achieved in this study are much higher than have been achieved in other trials. A trial of educational interventions with US child care providers improved reported supine sleep position placement from 65.0% to 87.8% and observed supine sleep position placement from 51.0% to 62.1%.[34] Individual education with Brazilian mothers improved supine sleep position rates 2.2-fold 3 months after the intervention.[35] A recent RCT of health messages that emphasized the importance of suffocation prevention had no effect on infant sleep position or sleep location, but demonstrated small significant decreases in soft bedding use.[36] To our knowledge, there have been no RCTs to improve pacifier use.

The safe sleep NQI intervention did not influence infant safe sleep practices. Other studies have found that mothers usually intend to adhere to infant safe sleep practices before they are discharged from the hospital, but that the challenges of caring for a newborn may result in changes in practice.[14] It is possible that hospital staff teaching and modeling (although important in establishing the practice standard) may not be sufficient, or that already existing hospital educational policies may have limited the incremental effect of this NQI intervention.

The safe sleep mHealth intervention was effective in improving infant safe sleep practices. It was particularly effective for improving room sharing without bed sharing and increasing

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

elimination of soft bedding use, both of which demonstrated absolute risk differences of greater than 10 percentage points. Even though improvements in supine sleep position placement and any pacifier use were statistically significant, these improvements did not meet the study sample size–based minimal clinically important difference of 10%.

The messages and videos were timed to address challenges and questions that arise at specific time points; therefore, providing this additional information to parents at critical times may have been important in assuaging concerns about adherence to recommended practices. Furthermore, receiving frequent videos and email or text messages may have served as a virtual support system for mothers, reinforcing safe parental practices. Analyses of mHealth interventions for multiple health issues have found that messages tailored to clinical situations and sent on a daily to weekly basis are associated with positive effects.[37]

There are persistent racial/ethnic disparities with regard to adherence to infant safe sleep practices,[6,9,10,12] and this was reflected in the rates of adherence in the control group. However, in a post hoc analysis, these disparities were no longer significant in the group receiving both the NQI and mHealth safe sleep interventions. This analysis should only be considered as hypothesis-generating and requires further study before reaching any conclusions.

An important goal of this study was to test interventions that, if effective, could be implemented widely and cost-efficiently. Messages and scripts that could easily be incorporated in plan-do-study-act cycles to improve safe sleep teaching were developed. Furthermore, because the rates of opening and viewing messages in this study were consistently higher than 50% and almost all adults now have cell phones or email access, it is likely that this type of intervention would be feasible and well received by parents. Although it may seem labor intensive to send daily messages, the email and text messages can be automated to easily reach large populations. In addition, messages can be retrieved asynchronously when convenient to the patient.[38] This study did not measure intervention costs or the efficacy for clinical end points so it is possible that the intervention may not be cost-effective.

Limitations

This study had several limitations. First, there was a lost to follow-up rate of 21%. Nonrespondents were predominantly younger, black, single, and less well educated, which are all factors typically associated with higher rates of non-adherence with safe sleep recommendations. Although this may indicate a lack of engagement in this subgroup, respondents with similar demographics demonstrated changes in practice (eTable 5 in Supplement 2). Nonetheless, other approaches may be needed to reach these mothers. Second, because enrollment was limited to English speakers, the results cannot be generalized to non–English-speaking populations. Third, the large majority of responses (72.6%) occurred when infants were aged 8 to 12 weeks. It will be important to assess continued adherence, particularly as mothers return to the workplace. Fourth, this study was not powered to assess adverse events. Fifth, this study did not measure clinical outcomes (ie, rates of sudden unexpected infant death). Sixth, this trial has limitations inherent in self-reporting.

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

Mothers who received the NQI and mHealth safe sleep interventions may have been more reluctant to report practices inconsistent with the messages received in the interventions, which would overestimate the effect of the messaging. However, the prestudy levels for each behavior are comparable with other studies,[9,12,39] suggesting the validity of the study methods used and the analyses adjusted for prestudy between-group differences. Furthermore, to minimize reporting bias, queries about infant care practices other than sleep and feeding (eg, immunizations) were in the survey so that specific outcome measures were less obvious. To minimize contamination of the various intervention groups, a cluster randomization scheme that randomized by hospital was used. Given the consistency of results across all end points, in the different groups, and with SAFE prestudy data, these results are likely to be valid.

Conclusions

Among mothers of healthy term newborns, a mobile health intervention, but not a nursing quality improvement intervention, improved adherence to infant safe sleep practices compared with control interventions. Whether widespread implementation is feasible or if it reduces sudden and unexpected infant death rates remains to be studied.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

Funding/Support: This study was funded by grant 1R01HD072815-01 from the National Institute of Child Health and Human Development and funding from the CJ Foundation for SIDS.

Role of the Funder/Sponsor: Neither funder had any role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

References

1. Centers for Disease Control and Prevention. [Accessed June 23, 2017] Linked birth/infant death records on CDC WONDER online database. https://wonder.cdc.gov/lbd.html
2. Shapiro-Mendoza CK, Tomashek KM, Anderson RN, Wingo J. Recent national trends in sudden, unexpected infant deaths: more evidence supporting a change in classification or reporting. Am J Epidemiol. 2006; 163(8):762–769. [PubMed: 16582034]
3. Oden RP, Joyner BL, Ajao TI, Moon RY. Factors influencing African American mothers' decisions about sleep position: a qualitative study. J Natl Med Assoc. 2010; 102(10):870–872. 875–880. [PubMed: 21053701]
4. Colson ER, Levenson S, Rybin D, et al. Barriers to following the supine sleep recommendation among mothers at four centers for the Women, Infants, and Children Program. Pediatrics. 2006; 118(2):e243–e250. [PubMed: 16882769]
5. Colson ER, McCabe LK, Fox K, et al. Barriers to following the Back-to-Sleep recommendations: insights from focus groups with inner-city caregivers. Ambul Pediatr. 2005; 5(6):349–354. [PubMed: 16302836]
6. Hauck FR, Signore C, Fein SB, Raju TN. Infant sleeping arrangements and practices during the first year of life. Pediatrics. 2008; 122(suppl 2):S113–S120. [PubMed: 18829826]

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

7. Joyner BL, Oden RP, Ajao TI, Moon RY. Where should my baby sleep: a qualitative study of African American infant sleep location decisions. J Natl Med Assoc. 2010; 102(10):881–889. [PubMed: 21053702]
8. National Institute of Child Health and Human Development. [Accessed January 10, 2016] National infant sleep position. http://slone-web2.bu.edu/ChimeNisp/Main_Nisp.asp
9. Colson ER, Willinger M, Rybin D, et al. Trends and factors associated with infant bed sharing, 1993–2010: the National Infant Sleep Position Study. JAMA Pediatr. 2013; 167(11):1032–1037. [PubMed: 24080961]
10. Shapiro-Mendoza CK, Colson ER, Willinger M, Rybin DV, Camperlengo L, Corwin MJ. Trends in infant bedding use: National Infant Sleep Position study, 1993–2010. Pediatrics. 2015; 135(1):10–17. [PubMed: 25452654]
11. Hauck FR, Omojokun OO, Siadaty MS. Do pacifiers reduce the risk of sudden infant death syndrome? a meta-analysis. Pediatrics. 2005; 116(5):e716–e723. [PubMed: 16216900]
12. Colson ER, Rybin D, Smith LA, Colton T, Lister G, Corwin MJ. Trends and factors associated with infant sleeping position: the national infant sleep position study, 1993–2007. Arch Pediatr Adolesc Med. 2009; 163(12):1122–1128. [PubMed: 19996049]
13. Viswanath, K. Perspectives on models of interpersonal health behavior. In: Glanz, K.Rimer, BK., Viswanath, K., editors. Health Behavior and Health Education: Theory, Research, and Practice. San Francisco, CA: Wiley & Sons; 2008.
14. Hauck FR, Tanabe KO, McMurry T, Moon RY. Evaluation of bedtime basics for babies: a national crib distribution program to reduce the risk of sleep-related sudden infant deaths. J Community Health. 2015; 40(3):457–463. [PubMed: 25331608]
15. Corwin MJ, Lesko SM, Heeren T, et al. Secular changes in sleep position during infancy: 1995–1998. Pediatrics. 2003; 111(1):52–60. [PubMed: 12509554]
16. Eisenberg SR, Bair-Merritt MH, Colson ER, Heeren TC, Geller NL, Corwin MJ. Maternal report of advice received for infant care. Pediatrics. 2015; 136(2):e315–e322. [PubMed: 26216322]
17. Hwang SS, Rybin DV, Heeren TC, Colson ER, Corwin MJ. Trust in sources of advice about infant care practices: the SAFE study. Matern Child Health J. 2016; 20(9):1956–1964. [PubMed: 27129949]
18. Smith LA, Geller NL, Kellams AL, et al. Infant sleep location and breastfeeding practices in the United States, 2011–2014. Acad Pediatr. 2016; 16(6):540–549. [PubMed: 26851615]
19. Hauck FR, Moore CM, Herman SM, et al. The contribution of prone sleeping position to the racial disparity in sudden infant death syndrome: the Chicago Infant Mortality Study. Pediatrics. 2002; 110(4):772–780. [PubMed: 12359794]
20. Colson ER, Joslin SC. Changing nursery practice gets inner-city infants in the supine position for sleep. Arch Pediatr Adolesc Med. 2002; 156(7):717–720. [PubMed: 12090841]
21. Kramer MS, Chalmers B, Hodnett ED, et al. PROBIT Study Group (Promotion of Breastfeeding Intervention Trial). Promotion of Breastfeeding Intervention Trial (PROBIT): a randomized trial in the Republic of Belarus. JAMA. 2001; 285(4):413–420. [PubMed: 11242425]
22. Philipp BL, Merewood A, Miller LW, et al. Baby-friendly hospital initiative improves breastfeeding initiation rates in a US hospital setting. Pediatrics. 2001; 108(3):677–681. [PubMed: 11533335]
23. Perrine CG, Scanlon KS, Li R, Odom E, Grummer-Strawn LM. Baby-Friendly hospital practices and meeting exclusive breastfeeding intention. Pediatrics. 2012; 130(1):54–60. [PubMed: 22665406]
24. National Institute of Child Health and Human Development. [Accessed June 23, 2017] Continuing education activity on risk reduction for sudden infant death syndrome (SIDS) and other sleep-related causes of infant death: curriculum for nurses. https://www.nichd.nih.gov/sids/Pages/sidsnursesce.aspx
25. Breastfeeding Friendly Consortium. [Accessed June 23, 2017] Breastfeeding training. https://bfconsortium.org/
26. Baby-Friendly USA. [Accessed November 21, 2016] The ten steps to successful breastfeeding. https://www.babyfriendlyusa.org/about-us/baby-friendly-hospital-initiative/the-ten-steps

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

27. Joyner BL, Oden RP, Moon RY. Reasons for pacifier use and non-use in African-Americans: does knowledge of reduced SIDS risk change parents' minds? J Immigr Minor Health. 2016; 18(2): 402–410. [PubMed: 25864091]

28. Rojjanasrirat W, Sousa VD. Perceptions of breastfeeding and planned return to work or school among low-income pregnant women in the USA. J Clin Nurs. 2010; 19(13–14):2014–2022. [PubMed: 20920027]

29. Bartick M, Edwards RA, Walker M, Jenkins L. The Massachusetts baby-friendly collaborative: lessons learned from an innovation to foster implementation of best practices. J Hum Lact. 2010; 26(4):405–411. [PubMed: 20876344]

30. Whalen B, Cramton R. Overcoming barriers to breastfeeding continuation and exclusivity. Curr Opin Pediatr. 2010; 22(5):655–663. [PubMed: 20693904]

31. MacGregor E, Hughes M. Breastfeeding experiences of mothers from disadvantaged groups: a review. Community Pract. 2010; 83(7):30–33.

32. Haughton J, Gregorio D, Pérez-Escamilla R. Factors associated with breastfeeding duration among Connecticut special supplemental nutrition program for Women, Infants, and Children (WIC) participants. J Hum Lact. 2010; 26(3):266–273. [PubMed: 20689103]

33. Moon RY, Oden RP, Grady KC. Back to Sleep: an educational intervention with women, infants, and children program clients. Pediatrics. 2004; 113(3 pt 1):542–547. [PubMed: 14993547]

34. Moon RY, Calabrese T, Aird L. Reducing the risk of sudden infant death syndrome in child care and changing provider practices: lessons learned from a demonstration project. Pediatrics. 2008; 122(4):788–798. [PubMed: 18829803]

35. Issler RM, Marostica PJ, Giugliani ER. Infant sleep position: a randomized clinical trial of an educational intervention in the maternity ward in Porto Alegre, Brazil. Birth. 2009; 36(2):115–121. [PubMed: 19489805]

36. Mathews A, Joyner BL, Oden RP, He J, McCarter R Jr, Moon RY. Messaging affects the behavior of African American parents with regards to soft bedding in the infant sleep environment: a randomized controlled trial. J Pediatr. 2016; 175:79–85. e2. [PubMed: 27263400]

37. Hall AK, Cole-Lewis H, Bernhardt JM. Mobile text messaging for health: a systematic review of reviews. Annu Rev Public Health. 2015; 36:393–415. [PubMed: 25785892]

38. Cole-Lewis H, Kershaw T. Text messaging as a tool for behavior change in disease prevention and management. Epidemiol Rev. 2010; 32(1):56–69. [PubMed: 20354039]

39. Degan VV, Puppin-Rontani RM. Prevalence of pacifier-sucking habits and successful methods to eliminate them—a preliminary study. J Dent Child (Chic). 2004; 71(2):148–151. [PubMed: 15587099]

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

Key Points

Question

Will 2 separate, complementary interventions (nursing quality improvement intervention and mobile health intervention) promote safe infant sleep practices?

Findings

In a 4-group cluster randomized clinical trial with 1263 families, mothers who received a mobile health intervention with regular text or email messages and videos reported statistically significantly higher rates of placing their infants supine to sleep compared with mothers who received control interventions (adjusted prevalence, 89.1% vs 80.2%, respectively), room sharing without bed sharing (82.8% vs 70.4%), no soft bedding use (79.4% vs 67.6%), and any pacifier use (68.5% vs 59.8%). A nursing quality improvement intervention did not influence infant safe sleep practices.

Meaning

A mobile health intervention improved adherence with infant safe sleep practices. Whether widespread use of this type of intervention is feasible and reduces sudden and unexpected infant death rates remains to be studied.

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

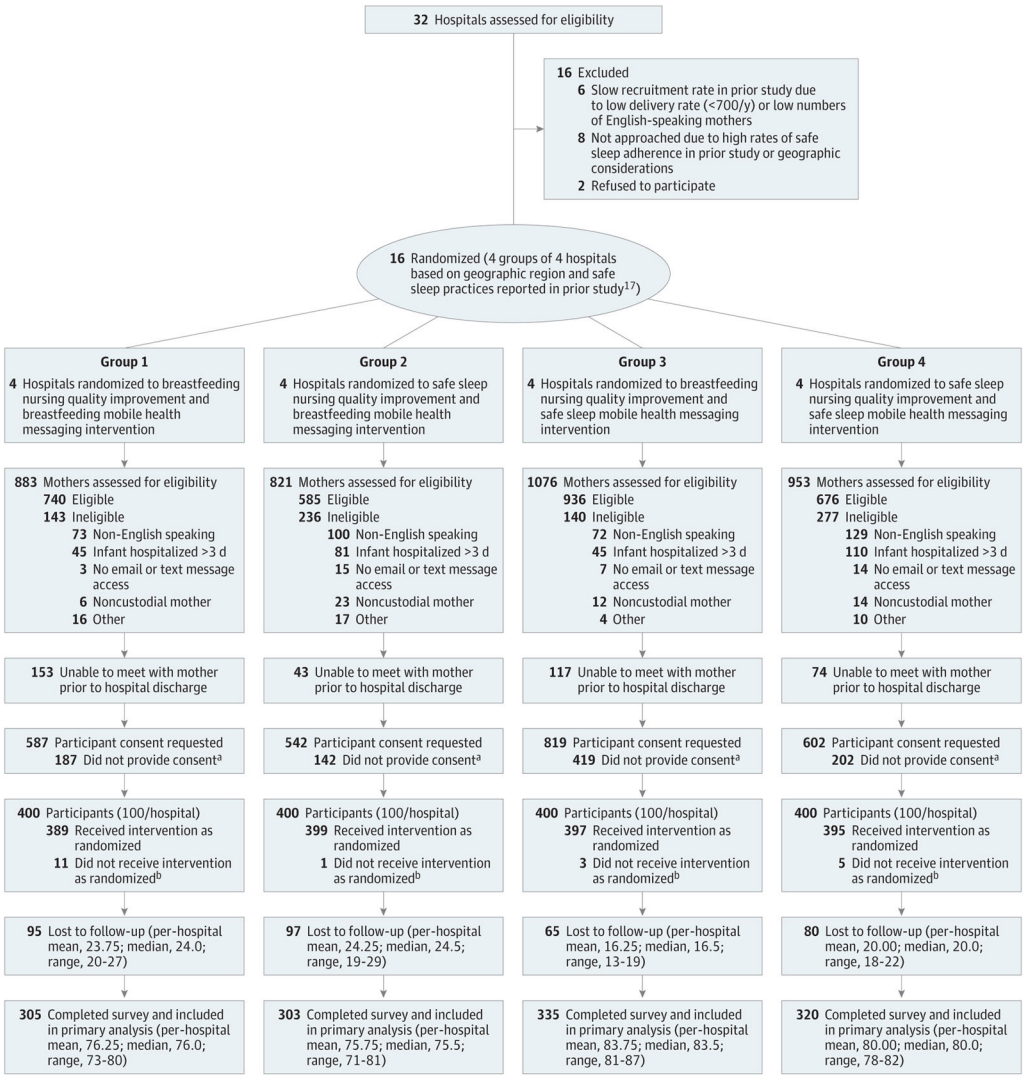

Figure. Flow Diagram for Study

Of 3733 mothers assessed for eligibility, 2937 (78.7%) were found to be eligible based on chart review or interview with the mother.

[a]Eligible mothers were approached for consent until there were 400 participants per group.

[b]The mobile health messaging intervention was not correctly enabled on the cell phones of 20 women at enrollment (these women did not receive the videos or queries).

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

Table 1

Demographic Characteristics of Participants at Enrollment During Birth Hospitalization (N = 1263)

	No. (%)			
	Breastfeeding Nursing Quality Improvement and Breastfeeding Mobile Health Messaging Intervention	**Safe Sleep Nursing Quality Improvement and Breastfeeding Mobile Health Messaging Intervention**	**Breastfeeding Nursing Quality Improvement and Safe Sleep Mobile Health Messaging Intervention**	**Safe Sleep Nursing Quality Improvement and Safe Sleep Mobile Health Messaging Intervention**
No. of participants	305	303	335	320
Sex of infant				
Male	137 (44.9)	156 (51.5)	161 (48.1)	162 (50.6)
Female	168 (55.1)	147 (48.5)	174 (51.9)	158 (49.4)
Parity				
1 Child	121 (39.7)	116 (38.3)	147 (43.9)	142 (44.4)
2 Children	105 (34.4)	99 (32.7)	112 (33.4)	103 (32.2)
≥3 Children	79 (25.9)	88 (29.0)	76 (22.7)	75 (23.4)
Age group of mother, y				
<20	16 (5.2)	23 (7.6)	12 (3.6)	34 (10.6)
20–29	156 (51.1)	165 (54.5)	155 (46.3)	168 (52.5)
≥30	133 (43.6)	115 (38.0)	168 (50.1)	118 (36.9)
Race/ethnicity of mother				
Non-Hispanic white	91 (29.8)	64 (21.1)	131 (39.1)	128 (40.0)
Non-Hispanic black	83 (27.2)	119 (39.3)	72 (21.5)	70 (21.9)
Hispanic	100 (32.8)	99 (32.7)	99 (29.6)	110 (34.4)
Other[a]	31 (10.2)	21 (6.9)	33 (9.9)	12 (3.8)
Education of mother				
<High school	10 (3.3)	36 (11.9)	11 (3.3)	31 (9.7)
High school graduate or GED	88 (28.9)	84 (27.7)	63 (18.8)	77 (24.1)
Some college	104 (34.1)	102 (33.7)	114 (34.0)	118 (36.9)
≥College	101 (33.1)	80 (26.4)	147 (43.9)	92 (28.8)
Unknown	2 (0.7)	1 (0.3)	0	2 (0.6)
Marital status				
Married	163 (53.4)	127 (41.9)	203 (60.6)	147 (45.9)
Never married	132 (43.3)	158 (52.1)	111 (33.1)	151 (47.2)
Separated, divorced, or widowed	8 (2.6)	14 (4.6)	20 (6.0)	14 (4.4)
Unknown	2 (0.7)	4 (1.3)	1 (0.3)	8 (2.5)
Household income, $				
<20 000	47 (15.4)	49 (16.2)	30 (9.0)	55 (17.2)
20 000–49 999	62 (20.3)	59 (19.5)	62 (18.5)	56 (17.5)
≥50 000	88 (28.9)	81 (26.7)	175 (52.2)	91 (28.4)

Author Manuscript

Author Manuscript

Author Manuscript

Author Manuscript

	No. (%)			
	Breastfeeding Nursing Quality Improvement and Breastfeeding Mobile Health Messaging Intervention	**Safe Sleep Nursing Quality Improvement and Breastfeeding Mobile Health Messaging Intervention**	**Breastfeeding Nursing Quality Improvement and Safe Sleep Mobile Health Messaging Intervention**	**Safe Sleep Nursing Quality Improvement and Safe Sleep Mobile Health Messaging Intervention**
Unknown	108 (35.4)	114 (37.6)	68 (20.3)	118 (36.9)
Infant age at maternal follow-up survey, wk				
8–11	205 (67.2)	214 (70.6)	262 (78.2)	236 (73.8)
12–15	53 (17.4)	40 (13.2)	38 (11.3)	42 (13.1)
16–19	25 (8.2)	25 (8.3)	17 (5.1)	19 (5.9)
≥20	22 (7.2)	24 (7.9)	18 (5.4)	23 (7.2)

Abbreviation: GED, general equivalency diploma.

[a]Included American Indian/Alaska Native, Asian, Native Hawaiian/Pacific Islander, and multiracial/multiethnic.

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

Table 2

Safe Sleep and Feeding Practices Prior to Study Enrollment From the SAFE Study[a]

	No./Total (%)				
	Breastfeeding Nursing Quality Improvement and Breastfeeding Mobile Health Messaging Intervention	**Safe Sleep Nursing Quality Improvement and Breastfeeding Mobile Health Messaging Intervention**	**Breastfeeding Nursing Quality Improvement and Safe Sleep Mobile Health Messaging Intervention**	**Safe Sleep Nursing Quality Improvement and Safe Sleep Mobile Health Messaging Intervention**	**Total**
Supine sleep position	299/417 (71.7)	272/387 (70.3)	315/421 (74.8)	278/379 (73.4)	1164/1604 (72.6)
Room sharing without bed sharing	266/405 (65.7)	260/370 (70.3)	265/407 (65.1)	242/366 (66.1)	1033/1548 (66.7)
Any pacifier use	271/410 (66.1)	250/375 (66.7)	284/415 (68.4)	244/367 (66.5)	1049/1567 (66.9)
Any breastfeeding	262/413 (63.4)	221/386 (57.3)	244/419 (58.2)	212/378 (56.1)	939/1596 (58.8)
Exclusively breastfeeding	143/413 (34.6)	93/386 (24.1)	119/419 (28.4)	90/378 (23.8)	445/1596 (27.9)

[a]Data were collected during the Study of Attitudes and Factors Effecting Infant Care Practices (SAFE) study (2011–2014),[17] which was an observational study with no interventions. These data are limited to English speakers to be most comparable with the inclusion criteria for this study. Infants were aged 60 to 227 days when SAFE survey given to mothers. Soft bedding data were not available in the SAFE study. Sample size for individual questions varied due to missing data.

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

Table 3

Main and Interaction Effects of the Nursing Quality Improvement (NQI) and Mobile Health (mHealth) Interventions for Breastfeeding (BF) and Safe Sleep (SS)

	At Infant Age =60 d, No./Total (%)				Adjusted Risk for NQI Only, %[a]				Adjusted Risk for mHealth Only, %					Adjusted Risk for mHealth and NQI, %			
During Past 2 wk	BF NQI and mHealth	SS NQI and BF mHealth	BF NQI and SS mHealth	SS NQI and mHealth	Intervention	Control	Difference (95% CI)[b]	*P* Value[c]	Intervention	Control	Difference (95% CI)[b]	*P* Value[c]	*P* for Interaction[d]	Intervention	Control	Difference (95% CI)[b]	*P* Value[c]
Supine Sleep Position																	
Main effect	243/303 (80.2)	230/301 (76.4)	294/333 (88.3)	294/318 (92.5)	82.8	80.2	2.6 (−3.1 to 7.2)	.34	89.1	80.2	8.9 (5.3 to 11.7)	<.001					
Interaction					78.5	80.2	−1.7 (−10.1 to 4.7)	.74	85.2	80.2	5.0 (1.5 to 8.0)	.02	.01	89.6	80.2	9.4 (2.9 to 13.6)	.03
Room Sharing Without Bed Sharing																	
Main effect	205/291 (70.4)	218/293 (74.4)	262/328 (79.9)	269/313 (85.9)	74.1	70.4	3.7 (−0.4 to 7.2)	.22	82.8	70.4	12.4 (9.3 to 15.1)	<.001	.08				
No Soft Bedding Use[e]																	
Main effect	202/299 (67.6)	204/300 (68.0)	259/333 (77.8)	262/320 (81.9)	70.9	67.6	3.3 (−1.4 to 7.8)	.33	79.4	67.6	11.8 (8.1 to 15.2)	<.001	.29				
Any Pacifier Use[f]																	
Main effect	174/291 (59.8)	193/290 (66.6)	226/326 (69.3)	240/315 (76.2)	66.6	59.8	6.8 (1.4 to 11.9)	.07	68.5	59.8	8.7 (3.9 to 13.1)	<.001	.54				

[a] Adjusted for infant age at survey and sex, and mother's age, parity, race, educational level, marital status, household income, and SAFE outcome rate (by hospital; rates from SAFE study[17] not available for soft bedding use).

[b] Calculated from odds ratios and 95% CIs from logistic regression.

[c] Calculated from logistic regression adjusted for multiple outcome measures using the Hochberg method.

[d] Calculated from test for multiplicative interaction in the logistic regression model.

[e] Defined as nonuse of a heavy blanket or quilt or comforter, rug, stuffed toys, cushion or pillow, adult sleeping bag, cloth diaper or towel, pad on top of sheet, bumpers, and sleep positioners or wedges.

[f] Includes responses of "usually use pacifier" and "sometimes use pacifier."