Baby's First Years: Design of a Randomized Controlled Trial of Poverty Reduction in the United States

Kimberly G. Noble, MD, PhD, a Katherine Magnuson, PhD, Lisa A. Gennetian, PhD, Greg J. Duncan, PhD, e Hirokazu Yoshikawa, PhD, f Nathan A. Fox, PhD, g Sarah Halpern-Meekin, PhDc

Childhood economic disadvantage is associated with lower cognitive and social-emotional skills, reduced educational attainment, and lower earnings in adulthood. Despite these robust correlations, it is unclear whether family income is the cause of differences observed between children growing up in poverty and their more fortunate peers or whether these differences are merely due to the many other aspects of family life that co-occur with poverty. Baby's First Years is the first randomized controlled trial in the United States designed to identify the causal impact of poverty reduction on children's early development. A total of 1000 low-income mothers of newborns were enrolled in the study and began receiving a monthly unconditional cash gift for the first several years of their children's lives. Mothers were randomly assigned to receive either a large monthly cash gift or a nominal monthly cash gift. All monthly gifts are administered via debit card and can be freely spent with no restrictions. Baby's First Years aims to answer whether poverty reduction in early childhood (1) improves children's developmental outcomes and promotes healthier brain functioning, and (2) improves family functioning and better enables parents to support child development. Here we present the rationale and design of the study as well as potential implications for science and policy.

Early life experience has a profound and enduring influence on the developing child. Family economic resources shape the nature of many early experiences, which may explain the negative correlations between child poverty and cognitive skills, educational attainment and earnings in adulthood, and self-regulation and other socioemotional skills. Despite robust correlations, it is unclear if family income is the cause of cognitive and behavioral differences observed between children growing up in poverty and their more fortunate peers or if differences are the product of other aspects of family life that co-occur with poverty.

Social science research has generated considerable evidence that supports such causal inferences.² In the United States and Canada, quasi-experimental studies that take advantage of boosts in income from casino disbursements³ and tax credits^{4,5} find that the resulting increases in income are associated with improved achievement and schooling outcomes for low-income students. Welfare-to-work policy experiments revealed that a \$4000 increase in annual income (in current dollars) for 2-3 years led to increased school achievement by 0.16 standard deviations.6





a Departments of Biobehavioral Sciences and Human Development, Teachers College, Columbia University, New York, New York; ^bSandra Rosenbaum School of Social Work and; ^cDepartment of Human Development and Family Studies and La Follette School of Public Affairs, University of Wisconsin-Madison, Madison, Wisconsin; dSanford School of Public Policy, Duke University, Durham, North Carolina: eSchool of Education, University of California. Irvine, Irvine, California; ^fDepartment of Applied Psychology, New York University, New York, New York; and g Department of Human Development and Quantitative Methodology, University of Maryland, College Park,

Drs Noble and Duncan conceptualized and designed the study, drafted the initial manuscript, and reviewed and revised the manuscript; Drs Magnuson, Gennetian, Yoshikawa, Fox, and Halpern-Meekin conceptualized and designed the study and reviewed and revised the manuscript; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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Address correspondence to Kimberly Noble, MD, PhD, Teachers College, Columbia University, 525 W 120th St, New York, NY 10027. E-mail: kgn2106@tc.columbia.edu

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Globally, conditional cash transfers, which reward meeting certain behavioral benchmarks with cash payments, have been revealed to increase school attendance and preventive medical care. Although conditional cash transfers often produce improvements in children's education and health, it is unclear whether this is due to completing the targeted benchmarks or the payments themselves. Unconditional cash transfers, in which money is paid with no strings attached, also indicate promise in reducing material hardship and increasing entrepreneurial and educational investments, 8,9 but effects on child well-being are not well understood.

The question of whether poverty has a causal effect on child development has also been informed by neuroscience, in identifying plausible biological pathways related to the experience of poverty. 10 Studies have documented associations between family income and children's language, memory, executive function, and socioemotional processing early in childhood. $^{11-14}$ Extensions of this work have examined the extent to which poverty is related to the structure and function of brain networks that support these skills. 15-19 Several large studies have reported a positive association between family income and the surface area of the cerebral cortex, particularly in regions supporting children's language and executive functioning. ^{20,21} This association is strongest among the most economically disadvantaged families, suggesting that modest differences in family income among economically disadvantaged families may be associated with disproportionately greater differences in brain structure.²⁰

Research in both the social sciences and neuroscience find strikingly consistent associations between family income and children's achievement, behavior, and brain development.²² However, correlational or quasi-experimental studies cannot provide unequivocal evidence that increasing family income would support children's developmental trajectories.²³ Establishing whether poverty reduction has a causal impact on child development is of crucial importance for policy and practice: Should interventions and policies target poverty reduction directly, or should policies focus on other aspects of family life experienced by children living in poverty? A careful randomized control trial (RCT) is ideal for answering this causal question. Although it would be unethical to assign some families to reside in poverty and others not, it is feasible to provide different levels of cash support to randomly assigned groups of low-income families. The Baby's First Years (BFY) study is doing just that.

BFY (www.babysfirstyears.com) is the first RCT in the United States designed to identify the causal impact of poverty reduction on early childhood development. It does so by randomizing low-income mothers of newborns to receive a monthly unconditional cash gift of either \$333 per month or \$20 per month for the first several years of their child's life. BFY aims to answer whether providing a large unconditional cash gift to low-income mothers (1) improves children's developmental outcomes, and (2) better enables parents to support child development.

We hypothesized two main pathways that may mediate a causal relationship between poverty reduction and children's development. First, families with higher incomes may be better able to purchase or produce high-quality inputs to support young children's development.²⁴ This investment

pathway suggests that children may experience more enriching early environments when their families have more financial resources. Second, economic disadvantage can impair child development through a stress pathway. This includes effects on parents' well-being and mental health, the quality of family relationships and interactions, 25-27 and biological indices of chronic stress.^{28–31} These hypothesized pathways differ in developmental mechanisms but overlap with and reinforce one another. For example, both increased material resources and improved parental mental health may result in higher quality care, more cognitively enriching and nurturing parenting, and more visits for preventive medical care. Moreover, downstream effects may be bidirectional (eg, when children are more verbal, parents may be more likely to talk and read books with them).³²

THE BFY INTERVENTION

The BFY intervention was designed by an interdisciplinary team of economists, neuroscientists, and developmental psychologists. The group first met in August 2012, nearly 6 years before study enrollment began, and, in early 2013, they began holding weekly meetings focused on study design and fundraising from both federal and private sources. (The cash gifts were funded exclusively through private philanthropic charities.) In 2014, we also conducted a 30mother pilot study to demonstrate feasibility.33

The BFY intervention consists of a monthly cash gift disbursed to low-income mothers of newborns. The gifts began shortly after the birth of the child, at which time the mothers were told the gifts would continue for the first 40 months of the child's life. (As described below, the gifts are now being extended for an

additional year.) Mothers in the treatment group (termed the "highcash gift group") receive monthly gifts of \$333 (\sim \$4000 per year). The cash gift is automatically loaded on an electronic debit card, branded as the "4MyBaby card," and is disbursed on the day of the month of the child's birthday. To put the magnitude of these gifts in context, an extra \$4000 per year in cash gifts would increase the annual income of a family of 3 residing in poverty by \sim 20%. The control group (termed the "low-cash gift group") also receives a cash gift on a debit card in the amount of \$20 per month, or \$240 per year, delivered in the same manner. A debit card is used for both groups to minimize confounding the effect of the monthly gift with the experience of having a debit card, which could, for example, promote connections with financial institutions.

The debit cards can be used widely at automated teller machines or for any point-of-sale transaction in person or online. Mothers receive a text message each month when the gift is automatically loaded onto the card. The receipt of these monthly gifts for \sim 4 years corresponds to a medium-term time horizon for mothers' decision-making about spending or saving. The capstone child outcome data collection (a laboratory-based data collection, described below) is scheduled to occur before the final cash gift is disbursed.

The difference between the amount received by the high-cash gift group and the low-cash gift group amounts to \$313 per month, or \$3756 per year. This amount would increase the annual income of the average family in our study at baseline by \sim 20%, and was chosen because it is similar in magnitude (in today's dollars) to annual amounts received by families in welfare-to-work experiments, which produced

improvements of 0.15 to 0.20 standard deviations on the achievement of preschool- to schoolaged children. Studies of the earned income tax credit, which, on average, is a \$3200 lump-sum income transfer to families with children, also reveal similar impacts on children's cognitive outcomes.

The cash gift carries no spending restrictions, nor is it coupled with services such as financial literacy or mental health counseling. These choices were deliberate because placing limitations on how the money is awarded or spent, or coupling the cash gift with other services, would compromise our ability to pinpoint the causal impact of poverty reduction.

STUDY DESIGN

Site Selection and Point of Recruitment

Participating mothers were recruited from 12 hospitals in 4 metropolitan areas: New York City, New Orleans, the greater Omaha metropolitan area, and the Twin Cities of Minneapolis and St Paul. Selection of these metropolitan areas, termed "sites," was guided by a desire to enroll a racially and ethnically diverse sample of low-income mothers across geographic regions that vary in cost of living and generosity of state safety net programs. We chose sites that had local neuroscience expertise for the capstone data collection and where we could secure approvals from state or local officials to ensure that participants would not lose eligibility for public benefits because of the cash gift, including Temporary Assistance for Needy Families, Supplemental Nutrition Assistance Program, Medicaid, child care subsidies, and Head Start. In two of the sites, we secured state legislation to ensure this; in the other sites, we relied on other administrative strategies.

Mothers were recruited from the hospitals where they gave birth, allowing us to disburse cash gifts to all recruited mothers a day or two after childbirth, and maximizing the likelihood that families were representative of low-income communities served by the hospital. We elected not to recruit prenatally because engagement with prenatal care varies, whereas the vast majority of births occur in hospitals.³⁵

Inclusion Criteria

BFY sample recruitment was restricted to mothers of newborns whose self-reported income in the previous calendar year was below the federal poverty line. Additional study inclusion criteria were the following: (1) mother was of legal age for informed consent (aged ≥18 years in New York, Minnesota, and Louisiana or aged ≥ 19 years in Nebraska); (2) infant was admitted to the newborn nursery and not the NICU; (3) mother was residing in the state of recruitment (needed to ensure the cash gift would not count for eligibility for public benefits); (4) mother reported not being "highly likely" to move to a different state or country within 12 months; (5) infant was discharged in the custody of the mother; and (6) mother spoke either English or Spanish (necessary for measurement of some child outcomes).

We did not exclude or oversample certain subpopulations, including first-time mothers, because there is no theoretical basis for anticipating the impact of the cash gift to differ across subpopulations. In the case of family size, the target child may benefit more from the monthly gift if there are fewer children in the household. Additionally, because first-time parents tend to be younger and more likely to be employed in entry-level jobs, the economic conditions of first-birth children are, on average,

worse than for higher-parity children. The cash gift may thus be particularly helpful for these families. However, because first-time parents tend to be younger, they may have less experience with finances and family budgets than older mothers of higher-parity births. These competing considerations, coupled with the desire to maximize generalizability, led us to opt for full representation of children, irrespective of birth parity.

Ethical Issues

The Institutional Review Board (IRB) of Teachers College, Columbia University, has served as the single IRB of record for most of the study sites. To meet local requirements, stand-alone IRB reviews were conducted in 5 of the 12 recruitment hospitals.

To address ethical concerns regarding the possibility that cash gifts might coerce mothers to participate in research-based data collections, informed consent to participate in the research was uncoupled from agreement to receive the monthly cash gift. Interviewers first described the longitudinal research study focused on child development and family life. After mothers consented to participate and were compensated for completing the baseline survey, the mothers were offered the opportunity to receive a monthly cash gift. Mothers who agreed then learned their treatment group assignment, and their debit card was activated. We sought optional consent to collect state and local administrative data regarding parental employment, use of public benefits such as Medicaid and Supplemental Nutrition Assistance Program and involvement in child protective services as well as consent to track financial transactions on the debit card. In a debriefing at the end of the hospital visit, mothers were told that the

study randomly assigned \$333 or \$20 monthly cash gifts.

In each site, we established a community engagement board to promote communication about the study with local community stakeholders. The goal of these boards is to facilitate feedback from the local communities on study procedures and findings as they emerge in the context of local communities and audiences.

Data Collection Waves

The study was designed to collect data from families in 4 waves. Original plans included a baseline wave of data collection in the hospital shortly after the child was born, an in-person home visit at child ages 12 and 24 months, and a university-based laboratory visit at child age 36 months. (Modifications in light of the pandemic are described below.)

To understand how poverty reduction affects child development and family life, these data collection activities were organized around the theory of change described above. Specifically, the measures of the investment pathway were focused on what money might buy, whereas measures of the stress pathway were focused on maternal stress, mental health, and well-being. Both the investment and stress pathways were expected to impact parenting practices (Table 1). Child outcomes include children's cognitive, emotional, and neurobiological development, including stress physiology and brain function. Survey self-report was intended to be combined with objective measures and assessments, including biological samples to assess stress physiology, videorecorded interactions of the mother and child, and assessment of child brain function, as indexed by electrophysiological measures (resting electroencephalography and event-related potentials).

Participants could elect not to participate in all or part of a research wave; unless they formally opt out of the study altogether, contact will still be attempted for the next wave. They were told explicitly that opting out of part or all of the research would not lead to cessation of the cash gift.

Because of the pandemic, data collection has been modified in several ways. For some participants in the 12month data collection wave and all participants in the 24 and 36-month waves, data collection has been limited to phone interviews. In addition, we added a number of survey questions to better understand families' pandemic-related experiences, including changes in health and employment. Although the pandemic changed the context of the study in complicated ways, the experimental design ensures the ability to estimate the causal impact of the cash support provided to participants. We will attempt to understand pandemicrelated differences in family life and economic disruptions, noting the analytical challenges around disambiguating the onset of these changes from the change of in-person data collection to phone interviews.

As of this writing, we have raised funds to extend the cash gifts for an additional year, enabling us to separate the capstone wave of data collection, originally planned for 36 months, into a phone survey that will be administered at 36 months, and a laboratory-based in-person assessment that will take place ~ 1 year later, around the child's fourth birthday. This was necessary because the pandemic rendered uncertain our ability to conduct high-quality, in-person data collection as originally planned at 36 months. The capstone visit will include laboratory-based assessments of children's cognitive development and brain functioning,

TABLE 1 Child Outcomes and Conceptually Related Family Processes

Child outcomes

Language development

Social-emotional development

Executive function and self-regulation

Child health

Child sleep

10

Brain function

Family investment pathway measures

Economic well-being

Household income

Indicators of economic hardship

Food insufficiency

Assets and debt

Household expenditures

Receipt of social services and public benefits

Neighborhood quality

Neighborhood poverty

Perceptions of neighborhood safety (safety, victimization)

Excessive residential mobility

Housing quality

Crowding and number of rooms

Type of housing

Housing problems

Homelessness

Child-related enrichment expenditures

Children's books and toys

Out-of-pocket nonparental care

Number and type of providers, hours in care, regularity of care, qualities of care

Parent-child interaction and environment

Self-report of parent-child activities

Index of positive parenting behaviors (encouragement and teaching)

Adult word count/conversational turn count during free play

Family stress pathway measures

Family stress

Chaos in the home

Maternal perceived stress

Parenting stress

Global happiness

Maternal agency

Mother-father relationship

Maternal hair cortisol

Maternal cognitive bandwidth

Maternal depression

Maternal anxiety

Maternal substance use

Sensitivity of parenting

Index of positive parenting behaviors (affection and responsiveness)

Spanking discipline strategy

Child stress measures

Child hair cortisol

Child epigenetic age and DNA methylation

Related family processes and other measures

Mother demographics

Father demographics

Household roster

Maternal education and training

Parental work histories and schedules

Total hours (full- or part-time)

Number of jobs

Days worked

Regularity of work schedule

Maternity leave (time to labor market reentry after giving birth)

maternal and child stress physiology, and maternal and child BMI, along with survey-based measures of maternal and child health and well-being.

In addition to the 4 planned follow-up waves of quantitative data collection, qualitative semistructured interviews are being conducted with 80 randomly selected mothers in 2 of the 4 sites. Three interviews will occur over the course of the study, with a final interview scheduled after the cessation of the gifts. The goal of these interviews is to capture mothers' voices and their views and experiences of the cash gift in an open-ended narrative format.

Table 1 includes the child outcomes measured as well as investment and stress pathway measures. Preregistration details can be found at https://clinicaltrials.gov/ct2/show/NCT03593356. In keeping with best open science practices, data are being deposited with the Inter-university Consortium for Political and Social Research.³⁵

Statistical Power

Striking a balance between statistical power and project costs, we allocated 40% of the sample to receive the \$333 monthly cash gifts and 60% to receive the \$20 monthly gifts. With the sample size of n =1000 mother-infant dyads, and after accounting for a predicted 20% attrition by the capstone wave of data collection, the anticipated sample size of 800 dyads will provide 80% power to detect a 0.207 SD impact at P < .05 in a 2tailed test on cognitive functioning and family process outcomes, noting that the literature on income effects on family process measures is much less extensive than the literature on child outcomes, reviewed above.

TABLE 1 Continued

Breastfeeding practices
Home language exposure
Maternal physical health
Maternal reproductive health
Maternal experience of COVID-19
Experience of structural racism

COVID-19, coronavirus disease 2019.

BASELINE RECRUITMENT AND DATA COLLECTION

Between May 2018 and June 2019, all 1000 mother-infant dyads were recruited. The baseline Consolidated Standards of Reporting Trials (CONSORT) diagram details how the sample was constructed (Supplemental Fig 1). Recruitment took place at each recruitment hospital several days per week over the course of the year. On recruitment days, nurses in the wellbaby nurseries of the hospitals were asked for a list of all admitted mothers who had given birth at that hospital within the past 3 days, excepting any mothers who, for medical or other reasons, they felt should not be approached to participate in research. A total of 13 483 mothers were identified, 8243 of whom agreed to be assessed for eligibility through a brief screener. Of these, 6839 did not meet the inclusion criteria and 341 declined to consent. A baseline interview was completed with the remaining 1051 mothers. Of these 1051 mothers, 1003 agreed to receive cash gifts and were randomly assigned to the high-cash or low-cash gift groups. Randomization into the high-cash or low-cash group occurred at the site level. Of the 1003 mothers who were randomly assigned, 3 were excluded because they notified the interviewer within 2 days after completing the baseline interview that they wanted to withdraw and stop receiving cash gifts. The result is our final sample of 1000 mothers and infants.

Our intention was to recruit 250 mother-infant dyads in each of the

4 sites. Owing to a number of IRBand hospital-related recruiting challenges, the sample is distributed as follows: 295 motherinfant pairs in New Orleans, 295 in the greater Omaha area, 289 in New York, and 121 from the Twin Cities. For the qualitative interviews, 60 mothers were drawn from New Orleans and 20 from the Twin Cities. As described below, the majority of participants are women of color.

Baseline Equivalence of the Highand Low-Cash Gift Groups

Supplemental Table 2 reveals means (and, for continuous variables, SDs), plus sample sizes, of preregistered baseline characteristics. Standardized mean differences between treatment and control groups are indicated by Hedge's g for continuous variables and by Cox's index for dichotomous variables. The P values shown in the final column were generated from regressing cash gift group status on covariates generated from the baseline data, including site fixed effects, with robust standard errors. Of the 26 individual tests. 2 have a P value < .05. The best indicator of overall baseline balance is given by the *P* value of a joint test of orthogonality from a probit model with robust standard errors and site-level fixed effects. As revealed in Supplemental Table 2, the *P* value is 0.238, indicating that high- and low-cash gift groups were similar to one another at baseline. All baseline covariates are included in our prespecified intent-to-treat models.

CONTRIBUTIONS TO SCIENCE

The BFY study is the first large-scale US clinical trial involving unconditional cash transfers to lowincome families with young children. As such, BFY is poised to provide the strongest evidence to date as to whether family income in and of itself is the cause of many of the negative outcomes faced by children living in poverty. BFY improves on previous research by employing a rigorous RCT design, which directly tests the impact of income (disbursed without restrictions or instructions) on child development and family life. In addition, by targeting families during children's earliest years, BFY will provide important evidence of the effect of income during a time when children's brains are particularly sensitive to experience.

CONTRIBUTIONS TO POLICY

Findings will inform policy at the national, and state and local levels. The BFY cash gifts are structurally related to child allowances found in most industrialized nations.² Historically, the United States has had a child tax credit (CTC) for lower- and middle-income families but not for families with little or no taxable income. Since 2017, the CTC benefit amounted to \$2000 per child per year. The 2021 American Rescue Plan increased CTC benefit levels to \$3600 per year for children aged <6 years, and \$3000 per year for children aged ≥6 years. Importantly, the legislation extended CTC payments to almost all low-income families, regardless of their taxable income, converting the CTC into a child allowance available to all but the wealthiest families.

BFY cash gifts differ in several key ways from the expanded CTC. Perhaps most notably, the BFY \$4000 annual payments are the same for all families regardless of the number of children, whereas the

new federal policy provides a similarly sized payment for each child in the family, and thus has the potential to increase family income much more than BFY payments. For BFY participants, the cash gifts are automatic, monthly, and predictable, whereas the first year of federal payments consist of a combination of monthly and lump-sum payments and will require families that have not previously paid taxes to formally file.

Although BFY will provide some evidence on the likely impact of cash transfer policies in the first several years of life, several elements of the study limit its ability to inform debates over these kinds of policies. Our branding of the debit card with "4MyBaby" may shape mothers' views about the money differently than a government-delivered refundable CTC. As with any research study, participants' behavior may be altered because of their awareness of being observed.

The generalizability of findings from any study are limited by conditions and events during the study period. Most BFY newborns spent the first 2 years of life in a booming economic environment followed by a pandemic-induced shutdown that included 2 stimulus payments sent to most families. The impacts of BFY payments may well be reduced during favorable economic periods and enhanced during economic downturns.

The incomes of most families during the third and possibly subsequent years of BFY children's lives will be boosted by the expanded CTC. Indeed, CTC payments for families with multiple children will be especially large. Although this does not threaten the internal validity of the study, it is possible that the increased incomes of both high- and low-cash gift groups will mitigate impacts of the BFY cash gifts on child development. Past studies do not provide clear evidence on the family income threshold at which the added \$4000 of BFY money begins to matter less for children's development. Additionally, some implementation details about the expanded CTC are unknown at the time of this writing, including likely uptake among families who have not previously paid taxes or who do not have a bank account.

Both the expanded CTC and previous stimulus payments and other programs expanded through legislation will have varied and complicated economic impacts. Critically, BFY's randomized design means that, although the context of the BFY cash gift is shifting, we will still learn a great deal about whether providing reliable monthly financial support to low-income families will help their children have a healthier start in life.

A broader limitation is vital to bear in mind: Policies that provide financial resources to families are only one of many kinds of programs and policies that promote the wellbeing of children. Although we concentrate our attention on cash transfers, we note the vital role for programs and policies that provide health services, parenting support, early education and other services to low-income families with young children.

Bearing these limitations in mind, BFY is the first study to provide clear, causal evidence on the consequences of poverty reduction on early childhood development, with direct implications for policy. Traditionally, discussions of such policies in the United States have centered on effects on labor supply rather than child well-being. BFY will be important in shifting the focus of the conversation toward how best to support children.

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ABBREVIATIONS

BFY: Baby's First Years CTC: child tax credit

IRB: institutional review board RCT: randomized controlled trial

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