BMC Pediatrics

STUDY PROTOCOL

Open Access

CuddleCard: Protocol for a randomized controlled trial evaluating the effect of providing financial support to low-income mothers of preterm infants on parental caregiving in the neonatal intensive care unit (NICU)

Margaret McConnell[1,2*], Alya Alsager[1,3], Plyce Fuchu[4], Shrivaths Sriprasad[4], Lindsey Simoncini[4,5], Mari-Lynn Drainoni[6,7,8], Erika G. Cordova-Ramos[7,9], Michelle-Marie Peña[10], Laura Madore[11], Nikita S. Kalluri[4], Michael Silverstein[12], Heather Schofield[13], Martha J. Farah[14], Günther Fink[15] and Margaret G. Parker[4]

Abstract

Background Preterm birth is a leading cause of childhood mortality and developmental disabilities, with persistent socioeconomic disparities in incidence and outcomes. Maternal presence during prolonged neonatal intensive care unit (NICU) hospitalization is critical for preterm infant health, enabling mothers to provide breast milk, directly breastfeed, and engage in skin-to-skin care—all of which promote infant physiological stability and neurodevelopment. Low-income mothers face significant barriers to visiting the NICU and participating in caregiving due to financial burdens and the psychological impact of financial stress. This randomized controlled trial aims to evaluate the effectiveness of financial transfers in promoting maternal caregiving behaviors that directly impact preterm infant health outcomes during NICU hospitalization.

Methods We will conduct a two-arm, single-blinded randomized controlled trial with 420 Medicaid-eligible mothers of infants born between 24 weeks 0 days to 34 weeks 1 day gestation across four Level 3 NICUs in Georgia and Massachusetts. Mothers in the intervention arm will receive standard of care enhanced with weekly financial transfers and will be informed that these funds are intended to help them spend more time with their infants in the NICU. All participants will be provided with a hospital-grade breast pump and educational materials on the benefits of breast milk and skin-to-skin care. Participants will complete surveys during their infant's hospitalization and following discharge, capturing outcomes related to maternal mental and physical health, caregiving behaviors, cognitive function, financial and socioeconomic factors, infant health and growth, and perceptions of NICU care quality. Primary outcomes are the provision of breast milk and engagement in skin-to-skin care. Secondary outcomes include infant

*Correspondence:
Margaret McConnell
mmcconne@hsph.harvard.edu
Full list of author information is available at the end of the article

growth and health outcomes, NICU visitation, financial and socioeconomic hardship, maternal physical and mental health measures, cognitive function, and perception of NICU care quality.

Discussion This study will provide evidence of the impact of financial transfers on maternal caregiving behaviors in the NICU, addressing critical gaps in our understanding of how financial stress affects low-income mothers. Findings may inform health policy, particularly regarding Medicaid coverage of non-medical services, and contribute to understanding how to address disparities in preterm infant care.

Trial registration The trial was prospectively registered with the American Economic Association Trial Registry, the primary registry for academic economists conducting policy trials, on 16 April 2024 (AEARCTR-0013256). It was also registered on ClinicalTrials.gov (NCT06362798) on 10 April 2024.

Keywords Preterm birth, Financial transfers, Randomized controlled trial, Breastfeeding, Skin-to-skin

Administrative information

Title	Protocol for a randomized controlled trial evaluating the effect of support for low-income mothers of preterm infants on parental caregiving in the neonatal intensive care unit (NICU)
Primary registry identifying number	Clinicaltrials.gov: NCT06362798
Date of registration in primary registry	10 April 2024
Secondary identifying number	AEA RCT Registry: AEARCTR-0013256
Protocol version	Protocol amendment number: 01 Revision chronology: November 16, 2024—Draft for first journal submission
Funding	Margaret McConnell and Margaret Parker received funding from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (1R01HD109293-01) and March of Dimes (6-23FY-0012). Michelle-Marie Peña was also supported by the Building Interdisciplinary Research Careers in Women's Health of the National Institutes of Health under Award Number K12HD085850. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. Erika Cordova-Ramos is supported by the Harold Amos Medical Faculty Development Program of the Robert Wood Johnson Foundation

Author details MM[1, 2], AA[1, 3], PF[4], SS[4], LS[4, 5], MD[6–8], ECR[9], MMP[10], LM[11], NSK[4], MS[12], HS[13], MF[14], GF[15], MP[4]
1 Department of Global Health and Population, Harvard T.H. Chan School of Public Health, Boston, MA, USA
[2]Abdul Latif Jameel Poverty Action Lab (J-PAL), Massachusetts Institute of Technology, Cambridge
[3] Department of Social and Behavioral Sciences, College of Public Health, Kuwait University, Kuwait City, Kuwait
[4] Department of Pediatrics, University of Massachusetts Chan Medical School, Worcester, MA, USA
[5] Frank H. Netter MD School of Medicine at Quinnipiac University, North Haven, CT, USA
[6] Section of Infectious Diseases, Department of Medicine, Boston University Chobanian and Avedisian School of Medicine, Boston, MA, USA
[7] Evans Center for Implementation and Improvement Sciences, Department of Medicine, Boston University Chobanian and Avedisian School of Medicine, Boston, MA, USA
[8] Department of Health Law Policy & Management, Boston University School of Public Health, Boston, MA, USA
[9] Department of Pediatrics, Boston Medical Center, Boston, MA, USA
[10] Division of Neonatology, Emory University School of Medicine and Children's Healthcare of Atlanta, Atlanta, GA, USA
[11] Department of Pediatrics, Baystate Medical Center, Springfield, MA, USA
[12] Brown University School of Public Health and Hassenfeld Child Health Innovation Institute, Providence, RI, USA
[13] Department of Medical Ethics and Health Policy, University of Pennsylvania, Philadelphia, PA, USA
[14] Center for Neuroscience & Society, Department of Psychology, University of Pennsylvania, Philadelphia, PA, USA
[15] Swiss Tropical and Public Health Institute and University of Basel, Basel, Switzerland

Name and contact information for the trial sponsor	Trial Sponsor: Harvard T.H. Chan School of Public Health Contact name: Margaret McConnell, PhD Address: 677 Huntington Avenue, Boston Massachusetts Telephone: (203)745–8321 Email: mmcconne@hsph.harvard.edu
Contact for public queries	Margaret McConnell mmcconne@hsph.harvard.edu
Contact for scientific queries	Margaret McConnell mmcconne@hsph.harvard.edu
Role of sponsor	The sponsor had no role in the design of the study, approval of the manuscript or decision to submit the manuscript for publication
Public title	Support to low-income mothers of preterm infants
Scientific title	CuddleCard: Protocol for a randomized controlled trial evaluating the effect of providing financial support to low-income mothers of preterm infants on parental caregiving in the neonatal intensive care unit (NICU)
Countries of recruitment	United States of America
Health condition(s) or problem(s) studied	Preterm birth; maternal caregiving behaviors
Intervention(s)	Intervention: Participants in the intervention group will receive weekly financial transfers of $160, deposited on a debit card called the "CuddleCard." The CuddleCard will be delivered with a one-time "label" or scripted message that states: "The money you will receive on the CuddleCard is intended to help you spend more time visiting and caring for your baby/babies in the NICU, including doing things like making breastmilk or breastfeeding and skin-to-skin care." Control: Participants in the control group will receive the standard of care without any additional financial support
Key inclusion and exclusion criteria	Inclusion Criteria: • Mother is eligible for Medicaid insurance • Has an infant or infants born 24 0/7–34 1/7 weeks gestation • Mother is eligible to breastfeed (per hospital criteria) • Mother's baby is cared for at one of the four enrolling study sites located in Massachusetts or Georgia Exclusion Criteria: • Mother is not English- or Spanish-speaking
Study type	• Type of Study: Interventional • Study Design: o Method of Allocation: Randomized o Masking: Single-blinded; clinical staff are masked, participants are not o Assignment: Parallel o Purpose: Evaluate the impact of financial support on maternal caregiving behaviors in the NICU • Randomized Trials Details: o Allocation Concealment Mechanism: Implemented using a secure, web-based randomization module in REDCap o Sequence Generation: Computer-generated sequence stratified by hospital site and gestational age strata
Date of first enrollment	24 October 2024
Target sample size	420
Recruitment status	Open
Primary outcome(s)	Maternal provision of breast milk, engagement in skin-to-skin care
Key secondary outcomes	Infant growth and health outcomes, postpartum bonding, NICU visitation, safe sleep practices, post-discharge breastfeeding and care, perception of hospital care, physical and mental health, well-being, cognitive functioning, health-seeking behaviors, financial distress and hardship, and food, housing, and transportation insecurity
Ethics review	Approved by the Harvard T.H. Chan School of Public Health Institutional Review Board (IRB22-0729)

Introduction

One in ten births in the United States was preterm in 2022 [1]. Preterm birth is the leading cause of childhood mortality and developmental disabilities [2]. There are persistent socioeconomic disparities in the incidence of preterm birth [2] and morbidities, mortality, and quality of care for preterm infants [3–5]. An important predictor of the long-term consequences of preterm birth is maternal presence during the prolonged infant hospitalization (weeks to months) in the neonatal intensive care unit (NICU). Mothers who visit the NICU can pump breast milk, directly breastfeed and engage in skin-to-skin care, which facilitates breast milk production and promotes infant physiologic stability and neurodevelopment [6–8]. Studies of maternal caregiving in the NICU have found evidence of reduced length of stay, lower likelihood of re-admission and reduced billing costs [9–12]. Mothers also benefit from modeling and training in infant care practices [6, 7, 13]. Randomized trials of innovative family integration programs predicated on frequent maternal presence in the NICU have repeatedly demonstrated health benefits for mother-preterm infant dyads [9, 13–16].

Being consistently present in the NICU poses a major challenge for low-income mothers [17]. Regularly visiting a NICU requires mothers to shoulder significant costs, including parking, childcare for other children, transportation, and accommodations, in addition to forgoing income [18, 19]. Low-income mothers report that these costs impede their ability to visit their infants in the NICU as often as they desire [18, 20]. Moreover, the psychological impact of financial stress can impede cognitive functions such as attention and inhibitory control [21–23], further hindering low-income mothers' ability to actively participate in NICU caregiving activities. Low-income mothers are less likely than their more affluent counterparts to provide breast milk [24], participate

in skin-to-skin care [25], and adhere to health-promoting post-discharge infant care practices, such as safe sleep positioning [26].

We will conduct a RCT to test the effectiveness of labeled financial transfers among 420 Medicaid-eligible mothers with infants 24 weeks 0 days to 34 weeks 1 day gestation in four level 3 NICUs: Boston Medical Center (BMC) in Boston, MA, UMass Memorial Medical Center (UMass) in Worcester, MA, Baystate Medical Center in Springfield, MA, and Grady Memorial Hospital in Atlanta, GA. Mothers in the intervention arm will receive standard of care enhanced with financial transfers of $160/week and will be informed that these transfers are meant to help them spend more time with their infant in the NICU vs. a control arm (standard of care). Our primary hypothesis is that labeled financial transfers can enable economically disadvantaged mothers to visit the NICU, reduce the negative psychological impacts of financial distress, and increase maternal caregiving behaviors associated with positive preterm infant health and development.

Identification of effective, replicable interventions that offset the burdens of prematurity and reduce disparities in preterm infant outcomes is a national public health priority [27]. The median cost of a day of NICU care in the US for infants < 32 weeks was $3,045 in 2017 [28]. Temporary financial transfers provided within the high cost NICU environment could be highly cost-effective or potentially cost saving if they can reduce the length of a NICU stay. Our study will provide evidence on the cost implications of providing cash transfers and will contribute to discussions around financing similar programs through health insurance systems such as Medicaid. Medicaid insurers are increasingly covering non-medical, social services that directly impact health [29].

Methods/design

Study design

We will conduct a two-arm single-blinded 1:1 superiority RCT of providing labeled financial transfers ($160 per week) vs. standard of care. In all sites, we have enhanced supports available for maternal caregiving to meet recommended guideline-based care, including providing additional training and support for clinical staff surrounding skin-to-skin care and the provision of hospital-grade breast pumps for mothers to take home during their infant's NICU stay [30]. We will enroll 420 Medicaid-eligible mothers with preterm infants 24 weeks 0 days to 34 weeks 1 day gestation within four Level 3 NICUs to assess its effectiveness in improving maternal caregiving outcomes linked to preterm infant health and development. We will also conduct qualitative interviews with a subset of mothers enrolled in the RCT (~ 48 participants) to gain perspectives and understand barriers and facilitators to NICU visitation and caregiving behaviors.

Setting and study population

The study will be conducted at Boston Medical Center (BMC) in Boston, MA, UMass Memorial Medical Center (UMass) in Worcester, MA, Baystate Medical Center in Springfield, MA, and Grady Memorial Hospital in Atlanta, GA, Level 3 NICUs that serve mother-infant dyads with Medicaid insurance (at least 40% of NICU population in all sites) and have high rates of discharge home (≥ 85%). The four NICU sites serve urban, suburban and rural communities and vary in material supports provided to families during hospitalization such as parking costs, accommodations for families to sleep overnight and the availability of vouchers for transportation, and food. This degree of heterogeneity in geography and material support is representative of similar variation across U.S. NICUs. We chose these study sites because of the low-income populations served and the NICUs themselves are generalizable to many other areas in the U.S.

Eligibility criteria

We will enroll English and Spanish-speaking Medicaid-eligible [31] mothers (in this study, we use the term mothers to describe birthing and lactating people, however, we recognize that not all of these individuals may consider themselves mothers) with infants 24 weeks 0 days to 34 weeks 1 day gestation who are at least 18 years old and eligible to breastfeed per medical record review (according to the hospital criteria at the time of the study) [32]. The study will initially launch in English only, followed shortly by expansion to Spanish-speaking families. If there are sufficient resources, the study will expand to Portuguese- and or Haitian Creole-speaking mothers. The study will also enroll mothers whose babies are cared for at one of the four enrolling study sites located in Massachusetts or Georgia. We include infants weeks' 24 weeks 0 days to 34 weeks 1 day gestation because the vast majority (98%) survive until discharge [33, 34], have lengthy hospitalizations (average 60 days for a 24–30 week and 22 days for a 31–34 week infant) [34], and are highly medically vulnerable. We exclude infants with anticipated short hospitalizations where the intervention will have less time to provide support to families. Short hospitalizations may occur among infants < 24 weeks' gestation because up to 40% may not survive and those > 34 weeks' gestation, many of whom experience relatively short NICU stays (3–10 days) [34]. Mothers with multiples will be included, as multiples are very common among preterm infants and excluding mothers of multiples would make our study results less generalizable.

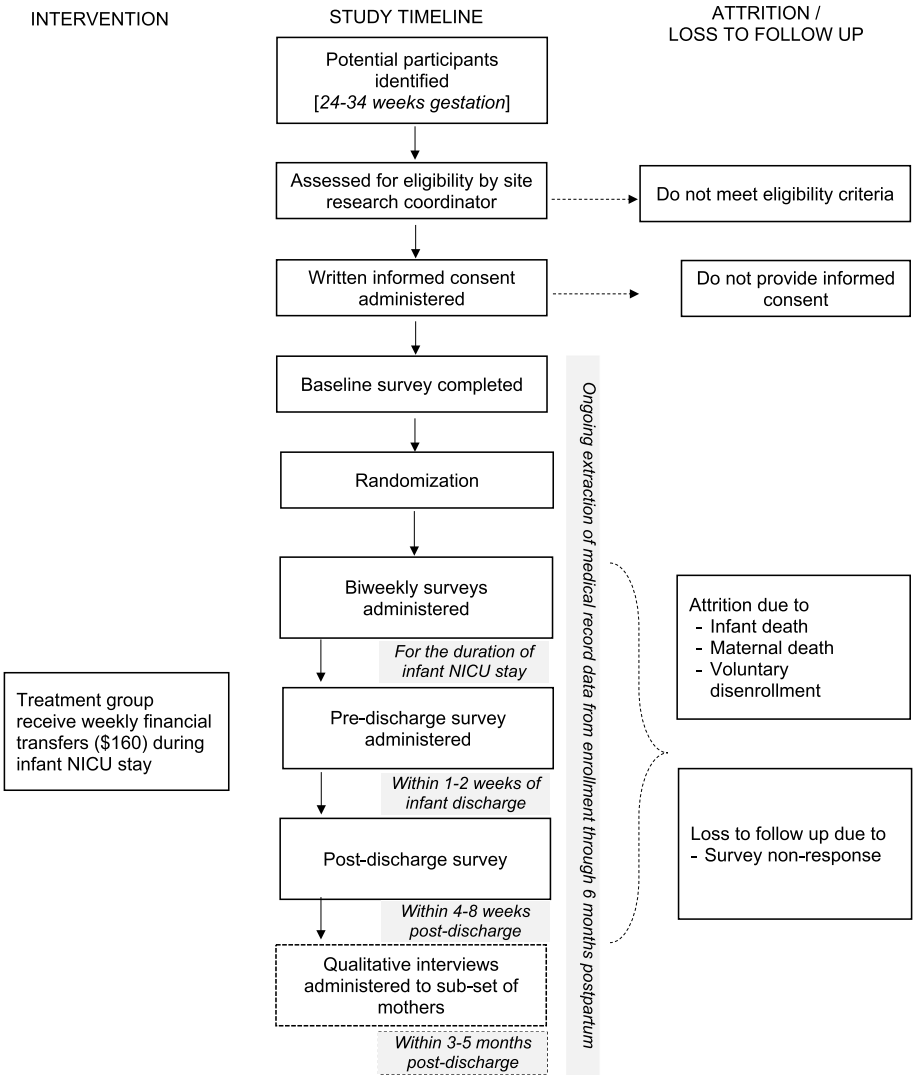

Fig. 1 Study timeline

Enrollment and consent procedures

A screening log of NICU admissions and maternal eligibility will be tracked daily on weekdays by study staff. Trained research assistants will manage the recruitment and enrollment procedures. For Spanish-speaking mothers, study staff will facilitate recruitment and enrollment in Spanish. Eligible mothers will be approached within the first 10 days after birth. Teams will attempt to approach mothers during their postpartum hospitalization (2–7 days) while they are in postpartum rooms. If a mother is discharged prior to being enrolled, she will be approached in a private space in the NICU, such as a family meeting room. Mothers who consent will sign a paper consent form (Additional File 2), which will be scanned and uploaded to a secure database. They will then complete a baseline survey on sociodemographic data, finances, mental health, and cognitive functions via a study tablet or web-based link sent to their smart phone devices. An overview of the study timeline is provided in Fig. 1.

Randomization procedures

Immediately following completion of the baseline survey, we will randomize mothers to either the financial transfer group or control group. Randomization will be stratified by hospital and gestational age strata (24–30 and 31–34 weeks). We stratify by hospital because some structural and material supports provided to families during hospitalization vary by hospital and by gestational age strata because illness and length of stay vary by gestational age. Randomization will be conducted via

Fig. 2 CuddleCard for NICU financial transfers

computer-generated sequence using stratified randomization by site, and gestational age strata. The allocation sequence will be implemented using a secure, web-based randomization module in REDCap and concealed from research staff until participants are assigned. Clinical staff will be blinded to group assignments. Participants cannot be blinded due to the nature of the intervention. Blinding is maintained by instructing participants not to disclose their group to clinical staff and by ensuring intervention-related questions are directed only to the site research coordinator or central research team via study email or phone maintained only by the site research coordinator (not by the clinical team).

The intervention

The intervention consists of financial transfers of $160 every week delivered via a debit card that we call a "CuddleCard" (Fig. 2). The CuddleCard will be delivered with a one-time "label" or scripted message that states: "The money you will receive on the CuddleCard is intended to help you spend more time visiting and caring for your baby/babies in the NICU, including doing things like making breastmilk or breastfeeding and skin-to-skin care." The use of a "label" is based on evidence that labeled transfers – which provide guidance on how financial transfers is intended to be used but maintain individual autonomy – can be as effective in directing behaviors as conditional incentives without the need for costly monitoring of behaviors to verify conditions [35]. Because receiving the transfers is not conditional on maternal behaviors, we reduce the possibility that the transfer is viewed as coercive [36]. The intervention was developed based on evidence from a pilot trial of cash transfers conducted by members of the study team between 2016 and 2018 that demonstrated increases in maternal visitation in the NICU and increased breastmilk provision and skin-to-skin care [37]. Compared to the pilot study, this study will identify the impacts of financial transfers within a larger sample of younger infants, expand our outcomes to include mental health, cognitive function and post-discharge infant care practices, and explore cost outcomes. While the weekly financial transfer amount in this study is slightly less than what was tested in our feasibility pilot ($160 compared to $200), the transfers will take place over a longer period of time and sum to a more substantial amount (total maximum payment of $2,560, compared to a maximum of $600 provided in our pilot).

Financial transfers of $160/week will begin within 48 h of consent and continue until the infant is discharged or reaches 42 weeks corrected age, whichever comes first. The funds will be automatically deposited on a weekly basis, regardless of whether prior funds were spent, and lost or stolen cards will be replaced at no cost. In cases of multiple births, transfers will continue until the last infant is discharged. Participation in research activities is not required for continued financial support.

Intervention consent procedures

Mothers in the intervention group will be informed privately that they are eligible for the intervention by the research assistant in a private location away from NICU clinical staff to facilitate blinding of clinical staff, either in her postpartum room or in a private family room in the NICU. Mothers assigned to the intervention will go through an additional separate informed consent process to consent to the intervention. This consent process provides information about the transfers and their

implications for mothers' access to other public benefits. We developed benefits counseling materials (written materials and high-yield didactic videos, which can be found in Additional File 4) with support from legal advisors and trained benefits counselors for each state, and we worked with federal and state agencies in Massachusetts and Georgia to obtain specific waivers for benefit programs, ensuring that cash transfers would not impact participants' eligibility for those programs whenever possible. Waivers were obtained from the U.S. Department of Housing and Urban Development (HUD) to exclude CuddleCard transfers from income calculations for housing assistance programs in both states. In Massachusetts, additional waivers were granted for specific programs, including SNAP, TAFDC, and EAEDC, ensuring that the cash transfers do not affect eligibility for these benefits. In Georgia, a similar waiver was not granted; however, the state confirmed that CuddleCard transfers would not impact eligibility for Medicaid. Mothers who consent will sign a paper consent for intervention form (Additional File 3), which will be scanned and uploaded to a secure database. Mothers have until the infant's 7th day of life to decide whether to consent to the intervention. Mothers are asked not to discuss the transfers with clinicians or other patients. A packet will be provided to participants that outlines details about the debit card, fees, how to use the debit card mobile app, and guidance on how transfers might impact taxes and government benefits, with links to benefits counseling videos created specifically for the purpose of the study, and the option to connect with a trained benefits counsellor. All documents will be available both in English and Spanish.

Post-randomization procedures

Immediately following randomization, all participants will be offered a hospital-grade breast pump and pump kit, regardless of their assignment group, as part of the standard of care. This standard of care includes enhancements to meet recommended guidelines for supporting breast milk provision and skin-to-skin care. Specifically, we are providing all participants with information sheets on the benefits of breast milk for premature babies, methods for milk production, timing of breastfeeding initiation, and techniques for milk expression by pump or hand. Participants will also receive materials on the benefits of skin-to-skin contact, who can engage in it, and how to practice it. Additionally, NICU lactation consultants will offer instructions on using the hospital-grade breast pump, and local research teams will provide guidance on returning the pump before the infant's discharge, handling lost or damaged pumps, and seeking assistance before maternal discharge. All documents will be available in both English and Spanish.

Data collection procedures

In addition to the baseline survey conducted prior to randomization, mothers will receive biweekly follow-up surveys during their infant's NICU stay, measuring mother's time use, hospital-related spending, financial distress, cognitive function, and mental health. These surveys will be administered through a web-based link that are provided to mothers via text or email. Within 1–2 weeks of discharge mothers will complete a pre-discharge survey assessing household finances, housing stability, access to utilities, food security, transportation challenges, overall NICU experiences, and support received during the NICU stay. Four to eight weeks post-discharge, mothers will complete a post-discharge survey covering caregiving practices at home, parental bonding, ongoing financial and housing stability, and the infant's follow-up healthcare needs. For multiple births, the surveys will be timed according to the latest infant's discharge, and mothers will report on care practices for all infants. In the baseline biweekly and discharge surveys, participants will be asked to participate in cognitive tasks designed by cognitive scientists to measure attention, executive control, sustained vigilance, and reaction time. These tasks are typically administered in-person, in highly standardized settings with substantial amounts of training and controlled procedures. We have partnered with the Cognition Lab, which runs a web-based software, to adapt procedures that make it possible for these tasks to be self-administered on a participant's phone, tablet or computer in any setting. At baseline, research staff will provide training and support on completing the cognitive tasks and in all follow-up surveys, tasks will be self-administered on a participant's device. To streamline data collection and ensure secure tracking, we have directly linked the Cognition Lab database with the REDCap platform using a unique ID linked to a participant. Additional details on the adaptation of tools to this setting is provided in Additional File 5. To encourage participation, mothers will receive a $10 gift card for each biweekly survey and $20 gift card for baseline, discharge, and post-discharge surveys (provided after completion of both the survey and cognitive tasks). Mothers will receive reminders every other day for a total of 3 reminders to encourage survey completion.

In addition to data from surveys, we will collect data from maternal and infant charts, including medical factors, access to NICU supports (lactation consulting, social work, discharge planning), and daily tracking of breast milk provision, skin-to-skin care, and NICU visits. These data will be abstracted from EMR systems and inputted into the central secure database. For Baystate Medical Center and Grady Memorial Hospital, nurses will complete paper forms for skin-to-skin, feeds, and

visitation data. Additionally, medical billing data will assess length of stay, hospital readmission, emergency department visits, and total costs. We will extract transaction data from study debit cards on the platform managing the CuddleCard, including withdrawals, charges, transaction dates, business where the transaction was made, and balances for each participant.

All collected data will be securely stored in a password-protected REDCap system managed by the coordinating center, with de-identified data from external platforms securely transferred and linked by participant IDs. Participant identifiers will be replaced with unique study IDs in all datasets. Personal information will be stored separately from study data in encrypted files. Access to the linkage key is restricted to authorized personnel. Data will be entered into REDCap with built-in range checks and validation rules. Weekly backups will be performed. A Data Safety Monitoring Committee (DSMC) will be established, consisting of three external clinicians and researchers with expertise in neonatology and clinical trials. The DSMC will meet annually and as needed to review study progress, data quality, and participant safety. The committee will have the authority to recommend modifications to the study protocol if required.

Participants can voluntarily withdraw from the intervention at any time without penalty. To improve adherence, participants will receive regular reminders about upcoming surveys, have flexibility in when surveys are completed, and contact information will be updated regularly to maintain communication. Concomitant care, including standard of care provided by the NICU, remains permitted and unchanged by intervention, except that this standard of care includes enhancements to meet American Academy of Pediatrics recommended clinical guidelines [30]. Specifically, this includes providing all participants with a hospital-grade breast pump for home use during NICU hospitalization, materials on the benefits of breast milk and skin-to-skin contact (STSC), and additional training and support for nurses on STSC practices at all sites.

Infant transfer and maternal or infant death procedures

For infants transferred to another facility for any reason before 42 weeks corrected gestational age, RAs will call facilities weekly to track whether or not they are still admitted. Similar to infants that are not transferred, the cash transfers will stop when the infants are discharged or reach 42 weeks corrected age, whichever occurs earlier. In the case of maternal death, all study procedures and cash support are discontinued, and in the case of infant death(s), cash support continues for one additional week after infant death, and mothers will receive a version of the discharge survey that is sensitive to infant death (e.g., no questions about post-partum bonding, etc.). For multiples, the study continues unless all infants have passed, in which case the same protocol applies as for singletons.

Maternal mental health monitoring and support procedures

We will administer the Edinburgh Postnatal Depression Scale (EPDS) [38] during the baseline survey, every other biweekly survey, and the discharge-survey. Given that postpartum depression affects 33% of this population [39] and is routinely assessed in the NICU, our study includes additional safety measures. A score of 14 or higher, indicating moderate depression, will trigger a prompt with a link to Postpartum Support International and a recommendation to consult a healthcare provider. A score of 19 or higher, indicating severe depression, or any positive response to physical harm in question 10, will prompt similar resources along with a suicide hotline link. In addition, a score of or higher, or any positive response to physical harm in question 10, both the research team and the site clinical staff will be notified immediately. Clinical staff, including the site PI or social worker, will contact the mother within 72 h for further assessment, referrals, or guidance to seek emergency care. For post-discharge assessments showing severe depression or suicidality, the site PI will work with their local social worker to directly contact the mother to provide referrals or encourage an emergency room visit if necessary. This approach aligns with standard clinical care practices for addressing maternal mental health concerns in the NICU.

Qualitative interviews

We will approach a sub-sample of approximately 48 mothers for more extensive qualitative interviews following the participant's completion of the post-discharge survey. We will conduct maximum variation sampling, selecting mothers for interviewing by stratifying based on frequency of visitation and treatment group. We plan to interview ~ 48 mothers in total (10–12 per category) but will continue to sample until thematic saturation is reached. Interviews will be conducted by Zoom or telephone and scheduled at the mothers' convenience up to 2 months after completion of the post-discharge survey (3–5 months post-discharge). Interviews will last approximately 30–60 min and will be audio-recorded. Mothers will receive a $40 gift card incentive for participation in qualitative interviews.

Outcome measures

We designed the intervention with four key objectives in mind as outlined in the conceptual model and summarized in Fig. 3. The intervention aims to enable maternal

Table 1 Program objectives and corresponding primary and secondary outcomes

	Definition	Data Source(s)	Time Frame
Objective 1. Enable maternal caregiving behaviors linked to preterm infant health and development			
Primary Outcome(s)			
Provision of breast milk (proportion)	Proportion of nursing shift-total enteral intake that is maternal breast milk fed via gavage tube or bottle.	Medical records	Measured from NICU admission to discharge or 42 weeks corrected gestational age, whichever comes earlier (maximum of 18 weeks)
Provision of skin-to-skin care	Proportion of nursing shifts where mother performs skin-to-skin care for at least one hour.	Medical records	Measured from NICU admission to discharge or 42 weeks corrected gestational age, whichever comes earlier (maximum of 18 weeks)
Secondary Outcome(s)			
Duration of mother's milk expression	Weeks of milk expression via direct breastfeeding or pumping.	Medical records	Measured from NICU admission to discharge or 42 weeks corrected gestational age, whichever comes earlier (maximum of 18 weeks)
Gestational weight-for-age	Change in sex-specific gestational weight-for-age z-score while admitted to the NICU.	Medical records	Measured within 1–2 weeks of discharge from the NICU
Gestational length-for-age z-score	Change in sex-specific gestational length-for-age z-score while admitted to the NICU.	Medical records	Measured within 1–2 weeks of discharge from the NICU
Gestational head circumference	Change in sex-specific gestational head circumference z-score while admitted to the NICU.	Medical records	Measured within 1–2 weeks of discharge from the NICU
Necrotizing enterocolitis (NEC)	Experienced NEC during NICU stay according to Vermont Oxford Network (VON) definition; criteria: yes/no.	Medical records	Measured within 1–2 weeks of discharge from the NICU
Late-onset bacterial or fungal sepsis (LOS)	Experienced with LOS during NICU stay according to Vermont Oxford Network (VON) definition; criteria: yes/no.	Medical records	Measured within 1–2 weeks of discharge from the NICU
Postpartum bonding	Score of mother-infant bonding assessed inspired by the Postpartum Bonding Questionnaire, where participants rate their agreement of statements on Likert scales ranging from 0 (always) to 5 (never); scores range from 0 to 50, with higher scores indicating more bonding challenges.	Surveys	Measured between 4–8 weeks after discharge of infant from NICU
Provision of breast milk (volume)	Milliliters of nursing shift-total enteral intake that is maternal breast milk fed via gavage tube or bottle.	Medical records	Measured from NICU admission to discharge or 42 weeks corrected gestational age, whichever comes earlier (maximum of 18 weeks)
Breastfeeding episode	Occurrence of direct breastfeeding episode during each nursing shift.	Medical records	Measured from NICU admission to discharge or 42 weeks corrected gestational age, whichever comes earlier (maximum of 18 weeks)
Objective 2: Enable NICU presence to improve discharge readiness and enable post-discharge caregiving			
Secondary Outcome(s)			
Sleep position	Mothers report of exclusive infant supine position to sleep in the last two weeks.	Surveys	Measured between 4–8 weeks after discharge of infant from NICU

Table 1 (continued)

Sleep location	Mothers report exclusively using the room-sharing sleep method, where the infant sleeps in the same room as an adult but on a separate crib or sleep surface, without bed-sharing, in the last two weeks.	Surveys	Measured between 4–8 weeks after discharge of infant from NICU
Breastfeeding expression continuation	Mothers report of breastfeeding continuation.	Surveys	Measured between 4–8 weeks after discharge of infant from NICU
Skin-to-skin care knowledge	Mothers report of knowledge about skin-to-skin (STS) care based on 4 questions. Scored as a count variable that ranges between 0 and 4.	Surveys	Measured within 1–2 weeks of discharge from the NICU
Breastfeeding knowledge	Mothers report of knowledge about breastfeeding based on 7 questions. Scored as a count variable that ranges between 0 and 7.	Surveys	Measured within 1–2 weeks of discharge from the NICU
NICU Visitation	Proportion of nursing shifts where mother is present in the NICU.	Medical records	Measured from NICU admission to discharge or 42 weeks corrected gestational age, whichever comes earlier (maximum of 18 weeks)
Perception of hospital experience	Assesses mothers' overall perception of hospital experience and hospital services during their stay, using a scale from 0 (worst hospital possible) to 10 (best hospital possible).	Surveys	Measured between 4–8 weeks after discharge of infant from NICU
Objective 3: Alleviate strain on maternal well-being			
Secondary Outcome(s)			
Maternal physical health	Score of self-reported Short Form Health Survey −1 Physical Health Item; assesses participants' perception of their current physical health. Lower score indicates worse perceived physical health.	Surveys	Measured biweekly from NICU admission to discharge or 42 weeks corrected gestational age, whichever comes earlier (maximum of 18 weeks)
Maternal mental health (anxiety)	Score of self-reported 10-item Perceived Stress Scale (PSS-10); assesses the perceived stress levels experienced in terms of overstrain, unmanageability, and unpredictability in the past month. Higher score indicates worse outcome.	Surveys	Measured monthly from NICU admission to discharge or 42 weeks corrected gestational age, whichever comes earlier (maximum of 18 weeks) and within 1–2 weeks of discharge from the NICU
Maternal mental health (depression)	Score of the Edinburgh Postnatal Depression Scale (EPDS), a 10-item self-report measure of postpartum depression (ranges from 0–30) with a higher score indicating worse depressive symptoms. The EPDS was developed to assist health professionals in detecting mothers suffering from postpartum depression (PPD).	Surveys	Measured monthly from NICU admission to discharge or 42 weeks corrected gestational age, whichever comes earlier (maximum of 18 weeks) and within 1–2 weeks of discharge from the NICU
Reaction Time Attention Network Test-Revised (ANT-R)	Average response time across all trials to assess overall speed of responses. Lower scores indicate faster reaction times and better attentional performance.	Self-administered cognitive assessments	Measured biweekly from NICU admission to discharge or 42 weeks corrected gestational age, whichever comes earlier (maximum of 18 weeks)

Table 1 (continued)

Accuracy Performance Attention Network Test-Revised (ANT-R)	Proportion of accurate responses on the ANT-R. Higher scores indicate higher accurate responses.	Self-administered cognitive assessments	Measured biweekly from NICU admission to discharge or 42 weeks corrected gestational age, whichever comes earlier (maximum of 18 weeks)
Reaction Time Psychomotor Vigilance Task	Average reaction time across trials, assessing overall speed and vigilance. Lower scores indicate quicker reaction times and heightened vigilance.	Self-administered cognitive assessments	Measured biweekly from NICU admission to discharge or 42 weeks corrected gestational age, whichever comes earlier (maximum of 18 weeks)
Accuracy Psychomotor Vigilance Task	Percentage of correct responses out of the total number of trials on the Psychomotor Vigilance Task (PVT). Higher scores indicate higher accurate responses.	Self-administered cognitive assessments	Measured biweekly from NICU admission to discharge or 42 weeks corrected gestational age, whichever comes earlier (maximum of 18 weeks)
Happiness	Score on Happiness Indicator from Integrated Values Surveys; assesses the overall and current perceived level of happiness experienced; with a 4-point scale from 0 (Not at all happy) to 3 (Very Happy). Higher score indicates better perceived level of happiness.	Surveys	Measured biweekly from NICU admission to discharge or 42 weeks corrected gestational age, whichever comes earlier (maximum of 18 weeks)
Life satisfaction	Score of the Life Satisfaction Scale Item; assesses participants' perception of their current overall life satisfaction; with a 4-point scale from 0 (Very Satisfied) to 3 (Not at All Satisfied), and was reverse-coded such that higher scores indicate better perceived life satisfaction.	Surveys	Measured biweekly from NICU admission to discharge or 42 weeks corrected gestational age, whichever comes earlier (maximum of 18 weeks)
Sleep	Score of Sleep Quality Score (SQS) with 7-Day Recall; evaluates the overall quality of sleep. Core components include sleep duration, ease of falling asleep, frequency of waking during the night (excluding bathroom visits), early waking, and sleep refreshment. The respondent marks an integer score from 0 to 10, according to the following five categories: 0 = terrible, 1–3 = poor, 4–6 = fair, 7–9 = good, and 10 = excellent. Higher score indicates better perceived sleep quality.	Surveys	Measured biweekly from NICU admission to discharge or 42 weeks corrected gestational age, whichever comes earlier (maximum of 18 weeks)
Routine postpartum care	Number of routine postpartum follow-up visits attended by mom.	Surveys	Measured between 4–8 weeks after discharge of infant from NICU
Objective 4: Reduce household financial distress			
Secondary Outcome(s)			
Financial distress	Score of financial stress during the NICU stay based on two metrics: difficulty in paying bills and remaining money at the end of the week. Scoring for each question is summed to create an overall financial distress score, ranging from 0 to 8. Higher score indicates higher financial distress.	Surveys	Measured biweekly from NICU admission to discharge or 42 weeks corrected gestational age, whichever comes earlier (maximum of 18 weeks)

Table 1 (continued)

Financial hardship	Score of financial hardships experienced during the NICU stay, including using up all savings, taking out loans, borrowing from friends, incurring debt, being threatened by eviction, or having a shut-off of an energy utility. Scoring for each question is yes/no and is summed to create an overall score that ranges between 0 and 6.	Surveys	Measured within 1–2 weeks of discharge from the NICU
Food insecurity	Score of Food Insecurity Screening Tool; assesses the risk of food insecurity (availability and affordability) in households based on questions derived from the U.S. Household Food Security Survey Module. Response options include: "Often True," "Sometimes True," "Never True". An affirmative response on either item will be considered to be positive for food insecurity.	Surveys	Measured biweekly from NICU admission to discharge or 42 weeks corrected gestational age, whichever comes earlier (maximum of 18 weeks)
Housing instability	Number of moves family has made since their child's birth.	Surveys	Measured within 1–2 weeks of discharge from the NICU
Housing insecurity	Score on housing insecurity scale; assesses participants' worry that they may not have stable housing in the next 2 months. Likert scales ranging from 0 (not at all worried) to 3 (very worried). Higher scores indicate greater levels of housing insecurity.	Surveys	Measured within 1–2 weeks of discharge from the NICU
Transportation insecurity	Score on transportation insecurity item; assesses participants' experience of transportation-related issues affecting their ability to visit the NICU. Likert scales ranging from 0 (never) to 3 (always). Higher scores indicate greater levels of transportation insecurity.	Surveys	Measured biweekly from NICU admission to discharge or 42 weeks corrected gestational age, whichever comes earlier (maximum of 18 weeks)
Exploratory objective: Impact of financial transfers on healthcare utilization, cost drivers, and total medical cost billed			
Secondary Outcome(s)			
Length of stay	The total number of days from infant admission to discharge from the hospital.	Medical records	Measured within 1–2 weeks of discharge from the NICU
Mother readmission between 4–8 weeks post-discharge	Any mother readmission to the hospital after her initial discharge.	Medical records	Measured between 4–8 weeks after discharge of infant from NICU
Baby readmission between 4–8 weeks post-discharge	Any infant readmission to the hospital after initial discharge.	Medical records	Measured between 4–8 weeks after discharge of infant from NICU
Mother emergency department visit between 4–8 weeks post-discharge	The number of emergency department visits by the mother in the immediate postpartum period.	Medical records	Measured between 4–8 weeks after discharge of infant from NICU
Infant emergency department visit between 4–8 weeks post-discharge	The number of emergency department visits by the infant after discharge.	Medical records	Measured between 4–8 weeks after discharge of infant from NICU

caregiving including breastfeeding and skin-to-skin care, which improve infant health outcomes. By alleviating financial burdens, it also seeks to encourage maternal presence in the NICU, improving discharge readiness through bonding with the infant and increased interaction with NICU staff. Additionally, the intervention aims to reduce maternal stress by addressing financial pressures, which can positively affect maternal mental health. Financial support may also address maternal barriers to care with the potential to directly impact maternal health through utilization of postpartum care and adherence to recommended postpartum care for those with chronic conditions. Furthermore, cash transfers are intended to alleviate household financial distress, supporting family stability during the NICU stay and beyond. Finally, our study has the exploratory objective of determining whether changes in maternal caregiving can impact drivers of cost including maternal and infant health care utilization. We outline specific primary and secondary outcomes below and map outcomes into their objectives in Table 1.

The primary outcome measures for this study include the provision of breast milk and skin-to-skin care. The provision of breast milk will be measured as the proportion of nursing shift-total enteral intake that is maternal breast milk fed via gavage tube or bottle, assessed from NICU admission to discharge or 42 weeks corrected gestational age, whichever comes first. We chose the percentage of all nutritional intake that is mother's milk as a primary outcome because it is associated with dose-dependent reductions in life-threatening infections in the blood and gut and improvements in neurodevelopment [40–42]. One study demonstrated that an increase of 10 percentage points in the proportion of total nutritional intake that was human milk was associated with a 17% reduction in the relative risk of necrotizing enterocolitis or death in a sample of extremely low birth weight infants [42]. Furthermore, as overall nutritional intake is comparable across infants at similar gestational ages (i.e. ~ 150–160 ml/kg/day is the typical goal for "full feeds" for an infant at 25 through 35 corrected gestational weeks), the percentage of nutritional intake that is mothers' milk will provide a strong signal of the amount of milk provided by mothers. Skin-to-skin care will be measured as the proportion of nursing shifts where the mother performs skin-to-skin care for at least one hour, during the same time frame. We chose skin-to-skin care because it has been linked to a myriad of health benefits for preterm infants during the NICU period and beyond [6], with some evidence suggesting improvements in developmental outcomes as many as ten years after hospitalization [8]. Existing literature does not provide guidance on metrics for a specific "dose" of skin-to-skin care that is sufficient to generate clinically meaningful changes in longer-term outcomes [6]. A greater amount and frequency of skin-to-skin care has been linked to increased cognitive and communication Bayley Scales of Infant Development (Second Edition) scores at six and twelve month follow-up [43, 44]. We therefore define an outcome that captures duration and frequency—whether a mother performed skin-to-skin care for at least 60 min measured daily, the recommended duration per professional nursing guidelines [45]. Whenever possible, we will also document the number of minutes of skin-to-skin care provided and will conduct exploratory analyses on continuous measures of skin-to-skin care.

Secondary outcome measures include various aspects of the four key objectives defined in Fig. 3 and Table 1. The duration of the mother's milk expression will be tracked in weeks, from NICU admission to discharge or 42 weeks corrected age. Infant growth will be assessed through changes in sex-specific gestational weight-for-age, length-for-age, and head circumference z-scores while admitted to the NICU, with data extracted from medical records 1–2 weeks post-discharge. Additional health outcomes include occurrences of necrotizing enterocolitis and late-onset bacterial or fungal sepsis, both measured using Vermont Oxford Network (VON) definitions, also from medical records. Safe sleep practices will be assessed, including sleep position (exclusive supine) and sleep location (room-sharing without bed-sharing), reported 4–8 weeks post-discharge within the last 2 weeks. Maternal NICU visitation will be measured by the proportion of nursing shifts where the mother is present in the NICU, while postpartum bonding will be assessed using a modified version of the Postpartum Bonding Questionnaire, measured within 4–8 weeks post-discharge. The occurrence of direct breastfeeding episodes during each shift will be recorded. Breastfeeding continuation will also be measured 4–8 weeks post-discharge. Maternal physical health will be assessed using the Short Form Health Survey-1 Physical Health Item [46], while mental health will be evaluated using the Perceived Stress Scale (PSS-10) [47] for anxiety, which has been validated and used to assess perceived stress in a number of different populations, including pregnant and postpartum women [48, 49], and the Edinburgh Postnatal Depression Scale (EPDS) [38], which has been validated for detecting depression in postpartum populations and is sensitive to changes in maternal mental health [50]. Maternal knowledge of skin-to-skin care and breastfeeding will be assessed through survey questions post-discharge. Additionally, maternal happiness and life satisfaction will be tracked using the Happiness Indicator and Life Satisfaction Scale [51]. Sleep quality will be measured using the Sleep Quality Score (SQS)

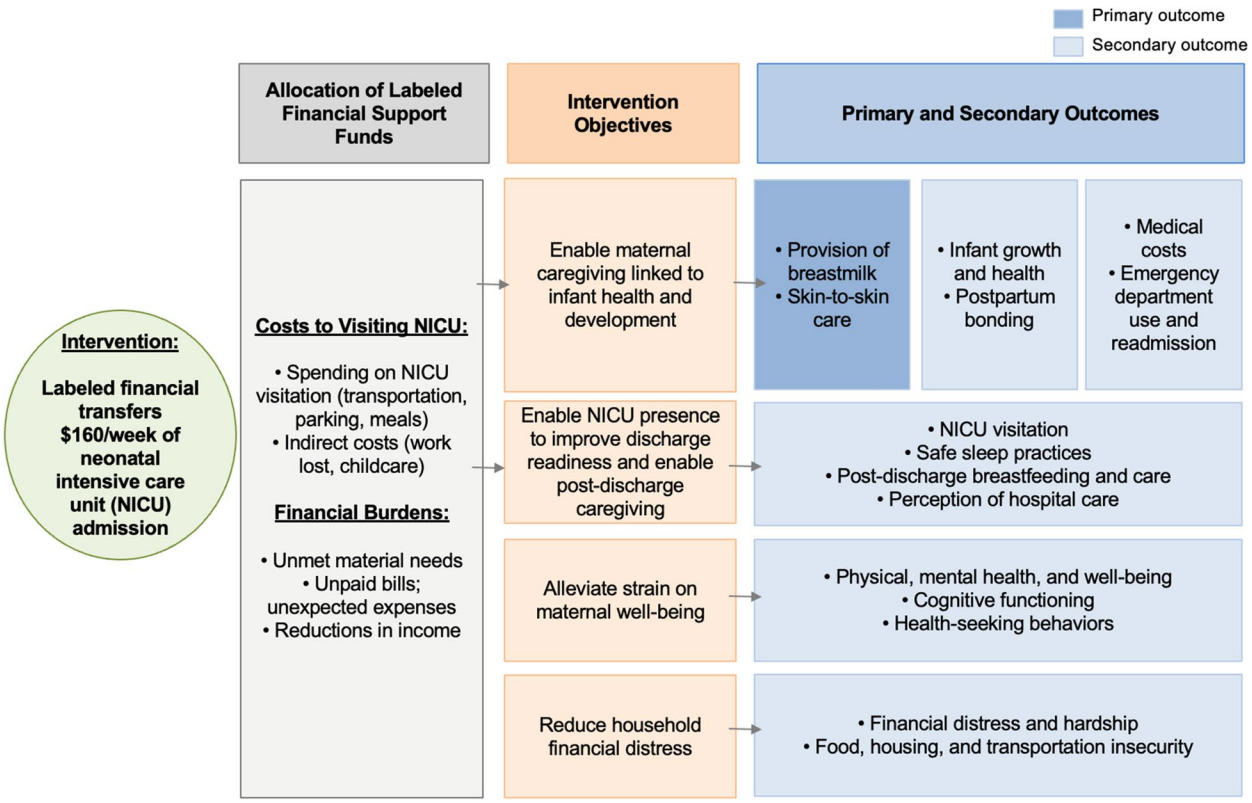

Fig. 3 Program conceptual model

[52]. Health care utilization (and cost-related) outcomes include maternal and infant hospital readmissions and emergency department visits, as well as the total length of stay during the NICU admission. The number of routine postpartum visits attended by the mother will also be tracked between 4–8 weeks post-discharge. Cognitive function will be assessed through the Reaction Time and Accuracy Performance of the Attention Network Test-Revised (ANT-R) [53] and the Psychomotor Vigilance Task (PVT) [54], measured at baseline, biweekly during the NICU stay, and at discharge. The ANT-R measures attentional contrasts among alerting, orienting, and executive control networks, with performance evaluated using reaction time (RT) and accuracy across cue conditions. Efficiency is calculated by comparing performance differences between conditions. The PVT assesses sustained attention and psychomotor speed, with performance evaluated using response speed and lapse frequency to gauge fatigue effects and attentional lapses. The demands of maternal NICU caregiving, such as sustained pumping schedules and long periods of skin-to-skin care, are influenced by cognitive functions like attention and inhibitory control, which can be heavily taxed under stress and fatigue [55, 56]. As the adaptation of cognitive function measures for this study

Table 2 Statistical Power under Different Assumptions (MDE = minimal detectable effect)

Primary outcome	Control group assumption	Assumed correlation across days	MDE 90% power	MDE 80% power Bonferroni correct
Daily percentage of all nutritional intake that consists of mothers' milk	Mean: 59%; SD: 40%	0.56 (based on pilot data)	10 percentage points (pp)	9.5 pp
		0.30	7.7 pp	7.3 pp
Mother performs skin-to-skin care for ≥ 60 min (measured daily)	Percentage of days: 0.23	0.24 (based on pilot data)	7.7 pp	7.3 pp
		0.15	6.5 pp	6.2 pp

is innovative, we provide additional details about their specification in Additional File 5.

Sample size and power

Randomization will occur at the level of the mother, and we expect that NICU caregiving behaviors, such as breastfeeding and skin-to-skin care, will be observed on at least 15 days of infant hospitalization. Based on pilot data, we assume within-mother correlations of 0.56 for breastfeeding and 0.24 for skin-to-skin care. To account for variability, we also estimate power assuming lower correlation rates, particularly in younger infants. Minimum detectable effects (MDEs) are calculated for both 90% power with a 5% significance level and 80% power with a 2.5% significance level using Bonferroni correction for multiple hypotheses testing across two outcomes, yielding conservative estimates. For breastfeeding, the sample size is designed to detect a 10 percentage-point increase in the proportion of nutritional intake from mother's milk, which is expected to significantly reduce risks of necrotizing enterocolitis or mortality. Assuming the control group's average intake is 59%, with a standard deviation of 40%, a sample size of 200 mothers per arm is required, accounting for 5% attrition. Thus, 420 mothers will be enrolled to achieve 90% statistical power. For skin-to-skin care, we anticipate mothers in the control group will perform at least 60 min of care on 23% of hospital days. Minimum detectable effects for this outcome are provided in Table 2.

Analysis plan

We will estimate intent-to-treat effects for our primary outcomes comparing outcomes for mothers assigned to the intervention to those assigned to control. While study arms are not expected to differ on demographic characteristics due to randomization, we will adjust for participant demographics and variables used for stratification of randomization (site and gestational age). All outcomes will be defined at the level of the mother, which is where random assignment to treatment will occur. We will analyze primary caregiving outcomes daily to maximize power by measuring repeated endpoints for each mother. Similarly, we will consider secondary outcomes measured during NICU hospitalization and at discharge as repeated measures to maximize power. We will aggregate outcomes for mothers who have multiple births by averaging across measures for continuous outcomes and by measuring whether the indicated behavior or outcome occurs for any infant in the case of binary outcomes. We assume that maternal behaviors will be highly similar across infants. We will use case deletion for missing outcome data and will use multiple imputation to impute missing covariates. Missing data may occur for primary outcomes related to NICU-based caregiving; since we are collecting repeated measures for each mother the potential bias appears small. We will estimate the impact of financial transfers using linear regression models for the primary provision of breast milk outcome and binomial regression models for the primary skin-to-skin care outcome, including a random effect for mother to account for repeated measures since these outcomes will be observed during each day of hospitalization. Given the significant number of secondary outcomes we are measuring, we may report analysis with adjusted p-values that control for the False Discovery Rate [57] within each of our four outcome domains (Table 1) [58]. If attrition rates are higher for biweekly surveys, we may include robustness analyses that focus on endpoints measured at the pre-discharge survey (within 1–2 weeks of discharge), as we expect to take additional measures to reduce attrition at this endpoint. Furthermore, we may consider exploratory analyses that analyze how treatment effects vary over the course of the NICU stay. Finally, we may run exploratory analyses that consider whether the impacts differ across the 4 sites or for infants at younger or older gestational ages (using our stratification of infants 24–30 weeks and 31–34 weeks).

For the qualitative analysis, recordings will be professionally transcribed verbatim following a structured protocol including replacing identifiers with pseudonyms [59]. Spanish interviews will be translated and back translated to ensure accuracy. Qualitative analysis software will be used to organize, code and analyze the data. Data will be initially coded based on constructs in our conceptual framework, and using inductive coding principles and a grounded theory-based iterative approach [60], we will also identify additional themes that emerge organically from the data. After consensus coding is reached, research team will code the transcripts independently and convene to assure uniform coding. Coding inconsistences will be discussed to achieve consensus. Themes will be revised iteratively as patterns within the data emerge until no new themes emerge (thematic saturation). We will assess validity of our data by: 1) investigator triangulation, where investigators read transcripts independently before meetings to reach consensus; 2) expert triangulation, where investigators convene separate meetings in which the methodology, coding scheme, and results will be presented to a group of researchers and other providers who interact with mothers of preterm infants; and 3) member checking, where findings are communicated to mothers to ensure their accuracy and intended meaning [61, 62].

Study status

At the time this manuscript was submitted for review, three subjects had enrolled, and no participants have completed outcome assessments to date.

Discussion

In this protocol, we provide details of the design of an intervention to provide direct financial support to low-income families of preterm infants who are expected to experience an extended stay in the NICU. The intervention differs from common clinical approaches to addressing social needs which rely on screening and referral to a variety of different organizations and programs, each of which may have different eligibility and application processes [63]. Our intervention increases access to critical caregiving behaviors that are already well-supported in U.S. NICUs by addressing immediate, short-term financial burdens of low-income mothers.

We considered several "doses" of transfers, weighing the importance of establishing the intervention's impact on key outcomes and future scalability. Our goal was to choose a transfer level that could address short-term pressing financial needs for mothers (maximizing effectiveness) and still be on par with other programs addressing specific social needs of low-income families (maximizing potential scale-up). Regarding intervention effectiveness, the goal of our project is to allow families to cover their most pressing expenses during the birth hospitalization, not to resolve the underlying conditions contributing to financial vulnerability. For intervention replicability, we considered that the transfer amount should likely not be higher than other kinds of assistance programs for low-income families in the U.S. We chose $160/week because this represents the maximum weekly food assistance (SNAP) benefits to a family of 4 [64]. Our average total transfer amount would be sufficient to cover a month of rent for a low rental rate apartment [65]. In our study, we anticipate that mothers of 24 0/7 to 30 week infants would receive an average payment of $1,120 (average length of stay 60 days [34]) and mothers of 31 to 34 1/7 week infants would receive an average payment of $480 (average length of stay 22 days) [34]. The maximum total payment would be $2,560, similar in size to the average annual earned income tax credit nationally (average payment of $2541 in 2022 [66]) – a program with an explicit objective to provide a pathway out of child poverty [67]. We see this amount as the upper bound for a policy-relevant intervention seeking to offset short-term financial stressors for low-income families. The cost of our intervention at $160/week is still substantially lower than a NICU hospitalization, where the median cost of a single NICU care day for infants < 32 weeks in 2017 dollars was $3,045 [28].

We also considered a multi-arm trial to compare features of our intervention, such as conditional vs. unconditional transfers, transfers vs. vouchers, or high vs. low doses of financial transfers. However, this trial is a necessary next step at providing formative, policy relevant evidence of the potential of financial transfers to impact key outcomes. Therefore, we chose to maximize our statistical power to compare the financial transfer group with a control group instead of spreading the sample more thinly across 3 or more study arms. Follow-up studies may compare impacts across different transfer amounts or delivery vehicles for financial transfers. We also considered whether the "dose" should differ across sites, as the cost of living and expenses related to hospitalization may differ by geographic area. We chose to maintain the same "dose" for all participating sites similar to other social programs like SNAP [68], as we expect this would be necessary for scale-up.

One concern about our intervention is that staff may alter their care if they know which mothers are receiving financial transfers (e.g. providing more food vouchers to the control group). We mitigate this concern by blinding clinical staff to treatment status, discreetly informing mothers of the financial transfers over the phone and asking them not to discuss with others and measuring reports of material support from NICU staff in both the control and treatment group at discharge, matching procedures used in our pilot study. Dozens of providers constantly interact with large numbers of families in the NICU, which makes it unlikely providers will become aware of treatment status.

To address potential reporting bias in self-reported data on sensitive topics, the survey instruments are designed with neutral questions, validated measures, and a comprehensive scope to encourage honest and accurate responses, acknowledging that mothers are likely to report non-recommended practices even when they do not align with best practices.

Our trial also innovates by measuring cognitive functions relevant to attentive parenting during the postpartum period for mothers of preterm infants in the NICU, a set of outcomes that have not been examined in previous studies. Adapting the cognitive function tasks for mobile devices presented several challenges, including the need to ensure the tests were both self-administered and smartphone-compatible, while still accurately capturing the constructs of interest. To address this, we partnered with Cognition Lab, a platform specifically designed to host and run computerized cognitive assessments. Together, we optimized the cognitive tasks for performance on smaller screens and integrated user-friendly

interfaces. Our study will provide new insights into the relative importance of direct financial costs, psychological distress and cognitive strain in explaining income disparities in critical maternal caregiving behaviors.

Conclusion

Maternal presence is increasingly recognized as a critical component to NICU quality of care. Evidence from our trial will help determine whether financial transfers can offset barriers to participating in clinical support for maternal caregiving among low-income mothers and therefore promote equity in preterm infant health and developmental outcomes.

Abbreviations

NICU	Neonatal Intensive Care Unit
RCT	Randomized Controlled Trial
NICHD	National Institute of Child Health and Human Development
LOS	Late-Onset Sepsis
NEC	Necrotizing Enterocolitis
MA	Massachusetts
GA	Georgia
UMass	University of Massachusetts
BMC	Boston Medical Center
PSS	Perceived Stress Scale
EPDS	Edinburgh Postnatal Depression Scale
PVT	Psychomotor Vigilance Task
ANT-R	Revised Attention Network Test
VON	Vermont Oxford Network
PHI	Protected Health Information
EMR	Electronic Medical Record
STSC	Skin-to-Skin Care

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12887-025-05621-9.

Supplementary Material 1.

Supplementary Material 2.

Supplementary Material 3.

Supplementary Material 4.

Supplementary Material 5.

Authors' contributions

MM and MP conceived and developed the study. All authors contributed to the study design. AA coordinated the selection and adaptation of cognitive tasks with input from HS, MF and MM. MM and AA contributed to the original draft of the manuscript. All authors contributed to the editing and review of manuscript and approval of final version.

Funding

Margaret McConnell and Margaret Parker received funding from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (1R01HD109293-01) and March of Dimes (6-23FY-0012). Michelle-Marie Peña was also supported by the Building Interdisciplinary Research Careers in Women's Health of the National Institutes of Health under Award Number K12HD085850. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. Erika Cordova-Ramos is supported by the Harold Amos Medical Faculty Development Program of the Robert Wood Johnson Foundation.

Data availability

The final trial dataset will be accessible only to members of the core research team, which includes the principal investigators, data analysts, and designated research staff who are directly involved in data analysis. Access will be granted through a secure, password - protected system to ensure data confidentiality and security. The research team will adhere to strict data - sharing protocols to protect participant privacy. Identifiable information will be stored separately from the de-identified dataset used for analysis. All data access will be governed by the Harvard T.H. Chan School of Public Health's data management policies. There are no contractual agreements that limit access to the dataset for the investigators listed in the study. Following the conclusion of the trial and publication of results regarding primary outcomes, we will make a de-identified public use dataset and replication code available to the maximum extent that is legally permissible. The research team has prior experience producing data and documentation that are accessible to outside researchers.

Declarations

Ethics approval and consent to participate

All participants in the study will provide documented informed consent. The study was approved by the Harvard T.H. Chan School of Public Health Institutional Review Board (IRB22-0729).

Consent for publication

Our manuscript does not include any individual person's data in any form.

Competing interests

The authors declare no competing interests

Author details

[1]Department of Global Health and Population, Harvard T.H. Chan School of Public Health, Building 1, 665 Huntington Avenue, Boston, MA 02115, USA. [2]Abdul Latif Jameel Poverty Action Lab (J-PAL), Massachusetts Institute of Technology, Cambridge, USA. [3]Department of Social and Behavioral Sciences, College of Public Health, Kuwait University, Kuwait City, Kuwait. [4]Department of Pediatrics, University of Massachusetts Chan Medical School, Worcester, MA, USA. [5]Frank H. Netter MD School of Medicine at, Quinnipiac University, North Haven, CT, USA. [6]Section of Infectious Diseases, Department of Medicine, Boston University Chobanian and Avedisian School of Medicine, Boston, MA, USA. [7]Evans Center for Implementation and Improvement Sciences, Department of Medicine, Boston University Chobanian and Avedisian School of Medicine, Boston, MA, USA. [8]Department of Health Law Policy & Management, Boston University School of Public Health, Boston, MA, USA. [9]Department of Pediatrics, Boston Medical Center, Boston, MA, USA. [10]Division of Neonatology, Emory University School of Medicine and Children'S Healthcare of Atlanta, Atlanta, GA, USA. [11]Department of Pediatrics, Baystate Medical Center, Springfield, MA, USA. [12]Brown University School of Public Health and Hassenfeld Child Health Innovation Institute, Providence, RI, USA. [13]Department of Medical Ethics and Health Policy, University of Pennsylvania, Philadelphia, PA, USA. [14]Center for Neuroscience & Society, Department of Psychology, University of Pennsylvania, Philadelphia, PA, USA. [15]Swiss Tropical and Public Health Institute and University of Basel, Basel, Switzerland.

Received: 18 November 2024 Accepted: 21 March 2025
Published online: 15 May 2025

References

1. Osterman MJK, Hamilton BE, Martin JA, Driscoll AK, Valenzuela CP. Births: final data for 2022. Natl Vital Stat Rep. 2024;73(2):1–56.
2. Institute of Medicine (US) Committee on Understanding Premature Birth and Assuring Healthy Outcomes. Preterm Birth: Causes, Consequences, and Prevention [Internet]. Behrman RE, Butler AS, editors. Washington (DC): National Academies Press (US); 2007 [cited 2019 Jan 28]. (The National Academies Collection: Reports funded by National Institutes of Health). Available from: http://www.ncbi.nlm.nih.gov/books/NBK11362/.
3. Profit J, Gould JB, Bennett M, Goldstein BA, Draper D, Phibbs CS, et al. Racial/ethnic disparity in NICU quality of care delivery. Pediatrics. 2017;140(3):e20170918.

4. Howell EA, Janevic T, Hebert PL, Egorova NN, Balbierz A, Zeitlin J. Differences in morbidity and mortality rates in black, white, and Hispanic very preterm infants among New York City hospitals. JAMA Pediatr. 2018;172(3):269–77.
5. Janevic T, Zeitlin J, Auger N, Egorova NN, Hebert P, Balbierz A, et al. Association of race/ethnicity with very preterm neonatal morbidities. JAMA Pediatr. 2018;172(11):1061–9.
6. Boundy EO, Dastjerdi R, Spiegelman D, Fawzi WW, Missmer SA, Lieberman E, et al. Kangaroo mother care and neonatal outcomes: a meta-analysis. Pediatrics. 2016;137(1):e20152238.
7. Reynolds LC, Duncan MM, Smith GC, Mathur A, Neil J, Inder T, et al. Parental presence and holding in the neonatal intensive care unit and associations with early neurobehavior. J Perinatol. 2013;33(8):636–41.
8. Feldman R, Rosenthal Z, Eidelman AI. Maternal-preterm skin-to-skin contact enhances child physiologic organization and cognitive control across the first 10 years of life. Biol Psychiat. 2014;75(1):56–64.
9. Melnyk BM, Feinstein NF, Alpert-Gillis L, Fairbanks E, Crean HF, Sinkin RA, et al. Reducing premature infants' length of stay and improving parents' mental health outcomes with the creating opportunities for parent empowerment (COPE) neonatal intensive care unit program: a randomized, controlled trial. Pediatrics. 2006;118(5):e1414-1427.
10. White-Traut RC, Rankin KM, Yoder JC, Liu L, Vasa R, Geraldo V, et al. Influence of H-HOPE intervention for premature infants on growth, feeding progression and length of stay during initial hospitalization. J Perinatol. 2015;35(8):636–41.
11. Gonya J, Martin E, McClead R, Nelin L, Shepherd E. Empowerment programme for parents of extremely premature infants significantly reduced length of stay and readmission rates. Acta Paediatr. 2014;103(7):727–31.
12. Vonderheid SC, Park CG, Rankin K, Norr KF, White-Traut R. Impact of an integrated mother-preterm infant intervention on birth hospitalization charges. Journal of perinatology : official journal of the California Perinatal Association. 2020;40(6):858–66. https://doi.org/10.1038/s41372-019-0567-7.
13. Welch MG, Firestein MR, Austin J, Hane AA, Stark RI, Hofer MA, et al. Family nurture intervention in the neonatal intensive care unit improves social-relatedness, attention, and neurodevelopment of preterm infants at 18 months in a randomized controlled trial. J Child Psychol Psychiatry. 2015;56(11):1202–11.
14. O'Brien K, Robson K. Bracht M, Cruz M, Lui K, Alvaro R, da Silva O, Monterrosa L, Narvey M, Ng E, Soraisham A, Ye XY, Mirea L, Tarnow-Mordi W, Lee SK, FICare Study Group and FICare Parent Advisory Board. Effectiveness of Family Integrated Care in neonatal intensive care units on infant and parent outcomes: a multicentre, multinational, cluster-randomised controlled trial. Lancet Child adolesc health. 2018;2(4):245–54. https://doi.org/10.1016/S2352-4642(18)30039-7.
15. Cheng C, Franck LS, Ye XY, Hutchinson SA, Lee SK, O'Brien K. Evaluating the effect of family integrated care on maternal stress and anxiety in neonatal intensive care units. J Reprod Infant Psychol. 2019;10:1–14.
16. Hane AA, Myers MM, Hofer MA, Ludwig RJ, Halperin MS, Austin J, et al. Family nurture intervention improves the quality of maternal caregiving in the neonatal intensive care unit: evidence from a randomized controlled trial. J Dev Behav Pediatr. 2015;36(3):188–96.
17. Bourque SL, Weikel BW, Palau MA, Greenfield JC, Hall A, Klawetter S, et al. The association of social factors and time spent in the NICU for mothers of very preterm infants. Hosp Pediatr. 2021;11(9):988–96.
18. Lewis TP, Andrews KG, Shenberger E, Betancourt TS, Fink G, Pereira S, et al. Caregiving can be costly: a qualitative study of barriers and facilitators to conducting kangaroo mother care in a US tertiary hospital neonatal intensive care unit. BMC Pregnancy Childb. 2019;19(1):227.
19. Greene MM, Rossman B, Patra K, Kratovil A, Khan S, Meier PP. Maternal psychological distress and visitation to the neonatal intensive care unit. Acta Paediatr. 2015;104(7):e306-313.
20. Parker MG, Lopera AM, Kalluri NS, Kistin CJ. "I Felt Like I Was a Part of Trying to Keep My Baby Alive": Perspectives of Hispanic and Non-Hispanic Black Mothers in Providing Milk for Their Very Preterm Infants. Breastfeeding medicine : the official journal of the Academy of Breastfeeding Medicine. 2018;13(10):657–65. https://doi.org/10.1089/bfm.2018.0104.
21. Shah AK, Mullainathan S, Shafir E. Some consequences of having too little. Science. 2012;338(6107):682–5.
22. Schilbach F, Schofield H, Mullainathan S. The psychological lives of the poor. Am Econ Rev. 2016;106(5):435–40.
23. Haushofer J, Fehr E. On the psychology of poverty. Science. 2014;344(6186):862–7.
24. Romaine A, Clark RH, Davis BR, Hendershot K, Kite V, Laughon M, et al. Predictors of prolonged breast milk provision to very low birth weight infants. J Pediatr. 2018;202:23-30.e1.
25. Pineda R, Bender J, Hall B, Shabosky L, Annecca A, Smith J. Parent participation in the neonatal intensive care unit: predictors and relationships to neurobehavior and developmental outcomes. Early Hum Dev. 2018;117:32–8.
26. 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):1122–8.
27. HRSA MCHB National Outcome Measures. Available from: https://mchb.tvisdata.hrsa.gov/PrioritiesAndMeasures/NationalOutcomeMeasures.
28. Phibbs CS, Schmitt SK, Cooper M, Gould JB, Lee HC, Profit J, et al. Birth hospitalization costs and days of care for mothers and neonates in California, 2009–2011. J Pediatr. 2019;1(204):118-125.e14.
29. Hinton E, Aug 05 LSP, 2021. Medicaid authorities and options to address social determinants of health (SDOH). KFF; 2021. Available from: https://www.kff.org/medicaid/issue-brief/medicaid-authorities-and-options-to-address-social-determinants-of-health-sdoh/. Cited 2021 Sep 23.
30. Parker MG, Stellwagen LM, Noble L, Kim JH, Poindexter BB, Puopolo KM, et al. Promoting human milk and breastfeeding for the very low birth weight infant. Pediatrics. 2021;148(5):e2021054272.
31. Medicaid and CHIP income eligibility limits for pregnant women as a percent of the federal poverty level. KFF. 2020. Available from: https://www.kff.org/health-reform/state-indicator/medicaid-and-chip-income-eligibility-limits-for-pregnant-women-as-a-percent-of-the-federal-poverty-level/. Cited 2020 Nov 8.
32. Breastfeeding SO. Breastfeeding and the use of human milk. Pediatrics. 2012;129(3):e827–41.
33. Ely D, Driscoll A. Infant Mortality in the United States, 2017: Data From the Period Linked Birth/Infant Death File. Report No.: https://www.cdc.gov/nchs/data/nvsr/nvsr68/nvsr68_10-508.pdf.
34. Manuck TA, Rice MM, Bailit JL, Grobman WA, Reddy UM, Wapner RJ, et al. Preterm neonatal morbidity and mortality by gestational age: a contemporary cohort. Am J Obstet Gynecol. 2016;215(1):103.e1-103.e14.
35. Benhassine N, Devoto F, Duflo E, Dupas P, Pouliquen V. Turning a shove into a nudge? A "labeled cash transfer" for education. Am Econ J Econ Pol. 2015;7(3):86–125.
36. Vlaev I, King D, Darzi A, Dolan P. Changing health behaviors using financial incentives: a review from behavioral economics. BMC Public Health. 2019;19. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6686221/. Cited 2020 Jan 29.
37. Andrews KG, Martin MW, Shenberger E, Pereira S, Fink G, McConnell M. Financial support to medicaid-eligible mothers increases caregiving for preterm infants. Matern Child Health J. 2020;24(5):587–600.
38. Cox JL, Holden JM, Sagovsky R. Detection of postnatal depression. Development of the 10-item Edinburgh Postnatal Depression Scale. Br J Psychiatry. 1987;150:782–6.
39. Garfield CF, Lee YS, Warner-Shifflett L, Christie R, Jackson KL, Miller E. Maternal and paternal depression symptoms during NICU stay and transition home. Pediatrics. 2021;148(2):e2020042747.
40. Chowning R, Radmacher P, Lewis S, Serke L, Pettit N, Adamkin DH. A retrospective analysis of the effect of human milk on prevention of necrotizing enterocolitis and postnatal growth. J Perinatol. 2016;36(3):221–4.
41. Furman L, Taylor G, Minich N, Hack M. The effect of maternal milk on neonatal morbidity of very low-birth-weight infants. Arch Pediatr Adolesc Med. 2003;157(1):66–71.
42. Meinzen-Derr J, Poindexter B, Wrage L, Morrow AL, Stoll B, Donovan EF. Role of human milk in extremely low birth weight infants' risk of necrotizing enterocolitis or death. J Perinatol. 2009;29(1):57–62.
43. Ohgi S, Fukuda M, Moriuchi H, Kusumoto T, Akiyama T, Nugent JK, et al. Comparison of kangaroo care and standard care: behavioral organization, development, and temperament in healthy, low-birth-weight infants through 1 year. J Perinatol. 2002;22(5):374–9.
44. Feldman R, Eidelman AI, Sirota L, Weller A. Comparison of skin-to-skin (kangaroo) and traditional care: parenting outcomes and preterm infant development. Pediatrics. 2002;110(1 Pt 1):16–26.

45. Ludington-Hoe SM. Thirty years of kangaroo care science and practice. Neonatal Netw. 2011;30(5):357–62.
46. Ware, J. E., Jr, Sherbourne, C. D. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Medical care. 1992;30(6):473–83.
47. Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. J Health Soc Behav. 1983;24(4):385–96.
48. Bastani F, Hidarnia A, Kazemnejad A, Vafaei M, Kashanian M. A randomized controlled trial of the effects of applied relaxation training on reducing anxiety and perceived stress in pregnant women. J Midwifery Women's Health. 2005;50(4):e36-40.
49. Osman H, Saliba M, Chaaya M, Naasan G. Interventions to reduce postpartum stress in first-time mothers: a randomized-controlled trial. BMC Women's Health. 2014;14(1):125.
50. Levis B, Negeri Z, Sun Y, Benedetti A, Thombs BD. Accuracy of the Edinburgh Postnatal Depression Scale (EPDS) for screening to detect major depression among pregnant and postpartum women: systematic review and meta-analysis of individual participant data. BMJ. 2020;371:m4022.
51. Cheung F, Lucas RE. Assessing the validity of single-item life satisfaction measures: results from three large samples. Qual Life Res. 2014;23(10):2809–18.
52. Snyder E, Cai B, DeMuro C, Morrison MF, Ball W. A new single-item sleep quality scale: results of psychometric evaluation in patients with chronic primary insomnia and depression. J Clin Sleep Med. 2018;14(11):1849–57.
53. Fan J, McCandliss BD, Sommer T, Raz A, Posner MI. Testing the efficiency and independence of attentional networks. J Cognitive Neurosci. 2002;14(3):340–7.
54. Basner M, Mollicone D, Dinges DF. Validity and sensitivity of a brief psychomotor vigilance test (PVT-B) to total and partial sleep deprivation. Acta Astronaut. 2011;69(11):949–59.
55. Dean, E. B., Schilbach, F., Schofield, H., Carter, M. R., Barrett, C. B., & Chavas, J.-P. Poverty and Cognitive Function. In The Economics of Poverty Traps. University of Chicago Press; 2019: pp. 57–118. https://doi.org/10.7208/9780226574448-004.
56. Mani A, Mullainathan S, Shafir E, Zhao J. Poverty impedes cognitive function. Science. 2013;341(6149):976–80.
57. Benjamini Y, Hochberg Y. Controlling the false discovery rate: a practical and powerful approach to multiple testing. J Roy Stat Soc: Ser B (Methodol). 1995;57(1):289–300.
58. Westfall PH, Young SS. Resampling-based multiple testing: examples and methods for p-value adjustment. New York: John Wiley & Sons, Inc; 1993. Available from: https://books.google.com/books?hl=en&lr=&id=nuQXORVGI1QC&oi=fnd&pg=PR11&dq=resampling-based+multiple+testing+westfall+young&ots=Xnd_BMb3PQ&sig=tzsxK6wxdpHvmb1HyXcezkjsbAw#v=onepage&q=resampling-based%20multiple%20testing%20westfall%20young&f=false. Cited 2019 Apr 22.
59. McLellan E, MacQueen KM, Neidig JL. Beyond the Qualitative interview: data preparation and transcription: field methods. 2016 Jul 24; Available from: https://journals.sagepub.com/doi/10.1177/1525822X02239573. Cited 2020 Oct 18.
60. Locke K. The grounded theory approach to qualitative research. In: Measuring and analyzing behavior in organizations: advances in measurement and data analysis. San Francisco: Jossey-Bass; 2002. p. 17–43. (The Jossey-Bass business & management series).
61. Giacomini MK, Cook DJ. Users' guides to the medical literature: XXIII. Qualitative research in health care A. Are the results of the study valid? Evidence-Based Medicine Working Group. JAMA. 2000;284(3): 357–62. https://doi.org/10.1001/jama.284.3.357.
62. Giacomini MK, Cook DJ. Users' guides to the medical literature: XXIII. Qualitative research in health care B. What are the results and how do they help me care for my patients? Evidence- Based Medicine Working Group. JAMA. 2000;284(4): 478–82. https://doi.org/10.1001/jama.284.4.478.
63. McConnell M, Agarwal S, Hanson E, McCrady E, Parker MG, Bona K. Prescription for cash? Cash support to low-income families in maternal and pediatric health care settings. The Milbank Quarterly. 2023. Available from: https://www.milbank.org/quarterly/articles/prescription-for-cash-cash-support-to-low-income-families-in-maternal-and-pediatric-health-care-settings/. Cited 2023 Dec 18.
64. Center for Budget and Policy Priorities. A quick guide to SNAP eligibility and benefits. 2018. Available from: https://www.cbpp.org/research/food-assistance/a-quick-guide-to-snap-eligibility-and-benefits.
65. Corinna. Documenting the long-run decline in low-cost rental units in the US by State. 2019. Available from: https://www.jchs.harvard.edu/research-areas/working-papers/documenting-long-run-decline-low-cost-rental-units-us-state. Cited 2019 Oct 21.
66. Internal Revenue Service. EITC reports and statistics. Internal Revenue Service; 2023. Available from: https://www.irs.gov/credits-deductions/individuals/earned-income-tax-credit/eitc-reports-and-statistics.
67. National Academies of Sciences E. A roadmap to reducing child poverty. Washington, DC: The National Academies Press; 2019. Available from: https://www.nap.edu/catalog/25246/a-roadmap-to-reducing-child-poverty. Cited 2019 Apr 22.
68. Does SNAP Cover the Cost of a Meal in Your County? Urban Institute. 2018. Available from: https://www.urban.org/does-snap-cover-cost-meal-your-county. Cited 2021 Oct 4.

Publisher's Note