Generations in Families Talking Safe Sleep (GIFTSS): Randomized Controlled Trial of a Safe Sleep Educational Intervention for Young Pregnant Women

Mary E Aitken[1**], Beverly K Miller[2,3,4], Shasha Bai[5], Samantha H Mullins[2,3,4], S. Walton-Buford[2,3,4], Leanne Whiteside-Mansell[6]

[1]Department of Pediatrics, McGovern Medical School at UTHealth, Houston Texas 77030
[2]Center for Applied Research and Evaluation, Department of Pediatrics, University of Arkansas for Medical Sciences, Little Rock, AR, 72202, USA.
[3]Arkansas Children's Research Institute, Little Rock, AR, 72202, USA.
[4]Injury Prevention Center, Arkansas Children's Hospital, Little Rock, AR, 72202, USA.
[5]Center for Biostatistics, Department of Biomedical Informatics, The Ohio State University Wexner Medical Center, Columbus, Ohio 43210, USA. and Biostatistics Resources at Nationwide Children's Hospital, Columbus, Ohio 43205, USA.
[6]Department of Family and Preventive Medicine, University of Arkansas for Medical Sciences, Little Rock, AR, 72202, USA.

ABSTRACT

Sudden Infant Death Syndrome (SIDS) and suffocation account for more than half of all Sudden Unexpected Infant Deaths (SUID) and are leading causes of post-neonatal deaths. Risk reduction strategies, including supine sleep position and safe sleep environment, are critical for prevention. Teen mothers, especially those in rural, poor, southern states, are at higher risk due to low compliance with recommendations. We will conduct a randomized trial to test a tailored educational intervention on the sleep-related safety behaviors of teen mothers. In one study arm, the intervention will include not only the teen mothers but also senior caregivers (SCGs) to assess the influence they have in the decision-making of young mothers regarding infant health and safety. Our hypotheses are H1) teen mothers exposed to intervention will be more likely than controls to adopt safe sleep practices, and H2) teen mothers will be more likely to use those practices when they and their mothers or other significant female senior caregivers also participate in safe sleep education. Better understanding of the mediating role of female SCGs in the health decision of young mothers for their children may have implications for interventions addressing important health problems.

Keywords: safe sleep, teen mothers, injury prevention.

1. Background

The infant mortality rate in the United States (US) is 6.14 per 1000–a rate higher than most other developed countries (MacDorman & Mathews, 2010; Murphy, Xu, & Kochanek, 2013). Sudden Infant Death Syndrome (SIDS) and suffocation account for more than 60% of all Sudden Unexpected Infant Deaths (SUID) and represent a leading cause of post neonatal

* Correspondence to Mary E Aitken, Department of Pediatrics, McGovern Medical School at UT Health, Houston Texas 77030. Email: Mary.E.Aitken@uth.tmc.edu

infant death (death in an infant age 28 days to 1 year) in the US (Center for Disease Control and Prevention, 2019, September; 2020, March). The importance of SIDS and SUID is reflected by strategic planning efforts conducted by the NICHD over the past two decades.

The pathophysiology of SIDS is poorly understood and is currently framed as multiple risk factors. The Triple Risk model represents SIDS as the result of an intersection between a period of critical newborn development during the first months of life, underlying and often invisible vulnerability in the infant, and external stressors and triggers (including sleep position and environment) (Filiano & Kinney, 1994). Infants who succumb to SIDS are often unable to respond and protect themselves to challenges in the environment, such as nonsupine sleep position and an unfavorable sleep environment. Proposed underlying mechanisms for infant vulnerability to SIDS include genetically determined developmental issues, delays in maturity of arousal mechanisms, or abnormalities in autonomic, neurologic, or cardiac function (Moon, 2011; Paterson, 2013; Stéphan-Blanchard et al., 2013).

Given the uncertainty about *intrinsic* factors that may identify infants at increased risk for SIDS, current risk reduction measures focus on *extrinsic* variables caregivers can control. The American Academy of Pediatrics (AAP) first released a policy recommendation that infants be placed supine to sleep in 1992, followed by a national "Back to Sleep" (BTS) campaign (American Academy of Pediatrics, 1996; J. Kattwinkel, Brooks, & Myerberg, 1992; John Kattwinkel et al., 2005; Willinger, 1995; Willinger, Hoffman, & Hartford, 1994). The BTS campaign dramatically reduced the SIDS rate over a ten-year period (John Kattwinkel et al., 2005) but that reduction has since plateaued (Moon, 2011). Patterns of intrinsic and extrinsic risk factors have changed during the two decades since BTS was initiated, with increasing variability in risk factors (Trachtenberg, Haas, Kinney, Stanley, & Krous, 2012). It is unusual for an infant to die of SIDS without known risk factors. Less than 1% of SIDS infants in one study had no risk factors, *reinforcing the need to educate families broadly on multiple strategies to reduce SIDS risk* (Ostfeld, Esposito, Perl, & Hegyi, 2010). In addition, many risks associated with SIDS are linked to other SUIDs occurring during sleep including suffocation and entrapment. Thus, in 2011 and again in 2016, the AAP expanded its 2005 Policy Statement to encompass a variety of safe sleep practices that can reduce the risk for all types of sleep-related infant death. Level A recommendations discouraged bed sharing and smoking, and endorsed use of the supine position and appropriate surfaces for all sleep, breastfeeding, and adequate prenatal care (Moon, 2011; Moon, Darnall, Feldman-Winter, Goodstein, & Hauck, 2016).

1.1 Contributing risks for SIDS and other sleep-related deaths

SIDS among High Risk Populations: Young, poor, unmarried, and minority women are at elevated risk for SIDS. Infants born to mothers aged 15 – 19 years are at increased risk for infant mortality in general, with a rate of 9.59 per 1000 in 2008 (MacDorman & Mathews, 2012). Infants of unmarried women exhibit rates of infant mortality 75% higher than their married counterparts (8.87 and 5.06, respectively (MacDorman & Mathews, 2012). Lack of prenatal care, low socioeconomic status, and black race further increase the risk of infant mortality (Moon, Oden, & Grady, 2004). SIDS-related risk factors include failure to complete high school, smoking, and inadequate prenatal care (Kitsantas, 2008; Kitsantas & Gaffney, 2010; Moon et al., 2004). A higher prevalence of low birth weight infants and disproportionate poverty may also be contributing factors in increased SIDS risks among African Americans (Malloy & Hoffman, 1995; Malloy, Hoffman, & Peterson, 1992) and to teens (Balayla, Azoulay, & Abenhaim, 2011; Balayla, Azoulay, Assayag, Benjamin, & Abenhaim, 2011; Partridge, Balayla, Holcroft, & Abenhaim, 2012; Siva, 2010).

Teen mother adherence to safe sleep recommendations: The US has teen birth rates higher than many other industrialized nations, with 367,752 infants born to mothers aged 15-19 in 2010 (Center for Disease Control and Prevention, 2019, March). The teen birth rate is around nine times higher than in other developed countries. Birth rates for African Americans are nearly double that of white teens, and Hispanic teens are nearly three times more likely than teens of other races to become mothers before adulthood. The highest teen birth rates can be found among Southern states (Centers for Disease Control and Prevention, 2011).

National surveys including the National Infant Sleep Position Study (National Institute of Child Health and Human Development, 2019) and the Pregnancy Risk Assessment Monitoring System (Shulman, D'Angelo, Harrison, Smith, & Warner, 2018) show that teen mothers are less likely to adhere to recommendations for supine sleeping, bed surfacing (including bed sharing on an adult bed) and other environmental precautions (Bombard et al., 2018; Colson, Geller, Heeren, & Corwin, 2017; Hirai et al., 2019; Phares et al., 2004; Shapiro-Mendoza et al., 2015; Willinger, Ko, Hoffman, Kessler, & Corwin, 2003). Data for US and Arkansas (AR), the site for this study, demonstrate substantial risk. Specifically, teens place their infants in the prone position rather than back more often than mothers >19 years (National Institute of Child Health and Human Development, 2019). When asked whether they usually place their baby on its back to sleep, fewer US teen mothers (50%) responded in the affirmative, compared to 57% of mothers >20 and 61% of mothers >30 years(Colson et al., 2009; Shulman et al., 2018). AR teens report even greater risks than those nationally. Only 38.2% of AR teen mothers participating in a home visitation program always placed their infants supine for sleep(Aitken, Rose, Mullins, & Miller, 2012).

Nationally, teen mothers are less likely to bed their infants on an appropriate sleep surface (e.g. crib, portable crib, or play yard) than older mothers (76% vs. 86%, respectively). More than two thirds (69%) of teen mothers reported placing the infant to sleep on an adult bed/mattress during the past two weeks, while just 47% of mothers >19 years old reported doing so (Shulman, Gilbert, Msphbrenda, & Lansky, 2006). Bed sharing is more frequent among African American mothers <18 years and among families living in the South (Willinger et al., 2003). Among a sample (N=76) of AR teens, less than half (46.1%) reported regular use of an appropriate sleep surface. The most common sleep surface reported – an adult bed – was used by 34.3% of teens interviewed, with 75.3% of teen mothers reporting bed sharing at least sometimes. One-in-three also report using a pillow in the infant's crib, and soft items observed during home visits included stuffed animals (32.1%), heavy blankets (23.1%), and bumper pads (19.2%) (Aitken et al., 2012).

Additional risk factors for sleep-related infant deaths that are elevated among teen mothers include smoke exposure, lack of prenatal care, and not breastfeeding. AR pregnant teens ages 14 – 19 demonstrated smoking rates between 15.6% (Carpenter et al., 2013) and 25% (Schultz et al., 2012; UAMS Dept Psychiatry, 2011). Nearly one-third (28.1%) of teen mothers currently smoke. Infants born to AR teens are 2.5 times more likely to live in a home where someone smokes when compared to infants born to adult mothers(Shulman et al., 2018). From 2002–2009, 76% of AR women sought prenatal care, compared to 83.9% nationally, and, when compared to older mothers, teens are less than half as likely to receive prenatal care as early as desired (Natural Wonders Partnership Council, 2011; Shulman et al., 2018). Similarly, women initiate breastfeeding less frequently in AR (69% vs. 77% nationally) and only about 53% of AR teen mothers breastfeed (Natural Wonders Partnership Council, 2011; Shulman et al., 2018). In summary, teen mothers--particularly those in AR and similar poor areas--demonstrate many high-risk behaviors that contribute to their infants' risk for SIDS and other causes of infant mortality. Interventions tailored specifically to the high-risk teen mother are clearly indicated.

Research has demonstrated that mothers' decisions regarding infant sleep position and environment are influenced in part by the infants' grandmothers (Moon, 2011; Moon et al., 2004). Despite the documented influence of grandmothers on other health behaviors practiced by infants' parents, (Fuller-Thomson & Minkler, 2001) beliefs and practices of grandmothers or other senior caregivers (SCGs) related to infant sleep position and environment have been the subject of very few studies. To our knowledge, previous studies have not examined the effect of using the SCG as a change agent with a focus on young mothers and sleep safety.

Given the complexity and variability of teen-SCG relationships, we will include an examination of inter- and intra-personal factors that are key control variables or may mediate the uptake of safe sleep recommendations. The *Generations in Families Talking Safe Sleep (GIFTSS)* intervention has potential to empower SCGs to positively influence a teen mother's adoption of safe sleep recommendations.

The long-term goal of this study is to contribute to reduction in post-neonatal death rates by reducing SIDS and other sleep-related deaths in high-risk populations. The objective of the study is to develop, implement, and test the effectiveness of a tailored educational intervention for teen mothers and SCGs that will effectively change knowledge, attitudes, self-efficacy, intent, and behavior toward compliance with current safe sleep recommendations, specifically supine sleeping and safe sleep environments. The central hypotheses are as follows:

H_1) Teen mothers exposed to an intensive educational intervention will be more likely than controls to appropriately adopt safe sleep practices (supine position and in an appropriate sleep environment) with their infants, and

H_2) Because teen mothers will model their choice of infant sleep position and environment on behavior of their mothers or other significant female senior caregivers, they will be more likely to use those safe sleep practices when they and their mothers or other significant female senior caregivers also participate in tailored education about safe infant sleep.

The overall project goal will be met through the following specific aims:

1) to refine the safety baby shower program to include a novel infant safe sleep intervention tailored for pregnant teens and their mothers or other identified significant female SCGs, and
2) to conduct a blinded randomized controlled trial to determine if the educational intervention both with and without SCGs is associated with an increase both knowledge of appropriate safe sleep behaviors and in observed supine infant sleep positioning and appropriate sleep environment among teen mothers.

Grounded in the Theory of Reasoned Action, the intervention incorporates recognition that health decision-making is a based on a complex interplay of knowledge, attitudes, and beliefs, both personal; and normative, related to intent to change behavior and action itself (Ajzen & Fishbein, 1980). The intervention is also supported by the Health Belief Model to explain the modifying factors that increase compliance with safe sleep recommendations. This conceptual construct addresses the social learning, self-efficacy, and locus of control influences that can mediate or predict the uptake of desired behavior (Rosenstock, Strecher, & Becker, 1988).

2. Methods/Design

2.1 Ethics section

See Table 1 for the World Health Organization Trial Registration Data Set. The study was approved and monitored by the University of Arkansas for Medical Sciences (UAMS) Institutional Review Board. The protocol (Number**:** 203247) received an expedited review. The IRB approved waiver of documentation of consent for this study; however, a

standardized informed consent process was used during participant recruitment and enrollment. The Institutional Review Board approved this study on 09/24/2014, based on Title 45 CFR 46.110, using expedited review procedures under category 5. The IRB determined the risk for adults who enter this study to be minimal and the risk for children who enter this study to be Peds 1.

Table 1. World Health Organization trial registration data set.

Data category	Information[32]
Primary registry and trial identifying number	NIH US National Library of Medicine, NCT03186469
Date of registration in primary registry	Registered 14 June 2017
Secondary identifying numbers	NA
Source(s) of monetary or material support	Grant R01HD076702 through the Eunice Kennedy Shriver National Institute of Child Health and Human Development
Primary sponsor	Grant R01HD076702 through the Eunice Kennedy Shriver National Institute of Child Health and Human Development
Secondary sponsor(s)	Translational Research Institute (TRI), grant U54TR001629 through the National Center for Advancing Translational Sciences of the National Institutes of Health (NIH)
Contact for public queries	*SE*, MD, MPH [phone number] [email address]
Contact for scientific queries	*MEA,* Department of Pediatrics, McGovern Medical School at UTHealth, Houston Texas 77030
Public title	Generations in Families Talking Safe Sleep (GIFTSS): Randomized controlled trial of a safe sleep educational intervention for young pregnant women
Scientific title	NA
Countries of recruitment	United States of America
Health condition(s) or problem(s) studied	Sudden Infant Death Syndrome (SIDS), Sudden Unexpected Infant Deaths (SUID)
Intervention(s)	Safety Baby Shower (SBS) educational intervention. Enrolment for all three arms of the study will be by dyads consisting of a pregnant teen (TM) and an adult female identified by the teen as a support person (SP).

Data category	Information[32]
Key inclusion and exclusion criteria	Inclusion Criteria Female teens age 13-19, in 2nd or 3rd trimester (13-28 weeks) of pregnancy First child for teen Living in one of five target counties of central Arkansas Teen-identified senior support person age 30 or older Exclusion Criteria Non-English speaking teen mothers or support person Lack of support person willing to participate
Study type	Education Intervention Allocation: randomized Intervention model: parallel assignment Masking: double blind (subject, investigator, outcomes assessor) Primary purpose: prevention
Date of first enrolment	January 2016
Target sample size	400
Recruitment status	Recruiting
Primary outcome(s)	Safe vs. unsafe sleep- based on the observed sleep environment and maternal report of infant sleep position
Key secondary outcomes	Knowledge related to injury/SIDS, SIDS related attitudes, beliefs, and intentions

2.2 Protocol/trial design

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Randomization will be conducted by an electronic assignment through a secure web application, Research Electronic Data Capture (REDCap) (Harris et al., 2019) that is brokered by the UAMS domain login. The data will be collected using a username and password protected iPad and the data will be secured in REDCap app that is also password protected. Access to data will be limited to study staff and all identifiers will be removed once data collection and analysis for all study subjects has been completed. All study staff have completed human subject protection training. Data collection staff are blinded to randomization.

2.3 Study arms

Enrollment for all three arms of the study will be by dyads consisting of a pregnant teen (TM) and an adult female identified by the teen as a support person (SP). We expect the SP will typically be the TM's mother, grandmother, aunt, or other female adult seen as a support to the teen, but she may be anyone the TM chooses who fits the eligibility requirements of the

SP. After completion of baseline assessment, a computer will randomize the dyads into one of three groups, two intervention and one control:

Group1: TMs only will participate in the intervention

Group 2: TMs and SPs will participate in the intervention

Group 3: Control, Standard of care-standard information packet with no intervention.

2.4 Recruitment

TM or SP will be recruited via face-to-face interaction, word of mouth, study flyer distribution, social and mass media and through community organizations and "community connectors", lay people employed by a community organization who live in the target communities and know the key stakeholders. Community connectors will complete CITI human subject certification and HIPAA certification before participating as recruiters for the study. Community organizations may include, but are not limited to: WIC offices, pediatrician and obstetrician offices, ACH nutrition center, pregnancy resource centers, public/private schools and other groups who provide services for or have contact with pregnant teens. Social media may include Twitter, Facebook, text messages and other social media outlets. Mass media may include TV, radio, newspaper or local magazines. Project staff and/or community connectors will meet with community organizations to provide materials and explain the study. Recruiting materials will be provided to these key stakeholders in order to make potential study participants aware of the research study. Community groups, who request, will be provided a consent-to-contact form to provide to interested parties.

2.5 Inclusion exclusion criteria

Up to 400 pregnant teens, ages 13 to 19, in the 2nd or 3rd trimester of pregnancy and their female support person, age 30 or older, will be enrolled in the study. Both TM and SP must meet inclusion criteria to be enrolled.

Inclusion Criteria

- Female teens age 13-19, in 2^{nd} or 3^{rd} trimester (13-28 weeks) of pregnancy
- First child for teen
- Living in one of five target counties of central Arkansas
- Teen-identified senior support person age 30 or older

Exclusion Criteria

- Non-English speaking teen mothers or support person
- Lack of support person willing to participate

Experienced study staff will be responsible for subject screening and enrollment. If one member of the dyad is eligible and interested in participating in the study, as part of the screening process staff will ask for consent-to-contact the other person in the dyad. For consent-to-contact, study staff will collect name and contact information for the person (TM or SP) who needs to be contacted in regards to participating in the study. Study staff will wait a minimum of 24 hours before attempting to complete contact of the remaining dyad member unless given permission to contact the remaining dyad member sooner. After the minimum waiting period, study staff will make 3-5 attempts to contact the remaining dyad member to explain the study and complete screening. If the other dyad member cannot be reached, study staff will re-contact original dyad member to determine other appropriate means of contact. A teen may change her dyad support person (SP) before attendance at the interest session as long as there is enough time for the new SP to be screened before the interest session. A teen may only change her SP two times (for a total of 3 potential SPs).

The consent process includes a provision to provide participants with a written information sheet during screening. It includes an invitation to attend the interest session. At the interest session, the study will be explained in depth with time for questions. Participants will then be given an opportunity to verbally agree to participate in the study and stay for baseline completion or to opt out of the study. Every invitation for study activities includes a reminder that the research is voluntary. Additionally, participants have the option to self-withdrawal by not showing up for study activities. After three opportunities to participate for each study activity, failure to attend an activity will be considered withdrawal from the study and participants will no longer be contacted for additional study activities.

If, at any time during the study, we are unable to reach study participants at the phone number provided, we will send them a letter asking them to contact study staff with new contact information.

2.6 Intervention methods

All activities targeting Group 2 (TMs and SPs) will include intervention activities to the dyad. Before all events, the TM (or the TM and SP) will received reminder calls, texts, or emails prior to the interest session, from either study staff or community connectors, and if needed will be rescheduled up to two times. For Group 2, if both TM and SP do not participate, they will be dropped from the study. See Figure 1 for schedule of enrolment, interventions, and assessments.

Figure 1. GIFTSS schedule of enrolment, interventions, and assessments.

Enrollment	Baseline	Mid Point	Home Visit
Recruitment	X		
Screening w/informed consent process	X		
Interest session w/informed consent process	X		
Assignment to intervention arm	X		
Assessments (completed by all participants)	Baseline	Mid Point ~ 8 weeks pre birth	Home Visit >4 weeks post birth
Safe Sleep Knowledge Attitude Belief	X	X	X
Child Development Knowledge	X		X
Family Assessment Device	X		X
Family Cohesion	X		X
Generalize Anxiety Disorder	X		X
Depression	X		X
Alcohol and Smoking	X		X
Covariates (demographics, housing instability, parenting skills)	X		X
Car seat check			X
Behavioral observation			X
Behavioral interview			X
Activities/Intervention	Dyad	Teen Only	Control

Intervention- Safety Baby Shower (8 to 10 weeks prior delivery)	X	X	
Car Seat Education	X	X	X
Educational Material Distribution	X	X	X

2.7 Interest session

If both TM and SP agree to participate, they will be invited to an interest session. An invitation with location, date, time and an information sheet will be emailed and/or post mailed to both TM and SP. The interest session is an opportunity for the dyad to learn about the study and ask questions. The interest session will last no more than 30 minutes and everyone who attends the interest session will receive a gift valued around $10. After the interest session, those who express interest in participating in the study will be asked to complete baseline assessments. An interest session may be conducted with a group of potential subjects or may be conducted one-on-one with a teen and her support person. Both TM and SP must receive the information from the interest session, complete the enrollment, and complete the baseline assessment before moving on with study activities.

2.8 Baseline assessment

The baseline assessment will be conducted on IPads during the last trimester of pregnancy. In case of technology failure or subject preference, paper surveys will be available. Subjects may also choose to have study staff conduct the survey as an interview. The assessment will include socio-demographic information, child development, and safety knowledge. Additional questions will assess important co-factors that may mediate the uptake of educational intervention including family structure and demographics, family function and cohesion, adult attachment, maternal and family mental and physical health, infant temperament, and stressors. The assessment will take about 1 hour and participants will receive a $25 gift card.

After completion of baseline assessment, a REDCap will randomize the dyads into one of three groups, two intervention and one control. The intervention is a Safety Baby Shower (SBS) format, a standardized method of delivering information about effective strategies to keep babies safe.

2.9 Safety baby shower

After completion of baseline assessment but before the birth of the baby, Groups 1 and 2 will be invited to a Safety Baby Shower (SBS). A SBS is a two-hour event that educates participants on safe sleep for infants, abusive head trauma, and car seat safety. The shower will be held at a convenient time and community venue for the study participants and will include up to 24 participants. The event is organized like a baby shower with themed party decorations, food, hands-on activities, and safety products as shower gifts. Failure to attend a SBS by participants as per randomization will result in the dyad being dropped from the study.

2.10 Car seat fitting

All dyads, regardless of randomization, will be asked to the car seat fitting before delivery. Dyads will complete a survey of knowledge, attitudes and beliefs related to infant safety. The survey is expected to take 15 minutes to complete. Following the surveys, dyads will be educated by a certified child passenger safety technician on the appropriately use and install an infant car seat which can take up to 1 hour. A standardized infant car seat checkup form

will document the education. TM will be given birth announcements to send to study staff to indicate the day baby was born**.**

2.11 Home visit

Starting 2 weeks post due date, study staff will contact teens to schedule home visits regardless of whether or not the birth announcement has been received. Home visits will be rescheduled (up to 2 times) if a dyad member or the baby is not present. If no one from the dyad is at home at the time of the designated home visit, the study staff will leave a "missed you note" sealed in an envelope addressed to the participant to let the subject know a home visit was attempted.

The home visit will be conducted up to three months post birth for all three groups. During the 2-hour home visit, study staff will observe infant care activities and participants will complete surveys similar to those at baseline. The home visit will include a car seat check to review installment of the car seat, to correct any issues with car seat use, and retrain the TM if needed. At the home visit, TMs will get safety product incentives and SPs will get gift cards.

2.12 Data analysis

Multiple logistic regression will be used to estimate the likelihood of a positive primary outcome (i.e. infant environment is safe). Safe environment will be defined by ratings by reliable staff in home observation and TM interview. We will construct a dichotomous outcome variable (safe vs. unsafe sleep) based on the observed sleep environment and maternal report of infant sleep position. Analyses will examine SBS groups (1 and 2) compared to the control group (CG). Two degrees-of-freedom will be used to estimate this effect, one for each intervention group. Subsequently, the primary analysis will use a Bonferroni-corrected critical value of 0.025 to assess if either intervention group's likelihood for a positive outcome is statistically different from the CG while maintaining tight control for experiment-wide Type 1 error.

The primary analysis will be conducted according to the "Intention-to-treat" (ITT) principal, in which all participant data are analyzed according to the assigned intervention group irrespective of compliance and/or actual dissemination of the prescribed intervention (Ryan, Ryan, & Philip, 1998). Both "per-protocol" and "as treated" analyses will be conducted as a sensitivity analysis to ascertain the intervention effects. Multiple imputation will be used to account for any missing data, using all available data to best inform plausible values for the primary outcome based upon accepted robust methods (e.g. predictive mean matching and chained equation imputation both can impute binary data)(Chow & Liu, 2003; Horton & Kleinman, 2007; Jones et al., 2014; Ryan et al., 1998).

Additional explanatory variables (e.g.,. demographics, infant smoking exposure, adult attachment, family cohesion, maternal mental health, knowledge related to general parenting and injury/SIDS, attitudes, beliefs, and intentions) will be included in follow-up logistic regression models to examine mediation or moderation of the intervention. Variable selection will follow accepted best statistical practice, in which explanatory variables deemed scientifically important to the statistical inference are examined independent of the primary outcome to achieve a robust set of candidate predictors (e.g. principal component or statistical clustering). Additionally, explanatory variables will be examined for equality between treatment groups; any variables that significantly differ between groups will also be added to the model. Model development will then focus on model specification, investigating if explanatory variables should be modeled as additive or mediating (i.e. interaction) effects. Moreover, continuous variables may require variable transformation or the use of restricted

cubic splines to relax the strict linearity assumption between explanatory variable and outcome (Ryan et al., 1998). Model discrimination (i.e., determining how well the model distinguishes between the presence and absence of the outcome) will be estimated with the concordance statistic c, which is identical to the area under a receiver–operator characteristic curve in a logistic-regression setting (Ryan et al., 1998). Model calibration (i.e., determining agreement between outcome and prediction) will be visually assessed via a calibration plot in which a calibrated model is expected to follow a 45^{o} line (Harrell, 2001). Finally, for clustered outcomes that are measured on both dyad members (i.e. teen mom and senior caregiver) and are inherently correlated, a generalized linear mixed model will be used to estimate differences between groups accounting for the within dyad correlation. Study results will be disseminated to academic and lay audiences.

3. Discussion

The planned research builds upon a well-received educational program to include all AAP Level A SIDS reduction recommendations. The engaging format of the SBS will be specifically tailored to the teen's interests and needs. It will also include the persons that influence the decision making of the teen (often the infant's grandmother).

Improvement in sleep-related deaths of infants in high-risk populations will ultimately lower risk for leading causes of post-neonatal mortality and contribute to reduction in the unacceptably high infant mortality rates in the US nationally and among teen mothers. Further, better understanding of the mediating role of SCGs in the health decision making of young mothers may have implications for interventions addressing other important health problems affecting teen parents and their babies. Finally, the study has the potential to inform the field regarding an array of characteristics of at-risk teen mothers' environment and mental stat that may mediate or moderator interventions.

List of Abbreviations

American Academy of Pediatrics (AAP)
Arkansas (AR)
Back To Sleep" (BTS)
Control Group (CG)
Generations In Families Talking Safe Sleep (GIFTSS)
Intention-To-Treat (ITT)
Pregnant Teen (TM)
Research Electronic Data Capture (REDCap)
Safety Baby Shower (SBS)
Senior Caregivers (SCGS)
Sudden Infant Death Syndrome (SIDS)
Sudden Unexpected Infant Deaths (SUID)
Support Person (SP)
University of Arkansas for Medical Sciences (UAMS)

Declarations

Ethics approval and consent to participate: Ethics review and approval has been provided by the University of Arkansas for Medical Sciences Institutional Review Board. Although the Institutional Review Board approved waiver of documentation of consent for this study, we

used a standardized informed consent process during participant recruitment and enrollment for all participants regardless of age.

Availability of data and materials: The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests: The authors declare that they have no competing interests.

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Authors' contributions: All authors have read and approved the manuscript. Substantial contributions were made to the conception or design of the work (MA, BM, SM, LWM), or the acquisition (SWB), analysis or interpretation of data (MA, BM, SM, SB, LWM). All co-authors participated in drafting the work or revising it critically for important intellectual content, provided approval of the version submitted, and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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