Impact of a universal perinatal home-visiting program on reduction in race disparities in maternal and child health: Two randomised controlled trials and a field quasi-experiment

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Summary

Background Public health interventions must become accountable for reduction of race disparities, particularly among Black, Hispanic, and Non-Hispanic White families in the United States. Family Connects (FC) is a universal perinatal home-visiting program that assesses family-specific needs, offers support, and provides connections to community resources to address identified needs. Two previously-published randomised controlled trials and a field quasi-experiment have shown positive impact on maternal mental health, infant emergency medical care utilization, and government investigations for child maltreatment; however, these reports have not tested impact on reducing race disparities in these outcomes. The current report examined three questions in these trials: 1) the extent of race disparities in maternal and infant health and well-being, absent intervention; 2) whether intervention can be implemented with high reach and fidelity among all race groups; and 3) whether assignment to intervention reduces race disparities in important outcomes.

Methods Data were re-examined from: 1) a randomised controlled trial of 4777 birthing families in Durham, NC, USA; 2) a replication randomised controlled trial of 923 birthing families in Durham, NC, USA; and 3) a quasi-experiment of 988 birthing families in rural NC, USA. Families were classified as Black, Hispanic, Non-Hispanic White, or Other. Disparity reduction was tested by the interaction effect between treatment assignment and race.

Findings 1) In the absence of intervention, large and statistically significant differences between Black familes and Non-Hispanic White families were found in maternal anxiety, maternal depression, father non-support, child emergency medical care, and child maltreatment investigations. Few differences were found between Non-Hispanic White familes and Hispanic families.
2) High rates of participation in treatment were found for each race group.
3) Across studies, assignment to FC was associated with statistically significant reductions in 7 of 12 disparities, in maternal anxiety and depression, father non-support, infant emergency medical care, and child maltreatment investigations.

Interpretation This study provides a method, metric, and mandate to prioritise testing of whether public health interventions reduce race disparities in family outcomes.

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Keywords: Public health; Race disparities; Child maltreatment

Introduction

Families giving birth in the United States are in great peril. The U.S. maternal mortality rate ranks last among industrialised nations and is rising, with more than half of these deaths occurring in the first year after giving birth.[1] The U.S. infant mortality rate in the first year of life is 76% higher than the industrialised-world average, a worsening trend since the 1960s.[2] Disparities by race in maternal and child mortality and well-being are even

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Research in context

Evidence before this study

Past studies of the impact of early home-visiting programs as summarised by the Maternal, Infant, and Early Childhood Home Visiting Program (2022) have reported positive main effects on targeted families (Randomised controlled trial evaluation of universal postnatal nurse home visiting: Impacts on child emergency medical care at age 12-months. Pediatrics), but rarely have studies reported whether the intervention reduces well-known race and ethnic disparities (The prevalence of confirmed maltreatment among US children, 2004-2011. JAMA Pediatrics), and no known studies have reported the proportion of pre-existing disparities in the population that could be reduced by the intervention.

Added value of this study

This study adds three important empirical findings. First, without intervention, large disparities across race and ethnic groups exist in maternal and infant health and well-being. Second, a universal home-visiting intervention can be delivered to Black, Hispanic, and Non-Hispanic White families with high quality and high participation among all groups. Third, the Family Connects universal home-visiting intervention has been found to reduce race and ethnic group disparities in maternal and infant health and well-being. A final value added is a new metric for reporting the proportional magnitude of disparity reduction attributed to an intervention.

Implications of all the available evidence

This study demonstrates that a universal approach to early family intervention can have positive population impact while also reducing disparities in outcomes. All intervention programs should adopt goals of population impact and disparity reduction, and evaluations should test impact on population outcomes and disparities in outcomes.

more worrisome, with especially egregious disparities between Black and Non-Hispanic White families: In the last decade, pregnancy-related deaths (per 100,000) were 41 for Black women but only 13 for Non-Hispanic White women,[3] and infant mortality rates (per 100,000) were 1,075 for Black infants but only 463 for Non-Hispanic White infants.[4] Disparities in child maltreatment are huge: Based on 2004-2011 data from the National Child Abuse and Neglect Data System (NCANDS), the likelihood that a child will have been substantiated as a victim of child maltreatment between birth and age 5 was 11.4%, 6.2%, and 5.7% for Black, Hispanic, and Non-Hispanic White children, respectively.[5] The recently-released National Institutes of Health Strategic Plan responds to these issues by calling for increased focus on research and health policy to address population-level maternal and infant health and to reduce health disparities.[6] In this report, we focus on intervention to reduce disparities in reported child maltreatment by age 5.

One promising approach is perinatal home-visiting: in 2020, the federal Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program[7] awarded $341 million to 19 evidence-based programs that meet criteria on outcomes such as maternal mental health, father involvement, and infant health and well-being. Even though disparity reduction is a primary federal health policy goal, almost no studies test disparity reduction empirically, and no guidance is offered about how to report disparity reduction metrics. The goals of the current study were to identify race disparities in maternal and infant health and well-being absent intervention, to evaluate implementation of one MIECHV-eligible Program, Family Connects, across race groups, and to evaluate impact of this intervention on reducing race disparities.

Family Connects (FC) is a perinatal home-visiting program aimed to improve population outcomes in maternal and infant health and well-being; it has evolved a second aim to reduce race disparities in these outcomes. FC reaches universally just after birth to offer one to several home visits to support parents, screen and assess family psychosocial and health needs in each of 12 domains, problem-solve minor issues, and connect families with community resources to address critical family-specific needs. At $500-$700 per community birth during initial trials, the cost is modest enough for widespread dissemination, which is occurring in several dozen communities nationwide. Two randomised controlled trials and a field quasi-experiment document a pattern of high levels of program reach and overall positive impact on maternal mental health, father involvement, infant emergency medical care, and child maltreatment.[8–11] However, none of the published evaluations has addressed impact on the disparities among Non-Hispanic White, Black, and Hispanic families in these measures.

FC adopts a paradoxical strategy to reduce race disparities in outcomes through universal reach. By engaging every family giving birth in a community and addressing each family's specific needs, some of which could be due to systemic racism, FC aims to uplift all families to achieve health equity. The hope is that this universal approach will reduce mistrust experienced by Black families, eliminate stigma associated with a group-specific entitlement program, and provide equality in access to community resources. A contrary possibility is that this universally-offered intervention could have an equally positive impact on each family, thereby improving population outcomes, but without any reduction in the disparity across groups (i.e., each group

improves outcomes by x, so that the original disparity remains constant). Worse, this universal approach might perversely increase disparities if those with social advantage disproportionately take up this voluntary program because of their comparative readiness to benefit, or if socially disadvantaged groups choose not to participate because of mistrust or perceived stigma. In a systematic review of population-level programs, Shahidi et al.[12] found that some social assistance programs for economically disadvantaged families in high-income countries actually have adverse impact on participants, a caution against opt-in, conditional, entitlement/eligibility-based approaches.

The current study reports new analyses of each of three previously-published trials of FC[8–11]; those publications already report CONSORT diagrams and details of the research designs which are not repeated here. We ask three new empirical questions.

First, we test for disparities across Non-Hispanic White, Black, and Hispanic groups in maternal mental health, family functioning, and infant well-being, in the absence of intervention (that is, among the control group).

Second, we test whether the reach and quality of implementation of the Family Connects (FC) intervention differs across race and ethnicity groups. We report metrics and test the significance of differences in take-up of FC (i.e., participation rate, completion rate, identified need rate, proportion of sample connected to community resources) across groups.

Third, we address our primary question of whether assignment to FC reduces disparities in outcomes for which a race disparity had been identified and which previously-published evaluations revealed positive overall impact in at least two of the three trials. We define disparity reduction as a significantly greater positive impact of assignment to FC on Black than Non-Hispanic White families (and on Hispanic than Non-Hispanic White families). Our approach provides a template for public health programs to meet a new mandate for testing for disparity reduction.

Methods

The family connects program

Family Connects (FC) incorporates three components: individual family home visits, alignment of community resources to support families, and an integrated data system. All birthing families in a community are approached at the birthing hospital to participate in a voluntary, short-term, parent-support program. A trained public health registered nurse visits the family at about three weeks of infant age for an initial two-hour visit (with follow-up visits as necessary) to support the family and to assess and document in a record family needs on a 4-point scale (1=no need, 2=minor need addressable by the nurse; 3=major need; 4=imminent risk requiring emergency intervention) in each of 12 domains empirically linked to positive outcomes (maternal health, infant health, healthcare access, childcare plans, parent-infant relationship, management of infant crying, housing support, family safety, parenting skills, maternal anxiety and depression, parental substance use, and social isolation). Based on the family's expressed needs, the nurse directly addresses minor problems (i.e., those domains scored as 2) through brief intervention and connects families to community resources for major problems (i.e., those scored as 3 or 4). A community alignment specialist organizes the hundreds of community agencies available to support families giving birth through an electronic directory that is made available to the nurse and through quarterly advisory board meetings that facilitate cross-agency coordination.

The first evaluation trial (RCT I) in Durham, NC, USA, enrolled families between July 1, 2009, and December 31, 2010, and included training, supervision, and oversight of intervention program staff members by the university-based program developers.[8,9] The second trial (RCT II) in Durham, NC, USA, enrolled families between January 1, 2014, and June 30, 2015, and was led by a community-based nonprofit organization, with training and supervision by program developers.[10] The third trial (a field quasi-experiment) was led by public health departments in four counties in rural eastern NC, with enrollment between September 1, 2014, and December 31, 2015, with training and monitoring by the FC national office.[11] More detailed program description can be found in previous publications.[8–11] All trials were reviewed and approved by the Duke University IRB.

Participants and evaluation design

RCT I. The CONSORT figure and design features are described by Dodge et al.[8] All 4,777 resident births at two hospitals in Durham, NC, over an 18-month period were randomly assigned to be offered FC based on date of birth, with 2,327 even-date births assigned to FC and 2450 odd-date births to control. All even-date births (37.9% Black [African American or Caribbean American], 29.5% Non-Hispanic White, 21.9% Hispanic, 12.8% Other) were evaluated for implementation of intervention. For evaluation of impact on outcomes, one birth for each of the 549 dates of enrollment was selected randomly by computer without regard to whether the family participated in intervention (i.e., "intent to treat"). Families were sought in the community and solicited to participate in a research study without mention of any connection to the FC program so that interviewers and families were double-blinded to the purpose of FC evaluation. Families that could not be located or declined were replaced by a same-race, same-

birth-date birth to preserve population representativeness. Prior publications[8,9] document that participant characteristics did not differ consistently between participants and the full population or between treatment and control conditions. Of the 549 families participating in impact evaluation, 18 were discarded due to missing data or clerical error in hospital records (e.g., incorrect birthdate). Four mothers self-identified as Hispanic-Black and were coded as Hispanic.

RCT II. The CONSORT figure and design features are described by Dodge et al.[10] All 923 resident births at one hospital in Durham, NC, USA, over a 6-month period were randomly assigned to be offered FC and to participate in evaluation based on date of birth, with 443 odd-date births assigned to FC and 480 even-date births to control. All odd-date births (32.3 % Black [African American or Caribbean American], 24.8% Non-Hispanic White, 23.7% Hispanic, and 19.2% Other) were evaluated for implementation of intervention.

All births were sought out at about age 6 months for impact evaluation at that age. Of the 443 odd-date births, 302 were located and confirmed as eligible (based on local residency at age 6 months), and 185 (61.3% of eligible) completed interviews. Of the 480 even-date births, 303 were located and confirmed as eligible residents, and 182 completed interviews (60.1%). One randomly-selected member of twin pairs and families that had participated in FC for a prior birth were excluded. The final sample included 316 infants (158 intervention and 158 control). Prior publications[10] indicate population representativeness of the sample and no consistent pre-treatment or demographic differences across conditions.

Field quasi-experiment. The study design is described by Goodman et al.[11] All 988 resident births in four very low-income counties in rural eastern NC, USA, over a 16-month period were offered FC and were included in evaluation of implementation. All 434 births in the same counties over a 6-month period (February 1, 2014, through July 31, 2014) prior to training and implementation of FC were assigned as controls. At about age 6 months, all families were sought out for participation in an independent research study about child development. 528 families were located and successfully completed interviews (FC group n = 397, control group n = 131). Prior publications[11] document population representativeness of the evaluation sample and no consistent pre-treatment or demographic differences between FC and control groups.

Measures

Implementation. Four variables were recorded for each family assigned to FC in each trial: 1) whether the primary caregiver (usually the mother) consented and began participation; 2) whether the family completed all elements of the FC protocol; 3) whether the family was identified as having a major need (scored as 3 or 4) in any domain; and 4) whether the family was referred to a community agency for intervention (which was based primarily on having a major need but with family and nurse discretion).

Outcomes. Five variables were tested for FC impact.

Maternal anxiety. When infants were approximately six months of age, research interviewers who had no knowledge of the experimental condition of the family approached families to participate for compensation in a research study of normal child development. Families were not told of the relation between the research study and Family Connects (i.e., studies were "double-blinded"). Mothers completed the 7-item brief Generalized Anxiety Disorder-7 questionnaire (GAD-7).[13] The mean score is reported.

Maternal depression. At the same age six-month interview, mothers completed the 10-item Edinburgh Postnatal Depression Scale (EPDS).[14] The mean score is reported.

Lack of father support. At the age six-month interview, mothers completed the Survey of New Parents,[15] which asks her 4 items (each on a 4-point scale) about the frequency that the father helps with care of the infant (e.g., "how often does he look after (baby's name)?"). Items were reverse-scored and averaged so that all outcome variables are negatively valanced.

Infant emergency medical care utilisation. This variable was scored as the sum of all-cause infant emergency department visits and overnights in the hospital (post-birth hospital discharge), from local hospital administrative billing records for RCT I and RCT II and from parent report for the field quasi-experiment, covering the period from birth to age 60 months for RCT I, birth to 12 months for RCT II, and birth to 6 months for the field quasi-experiment.

Child maltreatment. The cumulative number of *child maltreatment investigations* was scored from the state Child Protective Services registry for the period from birth to age 60 months for RCT I and birth to 24 months for RCT II. Scores were not collected for the field experiment.

Control variables. *Birth risk* was measured from birth records as 1 if any maternal health condition, birthing event, or fetal distress affected immediate infant health status; gestational age < 27 weeks; or birthweight < 2500 g; and 0 otherwise. *Health insurance coverage* was scored as 1 if Medicaid or no insurance, and 0 otherwise. Infant *gender* was scored as 1 if female, and 0 if male. *Single-parent* family status was scored as 1 if mother lived without a partner, and 0 otherwise. *Infant age* was scored in months for RCT II and the field experiment.

Data-analytic plan

I. Identification of disparities in the absence of treatment. The hypothesis that race disparities exist in the participating community was evaluated within the control group, using a two-tailed simple main-effect test in a model that included covariates of birth risk, Medicaid coverage, infant gender, and single parent family. Models for RCT II and the Field Quasi-Experiment added infant age as a covariate. We made two contrasts: 1) between Black and Non-Hispanic White families; and 2) between Hispanic and Non-Hispanic White families.

II. Tests of differences in implementation of FC. Descriptive statistics for each of the four FC implementation measures are reported separately for each of the four race groups.

III. Tests of impact of FC on disparity reduction. Because overall main effects of assignment to FC have been reported in previous publications,[8–11] they are not considered further here. Instead, current analyses focus on whether assignment to FC reduced disparities between race groups in these outcomes. Little's Test[16] indicated that the missing pattern was not missing completely at random ($p<.05$), so we implemented multiple imputation (m=10) with chained equations to adjust for missing data.[17] Variables in the imputations included all outcomes, birth risk, Medicaid, infant gender, single-parent status, and treatment status. As will be shown below, large disparities were found between Black and Non-Hispanic White control families, and few disparities were found between Hispanic and Non-Hispanic White control families; therefore, tests of whether treatment reduced disparities were not conducted for the latter contrast. Models included covariates as described above and tested the main effects of treatment group (control = 0, FC = 1) and race group (Black = 0, Non-Hispanic White = 1), followed by the interaction effect between treatment and race (computed as mean-centered treatment x race). The magnitude of disparity reduction was calculated as 1 − [(Treatment M_{BLACK} − Treatment M_{WHITE}) / (Control M_{BLACK} − Control M_{WHITE})], capped at 100%.

We used SAS v.9.2 software with a two-tailed "intent-to-treat" design that included all interviewed families without regard to intervention adherence. Ordinary Least Squares (OLS) regression models estimated the impact of independent variables on outcomes. Poisson regression models were employed for count variables with skewed distributions.

Role of the funding source

Funders for the three studies had no role in the study design, data collection, data analysis, interpretation, and writing of the report.

Results

Test of race disparities in maternal and infant health and well-being, absent treatment

Cell sample sizes, group means, and standard deviations for each of the five outcome variables for each of the three trials are reported in Table 1. Race disparities, absent treatment, were tested by contrasting groups within the control condition, and test results are reported in Table 2. Overall, 11 of 14 tests indicated significant disparities that favor Non-Hispanic White families over Black families, whereas just 2 of 14 tests indicated significant disparities favoring Non-Hispanic White families over Hipanic families.

RCT I. Significant disparities favoring Non-Hispanic White families over Black families were identified for each of the five outcome variables, supporting hypotheses that Black families would demonstrate higher levels than non-Hispanic White families for maternal anxiety, maternal depression, father non-support, child emergency medical care, and child maltreatment investigations.

Two of five tests of disparities favoring Non-Hispanic White families over Hispanic families were found, indicating higher maternal depression and child maltreatment investigations for Hispanic families.

RCT II. Significant disparities favoring Non-Hispanic White families over Black families were identified for three of the five outcome variables, indicating higher levels of problems for Black families for father non-support, child emergency medical care, and child maltreatment investigations. A fourth variable, maternal depression, yielded a marginally significant ($p < .10$) disparity indicating higher levels for Black mothers than Non-Hispanic White mothers. Disparities between Hispanic and Non-Hispanic White families were not robust.

Field quasi-experiment. Disparities favoring Non-Hispanic White families over Black families were identified for maternal anxiety, maternal depression, and father non-support, indicating greater problems for Black families. Surprisingly, in this rural context, Black families utilized emergency medical care less than Non-Hispanic White families. The fifth variable, child maltreatment investigations, was not measured in this trial. Disparities between Hispanic and Non-Hispanic White families were not robust.

Implementation of family connects (FC) across groups

The second research question was whether the reach and quality of implementation of FC differed across race groups. Implementation metrics for each of the four race groups for each of the three trials are reported in Table 3, along with tests of differences between Black and Non-Hispanic White families and between Hispanic and non-Hispanic White families. The tests of "Other" race groups were not conducted because of the racial variability within this group.

	Control				Family Connects			
	Non-Hispanic White	Black	Hispanic	Others	Non-Hispanic White	Black	Hispanic	Others
RCT I								
Sample size	68	113	28	62	74	96	29	61
Maternal anxiety	2.96 (3.06)	3.56 (3.90)	3.36 (2.45)	2.03 (2.25)	2.51 (2.47)	2.82 (3.52)	2.83 (2.70)	3.26 (3.55)
Maternal depression	3.47 (3.70)	5.33 (4.88)	5.96 (4.97)	2.76 (3.50)	3.11 (3.86)	4.16 (4.76)	4.30 (2.76)	4.82 (4.62)
Father non-support	1.69 (0.75)	2.34 (1.18)	1.98 (0.93)	1.94 (1.01)	1.62 (0.59)	2.15 (1.05)	2.05 (0.95)	1.72 (0.72)
Emergency medical care	0.93 (1.68)	1.75 (3.80)	0.68 (1.06)	1.45 (4.62)	0.97 (1.45)	0.98 (1.20)	0.45 (0.57)	0.87 (1.24)
Child maltreatment investigations	0.10 (0.60)	0.81 (1.33)	0.32 (0.94)	0.21 (0.66)	0.11 (0.39)	0.55 (1.13)	0.17 (0.47)	0.07 (0.25)
RCT II								
Sample size	36	64	45	12	36	56	58	9
Maternal anxiety	3.69 (3.21)	3.97 (4.68)	2.87 (3.84)	2.09 (2.34)	2.81 (3.45)	2.96 (3.54)	2.88 (2.87)	2.00 (1.80)
Maternal depression	3.63 (3.07)	4.45 (4.77)	4.83 (5.07)	3.45 (3.40)	3.33 (3.84)	3.95 (4.31)	4.55 (4.77)	2.62 (1.78)
Father non-support	1.56 (0.61)	1.83 (0.81)	1.67 (0.59)	1.38 (0.35)	1.47 (0.41)	1.80 (0.90)	1.89 (0.76)	1.59 (1.03)
Emergency medical care	0.28 (0.78)	0.91 (1.27)	0.47 (0.92)	0.42 (1.16)	0.17 (0.38)	0.64 (0.86)	0.67 (1.19)	0.44 (0.53)
Child maltreatment investigations	0 (0)	0.38 (0.75)	0.02 (0.15)	0 (0)	0.06 (0.23)	0.21 (0.46)	0.05 (0.22)	0.11 (0.33)
Field Quasi-experiment								
Sample size	59	57	12	3	198	159	34	6
Maternal anxiety	3.38 (3.76)	4.09 (4.60)	1.73 (2.76)	2.33 (1.15)	3.33 (4.32)	2.88 (4.10)	2.45 (3.48)	1.00 (1.55)
Maternal depression	4.13 (4.42)	5.95 (4.29)	3.73 (3.93)	3.00 (1.00)	3.77 (4.18)	4.87 (5.11)	3.38 (5.27)	3.17 (2.64)
Father non-support	1.73 (0.66)	2.13 (0.94)	1.82 (0.59)	1.5 (0)	1.64 (0.63)	1.68 (0.78)	1.65 (0.70)	1.35 (0.42)
Emergency medical care	1.80 (2.62)	1.11 (1.92)	1.83 (3.27)	0 (0)	1.27 (1.97)	0.92 (1.69)	0.91 (1.46)	1.33 (1.03)

***Table 1*: Sample sizes and group means (standard deviations) for Non-Hispanic White, Black, Hispanic, and Other families, separately for Family Connects and control groups.**

Variable	RCT I	RCT II	Field Quasi-Experiment
Black vs. Non-Hispanic White			
Maternal anxiety	0.18 (p<.05)	n.s.	0.19 (p<.05)
Maternal depression	0.43 (p<.01)	n.s.	0.36 (p<.01)
Father non-support	0.65 (p<.01)	0.32 (p<.05)	0.40 (p<.01)
Child emergency medical care	0.64 (p<.01)	1.56 (p<.01)	n.s.
Child maltreatment investigations	2.06 (p<.01)	0.38 (p<.01)	Not measured
Hispanic vs. Non-Hispanic White			
Maternal anxiety	n.s.	n.s.	−0.69 (p<.01)
Maternal depression	0.54 (p<.01)	n.s.	n.s.
Father non-support	n.s.	n.s.	n.s.
Child emergency medical care	n.s.	n.s.	n.s.
Child maltreatment investigations	1.14 (p<.01)	n.s.	Not measured

***Table 2*: Tests of disparities between Black and Non-Hispanic White families and between Hispanic and non-Hispanic White families in the absence of intervention.**

Note: Coefficients for the top five rows are defined as (Black Mean − Non-Hispanic White Mean). Coefficients for the bottom five rows are defined as (Hispanic Mean − Non-Hispanic White Mean). Models test the hypothesized (two-tailed) contrast within control condition between Black and Non-Hispanic White familes (top 5 rows) and between Hispanic and Non-Hispanic White families (bottom 5 rows). Multiple imputation (m=10) based on all outcomes, covariates, and treatment status was used to handle missing data Covariates are birth risk, Medicaid coverage, infant gender and single parent family. For RCT II and the Field Quasi-Experiment, infant age is also a covariate.

a. The valence of this coefficient indicates that Hispanic mothers displayed lower anxiety than Non-Hispanic White mothers; therefore, this difference is not considered a race-based disparity.

RCT I. The rate at which families took up the invitation and began participation in FC was high overall (80.1%) but significantly higher for Black families (84.9%) and for Hispanic families (89.6%) than for Non-Hispanic White families (67.2%) (each contrast, $p < .001$).

Among families that began participation, the rate of completion of the full FC protocol was higher for Non-Hispanic White families (85.3%) than for Black familes (80.6%) ($p < .05$), and higher for Hispanic families (92.6%) than for Non-Hispanic White families ($p < .001$).

Among families that completed the full FC protocol, the proportion scored as having a major need (3 or 4 on the 4-point scale) was lower for Non-Hispanic White families (23.8%) than for Black families (49.7%) or for Hispanic families (56.7%) (each contrast, $p < .001$).

The rate at which FC-participating families were connected with a community agency and service was initiated was lower for Non-Hispanic White families (.252) than for Black families (.493) and Hispanic families (.631) (each contrast, $p < .001$).

Implementation metrics were also high for the "Other" group. These metrics indicate that implementation of FC was very strong among all groups.

RCT II. The rate at which families took up the invitation and began participation in FC was high overall (76.1%) but higher for Black families (72.0%) and for Hispanic families (88.6%) than for Non-Hispanic White families (60.0%) (first contrast, $p < .05$; second contrast, $p < .001$).

Among families that began participation, the rate of completion of the full FC protocol was high overall and did not differ significantly across groups: for Non-Hispanic White families (90.9%), for Black familes (85.4%), and for Hispanic families (92.5%).

Among families that completed the full FC protocol, the proportion scored as having a major need (3 or 4 on the 4-point scale) was lower for Non-Hispanic White families (30.0%) than for Black families (58.4%) or for Hispanic families (69.8%) (each contrast, $p < .001$).

The rate at which FC-participating families were connected with a community agency and service was initiated was lower for Non-Hispanic White families (.136) than for Black families (.336) and Hispanic families (.543) (each contrast, $p < .001$).

Metrics indicate implementation with all four race groups was strong.

Field quasi-experiment. The rate at which families took up the invitation and began participation in FC was high overall (83.4%) but higher for Black families (78.6%) and for Hispanic families (87.1%) than for Non-Hispanic White families (59.9%) (each contrast, $p < .001$).

Among families that began participation, the rate of completion of the full FC protocol did not differ significantly across groups: for Non-Hispanic White families (96.7%), for Black familes (98.7%), and for Hispanic families (95.1%).

Among families that completed the full FC protocol, the proportion scored as having a major need (3 or 4 on the 4-point scale) was lower for Non-Hispanic White families (47.6%) than for Black families (61.2%) or for Hispanic families (62.3%) (first contrast, $p < .001$; second contrast, $p < .05$).

The rate at which FC-participating families were connected with a community agency and service was

	RCT I				RCT II				Field Study			
	Non-Hispanic White	Black	Hispanic	Other	Non-Hispanic White	Black	Hispanic	Other	Non-Hispanic White	Black	Hispanic	Other
Sample size	686	833	510	298	110	143	105	85	366	296	93	233
Voluntary participation rate	67.2%	84.9%	89.6%	79.9%	60.0%	72.0%	88.6%	88.2%	59.9%	78.6%	87.1%	97.4%
Among participating families, program completion rate	85.3%	80.6%	92.6%	88.2%	90.9%	85.4%	92.5%	57.3%	96.7%	98.7%	95.1%	54.0%
Among families completing assessments, rate having one or more major needs (score 3 or 4)	23.8%	49.7%	56.7%	39.0%	30.0%	58.4%	69.8%	41.9%	47.6%	61.2%	62.3%	55.3%
Among families completing assessments, proportion connected with community resources	.252	.493	.631	.389	.136	.336	.543	.165	.259	.450	.516	.246

***Table 3:* Implementation findings for each of three trials of family connects.**

Note: For each study, implementation scores for Non-Hispanic White families are compared to Black families and to Hispanic families using two-tailed tests. * $p < .05$; *** $p < .001$. Tests involving "Other" group were not conducted.

initiated was lower for Non-Hispanic White families (.259) than for Black families (.450) and Hispanic families (.516) (each contrast, $p < .001$).

Metrics indicate implementation with all four race groups was strong.

Impact of family connects on reducing race disparities

Because disparities between Hispanic and Non-Hispanic White families were not robust, tests of treatment impact on the differences between these groups were not considered further. Tests of FC treatment impact on reducing disparities between Black and Non-Hispanic White families were conducted for the 12 variables (5 in RCT I, 4 in RCT II, and 3 in the quasi-experiment) for which a race disparity had been identified within the control group. Disparity reduction was calculated as: $1 - (M_{\text{BLACK FC}} - M_{\text{WHITE FC}})/(M_{\text{BLACK CONTROL}} - M_{\text{WHITE CONTROL}})$ and tested as a significant treatment x race interaction effect. Table 1 lists group means and standard deviations, and Table 4 reports test statistics.

RCT I. Five variables were tested. Random assignment to FC significantly reduced the Black - Non-Hispanic White race disparity in maternal anxiety by 48.3% (p<.01), in maternal depression by 43.5% (p<.01), and in child emergency medical care by 98.8% (p<.05). Random assignment to FC also reduced the race disparity in father non-support by 18.5% and in child maltreatment investigations by 38.0%, but these reductions were not significant.

RCT II. Four variables were tested. Random assignment to FC significantly reduced the race disparity in child emergency medical care by 25.4% (p<.01), and in child maltreatment investigations by 60.5% (p<.05). Random assignment to FC also reduced the race disparity in maternal depression by 24.4%, but this reduction was not significant. FC did not reduce the race disparity in father non-support.

Field quasi-experiment. Three variables were tested. Assignment to FC significantly reduced the race disparity in maternal anxiety by 100% (p<.001) and in father non-support by 90.0% (p<.05). Assignment to FC also reduced the race disparity in maternal depression by 39.6%, but this difference was not significant.

Discussion

This study makes three important empirical contributions to our understanding of race-based disparities in family functioning in the first years of life, and in so doing, makes a valuable fourth contribution of advancing a mandate to measure race disparity reduction by proposing a metric for these tests.

The first contribution is to identify race disparities in important measures of family functioning around the time of birth. These disparities were tested in the control group that did not experience any treatment. Of the

Variable	RCT I			RCT II			Field Quasi-Experiment		
	Disparity Reduction	Test Coefficient	sig.	Disparity Reduction	Test Coefficient	sig.	Disparity Reduction	Test Coefficient	sig.
Maternal anxiety	48.3%	−.29	*p*<.01	Not tested	Not tested	–	100%	−.36	*p*<.001
Maternal depression	43.5%	−.32	*p*<.01	24.4%	.16	n.s.	39.6%	−.08	n.s.
Father non-support	18.5%	−.04	n.s.	No reduction	.13	n.s.	90.0%	−.26	*p*<.05
Child emergency medical care	98.8%	−.32	*p*<.05	25.4%	-1.33	*p*<.01	Not tested	Not tested	–
Child maltreatment investigation	38.0%	−.32	n.s.	60.5%	-.19	*p*<.05	Not measured	Not measured	–

***Table 4*: Impact of assignment to Family Connects on reducing disparities between Black and Non-Hispanic White families for each of three trials.**
Note: Disparity reduction is defined as as "1 - [(Treatment MBLACK - Treatment MWHITE) / (Control MBLACK - Control MWHITE)]". Models included the main effect of treatment group (Control = 0, FC = 1) and tested the hypothesized (two-tailed) interaction effect between treatment condition (Control = 0, FC = 1) x race (Black = 0, Non-Hispanic White = 1), including covariates of birth risk, Medicaid coverage, infant gender and single parent family; In RCT II and the Field Quasi-Experiment, infant age was also a covariate. Multiple imputation (m=10) based on all outcomes, covariates, and treatment status was used to handle missing data.

14 tests of disparities between Black and Non-Hispanic White control families across three trials, 11 disparities were found. Some identified disparities are large and had been reported in prior studies. For mothers' generalized anxiety and depression, the disparity is about a quarter to a half standard deviation and is found in both urban (Durham, NC) and rural (eastern North Carolina) contexts. Similar disparities were identified across contexts in father non-support and child maltreatment investigations.

A large race disparity in infant emergency medical care utilization was identified in both studies in an urban area. Black families in Durham utilize emergency care by about a third of a standard deviation more than non-Hispanic White families. However, in the rural context of eastern North Carolina, the opposite pattern was found: Black families utilize emergency medical care less than Non-Hispanic White families do. Other studies have also shown that rural families in general, and Black rural families in particular, report difficulty in accessing healthcare when needed.[19] The use of emergency medical care is undoubtedly part of a broader cultural pattern in community participation that needs further inquiry.

The second contribution, based on three independent trials, is to show that the Family Connects (FC) perinatal home-visiting intervention can be implemented with uniformly high participation rates and quality across families from all race groups studied (Black, Non-Hispanic White, Hispanic, and Other). Unlike some other government offers,[18] Black families accept the offer to participate in this program at comparable or higher rates than Non-Hispanic White families, perhaps because its universal reach promotes trust rather than stigma. Parents engage with the nurse to identify their family's specific identified needs (rather than assumed needs based on demographics) and then begin participation in community interventions that are tailored to these needs. From these findings, we assert a general principle: when a community intervention program is offered universally (not based on demographics) and is implemented with high quality, and when community interventions are offered based on clinically-identified, family-specific needs rather than demographics, the level of trust will be increased, self-labeling will be reduced, and participation rates will be high without disparities.

The third contribution is to show that the universal FC program significantly reduces race disparities in maternal and infant health and well-being outcomes. Of the 12 Black – Non-Hispanic White race disparities identified across the three trials, assignment to FC was associated with a reduction in disparity for 11 measures, with 7 of the 11 reductions being statistically significant.

The finding of a significant reduction in race disparities through a universally-offered intervention represents a paradox that we believe is worth further policy

discussion. Since the War on Poverty began in the 1960s, the dominant U.S. federal policy remedy to reduce disparities in outcomes for families with young children has been to target low-income families for compensatory intervention through programs such as Head Start and long-term home-visiting. Although these programs are creatively designed and may have positive impact on some families, they have not yet had the intended impact on population outcomes and disparity reduction, perhaps because families are hesitant to enroll or suffer secondary ill effects of labelling by selves or others. We believe a program offered universally may be more trustworthy and reduce labelling effects. A program with a universal offer does not imply one-size-fits-all treatment: Like primary care in medicine, primary family care can be offered and delivered universally but with individually-tailored interventions based on clinically-identified needs rather than demographic characteristics.

This conclusion about the paradox of universal care no doubt has limits. We do not pretend that huge disparities in income, wealth, and opportunity that are based in centuries of discrimination will be eliminated quickly through universal care. Reparations, cultural change, and other policies articulated in the Healthy People 2020 initiative[20] and the federal plan for disparity reduction in health[21] will be necessary.

The final contribution of this study is to shine light on the importance of empirically identifying race disparities and testing whether public health programs and policies actually reduce these disparities by demonstrating a metric and test (indicated in Table 4) that could be used in all trials of intervention impact on disparity reduction.

This study has numerous limits. The general lack of disparities found between Hispanic and Non-Hispanic White families was surprising and could indicate a lack of statistical power to detect differences. Studies with larger sample sizes are needed. Another limit is the small number and range of outcome variables tested. The findings reported here may differ for other variables, such as family economics or child behavioral development. A broader array of outcomes should be tested in future studies. Finally, whereas this study focused on the disparity between Black and Non-Hispanic White families (which we believe dominates the current moral imperative to remedy wrongs based on a history of slavery in the United States), other studies are needed to examine disparities based on income, race, ethnicity, and geography.

In sum, this study highlights the urgent need to address race disparities in population maternal and infant health. We show that disparities can be reduced through a universal preventive system of primary care, and we offer a template and a metric for future studies to use and a mandate to monitor race disparity reduction in public health interventions.

Contributors

Kenneth A. Dodge: conceptualisation, funding acquisition, methodology, project administration, resources, original writing, editing.
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Data sharing statement

Original data from the three studies can be made available upon application. Administrative data cannot be shared, according to the agreement that granted use of these data.

Declaration of interests

The authors declare no interests or conflicts other than acknowledgement of receipt of research grant funds.

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Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.lana.2022.100356.

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