



Messaging Affects the Behavior of African American Parents with Regards to Soft Bedding in the Infant Sleep Environment: A Randomized Controlled Trial

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Objective To evaluate the impact of specific health messages on the decisions of African American parents regarding soft bedding use, specifically related to the high degree of self-efficacy that African American parents have with regards to preventing infant suffocation vs low self-efficacy with regards to sudden infant death syndrome (SIDS) risk reduction.

Study design We conducted a randomized, controlled clinical trial of African American mothers of infants. The control group received standard messaging emphasizing safe sleep practices recommended by the American Academy of Pediatrics for the purposes of SIDS risk reduction. The intervention group received enhanced messaging emphasizing safe sleep practices for both SIDS risk reduction and suffocation prevention. Participants completed interviews at 2-3 weeks, 2-3 months, and 5-6 months after the infant's birth.

Results Of 1194 mothers enrolled, 637 completed all interviews. The use of soft bedding both in the past week and last night declined with age ($P < .001$). Infants in the enhanced group had a lower rate of use of soft bedding in the past week ($P = .006$) and last night ($P = .013$). Mothers who received the enhanced message were more likely to state that they avoided soft bedding to protect their infant from suffocation.

Conclusions African American mothers who receive an enhanced message about SIDS risk reduction and suffocation prevention are less likely to use soft bedding in their infant's sleep environment. (*J Pediatr* 2016;175:79-85).

Trial registration ClinicalTrials.gov: NCT01361880.

Sudden infant death syndrome (SIDS) and other sleep-related deaths, such as accidental suffocation and strangulation in bed and ill-defined causes of death, account for >3500 US deaths annually.¹ African American infants are affected disproportionately.² Soft bedding, including pillows and quilts, is hazardous when placed under the infant³⁻¹⁰ or loose in the infant's sleep area.^{5,7,10-15} It increases the risk of SIDS up to 5-fold in general and 21-fold when the infant is placed prone with soft bedding.^{8,10} An object (eg, blanket, pillow, or bumper pad) in the infant sleep environment is the factor most commonly associated with sudden and unexpected deaths in infants ≥ 4 months.¹⁶ The American Academy of Pediatrics (AAP) recommends avoidance of soft bedding and soft sleep surfaces¹⁷; however, 55% of families report using soft bedding with their infants, with African American families almost 20% more likely to report their use.¹⁸ Qualitative data suggest that parents primarily use soft bedding because of concerns about the infant's comfort and safety.¹⁹ Many African Americans also believe that SIDS is the result of "fate" or "God's will," and that there is no plausible connection between sleep behaviors and SIDS.²⁰ These beliefs may result in low parental self-efficacy (ie, parents are unlikely to believe that their actions can make a difference in whether SIDS occurs)²¹ and affect rates of safe sleep practices. In contrast, African American parents appear to have a high degree of self-efficacy with regards to preventing infant suffocation.^{20,21}

We therefore conducted a randomized controlled trial to evaluate the impact of specific health messages on African American parental decisions regarding the use of soft bedding and soft surfaces. We hypothesized that families receiving an enhanced message that included information about suffocation prevention would be less likely to use soft bedding and soft surfaces than families who only received the standard message about SIDS risk reduction.

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AAP American Academy of Pediatrics
SIDS Sudden infant death syndrome
WIC Special Supplemental Nutritional Program for Women, Infants, and Children

Methods

We conducted a randomized, controlled clinical trial of English-speaking, self-identified African American women who were admitted for delivery of an infant ([ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT01361880): NCT01361880). This was part of a larger study that examined baseline maternal self-efficacy,²¹ followed by a randomized controlled trial to determine the impact of specific health messages on infant care practices and maternal self-efficacy. Participants were excluded if the infant had congenital anomalies (eg, myelomeningocele) precluding use of supine positioning, was <36 weeks' estimated gestational age at birth, was hospitalized for >1 week, or had ongoing medical problems requiring subspecialty care.

All mothers were enrolled before hospital discharge. Because of concerns about study contamination if mothers sharing a hospital room were randomized to different groups, participants were randomized by hospital room number into 2 groups. The control group received standard messaging, which emphasized AAP-recommended safe sleep practices for the purposes of SIDS risk reduction only. The intervention group received enhanced messaging, which emphasized the need to follow AAP-recommended safe sleep practices for both SIDS risk reduction and suffocation prevention.

After written informed consent was obtained, a brief survey was completed. Questions were asked about baseline maternal self-efficacy with regards to SIDS and suffocation prevention, baseline knowledge of and attitudes towards safe sleep recommendations, current intent with regards to safe sleep recommendations, as well as demographics, including mother's age and education, marital status, infant sex, and eligibility for Special Supplemental Nutritional Program for Women, Infants, and Children (WIC) and Medicaid insurance. The latter 2 served as proxies for family income. We also asked about presence of other adults in the home, including the other parent and any senior caregivers (such as a grandmother) in the home, because these variables have been shown to impact risk for SIDS or sleep-related death^{22,23} or parental behaviors with regards to the infant sleep environment.^{24,25}

Mothers then received written and verbal safe sleep information from the research staff with the group-specific terminology. Mothers in the standard group were provided with the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development Safe Sleep for your Baby brochure, whereas mothers in the enhanced group received a brochure discussing prevention of suffocation, strangulation, and SIDS ([Appendix](#); available at www.jpeds.com). Although this intervention was directed at mothers, family members who were present at the time of enrollment also were exposed to the intervention; however, we did not analyze the impact of having other caregivers present.

Research staff not involved in participant recruitment and who were blinded to the study group assignments contacted participants for follow-up telephone interviews at 3 separate

times: (1) within 2-3 weeks of the infant's birth (to determine effectiveness of the education received); (2) when the infant was 2-3 months old (to ascertain potential changes in practices during the period when the infant is at greatest risk for SIDS and sleep-related deaths^{2,26-28} and when the parent is most likely to change sleep practices with regards to the infant)^{22,29,30}; and (3) when the infant was 5-6 months old (to assess continued parental adherence with safe sleep recommendations as the infant becomes more mobile and the risk for sleep-related deaths begins to decline).³¹ All survey questions were validated by parent groups and have been used in previous studies.^{32,33}

At each follow-up interview, mothers were asked to complete a brief survey about knowledge of and attitudes towards safe sleep recommendations, degree of self-efficacy with regard to preventing sleep-related death, and current infant care practices. Self-efficacy was determined by the mother's response to the question: "How confident are you that your actions can keep your baby safe from SIDS (suffocation)?" Mothers also were asked about specific measures that they took to protect their infants from SIDS or suffocation. Mothers were informed at recruitment about the incentives for participation; each family received a developmentally appropriate toy or book for the infant at the time of recruitment, \$10 gift card at the end of the first and second follow-up interviews, and \$50 gift card at the end of the final interview. This study was approved by the institutional review boards of MedStar Washington Hospital Center and Children's National Medical Center.

The primary outcome variable was the use of soft bedding and soft sleep surfaces. We asked about use of soft bedding in the past week and the night before each interview. Asking about both usual (in the past week) and last night practices is a well-established norm in SIDS research, because this has been found to encourage honest disclosure of actual sleep practices when the practice is not consistent with safe sleep recommendations.^{10,34} Responses about usual and last night practices were analyzed separately. Baseline characteristics between groups were expressed as means and frequencies to evaluate expected similarities and any differences that would need to be taken into account in multiple variable analyses. Repeated measures analyses of covariance were conducted to estimate the time-averaged and time-specific change in knowledge, attitudes, and practice in the 2 groups, controlling for baseline levels of each outcome. Longitudinal logistic regression models were conducted to assess the post-intervention groupwise differences in the change in soft bedding use over time measured across 3 time points. Subsequent models also controlled for socioeconomic status (using WIC and educational status), which has been associated with soft bedding use in previous studies.¹⁸ Measuring time-averaged groupwise differences allowed for full use of the repeated assessments to enhance study power and precision of estimates. Variance estimates were adjusted to account for correlation among measurements on the same person.

Our power calculation was based on current prevalence estimates for nonuse of soft bedding of 65%.¹⁸ We further

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