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Prenatal and Infancy Nurse-Home-Visit Effects on Mothers: 18-Year Follow-Up of a Randomized Trial

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Short Title: 18-year Effects of Nurse Home Visits on Mothers

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Potential Conflict of Interest: The Prevention Research Center for Family and Child Health (PRC), directed by DLO at the University of Colorado School of Medicine, has a contract with the Nurse-Family Partnership© to conduct research to improve the NFP program and its implementation; this contract covers part of Dr. Olds's salary and part of Michael Knudtson's salary. Dr. Olds and Mr. Knudtson were employed by this center at the time the study was conducted. Dr. Olds is the founder of the NFP and with the University of Colorado owns the NFP intellectual property. The University of Colorado receives royalties from governments and organizations outside of the US that implement the NFP and has contracts with those entities to guide implementation of the NFP with quality, but none of the royalties or fees go to Dr. Olds personally; they are used to support PRC research and implementation guidance. Dr. Miller performs economic analyses under contract for the non-profit Nurse-Family Partnership National Service Office. The remaining authors have indicated they have no potential conflicts of interest to disclose.

Data Sharing Statement:
Deidentified individual participant data (including data dictionaries) will be made available, in addition to study protocols, the statistical analysis plan, and the informed consent form. The data will be made available upon publication to researchers who provide a methodologically sound proposal for use in achieving the goals of the approved proposal. Please contact Michael Knudtson, the study biostatistician, at Michael.knudtson@ucdenver.edu 303-724-3199 for further details.

Clinical Trial Registration #: NCT00708695

Abbreviations:

AFDC	Aid to Families with Dependent Children
CIDI-SAM	Composite International Disease Interview – Substance Abuse Module
ES	Effect Sizes
MDD	Major Depressive Disorder
NFP	Nurse-Family Partnership
SNAP	Supplemental Nutrition Assistance Program
SSA	Social Security Administration
SSI	Supplemental Security Income
TANF	Temporary Assistance for Needy Families

Table of Contents Summary: This study summarizes the effects of prenatal and infancy home visits on maternal life-course in an 18-year follow-up of a randomized clinical trial.

What's Known on this Subject: Two randomized trials of prenatal and infant/toddler nurse home visiting found effects on high-risk families' public-benefit costs and pregnancy planning through early adolescence, effects in one trial that were more pronounced among mothers with higher psychological resources.

What This Study Adds: Over the 18-year follow-up, nurse-visited mothers incurred $17,310 less in public-benefit costs, had higher rates of marriage, and those with higher psychological resources at baseline had fewer cumulative years rearing subsequent children following birth of the first child.

Contributor's Statement Page

Dr. Olds conceptualized and designed the study, analyzed and interpreted data, drafted the manuscript, critically revised the manuscript for important intellectual content, obtained funding, and supervised the study.

Dr. Kitzman conceptualized and designed the study, analyzed and interpreted data, critically revised the manuscript for important intellectual content, obtained funding, and supervised the study.

Dr. Cole conceptualized and designed the study, analyzed and interpreted data, and obtained funding.

Ms. Anson, Dr. Smith acquired data, analyzed and interpreted data, and critically revised the manuscript for important intellectual content.

Mr. Knudtson acquired data, analyzed and interpreted data, critically revised the manuscript for important intellectual content, and performed statistical analysis on data.

Drs. Conti, Miller, Hopfer analyzed and interpreted data and critically revised the manuscript for important intellectual content.

All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Abstract

Background: Prenatal and infancy/toddler home visiting by nurses is promoted as a means of improving maternal life-course, but evidence of long-term effects is limited. We hypothesized that nurse-visitation would lead to long-term reductions in public-benefit costs, maternal substance abuse/dependence and depression; and that cost-savings would be greater for mothers with initially higher psychological resources.

Methods: We conducted an 18-year follow-up of 618 low-income, primarily African-American mothers with no previous live births enrolled in an RCT of prenatal and infancy/toddler home visiting by nurses. We compared nurse-visited and control-group costs for SNAP, AFDC/TANF and Medicaid (in 2009 dollars); rates of substance abuse/dependence and depression; and examined possible mediators of intervention effects, focusing on partnered relationships and spacing of subsequent children.

Results: Nurse-visited women, compared to controls, incurred $17,310 less in public-benefit costs (p=.03), an effect more pronounced for women with higher psychological resources ($28,847, p=.01). These savings compare to program costs of $12,578. There were no program effects on substance abuse/dependence or depression. Nurse-visited women were more likely to be married from child age 2 through 18 (19.2 vs. 14.8%, p=.04), and those with higher psychological resources had 4.64 fewer cumulative years rearing subsequent children following birth of the first child (p=.03), the latter a significant mediator of program effects on public-benefit costs.

Conclusions: Through child age 18, the program reduced public-benefit costs, an effect more pronounced for mothers with higher psychological resources and mediated by subsequent pregnancy planning. There were no effects on maternal substance abuse/dependence and depression.

Introduction

Home visiting by nurses for low-income mothers has been promoted as a promising strategy for improving mothers' life-course and reducing poverty and corresponding public-benefit costs. [1-3] The primary evidentiary foundation for this claim comes from three randomized clinical trials (RCT's) of the Nurse-Family Partnership (NFP), a program of prenatal and infant/toddler home-visiting by nurses for low-income mothers bearing first children,[4] carried out in Elmira, NY,[4-6] Memphis, TN,[4,7-12] and Denver, CO. [13,14]

Our team has found consistent program effects in these trials on rates of closely spaced subsequent pregnancies and reliance on public benefits, first through child age 15 in a trial with primarily low-income whites in Elmira, NY; [5,6] and then through age 12 in a trial with low-income primarily African-Americans living in a disadvantaged inner-city setting – Memphis, TN, the study on which the current report is based. [7-11] We also found program effects on closely spaced subsequent pregnancies and early maternal employment in a third trial with a large portion of Hispanics,[13] but no employment effects after the program ended. [14] In the current report from the Memphis trial, we examine the extent to which the program reduced public-benefit costs, maternal substance abuse and depression through mothers' first children's 18th birthdays.

We hypothesized that nurse-visited (NV) mothers, compared to controls, would incur fewer costs for SNAP, AFDC/TANF, and Medicaid over this 18-year period. Program effects on timing of subsequent children's births and public benefits in earlier phases of this trial [7,8,10,11] were more pronounced among women with higher psychological resources (HPR) to cope with adversity, i.e., in the upper half of the distribution on an index composed of maternal intellectual functioning, [16] mental health, [17] and sense of mastery[18] / self-efficacy (mothers' beliefs about the importance of and their confidence in accomplishing key NFP behavioral objectives) [19] measured at baseline. [7] We hypothesized corresponding conditional

effects on public-benefit costs for 18-year follow-up. Note that benefits for first-born children in the Memphis and Denver trials have been greater for those born to mothers with limited psychological resources (LPR), [7-10,12-14] indicating that beneficial program effects for mothers and children, in aggregate, cut across the range of maternal psychological resources.

Given replicated program effects on maternal substance-use behavioral impairments at child age 15 in the Elmira trial,[6] and at age 12 in the current (Memphis) trial,[11] we hypothesized that NV women would report fewer substance-abuse disorders (SUD's) than control-group women at child-age 18. We also reasoned that earlier program effects in the current trial on maternal life-course (e.g., improved sense of mastery and pregnancy planning, increased cohabitation, fewer behavioral impairments due to substance use) [7-11] and children's health and development, [7-10,12] would lead to reductions in maternal stress and depression at the 18-year follow-up, in spite of no intervention effect on women's reports of depression at child age 12.[11]

Prior to analysis of 18-year program effects, we modified the original hypotheses for this phase of follow-up: First, given little meaningful variation in sample neighborhood disadvantage (2.4SD above the national mean[20]), we eliminated a hypothesis that program effects would be greater among mothers who lived at registration in the most distressed neighborhoods. Second, we removed a hypothesis that program effects on SUD's and depressive symptoms would be greater for women with limited psychological resources, given no such moderation at the 12-year follow-up.[11]

In addition, given that the program increased inter-pregnancy intervals and aspects of partner relations in earlier phases of this study,[7-11] we removed them from the list of primary outcomes and examined them as possible mediators of public-benefit costs, substance-use disorders, and depression.[4] We focused the mediation analysis on the cumulative number of years that mothers reared subsequent children following birth of the first child (subsequent-child years). [10,11] Note that marriage and

cohabitation also are possible mediators of program effects on maternal life-course, given that both predict increased earnings for both male and female African Americans; [21] and that both are associated with partner health and economic wellbeing overall in the US; [22] but selection factors may account for some of these associations. [23]

Participants and Methods

We conducted an RCT of the NFP in a public system of obstetric and pediatric care in Memphis, Tennessee, with registration of the original sample completed between June 1990 and August 1991. We enrolled women <29 weeks gestation, with no previous live births, and at least 2 sociodemographic risk characteristics (unmarried, <12 years of education, unemployed). Ninety-two percent were African-American, and at enrollment, 98% were unmarried, 64% < 18 years of age, and 85% from households with incomes below the federal poverty guidelines. [7] Participants completed informed consent procedures approved by the University of Rochester Institutional Review Board.

Appendix Table A1 summarizes the CONSORT information. Eighty-eight percent (1,138) of 1,289 eligible pregnant women offered participation completed informed consent and were randomized to one of four treatment conditions following a procedure that concealed assignment from individuals involved in gathering participant data. [7] Seven hundred forty two participants were assigned to two treatment conditions created to estimate program effects on postnatal outcomes: 514 to Treatment 2 (Control) and 228 to Treatment 4 (NV), both described below. Sample size and assignment ratios were derived from statistical power calculations in the original phase of the trial.[7] Table A1 shows those lost to follow-up because of miscarriage or child death prior to age 2, maternal refusal to participate at earlier phases; and the number evaluated with maternal assessments at youth age 18. Some mothers, because of disabling conditions or refusal, did not complete all assessments at youth age 18. Numbers of

completed assessments for each outcome are given in Tables 1 and 2 below. Repeated measures over time increased n's for some outcomes and are noted by All under the column Assessment Timeframe.

Treatment Conditions

The study design contrasted women assigned to two treatment conditions established to estimate the effects of the NFP program (described below) after delivery (Table A1): Women in the T2 Control group (n = 514) were provided free transportation for scheduled prenatal care plus developmental screening and referral for children at 6, 12, and 24 months of age. Women in the T4 NV condition (n = 228) were provided the same services as the Controls, plus NFP home visiting through age two.

The NFP program was designed to 1) improve pregnancy outcomes by promoting women's prenatal health; 2) improve children's health and development by promoting parents' care of their children; and 3) enhance parents' health and life-course by guiding women to reduce closely spaced subsequent pregnancies, complete their educations, and find work. Nurses focused on reducing closely spaced subsequent pregnancies to protect the health of the mother [24,25] and offspring, [26-30] and to help women gain traction in education and employment. [4,31, 32] Nurses linked families with needed services and, when possible, involved other family members (especially children's fathers and grandmothers) in the visits. [4] Program protocols were grounded in developmental epidemiology and theories of human-attachment, human-ecology, and self-efficacy. [4]

The program was implemented by the Memphis/Shelby County Health Department during a nursing shortage, leading to nurse turn-over for 37% of the families. [7] Nurses carried a maximum caseload of 25 families each; relied upon detailed visit-by-visit guidelines structured around 62 visits; and used their clinical judgment to adjust visit dosage and content, including some telephone visits, to address individual family needs. [4, 33, 34] Visits were structured to coincide with particular maternal and child health issues likely to emerge at particular phases of gestation and the first two years of life that

addressed program goals. Overall, nurses completed a mean of 7 home visits during pregnancy and 26 visits during the first 2 years postpartum. [7, 34]

Data Gathering and Maternal Outcomes

Descriptions of baseline and intervening data are provided in earlier publications.[7-12] All data for the current follow-up were gathered by staff masked to treatment assignment. Most maternal interviews were conducted after their first-born children's 18th birthdays (mean age 18.67 years, SD=0.95, range-17.5 – 23.9). Interviews were completed between October 2008 and September 2014, with 618 of the 658 mothers whose children had not died before age 2, who had not died themselves, or had not refused participation prior to this assessment period. State administrative records for SNAP, AFDC/TANF, and Medicaid were reviewed by December 2015 for the 618 mothers interviewed at child age 18.

Primary, secondary, and exploratory (possible mediator) outcomes, the specific variables measured, and the bases for study hypotheses are shown in Appendix Table A2. The primary outcome was mother's total public-benefit costs in 2009 dollars for SNAP, AFDC/TANF, and Medicaid from the first child's birth through age 18. Secondary outcomes consisted of maternal substance abuse/dependence[35] and symptoms of depression that crossed borderline or clinical thresholds.[36]

We assessed a set of exploratory outcomes primarily to examine their role in mediating the effect of the program on primary and secondary outcomes. They included a variable that characterized the cumulative number of years mothers reared subsequent children following birth of the first child (labeled subsequent-child years); rates of partnered relationships, including co-habitation, and marriage from child age 2 through 18; number of months marital partners were employed (at the18-year interview); cumulative number of months mothers reported working; maternal income derived from Social Security Administration (SSA) records (available at the time of review through child age 16); current use of illicit and illegal substances; [37] borderline or clinical anxiety; [38] and sense of mastery. [18]

Measures for the current report were derived primarily from intake [7] and 18-year assessments, although intervening data [7-11] were integrated with 18-year measures to create longitudinal data sets.

Statistical Models and Methods of Analysis

Analyses are reported on all cases randomized insofar as outcome data were available (see Table A1). The core statistical model consisted of a 2-level treatment factor (NV vs. control), a 2-level maternal psychological resources factor (HPR/LPR), their interaction, and 2 covariates - household poverty and maternal childrearing attitudes associated with maltreatment (CAA)[39] measured at intake. Both covariates were predictors of maternal life-course outcomes. Examination of the maternal mastery outcome included intake mastery as an additional covariate. For quantitative outcomes on which we had multiple assessments (e.g., public-benefit costs), we analyzed data in mixed models that included, in addition to core model terms, women as levels of a random factor, a fixed repeated measures classification factor for time (first-born child age) of assessment, and all interactions of time with the other fixed classification factors. [Note that examination of SSA income (only available through 16-years following birth of the first child) included 3 additional covariates - a time-varying indicator of whether mother was 19 or older for each year following the first child's first birthday, smoking status, and years of education at intake; and that SSA income analyses were conducted by SSA staff, producing summary tables for this report.] For dichotomous outcomes, given small cell sizes, we examined outcomes in the 2-level treatment model, dropping the Treatment x HPR/LPR interaction, treating HPR/LPR as a simple classification factor; in all instances this interaction term was not significant (p-value>0.20).

Key tests focused on the treatment effect averaged over all other fixed classification variables, including those within subjects and the same treatment effect restricted to HPR mothers. The tables show the least squares (adjusted) means over time. For repeated outcomes, we report results averaged or

summed over the entire period, as well as the interval between child ages 12 and 18. In order to illustrate program effects on public-benefit costs and subsequent-child years over time, we plot point estimates with standard errors for the NV and control groups for every year following birth of the first child. As a means of comparing treatment differences on quantitative outcomes, we also show effects in standard deviation units (mean difference divided by pooled standard deviation), sometimes referred to as Effect Sizes, ES.

Preliminary mediation analyses were conducted using PROC CAUSALMED in SAS v9.4.[40] Variables included treatment condition, the two covariates (CAA and household poverty), exploratory mediator variables reported below for which there were NV-control differences (examined one at a time), and the outcome variable.

Results

Background Characteristics

The NV and Control groups were similar on background characteristics for participants on whom 18-year follow-up assessments were conducted (Table A3), with these exceptions: at intake, NV women, compared to Controls, lived in households with less discretionary income, higher person-per-room density, higher scores on a household poverty index, and higher CAA.

Primary and Secondary Outcomes

As shown in Table 1, there were no NV-Control differences in maternal reports of substance abuse/dependence or depression. There were, however, significant program effects on public-benefit costs over the 18-year period following birth of women's first children. NV women, compared to controls, incurred $17,310 less in public-benefit costs for SNAP, AFDC/TANF, and Medicaid (ES= -0.13; 95% CI: -0.24, -0.01; p=.03). This overall difference was driven by the intervention effect through child age 12, with no significant NV-Control difference between ages 12 and 18, although differences in

that age-range contributed to the overall estimated effect through age 18. While the overall difference was present for the sample as a whole, as shown in Figure 1, it was more pronounced ($28,847) for women with higher psychological resources measured at registration (ES=-0.21, 95% CI: -0.38, -0.04; p=.01). There were no overall NV-control differences in public-benefit costs for LPR women, but NV LPR mothers received fewer public benefits during the three-year period following end of the program, that is, from child age 3-5 (Figure 2) which contributed to the overall estimate of intervention effect. Table A4 shows estimates of each component of the total-benefit variable.

Exploration of Mediation

As shown in Table 2, there were no intervention-control differences in the number of months mothers worked since birth of their first child, substance use, or anxiety. As shown in Figure 3, however, NV HPR women, compared to control-group counterparts, had 4.64 fewer cumulative years rearing subsequent children following birth of the first child (ES=-0.22, 95% CI: -0.42, -0.02; p=.03). There were no intervention-control differences for LPR mothers (data not shown).

While there were no intervention-control differences in whether women were in partnered relationships from child age 2 to 18, NV women, as a trend, were more likely to co-habit (36.8% vs. 32.6%, AOR=1.20, CI=0.97, 1.49; p=.09) and, as shown in Figure 4, were significantly more likely to be married over this period (19.2% vs. 14.8%, AOR: 1.37, CI: 1.01, 1.85; p=.04). The treatment difference in marriage led to NV women's living, at the age-18-follow-up, with spouses employed for 13.96 more months than Control group women (ES=0.22, 95% CI: 0.05, 0.39, p=.012).

There were no intervention-control differences in mothers' SSA-derived incomes from the first child's birth through age 16, but NV women earned more than controls in years 4 and 5 following birth of the first child (Figure 5). NV women also reported greater sense of mastery through age 18 (ES=0.13, 95% CI: 0.03, 0.23; p=.009).

We examined each of the significantly different outcomes (or trends) in Table 2 as possible mediators of program effects on public-benefit costs. The only significant mediator was subsequent-child years, although all of the hypothesized mediators for which there were NV-Control differences predicted public-benefit costs as expected (data not shown).

Discussion

The program had no effect on reports of maternal substance abuse/dependence, depression, substance use, months worked since birth of their first child, or anxiety, but produced long-term effects on public-benefit costs for SNAP, AFDC/TANF, and Medicaid. Program effects on public-benefit costs were most pronounced for HPR mothers, an effect explained by the reduction in subsequent-child years.

NV women, compared to controls, had no increase in partnered relationships, but had increased co-habitation (as a trend); marriage; and sense of mastery. Moreover, while there were no program effects on income, NV women earned more than Controls during years 4 and 5 following the first child's birth. We have yet to fully understand whether improved sense of mastery, increases in early earnings, cohabitation, marriage, and marital-partner earnings, in aggregate, contribute to the program effect on public-benefit costs.

Given that the program cost about $12,578 in 2009 dollars, the $17,316 discounted savings reduced public-benefit costs by $4,738 per family. Other savings to government and society, such as reductions in first-born disability [45] and rates of low birthweight in second births [46] are not yet monetized.

The results found at this phase of the trial must be interpreted in light of their limitations. The first is that maternal substance use and abuse were evaluated with self-report and extensive evidence indicates that surveys substantially underestimate substance use. [47-49] Note that NV mothers in the

Elmira trial by the end of pregnancy became more accurate reporters of cigarette smoking than control-group women, when evaluated with serum cotinine.[50]

Second, the rate of depression reported here may underestimate its prevalence given low rates of Major Depressive Disorder reported by African-Americans, compared to non-Hispanic whites; [51] this may be traced to their reluctance to disclose vulnerabilities, given their historic identity in being strong in coping with discrimination.[52]

Third, the Medicaid-cost calculation combined administrative data indicating whether mother received benefits for each month following the first child's birth with maternal report of subsequent children's birthdates. This assumes that all children lived with mothers for all months following their births, which likely is imprecise.

Fourth, while marriage and co-habitation are associated with better wellbeing,[21,22] the findings on marriage and co-habitation presented here do not address relationship quality and stability, important predictors of partners' physical and mental health.[53]

Fifth, the return on investment needs to be interpreted in light of the extreme poverty, concentrated social disadvantage, and high rates of adolescent pregnancy found in this sample, as well as the pre-welfare-reform policy context in place when the trial began, [54] limiting generalizability of these findings.

In general, we found enduring program effects on public-benefit costs through child age 18, but no program effects on maternal substance abuse and depression. These findings, along with an accompanying article on child outcomes, [45] support the potential of this program to promote child development and reduce public-benefit costs when focused on very low-income families living in impoverished communities.

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Michael Knudtson had full access to all of the data in the study and takes responsibility for the integrity of the data and accuracy of the data analysis.

Additional Contributions

We thank Evelyn Collins for tracing and engaging study participants and for managing the Memphis study office since 1991; Benjamin Jutson (UC Denver) for help in preparing this manuscript, and Wendy Gehring (UC Denver) for help with data management. Collins, Jutson and Gehring received compensation from research grants for their work.

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Figure 1. Discounted estimates of public-benefit costs by year following birth of first child – high psychological-resource sample

Figure 2. Discounted estimates of public-benefit costs by year following birth of first child – Limited Psychological Resource sample

Figure 3. Subsequent child-years over time following birth of first child for nurse-visited and control mothers with initially high psychological-resources.

Figure 4: Rates of self-reported marriage from child age 2 through 18 for nurse-visited and control-group women.

Figure 5. Maternal wages from birth of first child through child age 16 reported to Social Security Administration for Nurse-Visited and Control-Group Women.

Table 1. Maternal outcomes at 18-year follow-up of Memphis Trial of NFP

		Control (T2)		Nurse Visited (T4)		T4-T2		
Variable	**Assessment Timeframe**	**N**	**LS[e]-Mean or % (SE)[f]**	**N**	**LS[e]-Mean or % (SE)[f]**	**LS[e]-Mean Diff (SE)[f]**	**ES[g] or AOR[h] (95% CI)[i]**	**P**
Primary Outcome								
Public-benefit costs - $ [a,b]	0-18y	472	$192,836 ($4,435)	208	$175,525 ($6,652)	$-17,310 ($8,009)	-0.13 (-0.24 , -0.01)	0.03 *
	12-18y	472	$58,776 ($2,219)	208	$55,405 ($3,317)	$-3,370 ($3,994)	-0.07 (-0.25 , 0.10)	0.40
Secondary Outcomes								
Substance Dependence/Abuse-% [c, d, 35]	Enrollment-18y	406	12.1% (1.63%)	183	12.7% (2.48%)		1.06 (0.62 , 1.81)	0.82
Depression (Clinical/Borderline)-% [c, 36]	18y	425	7.7% (1.33%)	192	8.5% (2.02%)		1.12 (0.61 , 2.04)	0.72

[a] Sum of annual costs for Supplemental Nutrition Assistance Program, Aid to Families with Dependent Children/Temporary Assistance for Needy Families, and Medicaid. Note that estimates derived from the current phase of follow-up differ from those reported at the 12-year follow-up. This difference is due to an error in the records provided by TN at the earlier phase of follow-up. It has been corrected in the current analysis.

[b] Model for analysis includes classification factors for treatment, maternal psychological resources (HPR/LPR), age of first-born child, and their interactions as well as two covariates: household poverty and maternal childrearing attitudes associated with maltreatment

[c] Model for analysis includes classification factors for treatment, maternal psychological resources (HPR/LPR) and their interaction as well as two covariates: household poverty and maternal childrearing attitudes associated with maltreatment

[d] Note that 18-year interview covered recall of abuse/dependence covering period following enrollment in trial during pregnancy

[e] LS = Least Squares (adjusted) mean

[f] SE=Standard Error

[g] ES = Effect Size expressed in standard deviation units

[h] AOR = Adjusted Odds Ratio

[i] 95% CI = 95% Confidence Interval

* P<.05

Table 2. Maternal outcomes assessed to explore mediation of program effects on primary and secondary outcomes at 18-year follow-up of Memphis Trial of NFP

		Control (T2)		Nurse Visited (T4)		T4-T2		
Variable	**Assessment Timeframe**	**N**	**LS[j]-Mean or % (SE)[k]**	**N**	**LS[j]-Mean or % (SE)[k]**	**LS[j]-Mean Diff (SE)[k]**	**ES[l] or AOR[m] (95% CI)[n]**	**P**
Subsequent-child years [a,b]	0-18y	480	26.53 (0.81)	214	24.79 (1.22)	-1.74 (1.47)	-0.08 (-0.22 , 0.05)	0.24
	12-18y	480	12.65 (0.32)	214	12.24 (0.48)	-0.41 (0.57)	-0.06 (-0.22 , 0.10)	0.47
Have current partner - %[c]	All[h]	479	70.7% (1.21%)	211	72.8% (1.76%)		1.10 (0.90 , 1.36)	0.35
	18y	425	61.5% (2.55%)	192	64.5% (3.72%)		1.14 (0.78 , 1.67)	0.51
Live with current partner - % [c]	All[h]	479	32.6% (1.35%)	211	36.8% (2.12%)		1.20 (0.97 , 1.49)	0.09 (*)
	18y	426	33.3% (2.50%)	192	38.7% (3.89%)		1.26 (0.85 , 1.87)	0.24
Married - % [c]	All[h]	479	14.8% (1.11%)	211	19.2% (1.96%)		1.37 (1.01 , 1.85)	0.04 *
	18y	426	20.9% (2.27%)	192	28.4% (3.92%)		1.50 (0.94 , 2.38)	0.09 (*)
Mos. current spouse employed [d]	18y	415	25.66 (3.09)	189	39.62 (4.60)	13.96 (5.56)	0.22 (0.05 , 0.39)	0.01 *
Cumulative months mothers worked [b]	0-18y[i]	463	92.96 (2.20)	205	90.63 (3.31)	-2.33 (3.98)	-0.03 (-0.14 , 0.08)	0.56
	12-18y	426	47.59 (1.25)	192	46.50 (1.88)	-1.09 (2.26)	-0.05 (-0.24 , 0.14)	0.63
SSA earnings birth to 16-years [e]	0-16y	490	$189,489 ($8,730)	217	$194,447 ($13,173)	$4,958 ($15,836)	0.02 (-0.10 , 0.14)	0.75
Current Substance Use - % [f, 37]	18y	425	27.0% (2.17%)	192	24.4% (3.12%)		0.87 (0.59 , 1.29)	0.49
Anxiety (Clinical/Borderline)-% [f, 38]	18y	425	9.5% (1.46%)	192	8.9% (2.04%)		0.94 (0.53 , 1.67)	0.82
Mastery [g,18]	All[i]	476	99.62 (0.28)	210	100.95 (0.42)	1.33 (0.51)	0.13 (0.03 , 0.23)	0.009 **
	18y	424	99.69 (0.45)	192	100.74 (0.67)	1.06 (0.81)	0.11 (-0.05 , 0.27)	0.19

[a] Count of subsequent children born to mothers indexed by subsequent child birth date. Units expressed as cumulative number of years following births of subsequent children from first child's birthdate through age 18.

[b] Model for analysis includes classification factors for treatment, maternal psychological resources (HPR/LPR), child age and their interactions as well as two covariates: household poverty and maternal childrearing attitudes associated with maltreatment

[c] Model for analysis includes classification factors for treatment, child age and their interaction as well as three covariates: household poverty, maternal childrearing attitudes associated with maltreatment, and maternal psychological resources (HPR/LPR)

[d] Note that non-married women were assigned values of zero. Model for analysis includes classification factors for treatment, maternal psychological resources (HPR/LPR), and their interaction as well as two covariates: household poverty and maternal childrearing attitudes associated with maltreatment

[e] Derived from Social Security Administration records. Model for analysis includes classification factors for treatment, maternal psychological resources (HPR/LPR), child age, and their interactions as well as five covariates: household poverty, maternal childrearing attitudes associated with maltreatment, a time-varying indicator of whether mother was 19 or older for each year following the child's first birthday, smoking status, and years of education at intake

[f] model for analysis includes treatment, maternal psychological resources (HPR/LPR), household poverty and maternal childrearing attitudes associated with maltreatment and no interaction terms

[g] model for analysis includes classification factors for treatment, maternal psychological resources (HPR/LPR), child age and their interactions as well as three covariates: baseline maternal mastery, household poverty and maternal childrearing attitudes associated with maltreatment

[h] Based upon interviews conducted at child age 2, 4.5, 6, 9, 12 and 18 years.

[i] Based upon interviews conducted at the 36th week of pregnancy, the 6th month of the child's life, and 2, 4.5, 6, 9, 12 and 18 years after delivery of first child.

[j] LS = Least Squares (adjusted) mean

[k] SE=Standard Error

[l] ES = Effect Size expressed in standard deviation units

[m] AOR = Adjusted Odds Ratio

[n] 95% CI = 95% Confidence Interval

(*) P<.10

* P<.05

** P<.01

APPENDIX

Table A1. CONSORT information for mothers enrolled in trial through 18-year follow-up

Eligible Subjects Invited to Participate	1290				
Number declined participation	151				
Number Randomized	1138				
Treatment Group Assignment	**T1 [a]**	**T2 [b]**	**T3 [c]**	**T4 [d]**	**Total (T2 & T4)**
Number allocated to each treatment [e]	166	514 [f]	230	228	742
Miscarriages (mothers not followed)	6	19	6	8	27
Stillbirths (mothers not followed)	0	5	3	2	7
Child death before age two (mothers not followed)		7		1	8
Mother declined participation after randomization & before child age 18		15		11	26
Maternal Death (prior to child age 18)		15		3	18
Available for 18-year follow-up		**453**		**203**	**658**
Completed maternal interview		426		192	618

[a] Treatment 1 - Prenatal transportation

[b] Treatment 2 - Prenatal transportation + developmental screening and referral

[c] Treatment 3 - Prenatal transportation + developmental screening and referral + prenatal nurse home visits

[d] Treatment 4 - Prenatal transportation + developmental screening and referral + prenatal and infant/toddler nurse home visits

[e] We assigned twice as many participants to the T2 control condition as T4 NV group to minimize costs, given that program costs were paid for with research dollars. Groups 1 and 3 were included in the original phase of the trial to meet statistical power requirements for estimating prenatal effects. The original publication describes the allocation methods and assignment ratios in detail. [7]

[f] Note that one mother was enrolled and randomized twice by mistake following a miscarriage. We included her only once with her original assignment to the control group

Table A2. Outcome Domains, Variables Measured, and Bases for Maternal Life-Course Hypotheses

Outcome Domains and Variables Measured [a]	**Basis for Hypotheses** [b]			
	Earlier Effect in Current Trial	**Effect in Other Trial**	**Predicted from Earlier Phases or Trials**	**Conditional Effect**
Primary Outcome				
Mother's Total Public-Benefit Costs in Dollars		X[5,6]	X[7]	HPR [h]
SNAP, AFDC/TANF, and Medicaid costs birth – 18yrs [c]	X[8-11]			
Secondary Outcomes				
Substance Abuse/Dependence			X[6,11]	
Composite International Disease Interview – Substance Abuse Module (CIDI-SAM) [35]				
Mother's Borderline or Clinical Depression			X[5-15]	
Beck Depression Screening Inventory [36]				
Exploratory Outcomes Examined as Mediators				
Cumulative Subsequent Children [d]		X[5-9,13,14]		HPR [h]
Subsequent child-years through 18 yrs.	X[10,11]			
Partnered Relationships [e]	X[8-11]			
Being in a partnered relationship (y/n) across assessments				
Co-habiting (y/n) across assessments				
Married (y/n) across assessments				
Duration of Employment – Marital Partners [e]	X[8,10]		X[9,11]	
Number of months marital partners reported to have worked at 18yr				
Duration of Employment - Mothers		X[5,13]		
Cumulative no. months mothers reported working birth-18 yrs.	X[7]			
Income [g]			X[5-15]	
SSA income birth to child age 16				
Illicit and illegal Drug Use - %	X[11]	X[6]	X[7-15]	
Any drug use in preceding 30-day period [37]				
Anxiety – Borderline or Clinical - %			X[5-15]	
Beck Anxiety Screening Inventory [38]				
Mastery [f]			X[5-15]	
Pearlin Mastery Scale [18]	X[7--11]			

[a] Outcome domains are listed in bold italics. Specific variables assessed are shown under each outcome domain. Outcomes were selected on the basis of their being affected in earlier phases of this trial, the preceding trial, or on theoretical and epidemiologic grounds, with attention to those aspects of functioning that are of clinical or public health importance and that could be assessed without over-burdening respondents.

[b] We show the bases for hypotheses in three categories: 1) an earlier effect on the same specific measure or construct in an earlier phase of the trial; 2) an effect on the same measure or construct in other trials; and 3) effects in earlier phases or trials that predict the current outcomes on theoretical or epidemiologic grounds. When the prediction was made from the same measure, the basis for the hypothesis is shown on the same row; otherwise it is shown on the construct row (bold italics). Note that those outcomes hypothesized to be greater for particular subgroups are shown in the last column.

[c] Monthly grant amounts for SNAP and AFDC/TANF were derived from the Center for Business and Economic Research, University of Tennessee, which provided administrative records of payments for those who lived in TN. In addition, CBER

provided monthly enrollment data for Medicaid. Medicaid costs were derived from TennCare per capita costs published annually by the state of TN and varied based on the number, age, and sex of live-born children alive each month. Estimates of enrollment for those who moved out of TN were based upon maternal report. Out of state grant amounts for SNAP and TANF/AFDC were imputed using average grant amounts in TN for a particular family size (mother + all live born children) and Medicaid costs were derived using the same per-capita costs published from TN. There were no treatment differences in the percentage of mothers who lived out of TN. Note that welfare reform went into effect in 1996, constraining eligibility requirements for receiving cash assistance. Costs were discounted at 3%, and adjusted to 2009 dollars, the midpoint during which this follow-up was completed.

[d] Exploratory outcome. Given that the program had increased inter-pregnancy intervals consistently in earlier phases of this trial [7-11] and in other trials,[5,13,14] beginning with the 9- and 12-year follow-ups,[10,11], we shifted the focus of the analysis to cumulative subsequent child-years following birth of the first child in an effort to understand the role of subsequent birth timing in accounting for public-benefit costs. Note that in earlier publications this variable was labeled cumulative subsequent births. The current definition is clearer but not different operationally other than defining the data in total cumulative subsequent child-years instead of annualized means. The variable is exploratory in the sense that we wanted to explore its role in accounting for public-benefit costs. Note that the prevention of closely spaced subsequent pregnancies was targeted to promote maternal and child health,[24-30]and to help women gain traction in the workforce.[31-32]

[e] Exploratory outcomes. Nurses systematically made an effort to involve fathers and mothers' partners in the program, along with grandmothers, to help create a supportive informal social environment to promote mother's own health and wellbeing, a broader system of care for the child, and financial resource for the family.[4] We found program effects on various aspects of mothers' partnered relationships, i.e., having a partner, co-habiting, and marriage, duration of these relationships at earlier phases of follow-up.[8,10,11] This set of variables was assessed to better understand the endurance of these effects and their role in mediating program effects on public-benefit costs and maternal substance abuse/dependence and depression.

[f] Exploratory outcome. We found consistent intervention effects on maternal sense of mastery reported at earlier phases of follow-up.[7,9-11] We measured it in the current phase to examine the endurance of this effect and to examine its possible role in mediating program effects on public-benefit costs. Note that the promotion of maternal self-efficacy is a core theoretical component of the program.[4]

[g] Exploratory outcome. We found short-term program effects on self-reported employment in an earlier trial,[5] and a subsequent trial,[13] but no effects on reported employment in the current trial. SSA income provided the first objective indicator of maternal earnings following the child's birth through age 16. We estimated SSA income from Social Security Administration records from the first child's date of birth through age 16; we relied upon analyses conducted by SSA, using code written by MDK. The SSA income values were discounted at 3%, and adjusted to 2008 dollars for each mother for each year following birth of the first child through age 16. SSA shared results of analyses in summary tables.

[h] HPR= High Psychological Resources. Subgroup defined by youths' mothers at registration [7] falling into the upper half of the distribution of an index composed of the average z-scores of women's intellectual functioning,[16] mental health,[17] and sense of mastery[18]/self-efficacy (based upon participants' confidence in their ability to accomplish key NFP behavioral objectives). [19]

Table A3: Background characteristics at randomization of those participants for whom 18-year assessments were completed

		Control (T2)		Nurse Visited (T4)	
Variable	Group	N	% or Mean(SD)	N	% or Mean(SD)
Male Sex - %	Whole	426	49.5%	192	51.6%
	HPR [a]	204	54.4%	88	48.9%
Mother Married- %	Whole	426	1.9%	192	0.5%
	HPR [a]	204	2.5%	88	0.0%
Maternal Race, Black- %	Whole	426	94.1%	192	91.1%
	HPR [a]	204	92.6%	88	89.8%
Head of Household Employed- %	Whole	425	56.0%	191	49.2%
	HPR [a]	204	59.3%	88	50.0%
Drank Alcohol Last 14 Days- %	Whole	425	4.2%	192	5.2%
	HPR [a]	204	2.9%	88	2.3%
Smoked Cigarettes Last 3 Days- %	Whole	425	7.1%	192	10.4%
	HPR [a]	204	7.8%	88	9.1%
Used Marijuana Last 14 Days- %	Whole	425	1.4%	192	1.0%
	HPR [a]	204	1.0%	88	0.0%
Any Sexually Transmitted Disease before Randomization- %	Whole	423	34.0%	192	37.5%
	HPR [a]	204	34.3%	88	36.4%
Maternal Age, y	Whole	426	18.00 (3.05)	192	18.10 (3.30)
	HPR [a]	204	17.97 (2.96)	88	17.81 (2.43)
Gestational Age, wks	Whole	426	16.62 (5.68)	192	16.64 (5.77)
	HPR [a]	204	16.76 (5.58)	88	16.68 (5.84)
Psychological Resources Index [b, c]	Whole	425	99.92 (10.00)	192	99.59 (10.83)
	HPR [a]	204	108.24 (6.07)	88	108.91 (6.54)
Highest Grade Completed – Mother	Whole	426	10.25 (1.89)	192	10.13 (2.02)
	HPR [a]	204	10.63 (1.78)	88	10.66 (1.84)
Discretionary Annual Household Income (/$1000) [d]	Whole	426	1.57 (6.97)	192	-0.08 (6.68)
	HPR [a]	204	3.49 (7.05)	88	1.26 (7.01)
% of Census Tract Below Poverty	Whole	426	34.95 (21.16)	192	35.76 (20.17)
	HPR [a]	204	33.19 (21.33)	88	36.52 (19.19)
Housing Density [e]	Whole	426	0.95 (0.49)	192	1.01 (0.54)
	HPR [a]	204	0.85 (0.43)	88	0.92 (0.60)
Conflict with Mother [f]	Whole	425	3.97 (0.87)	192	4.06 (0.80)
	HPR [a]	204	3.81 (0.57)	88	3.96 (0.67)
Conflict with Partner [f]	Whole	425	3.96 (0.84)	192	4.07 (0.80)
	HPR [a]	204	3.85 (0.67)	88	3.91 (0.58)

		Control (T2)		Nurse Visited (T4)	
Variable	Group	N	% or Mean(SD)	N	% or Mean(SD)
Attitudes toward Childrearing Predictive of Child Abuse [g]	Whole	426	99.99 (7.69)	192	101.04 (8.65)
	HPR [a]	204	97.23 (7.26)	88	97.97 (8.57)
Household Poverty Index [c, h]	Whole	426	99.65 (10.11)	192	101.93 (9.92)
	HPR [a]	204	97.21 (9.65)	88	99.98 (10.01)
Neighborhood Disadvantage Index [i]	Whole	426	2.34 (1.62)	192	2.37 (1.79)
	HPR [a]	204	2.16 (1.65)	88	2.48 (1.90)

[a] HPR = Subgroup defined by youths' mothers falling into the upper half of the distribution for psychological resources (high psychological resources) described in the following footnote.
[b] Average z-scores of women's intellectual functioning,[16] mental health,[17] and sense of mastery[18]/self-efficacy[19] (mastery and self-efficacy measures standardized and averaged; self-efficacy based upon participants' beliefs about the importance of and their confidence in accomplishing key NFP behavioral objectives).
[c] Standardized to sample mean = 100, SD = 10
[d] Annual household discretionary income based upon income subsistence standards for Medicaid eligibility, reported household income, and number of individuals in household at registration.
[e] Persons per room
[f] Locally developed scale that assesses degree to which mother experiences conflict in relationship with this person.
[g] Adult-Adolescent Parenting Inventory [39]
[h] Average z-scores of household discretionary income, housing density, and whether head of household was employed.
[i] Average of variables calculated in standard deviation units from the national means of components that comprise index of concentrated social disadvantage [% of block group residents: a) < federal poverty level, b) receiving public assistance, c) unemployed, d) headed by single women; e)< age 18; f) black]. [20]

Table A4: Estimates of numbers of months and costs for specific public benefits among control and nurse-visited families

		Control (T2)		Nurse Visited (T4)		T4-T2		
Variable	Child Age at Assessment	N	LS-Mean (SE)	N	LS-Mean (SE)	LS-Mean Dif (SE)	ES (95% CI)	P-value
SNAP[b] # months[a]	0-18y	472	122.08 (2.44)	208	112.84 (3.65)	-9.24 (4.40)	-0.11 (-0.22 , -0.01)	0.04 *
	12-18y	472	35.89 (1.17)	208	35.07 (1.75)	-0.82 (2.11)	-0.03 (-0.18 , 0.12)	0.70 *
SNAP[b] Costs (2009 $ 3% Discounted) [a]	0-18y	472	$66,518 ($1,657)	208	$60,040 ($2,482)	$-6,477 ($2,989)	-0.12 (-0.23 , -0.01)	0.03 *
	12-18y	472	$18,032 ($0,781)	208	$17,240 ($1,165)	$-791 ($1,403)	-0.04 (-0.20 , 0.11)	0.57
AFDC[c]/TANF[d] # months[a]	0-18y	479	84.90 (2.48)	214	78.90 (3.70)	-6.00 (4.47)	-0.07 (-0.17 , 0.03)	0.18
	12-18y	479	17.63 (1.08)	214	18.01 (1.61)	0.38 (1.94)	0.01 (-0.12 , 0.14)	0.85
AFDC[c]/TANF[d] Costs (2009 $ 3% Discounted) [a]	0-18y	479	$29,930 ($0,968)	214	$26,632 ($1,448)	$-3,298 ($1,744)	-0.09 (-0.19 , 0.00)	0.06 (*)
	12-18y	479	$4,978 ($0,344)	214	$4,585 ($0,513)	$-393 ($0,619)	-0.03 (-0.14 , 0.07)	0.53
Medicaid # months[a]	0-18y	472	146.30 (2.51)	208	139.18 (3.76)	-7.12 (4.52)	-0.09 (-0.19 , 0.02)	0.12
	12-18y	472	40.09 (1.26)	208	38.47 (1.88)	-1.61 (2.26)	-0.06 (-0.22 , 0.10)	0.48
Medicaid Costs (2009 $ 3% Discounted) [a]	0-18y	472	$95,793 ($2,105)	208	$88,817 ($3,153)	$-6,976 ($3,796)	-0.10 (-0.21 , 0.01)	0.07 (*)
	12-18y	472	$35,389 ($1,269)	208	$33,492 ($1,895)	$-1,897 ($2,282)	-0.08 (-0.28 , 0.11)	0.41

[a]model for analysis includes classification factors for treatment, maternal psychological resources (HPR/LPR), child age and their interactions as well as two covariates: household poverty and maternal childrearing attitudes associated with maltreatment

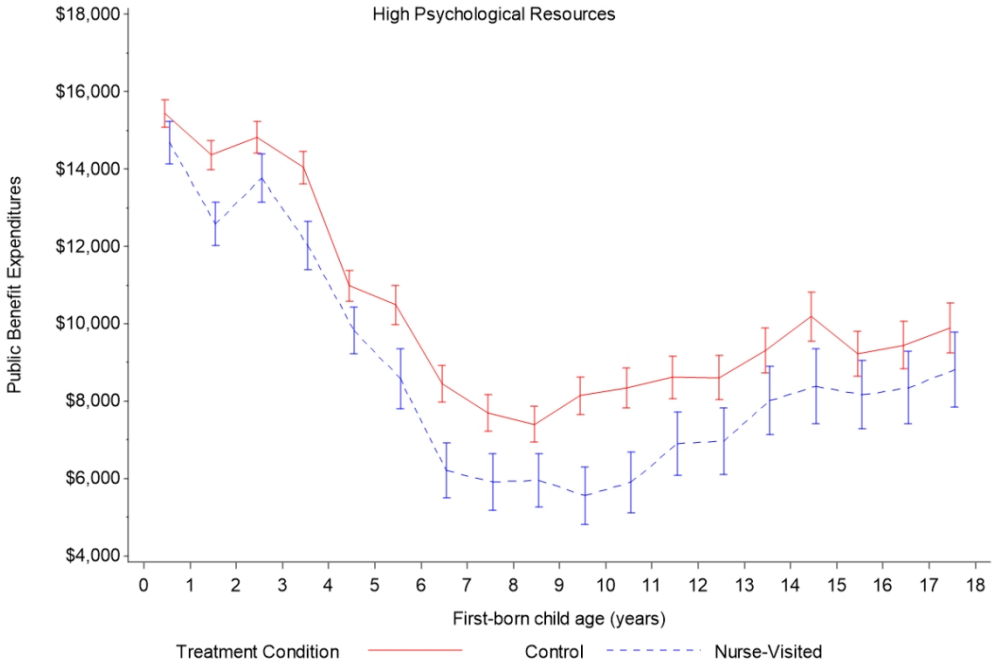
[b] SNAP= Supplemental Nutrition Assistance Program

[c] AFDC = Aid to Families with Dependent Children

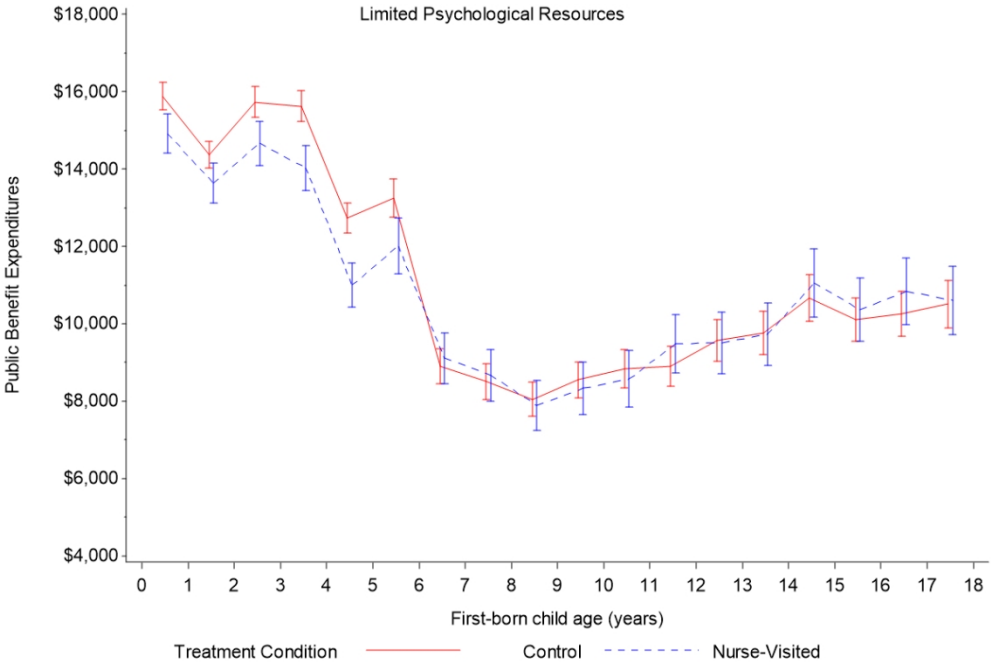
[d] TANF = Temporary Assistance for Needy Families

(*) P<.10

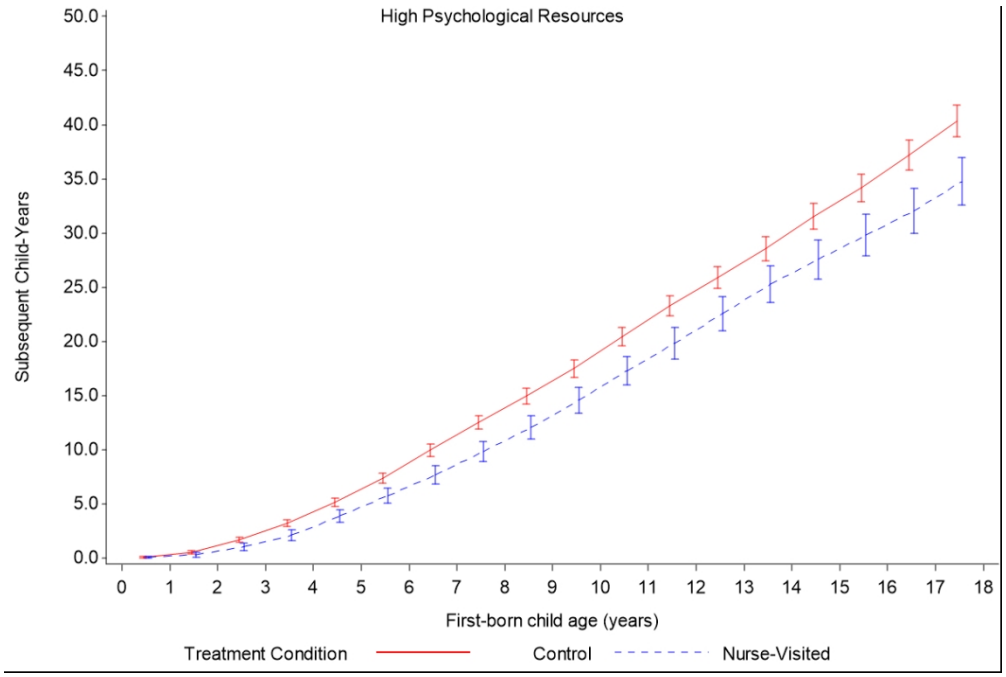
* P<.05



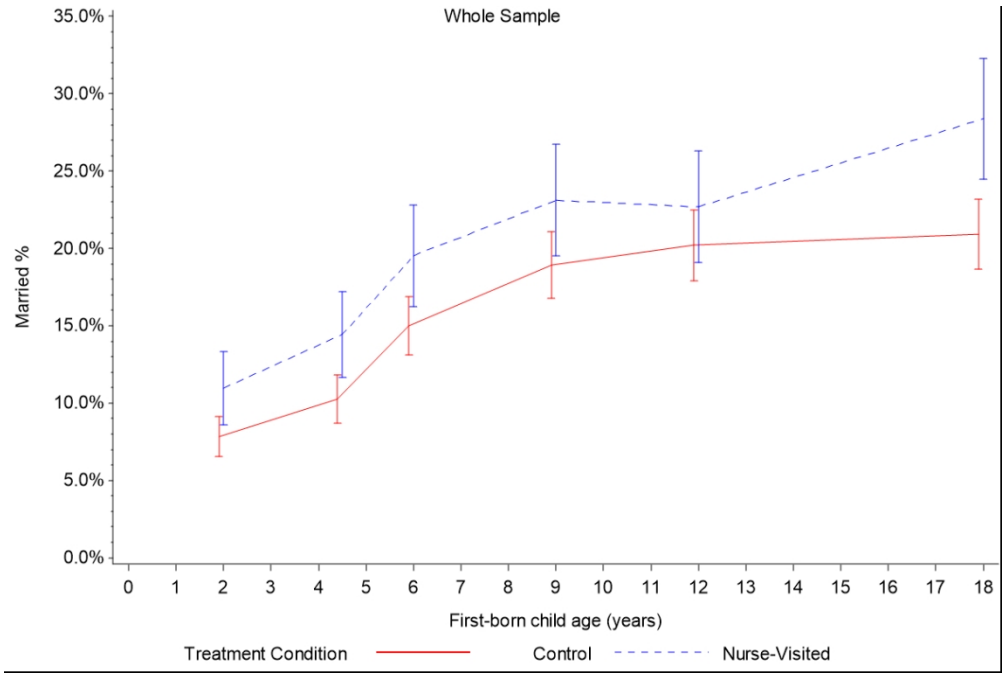
Discounted estimates of government benefit expenditures by year following birth of first child – high-resource sample



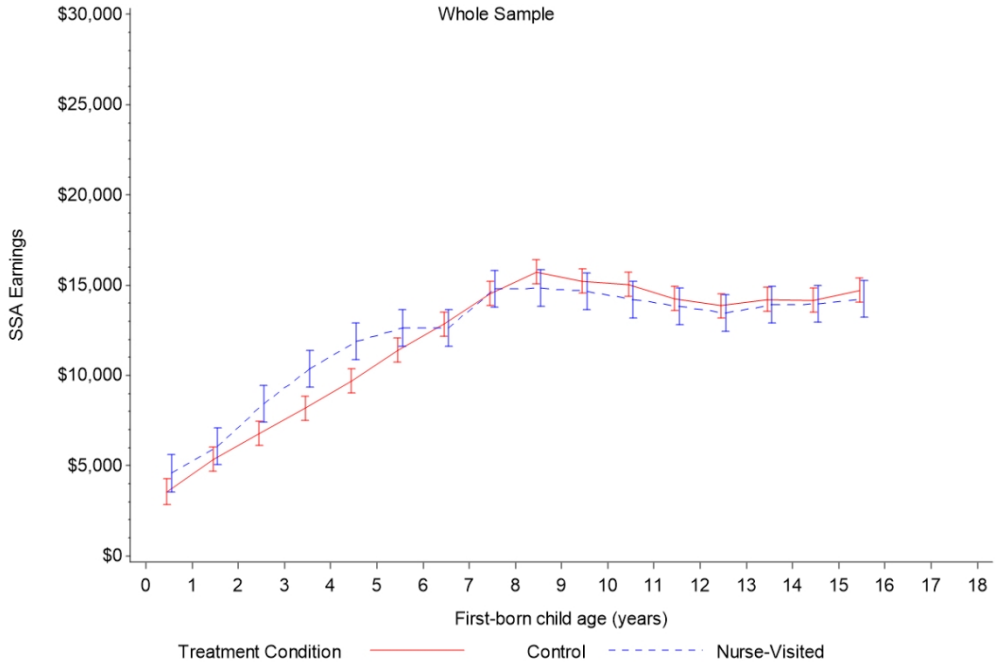
Discounted estimates of government benefit expenditures by year following birth of first child – Limited Psychological Resource sample



Subsequent child-years over time following birth of first child for nurse-visited and control mothers with initially high psychological-resources.



Rates of self-reported marriage from child age 2 through 18 for nurse-visited and control-group women.



Maternal wages from birth of first child through child age 16 reported to Social Security Administration for Nurse-Visited and Control-Group Women.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	4
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	5-7
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7, Table A1
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	6,7
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	7,8, Table A2
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8.9
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9,10 Table A2
	6b	Any changes to trial outcomes after the trial commenced, with reasons	6-7
Sample size	7a	How sample size was determined	7, Table A1
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7, Table A1
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7, Table A1
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7, Table A1
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7, Table A1
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	7

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10-11
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	10-11
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	7-9, Table A1
	13b	For each group, losses and exclusions after randomisation, together with reasons	7-10, Table A1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	7, 8
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table A3
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	10,11, Tables A1 and 1,2
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	11-12 Tables 1,2
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	11-12 Tables 1,2
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	11-13, Table 2
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	13, 14
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	14
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	12-14
Other information			
Registration	23	Registration number and name of trial registry	2
Protocol	24	Where the full trial protocol can be accessed, if available	ClinicalTrials.gov
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	1

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.