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The effect of VoorZorg, the Dutch Nurse Family Partnership, on child maltreatment and development: A randomized controlled trial.

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Submitted to Plos One

Abstract

Background

Child maltreatment is a great public health concern that has long-term mental and physical health consequences and can result in death. We studied the effect of a nurse home visiting program on child maltreatment among young disadvantaged families in the Netherlands. This study is the first to investigate the effects of this program outside of the United States.

Methods

We conducted a single blind, parallel-group, randomized controlled trial that compared usual care with the nurse home visitation program, which began during pregnancy and continued until the children's second birthdays, in 460 disadvantaged women who were pregnant for the first time and <26 years of age. The primary outcome was the existence of a report about the child from a child protecting services agency (CPS reports). Secondary outcome measures included home environment and child behavior.

Findings

Two hundred twenty-three participants were assigned to the control group, and 237 were assigned to the intervention group. Three years after birth, 19% of the children in the control group had a CPS report. The 11 percent of children in the intervention group with CPS files was significantly lower (relative risk 0.91, p-value 0.04). At 24 months, the intervention group scored significantly better on the IT-HOME. At 24 months after birth, the children in the intervention group exhibited a significant improvement in internalizing behavior (relative risk 0.56, p-value 0.04) but no difference from the control group in externalizing behavior (relative risk 0.71, p-value 0.12).

Interpretation

The number of CPS reports for the intervention group was significantly lower than that of the control group. Additionally, the long-term home environments were improved and internalizing behaviors of the children were lower in the intervention group.

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Introduction

Child maltreatment is a major public-health problem that is associated with grave physical and mental health and developmental consequences. Child maltreatment is associated with physical injury, growth retardation, obesity, anxiety, depression, posttraumatic-stress disorder, and long-term deficits in educational achievement.[1,2] Children die every year due to child maltreatment, although the actual number of deaths is unclear.[3] In adolescence, those who suffered from child maltreatment are more likely to be addicted to drugs and alcohol and to engage in risky behavior, such as juvenile delinquency, risky sexual behavior and dating violence. In adulthood, those who suffered from childhood maltreatment are more likely to have psychosocial problems and chronic diseases.[2,4] Furthermore, when these children become parents, they are at risk to abuse their own children.[1] The societal consequences of child maltreatment are also enormous not only in terms of direct costs but also in terms of greater use of community resources and lower levels of occupational functioning and employment. The mortality and morbidity associated with child maltreatment are assumed to be potentially preventable.[1]

Article 19 of the United Nations Convention on the Rights of the Child states that, “*Governments must do all they can to ensure that children are protected from all forms of violence, abuse, neglect and mistreatment by their parents or anyone else who looks after them.*” However, despite the negative effects of maltreatment on child development, most programs aim only at secondary prevention rather than primary prevention of child maltreatment. There is only one evidence-based program for the primary prevention of child maltreatment, which is the Nurse-Family Partnership (NFP) that was developed by Olds et al. The NFP is a nurse home visitation program in which high-risk pregnant women receive well-structured home visits during pregnancy until the child’s second birthday. The effectiveness of NFP in reducing child maltreatment has been evaluated in three randomized controlled trials (RCT) that were all conducted in the United States only.[5] At ages 2 and 15, the numbers of reports of child maltreatment to Child Protective Services (CPS) appeared to be significantly reduced among the NFP families.[6] Despite the effectiveness of NFP, this program has not been replicated in independent studies to date. In this study, we describe the effectiveness of VoorZorg, which is the Dutch adaption of the NFP, on the primary prevention of child maltreatment. To the best of our knowledge, this report describes the first RCT of the effectiveness of NFP outside the US.

Methods

Study design and participants

Detailed descriptions of the design have been published elsewhere.[7] In short, this is a single blind, parallel-group, randomized controlled trial (RCT) of VoorZorg. First, the NFP was translated and culturally adapted into VoorZorg.[8] Next, from January 2007 to April 2009, 460 participants were recruited for an RCT through a two-stage selection procedure.[9] In the first stage, general practitioners, midwives, gynecologists and others actively recruited women in 20 municipalities in the Netherlands using the following five criteria: < 26 age of age, low educational level (pre-vocational secondary education), first time pregnancy, maximum 28 weeks of gestation, and some understanding

of the Dutch language. Recruitment occurred in formal settings, such as primary and secondary health care practices, and in informal settings, such as community centers. Women who met all five criteria were assigned to the second stage of the selection procedure in which VoorZorg nurses interviewed women to assess whether they had at least one of nine additional risk factors (i.e., being single, a history or present situation of domestic violence, psychosocial symptoms, unwanted pregnancy, financial problems, housing difficulties, no employment and/or education, or alcohol and/or drug abuse). We obtained written informed consent from the participants (pregnant women), who also gave us permission to obtain (CPS) data on their children. The Medical Ethical Committee of the VU University Medical Center approved the study.

Randomization and masking

All eligible women were stratified by region and ethnicity and randomized into a control or intervention group by an independent researcher of the VU University Medical Center. Ethnicity was based on participants' self-reports. A participant was classified as a certain ethnicity if at least one of her biological parents was born in a country outside the Netherlands. Randomization was blind and accomplished through the use of a computer-generated list of random numbers (0, 1) created with the SPSS 14.0 software. Participants were assigned to the intervention or control group in a 1:1 ratio. The researcher then informed the VoorZorg nurses about the allocation. The interviewers were blinded for allocation, but it was not feasible to mask the participants or the caregivers to the allocations.

Intervention

The women in the control group received the usual care.[8] The women in the intervention group received the usual care plus the VoorZorg program. The VoorZorg program consisted of approximately 10 home visits during pregnancy, 20 during the first, and 20 during the second year of the life of the child by trained and experienced VoorZorg nurses. Nurses were trained prior to implementing the intervention, received regular supervision in their organizations, and received one-day training session at the national level twice a year. During each home visit, topics in 6 different domains that were relevant to the stage of pregnancy and the development of the child were addressed. These visits are described in well-structured manuals in which the goals, procedures and content of each visit are elaborated. VoorZorg nurses offered health education and aimed to teach women parenting skills, to enhance their self-efficacy to reduce risk factors of child maltreatment and to improve the utilization of social and community resources. In addition to the home visits, VoorZorg nurses also communicated with the participants via text messaging, telephone and social media. It is essential to the VoorZorg program that the nurses establish an enduring and trusting relationship with the participants.

Study outcomes

In the RCT on the effectiveness of VoorZorg the following outcomes were measured:

- Maternal cigarette smoking at 16-28 weeks and 32 weeks of pregnancy and two months after birth as well as maternal smoking near the child [13];
- Adverse pregnancy outcomes, birth weight and gestational age[13];
- Breast feeding [13];
- Intimate Partner Violence [11];
- Child development at six months, 18 months and 24 months of age, measured with, among others, the Home Observation for Measurement of the Environment, and the Child Behavior Checklist [26] [27];
- Child abuse reports.

This manuscript specifically addresses child abuse reports (primary outcome measure) and child development (secondary outcome measure).

Primary outcome measure

In the Netherlands, both professionals and citizens, such as family members, can report any case of suspected child maltreatment to a Dutch CPS agency (Advies en Meldpunt Kindermishandeling in Dutch)[10]. According to the CPS, 93% of reports to the CPS are valid cases of child maltreatment.[11] Child maltreatment is defined as follows: physical abuse, physical neglect, emotional/ psychological abuse, emotional/ psychological neglect, or sexual abuse. The primary outcome was whether the child was reported to CPS within three-and-a-half years after randomization (pregnancy and first three years of life of the child). Data from the CPS reports were obtained by contacting the CPS agencies of the ten regions in which VoorZorg was carried out. The eight CPS agencies that were willing to cooperate were sent a list with the names of the children living in their region and were asked to indicate whether CPS reports related to those children had been filed.

The secondary outcomes were assessed with questionnaires that were administered by trained female interviewers in the participants' homes. To decrease the participants' urges to provide socially desirable answers and for safety reasons, the interviewers requested that the interviews with the participants be conducted in private.

The Home Observation Measurement of the Environment (IT-HOME) was used at 6, 18 and 24 months of age to assess the environment of the child. The psychometric properties of this tool are as follows: the inter-observer agreement is 0.80, and the internal consistency is 0.80[12]. The total IT-HOME consists of 45 items that are scored as "yes" or "no", and the total scores is calculated as the sum of all positive scores. Higher total scores indicate more positive environments. Additionally, at 24 months after birth, the interviewers administered the Child Behavior Checklist 1.5-5 years (CBCL/1.5-5) to the mothers to assess the children's behavioral problems[13]. The psychometric properties of this tool are as follows: the inter-observer agreement is > 0.50, and the internal consistency is between 0.78 and 0.92.[14] The "internalizing behavior" and "externalizing behavior" subscales were used, and children were consid-

ered to exhibit internalizing or externalizing behaviors if they scored \geq the 90th percentile.

Statistics

The main outcome of the entire study that was defined to calculate power was a reduction of four cigarettes smoked per day during pregnancy in the intervention group [15], which conferred 80% power and using two-sided $p=0.05$ to the sample of 456 pregnant women (228 in the usual care and 228 in VoorZorg group). The data were analyzed with the SPSS 20.0 statistical package for Windows. The outcomes of the CPS reports and CBCL/1.5-5 were analyzed with multivariate logistic regression models to assess the differences between the control and intervention groups. Relative risks (RR), absolute risk differences (ARD) and their corresponding Confidence-Intervals were calculated using a Poisson log-linear model according to Zou.[16] For the missing CBCL/1.5-5 data (49%), we applied multiple imputation (MI) analyses and sensitivity analyses with the IBM SPSS statistics 20 program and generated 50 imputed datasets as recommended.[18,19] The total IT-HOME scores were first analyzed with multivariate linear regression to measure group differences and subsequently analysed with mixed model analyses to measure the longitudinal relationship between the VoorZorg intervention and the IT-HOME score over the three measurements. For the IT-HOME score we did not apply MI analyses, because mixed model analyses resulted in a higher power. And for the CPS outcomes we also did not conduct MI, because we had a relatively low dropout rate. Differences were considered significant when the p -values were <0.05 (2-sided). All models were tested for possible effect modifiers (region, age, ethnicity, gender of the child, weeks of gestation and birth weight). However, no effect modifiers were found significant. We conducted attrition analysis to evaluate differences on baseline characteristics between participants who remained in the study versus those who did not. This trial is registered with the Dutch Trial Register (number NTR854).

Results

Baseline characteristics

Of the 460 participants, 223 women were assigned to the control group and 237 women were assigned to the intervention group. There was no significant difference between control and intervention group in baseline characteristics. Eight of the ten CPS regions (both urban and rural) agreed to participate in this study. There were no significant differences in the characteristics of the CPS regions that cooperated in this study and those that did not. All children in these eight regions (164 children in the control and 168 in the intervention groups) were assessed regarding whether they had a CPS report (figure 1). At baseline, no significant differences were observed between the control and intervention groups in terms of demographic characteristics (table 1). The prevalence of risk factors at baseline was also similar across groups.

Primary outcome

From pregnancy to three years after birth, 19% (31 of 164) of the children in the control group had a CPS report; this percentage was 11% (18 of 168) in the intervention group, which was significantly lower (RR for VoorZorg vs. Usual care, 0.91; 95% CI(0.28 to 0.96); ARD 0.08).

Secondary outcomes

From 6 to 18 months after birth, the total IT-HOME scores increased in both groups; the control group increased from 33.0±6.0 to 36.8±6.1, and the intervention group increased from 33.4±6.9 to 36.0±6.0. However, the difference between groups was not statistically significant. At 24 months after birth, the intervention group exhibited significantly higher total IT-HOME scores (36.4±5.9 for the control group and 38.3±4.8 for the intervention group). Mixed model analyses (corrected for the age of the mother, ethnicity and the number of risk factors) revealed no significant differences between the groups over time in total IT-HOME scores (mean difference: 1.12; 95% CI: -0.59 to 2.83).

The prevalence of children with internalizing behavior at 24 months (C: 31% vs. I: 17%) was significantly lower in the intervention group than in the control group (RR for VoorZorg vs. Usual care group: 0.56; 95% CI 0.24 to 0.94; ARD: 0.14, 95% CI -0.27 to -0.00). The prevalence of children with externalizing behavior (C: 35% vs. I: 25%) was not significantly different across groups (RR for VoorZorg vs. Usual care group: 0.71; 95% CI 0.34 to 1.09; ARD: 0.10, 95% CI -0.23 to 0.03).

Discussion

Despite the negative impact of child maltreatment, there is currently only one evidence-based program for the primary prevention of child maltreatment: the Nurse-Family Partnership (NFP) that was developed by Olds et al.[6] The NFP is a nurse home visitation program for high-risk pregnant women that begins at pregnancy and continues until the child's second birthday. VoorZorg is a version of the NFP that has been translated and culturally adapted for use in Dutch populations. The present study is the first on the effectiveness of this tool to be conducted outside of the United States. Positive effects of VoorZorg on infants' passive exposure to smoking, breastfeeding and intimate partner violence (IPV), which is a form of child maltreatment, have previously been demonstrated.[8,20] The current study showed that the number of CPS reports was significantly lower among a group of young disadvantaged women who received VoorZorg than in a control group at three years after birth. At 24 months after birth, the intervention group scored higher than the control group on home environment. Furthermore, the prevalence of internalizing behavior was lower among the children of mothers who received VoorZorg. However, there was no significant difference in the prevalence of externalizing behavior. We conclude that the Dutch version of the NFP, VoorZorg, is an effective intervention for young disadvantaged pregnant women that improves child maltreatment, home environment and child behavioral problems.

Panel

Research in context

Systematic review

Medline, PsycINFO, CINAHL, Embase, and the Cochrane library were searched using the (MESH and TiAb) terms "Primary Prevention" OR "Health Education" AND "Child Abuse/prevention and control" AND "Child" for reports published between Jan 1, 2008 and Dec 6, 2013. This strategy identified 171 articles, of which only two were RCTs. [21,22] Furthermore, two systematic reviews using similar search terms for reports published between 1990 and 2007 and between Jan 1, 2000 and July 31, 2008 were included.[23,24] Mikton et al. reported that early childhood home visitation is the most

evaluated type of intervention and that there is strong evidence that early home visitation is effective in the prevention of child maltreatment. However, with the exception of Olds' NFP, for which the effectiveness has been unequivocally demonstrated, these conclusions are equivocal in a number of studies due to surveillance bias and poor internal validity. The evidence supporting the efficacy of the prevention of child maltreatment for other types of prevention programs is therefore insufficient.[24] Reynolds et al. found that only three programs (i.e., Child Parent Centers, NFP and the Parent Education Program) showed strong evidence for preventive effects in substantiated reports of child maltreatment.[23] Prinz et al. reported that the population-based dissemination of the Triple-P parenting program had positive effects on the prevention of child maltreatment.[21] Zielinsky et al. showed that the NFP appears to prevent child maltreatment early in life and confined first-time reports of neglect to the first four years of life compared to control children from whom CPS reports continued until age 12.[22]

Interpretation

The aim of the current study was to examine the primary prevention of child maltreatment due to systematic and well-structured home visits by nurses to young disadvantaged pregnant women. In terms of the recommendations and limitations of the studies identified in the above systematic review, our study utilized CPS reports in the evaluation of the intervention as recommended. Although the validity of these reports may be hampered by surveillance bias and liberal bias due to professionals' tendencies to report fewer incidents or only the more severe incidents of maltreatment, the net effect of these biases differed little in terms of reported incidents, severities and confirmations[25]. The NFP appears to be the only program that is effective in the primary prevention of child maltreatment. The current study adds strong evidence to this conclusion by showing that VoorZorg (i.e., the Dutch equivalent of the NFP) is effective in the prevention of child maltreatment based on official CPS data.

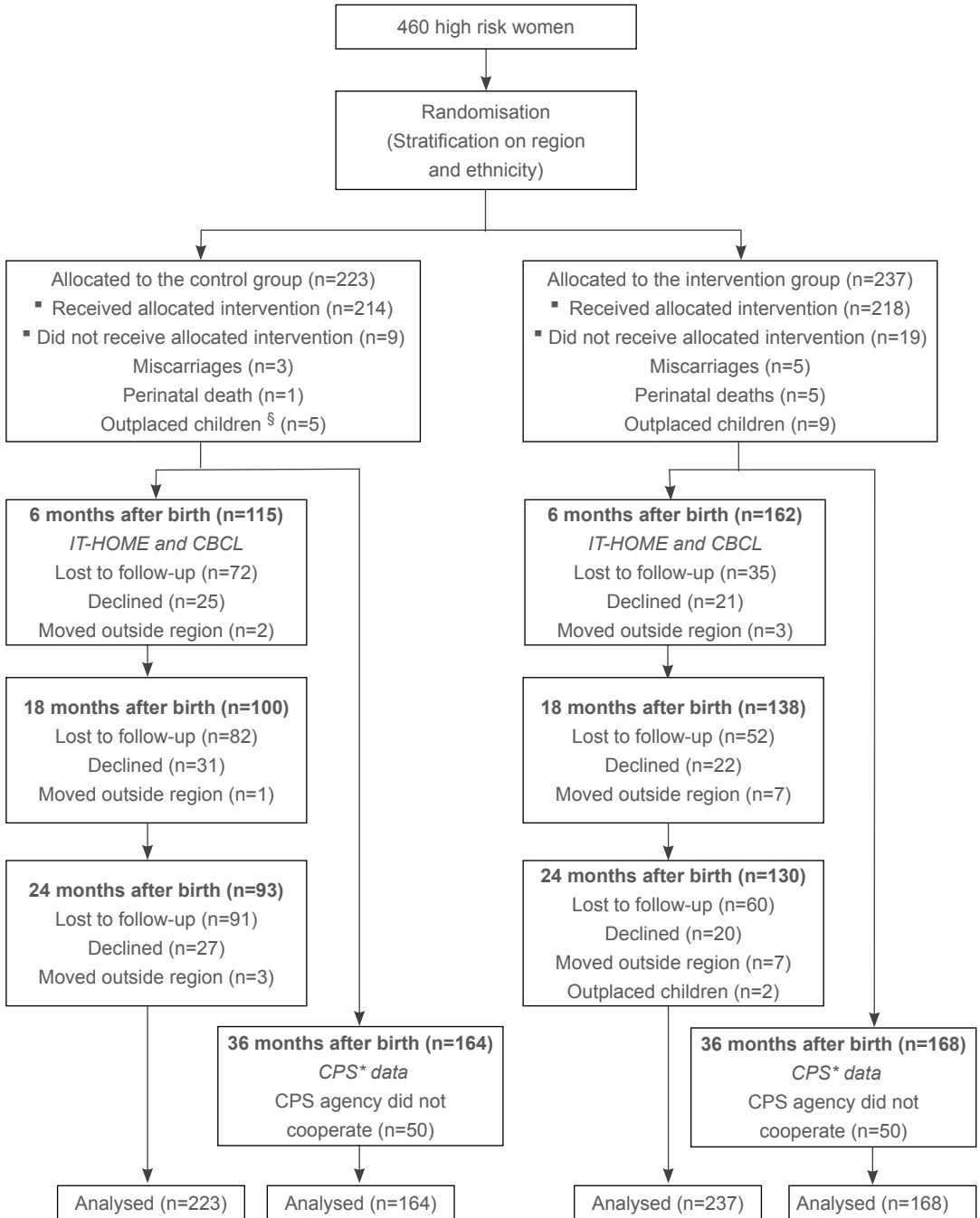
The validity of the use of the prevalence of CPS reports to indicate a reduction in child maltreatment due to home visitations is further supported by the observed improvements in the relevant risk factors for maltreatment, such as the home environment and the children's behaviors. The reduced prevalence of internalizing behavior at age two may be attributable to significant improvements on somatic complaints and withdrawn subscales. Withdrawn behavior during the elementary school period is associated with severe neglect in early life. It is assumed that neglect leads to insecure attachment relationships that may decrease the children's capacities to interact successfully with peers.[26] In the Early Start home visitation program, a similar reduction of the prevalence of internalizing behavior at age three was observed, and an additional reduction of parent-reported severe physical assault was also observed. However, no improvement in CPS contacts due to the provision of comprehensive services to high-risk families starting shortly after the birth of the child and lasting for 24 months has been observed for this intervention program.[27] Moreover, somatic complaints are often associated with anxiety disorders in children.[28] It is possible that the reduction in somatic complaints at the age of 24 months is the first indication of a reduction in anxiety and stress in these young children due to the decline in IPV and child maltreatment that resulted from VoorZorg.[8] As high-risk young mothers are often poorly prepared for their role as mothers, the increase in IT-HOME scores at 24 months indicates that the home environments were more enriched and more attuned to the inter-

actional needs of the toddlers due to the home visits by the nurses. The improvements in home environments and the children's behaviors accord with the reduction in CPS reports because there appeared to be less child maltreatment, more structure and more support for the children in the home-visited families.

A limitation of this study is that we were unable to assess the data from children who were untraceable or had moved to other regions. As each CPS agency only has access to data from the children who have been reported in their region, it is possible that the data from the children who were no longer living in the region were not addressed because this information was not in the database. Furthermore, the CPS agencies only document reports of child maltreatment, which represents only a low percentage of the actual prevalence of incidents of child maltreatment.[29] Nevertheless, the CPS data are considered reliable because these data are based on observations of people other than the parents, which should diminish the bias toward socially desirable answers. A second limitation is that we assumed that each CPS report was a valid case of child maltreatment. In general, 93% of the reports to CPS in the Netherlands appear to be substantiated cases of maltreatment based on subsequent CPS investigations. To examine whether a similar percentage of reports in our study population were substantiated cases of child maltreatment, we requested additional information about the reports from the CPS. We received this additional information for approximately 50% of the children with CPS reports, and 96% of these CPS reports were indeed substantiated cases of child maltreatment (unpublished data). Another limitation is the high loss to follow-up in the IT-HOME and CBCL data. However, attrition analyses showed that missing was at random and we also applied MI and linear mixed models. The final limitation is that the sample size calculation was conducted in an a priori manner that was based on smoking cessation around the time of childbirth and not on maltreatment. However, we performed a post-hoc calculation on child maltreatment that revealed that the estimated sample-size requirements of these two sample-size calculations were not different.

The results of this RCT of VoorZorg corroborate the positive effects of this type of intervention that have been shown in NFP trials conducted in the US; thus, nurse-home visits represent an efficacious strategy for the primary prevention of child maltreatment[5]. Compared to the costs and the lifetime effects of child maltreatment, VoorZorg is relatively inexpensive. In conclusion, VoorZorg is an evidence-based program for the primary prevention of child maltreatment. We recommend that future research examine whether modifications of VoorZorg that tailor the program to the specific needs of families with CPS reports (e.g., the inclusion of the Signs of Safety[30]) can prevent the reoccurrence of child maltreatment.

Figure 1: Flow chart VoorZorg study



§ When the development of the child is in danger the juvenile court can impose an outplacement of the child

* CPS stands for Child Protective Services; in the Netherlands this organization is called AMK

Table 1:*Baseline characteristics of participants*

	Control group (n=223)	Intervention group (n=237)	Significance level
Mean age, years mean(sd)	19.2 (2.6)	19.5 (2.8)	ns.
Weeks of gestation mean(sd)	19.6 (5.9)	20.1 (6.5)	ns.
Region			ns.
Urban	66 (147)	67 (158)	
Rural	34 (76)	33 (79)	
Ethnicity			ns.
Dutch	49 (110)	49 (115)	
Turkish/Moroccan	6 (13)	6 (13)	
Surinamese/Antillean	26 (58)	27 (64)	
Other	19 (42)	19 (45)	
Education level			ns.
Primary school	3 (7)	5 (11)	
Pre-vocational Secondary Education	67 (150)	76 (179)	
Married/living together	16 (36)	19 (46)	ns.
Having a boyfriend	22 (49)	30 (70)	ns.
Living with boyfriend	18 (40)	24 (58)	ns.
Lifetime prevalence of IPV	33 (74)	35 (84)	ns.

Note. In parentheses the number of participants for whom data were available is described.

Numbers are % (n) unless described otherwise.

Table 2:*Outcomes on home environment, child behavior and CPS reports*

		Control group (n=223)	Intervention group (n=237)	RR/MD3 (95% CI)
6 months	HOME¹	33.0(6.0)	33.4(6.9)	ns
18 months	HOME¹	36.8(6.1)	36.0(6.0)	ns
24 months	HOME¹	36.4(5.9)	38.3(4.8)	1.98 (0.16 to 3.80)
	Internalizing²	17(19%)	19(15%)	ns
	Internalizing MI⁴	69(31%)	40(17%)	0.56 (0.24 to 0.94)
	Externalizing²	27(30%)	28(22%)	ns
	Externalizing MI	78(35%)	59(25%)	ns
36 months	CPS reports²	31(19%)	18(11%)	0.58 (0.28 to 0.96)

¹ Mean (SD)² n (%)³ RR=Relative Risk; MD=mean difference⁴MI= Multiple Imputation

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