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The primary prevention of child maltreatment in early life: Study on the effectiveness of VoorZorg

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door
Jamila Mejdoubi
geboren te Amsterdam, Nederland

promotor:	prof.dr. R.A. HiraSing
copromotoren:	dr. S.C.C.M. van den Heijkant
	dr. A.A.M. Crijnen

To my dear parents,
Abdellah and Fatima Mejdoubi

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CHAPTER 1:

GENERAL INTRODUCTION

General introduction

There are still families in developed countries that live under circumstances that negatively affect their own health and their children's health and development. These families are characterized by having problems on multiple domains in life (relationship, parenting, health e.g.) combined with a low socioeconomic status (SES). Low SES is strongly linked with negative health behaviour and poor (psycho-social) health[1]. This population of families requires special attention from health care professionals. In general, this population is difficult to reach by caregivers or already have an overload of help without any result in their functioning and/or health [2]. Especially children growing up in these families are affected and cannot fully develop under these circumstances: 1) their foetal development is more likely to be impaired, 2) they have increased risk of being victims of child maltreatment and domestic violence, and 3) their health during adulthood and future perspective is affected [3–6]. An additional risk factor is that these families mostly consist of a single parent that takes care of the child alone [7]. Due to that, the parent has limited resources. Additionally, these families have few or even no protective factors like a supportive social network. For their children, this means growing up with risk factors and no protective factors, which is strongly associated with social disadvantage, and an increased risk of health and developmental problems[8]. On the other hand, even when growing up in low SES family, protective factors can contribute to the resilience of a child and to a more positive future.

Impaired development

Low socio-economic status is known to be a great risk factor for negative health behaviour of the parents which can influence the foetal development of the child. Young parents with low SES are more likely to use drugs and/or alcohol, engage in violent behaviour, and to have a poor diet[8,9]. Furthermore, they are more likely to have psychosocial problems like stress, anger and depression[10]. Figure 1 shows that during pregnancy and the first years of life the child is susceptible to environmental risk factors. Parental risk behaviour like substance abuse during pregnancy can affect the development of the child. When the foetus is exposed to toxic substances like nicotine during the first two months of pregnancy, the foetus is at risk of major physical abnormalities and the risk of spontaneous abortion is increased [11,12]. In the subsequent period and the first years after birth, the child is more likely to have functional defects when exposed to environmental risk factors. For example, stress during pregnancy influences the cortisol level of the child and thereby affects his or her brain development. Those children more likely develop behavioural problems[13]. Several studies underpin this by showing that children growing up in low SES families are more likely to have an impaired neurodevelopment and lower academic achievement compared to children growing up in high SES families[5]. Stirling et al. describe that children who grow up with adversity have a brain adapted to survive in the negative (harmful) environment they live in. They are not able to function

normally in society where there are no direct dangers. Also those children have an exaggerated (aggressive) response to normal daily stress, because they associate it with fear [14]. A child's behavioural problems can increase the risk of child maltreatment. Risk factors should therefore be addressed early in pregnancy to prevent health and developmental problems of the child.

Child maltreatment

Child maltreatment is a major risk factor for compromised development. Families with low SES have a five times higher risk to maltreat their children[15] and these children are more likely to witness intimate partner violence, (IPV) which is also a form of child maltreatment. Brown et al studied demographic and familial risk factors associated with child maltreatment[16]. Demographic risk factors for child abuse and/or neglect were low maternal education and welfare dependency. Family risk factors were maternal psychosocial problems and low father involvement. Furthermore, parental substance abuse and history of violence also increase the risk of child maltreatment[16]. Young age of the mother is also a risk factor for IPV: pregnant adolescents are approximately six times more likely to be victims of violence by a dating partner compared with their non-pregnant peers [9].

Child maltreatment is known to have consequences on the mental and physical health and development of the child lasting beyond childhood and even a lifetime. Therefore, great benefits result from preventing child maltreatment. Risk factors of child abuse should be addressed early in pregnancy to prevent child maltreatment and thereby prevent health and developmental problems of the child due to child maltreatment.

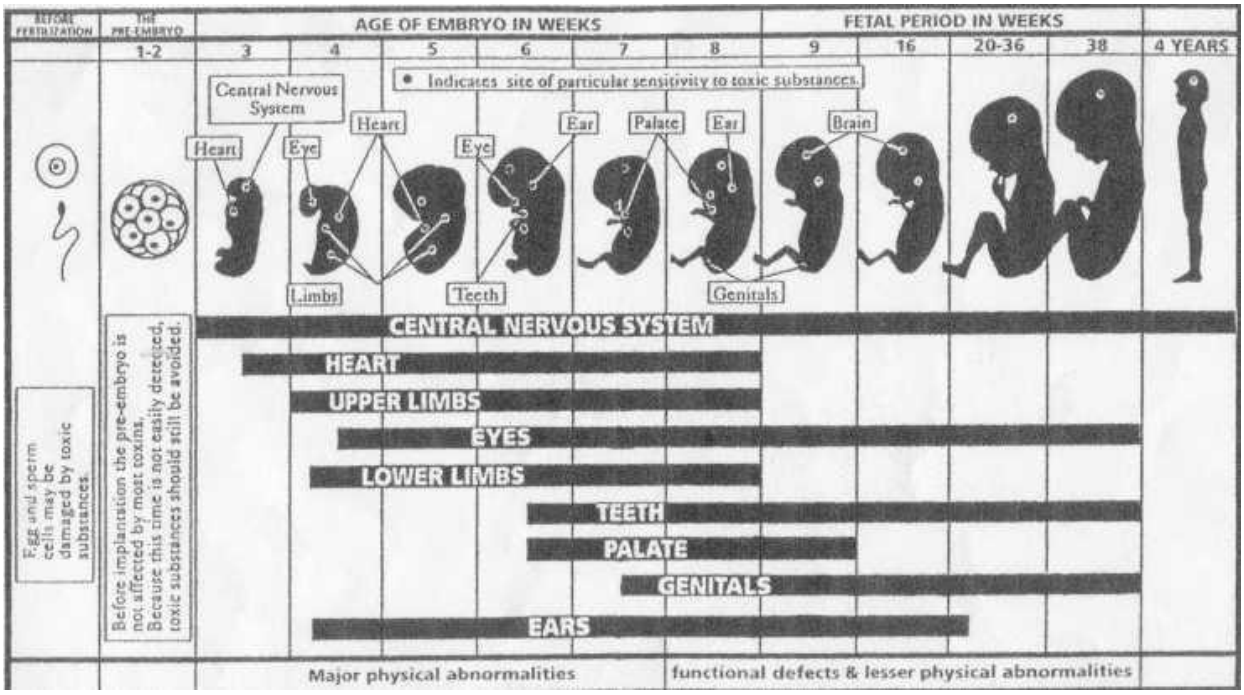

Figure 1. The development of the child is sensitive to toxic substances during pregnancy. Reprinted with permission of Elsevier [17]

The long-term consequences of low SES in children

Growing up in a low SES family means that the child is disadvantaged and has fewer opportunities in life and an increased risk of an impaired (mental) health. Felitti et. al have studied the effect of growing up in a high risk family. Children who grow up in low SES families are more likely to go through adverse childhood experiences (ACE). The researchers showed that the more ACEs a child has, the higher the risk of health problems and risk behavior in adulthood. As figure 2 shows, a child that experiences, for example, child maltreatment, has an impaired health throughout the life span[14]. These children, as discussed before, are more likely to be socially, cognitively or emotionally impaired, leaving them with fewer opportunities in life. They usually do not have a job or work in poor conditions, and are more likely to engage in criminal activities [14]. Later in life, these children are more likely to have chronic diseases and psychosocial problems, have relatively more disease years and die earlier than adults without ACEs. These health risks are also transmitted to the next generation, creating a cycle of health problems[8]. There is a strong need for an effective intervention to prevent ACEs to contribute to better health for these disadvantaged children.

Societal consequences of low SES

The problems of growing up in a disadvantaged family have great societal consequences [18,19]. As was clarified in the former paragraph, children of disadvantaged families are more likely to have behavioural problems and lower cognitive functioning. This is why they have a greater need for special education, which costs relatively more than regular education[20]. Their poor (mental) health and engagement in risky health behaviour leads to relatively more health care costs[20]. In addition,

the costs of treating the consequences of child maltreatment and intimate partner violence are enormous. These children are also more likely to involve themselves in criminal activities and anti-social behaviour, which lead not only to criminal justice costs but also to costs related to material and/or immaterial damage to their fellow citizens[19,20]. Furthermore, people with a low educational level make more use of the welfare system, invest less in the economy and participate less in society. With increasing poverty, these problems and related costs will also grow. These high societal costs are preventable by early intervention among high risk families.

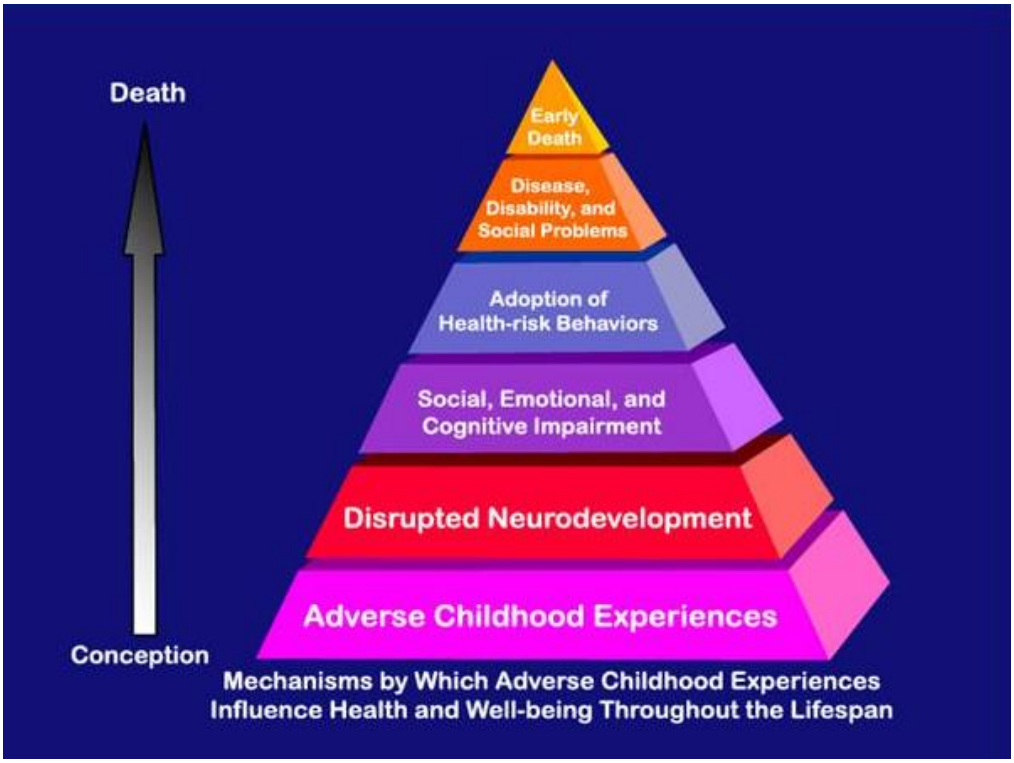

Figure 2. ACE pyramid illustrating the Conceptual Framework for the Adverse Childhood Experience (ACE) Study [21]

Protective factors

Studies have shown that protective factors in the environment can help the resilience of the child growing up in a high risk family [22]. Resilience is defined as a person's ability to cope with adversity. Even though the child is expected to have adverse health outcomes because of growing up in a disadvantaged family, protective factors can lead to a good physical and/or mental health and/or good academic achievements[23]. Heller et al. described many predictors of resilience, including personal characteristics, presence of spirituality, strong social network, (even if the parents are dysfunctional) and external support (e.g. a coach that supports the family)[23]. This information is valuable, because there is a way to cope with socio-economic disadvantages. And predictors known to contribute to resilience can be used in an intervention program for disadvantaged families.

Early intervention

"*Interventions may be directed at one level, but may ultimately affect many (cascade effect)..." John Stirling*

In the previous paragraphs we clarified the rationale of early interventions among high risk families. To find out which effective interventions are available to prevent child maltreatment we conducted a systematic review (chapter 6). In this review we found three effective interventions that are available for high risk families to prevent child maltreatment and impairment: *Triple P, Early Start and the Nurse-Family Partnership*. We will describe in short these programs below.

Triple P

Triple P (Positive Parenting Program) is a population-based intervention program developed by professor Sanders to support parents in parenting their children (0 to 12 years of age) by improving their knowledge, skills, and confidence [24]. This program aims at addressing severe behavioural, emotional, and developmental problems in children[25]. Triple P is a multilevel program (level 1 to 5) to meet the needs of different populations (from low to high risk). This program shows an effect on child maltreatment, child out-of-home placements and injuries due to child maltreatment[26]. After the intervention period there was an increase in child maltreatment in both conditions. However, the increase in the intervention group was lower compared to the control group and also lower than in the overall general population.

Early Start

The Early Start program is a home visiting program that starts after childbirth and aims at improving child health, reducing risk of child abuse, and improving parenting skills, with the aim of encouraging family and socioeconomic wellbeing[27]. The families will be provided with sources of assistance, support, empowerment, and advice to address issues relating to health, parenting, and related matters during the preschool years. This program is based on the social-learning model. The effect study on the Early Start intervention showed that families receiving the program had significantly fewer hospital visits due to childhood injuries and severe child maltreatment. However, no effect was found on the prevalence of Child Protecting Services reports [28].

The Nurse-Family Partnership

The Nurse-Family Partnership (NFP) is the most evaluated home visiting program and to the best of our knowledge it is the only effective intervention for the primary prevention of child maltreatment [29]. NFP is a nurse home visiting program for young high risk women with no previous live births. They are visited by trained nurses during pregnancy until the child's second birthday[30,31]. Figure 3 shows how the NFP affects three domains of risk and protective factors and how these eventually

influence child functioning until adulthood. In this program the nurse acts as an external coach to contribute to the resilience of the mother and child. The ultimate goals of the NFP are:

a. To improve outcomes of pregnancy by empowering women to improve their prenatal health
b. To improve children's subsequent health and development by empowering parents to provide competent care to their children
c. To improve women's economic self-sufficiency by empowering them to develop a vision for their future and make appropriate choices about completing their educations, finding work, and planning subsequent pregnancies.

Strengthening the mother's relationships with primary support people (including her partner), and linking the mother with other needed health and human services can accomplish the goals listed above.

Evaluation of the NFP

The NFP program is studied in several Randomized Controlled Trials in geographically diverse populations in the US (Elmira, New York, in 1977; in Memphis, Tennessee, in 1988; and in Denver, Colorado, in 1994). The effectiveness study showed many positive results.

Results found in at least two trials are: Improved prenatal health (mothers smoked fewer cigarettes during pregnancy), fewer childhood injuries, fewer subsequent pregnancies, increased maternal employment and improved school readiness. Follow-up research showed, among others, that child maltreatment was prevented and that the mothers provided a better home environment. Even at the age of 15 of the child, positive effects are measured. The children reported significantly less serious antisocial behavior and substance use. Furthermore, nurse visited mothers received fewer months of welfare and had fewer arrests[32]. Even the third generation seemed to benefit from the NFP program[33]. Another important finding was that the effect of the program on child maltreatment was diminished if IPV was present. This result underpins the fact that IPV should be addressed for high risk pregnant women.

According to Olds et al. important key elements of the NFP are:

- The NFP is based on three theories: Bandura's Self Efficacy Theory, Bowlby's Attachment theory, Bronfenbrenner's ecological model.
- The client is visited one-to-one, one nurse home visitor to one first-time mother or family and visited in her home.
- The nurse home visitors and nurse supervisors are registered professional nurses, using professional knowledge, judgment, and skill, apply the NFP visit guidelines, individualizing them to the strengths and challenges of each family and apportioning time across defined program domains.

- The program is performed by well-trained and experienced nurses with a maximum caseload to qualitatively fulfill all domains in the home visits.

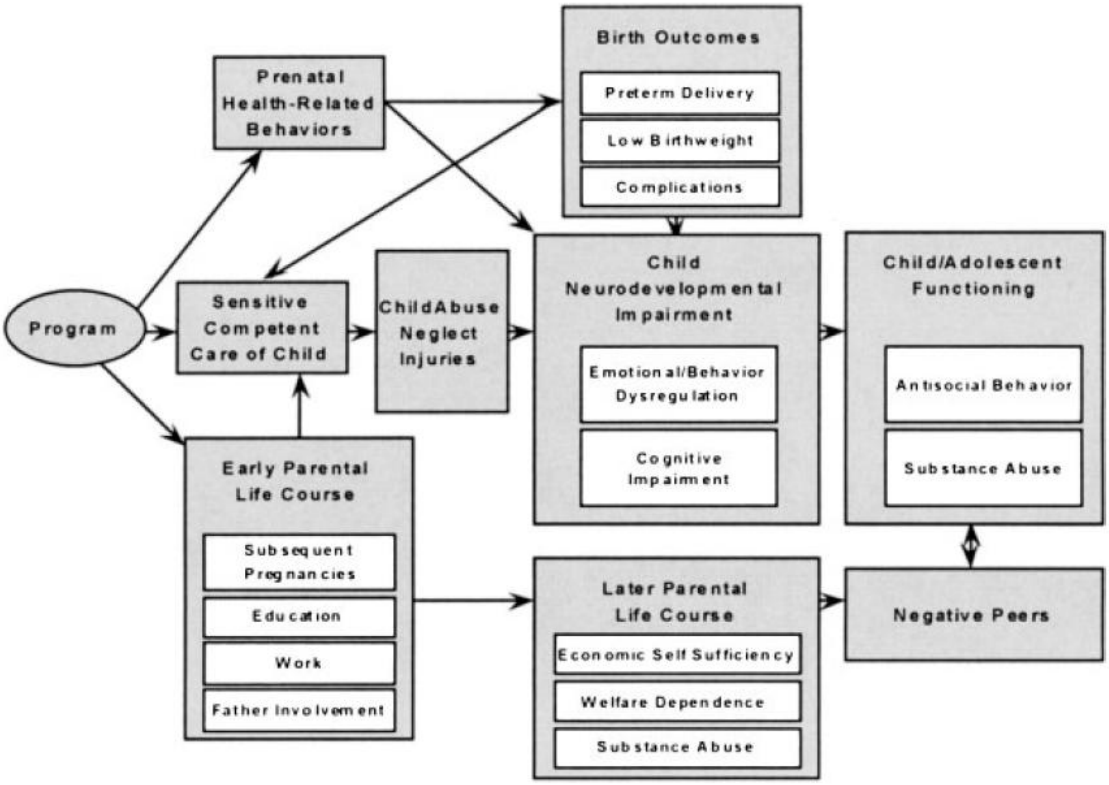

Figure 3. Conceptual model of program influences on maternal and child health and development[31]

VoorZorg, the Dutch NFP

Although NFP has been proven to be an evidence-based intervention for the primary prevention of child maltreatment, the program has not yet been examined outside the US. If the effectiveness of NFP in reducing child maltreatment could be proved in independent studies outside the US, it would significantly support the validity of the program.

As far as we know there is no evidence-based prevention program on the primary prevention of child abuse in the Netherlands. Also, there are no programs in the Netherlands that start during pregnancy and are proven to be effective in reducing risk behavior among women and improving the health-outcomes of both the child and the mother. The available interventions that start after childbirth focus on the needs of the mother rather than placing the focus on the needs of the developing child by systematically addressing the risk factors for the child.

Because of the lack of effective interventions in the Netherlands and because the NFP needed to be validated outside the US, we translated and culturally adapted this program into VoorZorg, which means "precaution" in Dutch. The translation and cultural adaptation of NFP is described in the study protocol of VoorZorg (chapter 2).

In short, VoorZorg is adapted to accommodate the needs of Dutch pregnant women, to address risk factors operating in the Dutch population and to fit in the Dutch Health Care system. Before implementation of VoorZorg in the Netherlands can take place, this program should be proved to be effective in a Randomized controlled trial (RCT) among high risk pregnant women in the Netherlands. The results of this RCT on addressing risk factors that compromise health and development of the child will be described in this thesis.

Panel

At the beginning of 2014 VoorZorg is implemented in 30 municipalities in the Netherlands, where approximately 50 trained VoorZorg nurses are active. These nurses are experienced Youth Health Care nurses currently working in a Youth Care Health organization. The Netherlands Youth Institute (NJi) is responsible for the training and support of the VoorZorg nurses, for the development of the material and monitoring of the practical side of the program.

Aims and outline of the thesis

The aim of this thesis is twofold. The first part describes the design of the VoorZorg program and the evaluation of the two-stage selection procedure to recruit high risk women for this program. The second part describes the results of the effect study of VoorZorg on: cigarette smoking, pregnancy outcomes, breastfeeding, intimate partner violence (perpetration and victimization), child maltreatment, home environment and child's externalizing and internalizing behaviour.

Outline of the thesis

In **Chapter two** the translation, culturally adaptation of VoorZorg and the design of the Randomized Controlled Trial to study the effectiveness of VoorZorg are described.

Chapter three describes whether the two-stage selection procedure designed in this study is adequate in identifying high-risk pregnant women. In this chapter we also report how many risk factors for child maltreatment these women have during pregnancy. **Chapter 4** describes the short-term effects of VoorZorg. We analysed (adverse) pregnancy outcomes, cigarette smoking during pregnancy and after birth and breastfeeding duration. In **Chapter 5** we describe the effectiveness of VoorZorg in reducing Intimate Partner Violence during 32 weeks of pregnancy and two years after birth. In **Chapter 6** we elaborate on whether VoorZorg was effective on child maltreatment and on the development of the child. In **Chapter 7** the main findings and implications for further research are discussed, followed by **Chapter 8**, a summary of this thesis.

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CHAPTER 2:

ADDRESSING RISK FACTORS FOR CHILD ABUSE AMONG HIGH RISK PREGNANT WOMEN: DESIGN OF A RANDOMISED CONTROLLED TRIAL OF THE NURSE FAMILY PARTNERSHIP IN DUTCH PREVENTIVE HEALTH CARE

Jamila Mejdoubi
Silvia CCM van den Heijkant
Elle Struijf
Frank JM van Leerdam
Remy A HiraSing
Alfons AM Crijnen

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Abstract

Background

Low socio-economic status combined with other risk factors affects a person's physical and psychosocial health from childhood to adulthood. The societal impact of these problems is huge, and the consequences carry on into the next generation(s). Although several studies show these consequences, only a few actually intervene on these issues. In the United States, the Nurse Family Partnership focuses on high risk pregnant women and their children. The main goal of this program is primary prevention of child abuse. The Netherlands is the first country outside the United States allowed to translate and culturally adapt the Nurse Family Partnership into VoorZorg. The aim of the present study is to assess whether VoorZorg is as effective in the Netherland as in the United States.

Methods

The study consists of three partly overlapping phases. Phase 1 was the translation and cultural adaptation of Nurse Family Partnership and the design of a two-stage selection procedure. Phase 2 was a pilot study to examine the conditions for implementation. Phase 3 is the randomized controlled trial of VoorZorg compared to the care as usual. Primary outcome measures were smoking cessation during pregnancy and after birth, birth outcomes, child development, child abuse and domestic violence. The secondary outcome measure was the number of risk factors present.

Discussion

This study shows that the Nurse Family Partnership was successfully translated and culturally adapted into the Dutch health care system and that this program fulfills the needs of high-risk pregnant women. We hypothesize that this program will be effective in addressing risk factors that operate during pregnancy and childhood and compromise fetal and child development.

Background

Adverse events

The Adverse Childhood Experience Study concluded that living in poverty combined with other risk factors affects a person's physical and psychosocial health from childhood to adulthood. Moreover, even next generation(s) experience the same consequences as their parents suffered; they are all trapped in a vicious circle[1].

Low SES affects the child, even before birth. The unborn child is at risk of adverse pregnancy outcomes because of the negative health patterns of the parents. For example, women of low SES use substances during pregnancy more frequently than other women, and maternal substance use during pregnancy contributes to premature birth and low birth weight and is strongly associated with morbidity and mortality of the newborn as well as in childhood [2–6]. Having psychosocial problems during pregnancy leads to many complications, such as spontaneous abortion or preterm delivery; it also increases the chances that a child will later develop conduct problems [7–9]. The lack of structure in the life of the children also increases their risk of displaying conduct problems and engaging in criminal activities. The low SES living area of the children is often unsafe; in this environment, children are more likely to experience injuries [10]. Child abuse is more common among these families. The consequences of child abuse are high: abused children have more psychosocial problems, low self esteem and morbidity [11]. In addition, abused children are more likely to engage in negative health behavior and criminal behavior when they get older [12]. Beyond these problems, the children are at risk of becoming a perpetrator of abuse themselves in the future [1,13,14].

When children living in low SES families grow up, they are more likely to have stress, anxiety and depression, because of their continued difficult lives. They usually have low income jobs and poor working conditions or are unemployed [1,15–18]. They live in bad housing conditions and struggle to live with limited financial resources. They can not pay for social activities, which leads to social isolation [19]. Their residential environment is also not favorable for their health and social network. They are more likely to engage in negative health related behavior, such as drinking alcohol, using drugs, smoking cigarettes and eating unhealthily [10]. In addition, chronic diseases like cardiovascular disease, diabetes and overweight are highest amongst these families. They therefore have a lower life expectancy and relatively more disease years [19–21].

Although several studies showed these consequences, only a few actually intervene on this issue. Meanwhile, the societal impact of the problems mentioned above is huge, not only in costs but also in higher use of resources and less participation in a positive society. Therefore, these problems should be effectively prevented wherever possible [15,19,22–25].

The Nurse Family Partnership

In the United States an intervention has been developed by David Olds that focuses on high-risk families, called the Nurse Family Partnership (NFP). Until now this is one of the few evidence-based

interventions in the world for the prevention of disruptive disorder and child abuse. However, the effect of this program has not been studied yet outside the United States. David Olds and Alfons Crijnen reached agreement that the NFP-intervention could be adapted for use in the Netherlands under the condition that the effectiveness was examined in a trial. The Netherlands is thereby the first country outside the United States that was allowed to translate and culturally adapt the NFP into VoorZorg. Before the VoorZorg-intervention can be implemented on a larger scale in the existing and well organized Youth Health Care system in the Netherlands, it is important to study whether the VoorZorgprogram will be as effective as NFP in the United States compared to the usual care in the Netherlands.

VoorZorg in the Netherlands

To our knowledge there are no interventions in the Netherlands that start during pregnancy and are proven to be effective in reducing risk behavior among women and improving the health-outcomes of the child and mother. The available interventions that start after childbirth focus on the needs of the mother rather than placing the focus on the needs of the developing child by systematically addressing the risk factors for the child.

The main goal of VoorZorg is primary prevention of child abuse. Other goals are: to improve the outcomes of pregnancy by improving the mothers health during pregnancy (especially reduce their use of cigarettes and obtain prompt and reliable treatment for obstetric and other health problems such as depression), to improve the child's health and development by helping parents provide more competent care of their children, and to improve the mother's own personal development.

Theoretical Framework of VoorZorg

VoorZorg is based on three theories of human ecology:

Bandura's Self Efficacy Theory

Bandura's model states that a person's behavior is determined by three factors: attitude, social influences and self-efficacy [figure 1][26,27]. The VoorZorg nurse is trained to affect a person's attitude towards behavioral change by providing the participant with knowledge about the negative effects of risk behavior. A person's intention to engage in a specific behavior is influenced by their social environment. The intervention focuses on the relationship of the participants with significant others, because they have a great influence on the participant. And VoorZorg focuses strongly on empowering the woman to stimulate her self efficacy [28,29].

Bronfenbrenner's ecological model

Bronfenbrenner formulated a model to explain the influence of environment on the development of a person. An individual's immediate environment most strongly determines their development. According to Bronfenbrenner, mother-infant interaction is the most powerful predictor of the development of the person. If this interaction is strong and positive, the other environmental factors have less of an influence. When, for example, the child lives in a low SES area, but the mother-child interaction is strong and positive, SES has a less negative impact on the child's development. VoorZorg is used to instruct the mother on positive parenting skills and to empower the mother to have a positive influence on her child, despite the many environmental risk factors present [30].

Bowlby's Attachment theory

Bowlby states that the quality of interaction between the caregiver and the child is an important factor that determines the attachment of a child. In this theory, the quality of attachment in early life has a profound influence on the development of a child in later life. Disrupted attachment results in irreversible behavioral and psychosocial problems. Four types of attachment are described by Bowlby: 1) secure, 2) avoidant, 3) ambivalent/resistant and 4) disorganized. VoorZorg aims for a secure attachment between mother and child by discussing the importance of attachment during home visits, and by teaching the mothers parenting skills that are helpful in developing secure attachment [31,32].

Home visits

VoorZorg consists of approximately 10 home visits during pregnancy, 20 during the first life year of the child and 20 during the second life year. The visits are conducted by trained VoorZorg nurses. The visits are more frequent during the first month of the intervention and six weeks after birth, because these periods are important for the mother. The duration of each visit is between one hour and one and a half hour. The purpose of the visits is: structured behavioral changes, health education, discussing

questions of the expectant mother, setting and maintaining realistic and achievable goals, increasing the mother's self-efficacy and involving the social network of the mother into the program. The VoorZorg nurses use three manuals that were designed for pregnancy, infancy and toddlerhood and focus on six domains: health status of the mother, child's health and safety, personal development of the mother, the mother as a role model, relation of the mother with her partner, family and friends and use of institutions. Each manual contains a full description of the visit. However, the visits are flexible and nurses are able to improvise when needed. It is important that VoorZorg nurses maintain a good relationship with the mother throughout the program.

Communication with stakeholders

Given the complexity of the tasks at hand, communication between the different stakeholders is considered very important to ensure successful implementation. To that end, several platforms were installed to discuss the implementation of VoorZorg, the monitoring and the study design: 1) a project group chaired by the initiator/child and adolescent psychiatrist consisting of experts from the EMGO+ Institute for Health and Care Research of the VU medical center, The Netherlands Youth Institute (NJi) and the Youth Health Care organization Evean; 2) an expert committee to settle arguments around inclusion; 3) a gathering of the managers of the ten participating Youth Health Care organizations; 4) a Committee of Advice consisting of experts at the national level. In addition to these platforms, prof. Olds and his co-workers are consulted by the researchers of VoorZorg.

The Care as Usual in the Netherlands

When pregnancy is confirmed (usually by a General Practioner) women visit a midwife. When complications are anticipated, the midwife refers the woman to an obstetrician. The aim of maternal health care is optimal pregnancy outcome. The caregiver (midwife or obstetrician) should offer health education, perform physical examinations and monitor the development of the fetus. Furthermore, the caregiver should support the parents and prepare them for the arrival of their baby. A pregnant woman will visit a midwife 4 times on average. After birth the mother can make use of the maternity care helper for a week. The costs of maternity care are reimbursed by health insurance companies. The maternity care helper visits the mother at home [33]. Her job is to take care of the mother, the newborn and the household and advice the mother about taking care for her baby and about breastfeeding the child.

In the Netherlands, every newborn will automatically be registered in a Youth Health Care organization (ambulatory well-baby clinic) to monitor the health and development of the child, and parents are supported in their parenthood. Furthermore, the child will be immunized five times. Parents can also consult the Youth Health Care organization at any moment. This program is free of charge and voluntary, and the attendance rate is very high (95%) [34].

At week 1 (usually between 4 to 7 days after birth) and week 2 after birth, the parent will be visited at home. During the first visit the baby gets a heel prick by a trained nurse to test for several

diseases. Early detection and treatment of those diseases is necessary to prevent serious mental and physical health problems. During this visit neonatal hearing screening is also conducted. The second visit will be performed by a Youth Health Care Nurse. During this visit, the child's health and environment will be observed and parents are informed about the development of their child. During four weeks after birth the parents can visit a Youth Health Care organization for a check-up. In total nine to eleven check-ups are performed until the child's second birthday. After the second birthday the consults will proceed in a less frequent schedule until the child's nineteenth birthday [35].

Objectives of this study

The implementation of VoorZorg in the Netherlands consists of three – partly overlapping – phases with their own objectives, preceded by preparation phase 0:

- Phase 1 aimed at translating, culturally adjusting and further developing the original intervention to accommodate the needs of pregnant women in the Netherlands and to address risk factors operating in the Dutch population. To identify women from the high-risk population, a screening procedure was developed and evaluated.
- Phase 2 aimed at assessing whether this intervention meets the needs of the at risk mothers and their yet-to-be-born children. Phase 2 also aimed at assessing whether the nurses visiting the mothers are capable of conducting the intervention as described in their protocols. This phase included an assessment of treatment integrity, and of the feasibility and adequacy of the intervention.
- Phase 3 aims at studying the effectiveness of VoorZorg in addressing the risk factors operating during pregnancy and early childhood that compromise fetal and early child development through a Randomized Controlled Trial.

Methods/design

PHASE 0.

Preparation phase

This phase included the following elements:

- David Olds, founder of NFP, was contacted by Alfons Crijnen, a Dutch child physiatrist, and the two of them discussed the conditions of implementing NFP in the Netherlands. It was agreed that NFP needed to be adapted to the Dutch setting carefully to ensure implementation, and that the effectiveness should be examined through a Randomized Controlled Trial (RCT) prior to implementing NFP in the Netherlands on a wide scale;
- An overall plan including translation and adaptation, implementation, and assessment of effectiveness was developed;
- Stakeholders were invited to participate and a long-term commitment was requested;

- Grant proposals were written to collect financial resources;
- A project group was set up to translate and culturally adapt the NFP

PHASE 1.

The Translation and cultural adaptation of the program

The translation and adaptation of the NFP for use in the Netherlands was conducted by the NJi together with the project group of VoorZorg and external experts.
The translation and adaption of the intervention occurred in steps:

1. Two members of the translation and development group and a manager of Youth Health Care organization Evean were trained in Denver (US) about the implementation of the NFP.
2. Program material was translated to Dutch. Furthermore, the material was adapted to fit in the Dutch Health Care System. In this way risk factors operating in the Dutch population were addressed and the needs of Dutch pregnant women were accommodated.
3. A reading group consisting of experts from the Netherlands Youth Institute (NJi) and the Youth Health Care organization Evean checked the translated and culturally adapted program material and made comments where necessary. The manuals were subsequently checked by representatives of the Dutch Societies for Midwives, Obstetricians and General Practitioners to ensure applicability in the Dutch health care system. Minor adjustments needed to be made. The adjusted parts of the manuals were then translated back into English by others in order to be verified by professor D. Olds.
4. A two-stage selection procedure was designed for recruitment of high-risk pregnant women.
5. The VoorZorg intervention was tested for applicability on a small-scale among eight high risk pregnant women

PHASE 2.

The Pilot implementation study

The pilot study was carried out in two Youth Health Care organizations in Zaanstreek-Waterland and Rotterdam. To conduct the evaluation, both qualitative data and quantitative data were collected from the 40 participating mothers who received the intervention and the VoorZorg nurses. The pilot study was evaluated by an independent research institute (The Trimbos institute).
The study showed, among other things, that the target population was reached adequately by means of the inclusion criteria formulated in VoorZorg. The program fulfilled the needs of the mothers and the mothers received significant support from the VoorZorg nurses. The VoorZorg nurses were able to carry out the intervention as described in the guidelines and the manuals were relevant to participants.

Training of the VoorZorg nurses

At the end of this phase twenty-five certified nurses were recruited by Youth Health Care organizations in twenty municipalities. The nurses were requested to comply with specified competences, including having a minimum of two years of working experience, affinity with high risk families, and experience with teaching parenting skills. All nurses received the following trainings to become a VoorZorg nurse: Video Home Training, training for pregnancy-, infant- and toddler period, and training about reducing smoking behavior with minimum intervention strategies (V-MIS). The trainers applied the training material that was used in the NFP.

In addition to these trainings, supervision at work on a weekly basis was a requirement for the execution of the program. The VoorZorg nurses were able to discuss difficulties in the implementation of the program with trained supervisors from their institution once a week. They could also discuss cases with other VoorZorg nurses during case conferences at the national level organized five times a year. The trainer or supervisor of the NJi could also be consulted. The maximum caseload for VoorZorg nurses with a full-time employment was 18 mothers.

PHASE 3.

RCT

The third component of the program was the study on the effectiveness of VoorZorg through an RCT.

Design of the study

The study was designed as a double blind, parallel-group, randomized controlled trial (allocation ratio 1:1) starting before 28 weeks of pregnancy with a follow up of two and a half years. All data were handled confidentially. The Committee of Ethics on Human Research of the VU University medical center (Amsterdam, the Netherlands) approved the study design, protocols, information letters and informed consent form.

Study population

460 women were selected with a two-stage selection procedure from the year 2006 to 2009. The selection procedure is described more in detail elsewhere (Mejdoubi J., Heijkant van den S., Struijf E., Leerdam van F., Olds D., Crijnen A., Hirasing R., unpublished data). During the first stage professionals like General Practioners, midwifes, gynecologists and street corner workers recruited women in 20 different regions in the Netherlands based on the following criteria: Age below 26 years, low educational level (primary school or primary school and secondary school on a low level), pregnant with her first child, maximum 28 weeks of gestation, and understanding the Dutch language at a minimum level. During the second stage of the selection procedure the women were interviewed by VoorZorg nurses on several risk factors ((1) no or little social support, (2) a history of violence or abuse, (3) or still in a situation of domestic violence or neglect, (4) psychological problems, (5) financial problems, (6) unemployed or (7) housing problems, (8) alcohol problems, smoking or using

drugs during pregnancy, or (9) having a non-realistic approach about motherhood) with the use of an inventory. Women who had at least one risk factor were included in the study. Furthermore, women had to understand the aim of the program and had to have the intention to complete the entire program. In addition, they were willing to participate in the study and be randomly assigned to an intervention or control group. Women who were found eligible for the study then signed, after the explanation of the study by the VoorZorg nurses, a written informed consent form. The participants were able to withdraw from the study at any time.

Outcome Measures

All participants' progress were measured six times during 16 to 28 and 32 weeks of pregnancy and during 2, 6, 12 and 24 months postpartum. The women received incentives for each measurement (a gift certificate of 15 euro's for each measurement and for the last measurement they received 30 euro's). All questionnaires were validated or were applied in other studies and published in the literature. Data about birth results were obtained from Youth Health Care organizations.

Interviewers

All measurements were performed by trained female interviewers who were blinded from randomization. The interviewers were recruited on strict competences; they were required to have a medicinal, nursing or pedagogic background. The interviewers were trained by a researcher of the VU University medical center according to the motivational training principles[36]. The interviewers were taught conversation skills to minimize social desirable answers and to increase reliability of the interviews. All interviewers met twice a year to discuss possible difficulties with each other. The researchers of the VU University medical center were present during these meetings to advise them.

Primary outcome measures

Smoking cessation

Specific questions were about numbers of cigarettes smoked at the gestational window of 16 to 28 weeks and during 32 weeks of pregnancy and 2 months postnatal. Smoking cessation by participant self report was measured at 32 weeks of pregnancy and 2 months postnatal.

Birth outcome

Both nominal and ordinal birth weight were studied, for which four categories were made: very low <1000 g., low 1000-2500 g., normal 2500-4000 g. and high >4000g. Gestational age was categorized in the following categories: extreme premature < 32 weeks, premature <37 weeks, normal gestation 37 to 41 weeks and serotine > 42 weeks. Dysmaturity was defined as a neonatal with a birth weight below the tenth percentile of the growth curve.

Domestic violence

Women were asked at baseline detailed questions about whether they had experienced any violence in the past and in their current relationship. To measure whether participants had a history of abuse, the following questions were asked "*Have you ever been abused by your spouse or a significant other*?" Abuse was defined as being physically maltreated (being hit, punched, kicked, cut, burned) with or without a weapon and with or without injury. Sexual abuse was defined as forced sexual contact. To determine whether participants had been abused in the present relationship women were asked: "*Have you been hit, punched, kicked or in another way abused which resulted in physical injury, this year*?" If a woman answered these questions positively, detailed questions were asked about the perpetrator and frequency of the abuse. This questionnaire was translated from the NFP. Furthermore, the Revised Conflict Tactics Scale (CTS2) was conducted at 32 weeks of pregnancy and at the child's second birthday [37]. The Composite Abuse Scale (CAS) was conducted at 16 to 28 weeks of pregnancy [38].

Child development

Child's development was measured at different periods:

At 6 months of age the Home Observation for Measurement of the Environment was conducted [39]. At 18 months, the language of the child and parental stress (Nijmeegse Ouderlijke Stress Index (NOSI)) were measured [40]. At the second birthday, the Child Behavior Checklist, Harsh Parenting and questions about raising the child were addressed[41].

Child abuse

Data about prevalence of child abuse were obtained from a maltreatment reporting agency where both professionals and the general public can report cases (Advies & Meldpunt Kindermishandeling) [42]. A contact person from this agency was asked whether the child had been reported. In case of a reported child, further questions were asked about the perpetrator, the frequency, type and severity of the abuse. The contact person was also asked whether the report had been further investigated.

Secondary outcome measures

Number of risk factors for child abuse

The number of risk factors present at baseline and two years after birth will be measured by self report by using the following questionnaires:

1. Demographic factors such as age, ethnicity, whether women received financial help or housing assistance from the government. Women were also asked whether the pregnancy was wanted. This questionnaire was translated from the registration forms used in the NFP.

2. Depression was measured by using the Edinburgh Post Natal Depression Scale (EPDS). The EPDS is effective in the detection of depression symptoms and can be used during pregnancy [43]. A total

score higher than 13 indicates that the participant is suffering from depression and a score of 10 or higher indicates that the participant is possibly suffering from depression.

3. Domestic violence was addressed through detailed questions about violence in the past and the present by spouses or significant others.

4. Substance use was addressed by asking the women whether they smoked cigarettes, drank alcohol or used other drugs.

Sample size

Sample size calculation was based on finding effect in smoking cessation at the time of birth, 12 months and 24 months post partum. The numbers in the formula were based on findings from the effect study of the NFP[44]. In order to detect an average improvement of decreasing smoking by 4 cigarettes a day with a standard deviation of 8 cigarettes, a power of 80% and an alpha of 5% were used. This resulted in a sample size of 57. Given the fact that 25% of all women smoke at the start of the pregnancy, 228 participants in the control group and 228 participants in the intervention group should at least complete the pregnancy-component.

Randomization

A total of 460 women were included and randomized in strata by region and ethnicity into a control or intervention group by a researcher of the VU University medical center. Randomization was made blind by using a computer-generated list of random numbers (0, 1) in software SPSS 14.0 [45]. The researcher then informed the VoorZorg nurse about allocation. 237 women were assigned to the intervention group and were visited by trained VoorZorg nurses. 223 women were allocated to the control group and received the care as usual. A flow-chart of the RCT is shown in Figure 2. Women who lived in the same house as another participant of VoorZorg were not randomized but assigned into the same treatment group to prevent contamination. This was relevant for one respondent who was assigned to the intervention group without randomization.

Analyses

The effectiveness of the VoorZorgprogram compared to care as usual will be analyzed with different statistical methods, using intention to treat analyses. Logistic Regression analyses will be used for comparing proportions between the intervention group and control group (smoking cessation, birth outcome, domestic violence and child abuse). Linear Regression analyses will be used for comparing means between the intervention and control group (numbers of cigarette smoked, birth weight, gestational age, child development and number of risk factors for child abuse). Multilevel analyses will be used for analyzing longitudinal data. The multilevel and regression analyses using the (longitudinal) data as dependent variables were adjusted for possible confounders and were also checked for possible effect modification like age and ethnicity.

Discussion

This article presents the design of the Nurse Family Partnership (NFP) intervention in the Netherlands. The program material of the NFP has been translated and culturally adapted to fit in the Dutch health care system and is called VoorZorg. In addition, a two-stage selection procedure has been designed to include mothers-at-risk for abusing their child. The feasibility of the VoorZorg intervention was evaluated positively in a pilot study. At the moment an RCT is conducted to study the effectiveness of the VoorZorg program. It is hypothesized that with the VoorZorg program risk factors operating during pregnancy and early childhood that compromise fetal and early child development are addressed.

Strengths of this study include the random controlled design and the communication between different stakeholders and several experts (research and practice). An additional strength is that the program was first tested for feasibility in a pilot study. In this way the program could be improved in the last phase. Furthermore, the study results are generalisable for all high risk pregnant women, because this study is conducted in the practice setting and in different regions in the Netherlands and carried out in both urban and rural areas.

This study has some limitations as well. One is that each phase is financed by a different organization. This is not efficient because each project must be accounted for separately. Another limitation was that the effect study on VoorZorg was conducted by a University Medical Center in Rotterdam and during the study a different University Medical Center took over the project. However, the project manager of VoorZorg stayed involved in the study and continued to be a co-author. Also, some of the interviewers did not stay throughout the RCT. Participants were sometimes difficult to motivate to participate in the study, especially in the control group. Therefore, interviewers experienced several difficulties in making appointments for the measurements. It is for that reason that it is important to teach interviewers strong motivation skills.

In conclusion, this article presents the design of a program that aims at primary prevention of child abuse among high risk pregnant women. This program was initially implemented in the United States. Because in the Netherlands there is a notable lack of interventions that systematically address the risk factors during the prenatal and early infancy period, the NFP was adapted in the Netherlands. If the program proves to be effective in the Netherlands, it can be used by Youth Health Care organizations in preventing child abuse in high risk families.

Figures

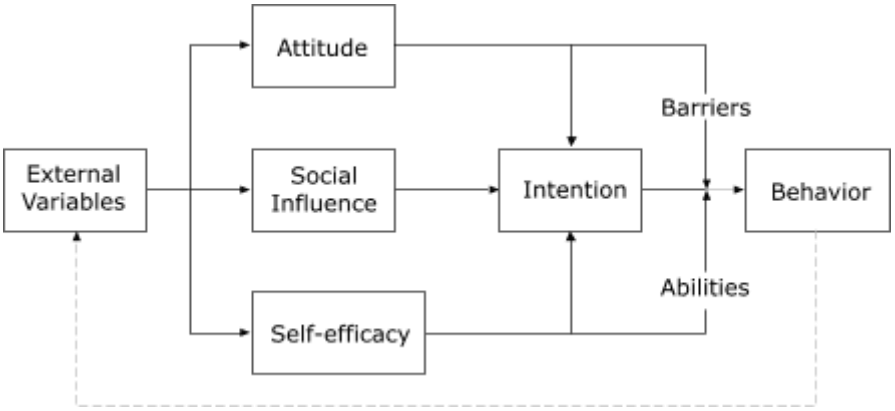

Figure 1: Bandura's self efficacy model, 1982

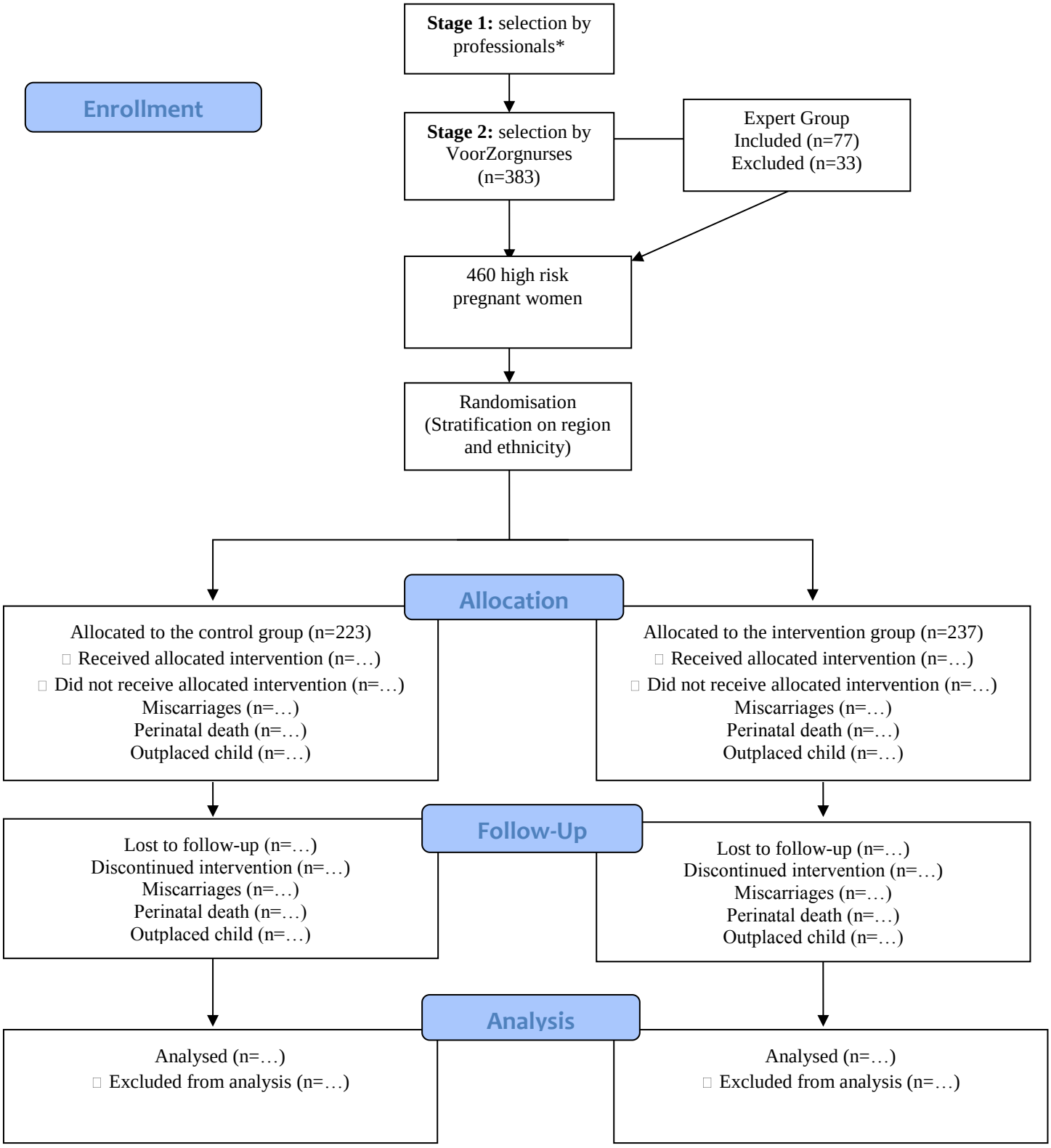

Figure 2: Flow of the participants through the study

* General Practioners, gynaecologists, midwifes, street corner workers etc.

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CHAPTER 3:
HOW TO SELECT PREGNANT WOMEN AT RISK FOR CHILD ABUSE: METHODOLOGY

Jamila Mejdoubi
Silvia CCM van den Heijkant
Elle Struijf
Frank van Leerdam
Alfons AM Crijnen
Remy HiraSing

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Abstract

Background

To prevent child abuse, it is important to start an intervention as early as possible in families who are most at risk. In this manuscript we describe a two-stage selection procedure to successfully identify high risk women. Furthermore, we assess whether women have risk factors of child abuse. The two stage selection procedure was developed for the VoorZorg intervention, the culturally adapted Dutch version of the Nurse Family Partnership program.

Methods

The first stage of the selection consists of five inclusion criteria applied by professionals (mostly midwives): maximum age of 25 years, low educational level, maximum gestational age of 28 weeks, no previous live birth and understanding of the Dutch language. In the second stage trained nurses interviewed all selected pregnant women by using a checklist with several risk factors for child abuse. Then trained interviewers measured risk behaviour of the selected participants with validated questionnaires.

Results

Using the two-stage selection procedure 460 high risk pregnant women were selected. The prevalence of risk factors for child abuse is, among others: single parent: 76%, drug or alcohol use: 25%, history of abuse: 50%, no current job and/or education: 74%. In total, 98% of the selected women had ≥ 4 risk factors for child abuse.

Conclusions

We conclude that the two-stage selection procedure selects pregnant women at high risk for abusing their child.

Introduction

Health and societal problems that occur during adulthood can be consequences of adverse childhood experiences (ACE)[1]. Child abuse is one of the most important examples of an ACE and is described as a global problem that can lead to a range of physical and mental problems, like high blood pressure, organ malfunction and depression [2]. Furthermore, child abuse can lead to cognitive impairments [3]. Families without risk factors have a 3% risk of child abuse, while in families with more than three risk factors, like substance abuse and low socioeconomic status, this percentage is up to 24% [4]. To prevent child abuse and to prevent health problems in adulthood, families with multiple risk factors should be offered an effective intervention during pregnancy [5].

Several studies emphasize the importance of targeted interventions at an early stage of pregnancy [6–8]. By intervening early in pregnancy, more health benefits for the unborn child as well as for the mother-to-be will be established. In addition, women are more susceptible and open to interventions when they are pregnant. During pregnancy and after birth women are open to learning and willing to stop negative behaviour that affects their unborn child [9]. Olds et al. showed that high risk women benefited the most from the intervention they offered starting early in pregnancy [2,10]. These women need someone to inform and empower them to stop negative behaviour and to encourage attachment with their child. Women in high risk groups often do not have those kinds of people in their environment. Therefore, a selection procedure is needed with strict criteria to select pregnant women at increased risk of abusing their child.

Many researchers have studied possible predictors of child maltreatment [11–14]. Berlin et al. showed that intergenerational factors increase the risk of child maltreatment [11,14]. And Begle showed that a low attendance rate in a parenting program (PACE) predicted child abuse [12]. However, the researchers did not develop a specific tool to select high risk families during pregnancy for a program to primary prevent child maltreatment [12–14].

In the present study we describe a two-stage selection procedure to identify high risk pregnant women by combining different key components of successful selection procedures described in previous studies and components that we believe are necessary, such as a trained nurse who performs the interview of the pregnant women. Also, we will test whether the two-stage selection procedure selects pregnant women at increased risk for abusing their child.

Participants and Methods

We designed the two-stage selection procedure to select pregnant women in the Netherlands who are at increased risk of abusing their child (high risk pregnant women) for participating in a Randomized Controlled Trial (RCT) studying the effectiveness of VoorZorg. VoorZorg is the translation and cultural adaption of the Nurse Family Partnership. In the present study we describe the two-stage selection procedure and compare our findings with questionnaires completed by trained interviewers (figure 1). The two-stage selection procedure took place before inclusion (≤ 28 weeks of pregnancy) and the interviews were conducted after including women into the study. This study was approved by the Committee of Ethics on Human Research of the VU University Medical Center (Amsterdam, the Netherlands). All participants signed forms acknowledging informed consent.

The two-stage selection procedure

Ten health care organisations in different regions in the Netherlands agreed to participate in the study. Experienced nurses working in these organisations were trained by the Netherlands Youth Institute in how to perform the two-stage selection procedure. The nurses visited all (health care) professionals (midwives, general practitioners, gynaecologists or street corner workers) in their region to inform them about the program. If the professional decided to participate, the nurses explained the first stage of the selection procedure which the professionals had to perform. The first stage was designed to be simple and not too time consuming for the professionals. It was therefore expected to be a rough selection of possible high risk women. The nurses performed the second stage of the selection; this stage was more specific and time consuming to make sure only high risk pregnant women were selected.

First stage selection

Professionals applied the following criteria to pregnant women: (1) maximum age of 25 years, (2) low educational level, (3) maximum 28 weeks of gestation, (4) no previous live birth and (5) understanding the Dutch language. These criteria are based on a literature study and were also used in the NFP [15,16]. Low educational level was defined as primary school or secondary school on a low level (pre-vocational education). The maximum gestational age was applied to allow for a longer intervention time during pregnancy. Only women with no previous live births were included because women with a previous child already have a personal parenting style that will interfere with the benefit that can be reached. Because the program material is in Dutch we applied the criterion "having some understanding of the Dutch language". Selected women were offered a contact with a nurse for the second stage selection.

Second stage selection

The second stage selection was an interview by specially educated and trained nurses. The nurse visited these women at home. For this interview a checklist was developed consisting of several risk factors of child abuse based on a literature search: (1) no or little social support, (2) a history or (3) present situation of domestic violence or neglect, (4) psychological symptoms, (5) financial problems, (6) unemployment, (7) housing difficulties, (8) alcohol use, smoking or drug use during pregnancy, or (9) having a non-realistic approach and expectations about motherhood. At least one of these risk factors was necessary for inclusion in the study. The nurse could also register a "gut feeling" that this woman is at risk for abusing her child. In the conversation between the nurse and the participant all these criteria were discussed. Furthermore, the nurse checks if the woman has protective factors, like for example a good social network, to determine whether she needs help or not. The nurses excluded women if they had severe psychological or psychiatric problems. Women with cognitive impairment or other problems that made them inadequate to learn from an intervention program were also excluded.

The nurse completed the checklist and added additional remarks if necessary. After the conversation the nurse could decide to:

1. Include the woman in the study.
2. Exclude the woman from the study (severe psychological problems, cognitive impairments or woman declines to participate).
3. Refer the woman to an expert committee to make a final decision on whether to include the woman (if the woman does not meet all criteria).

Expert committee

As part of the selection procedure the nurses must consult an expert committee in case of doubt. The committee consisted of a youth health care doctor (member of the VoorZorg implementation group), a child psychiatrist (initiator of VoorZorg) and a trainer of the nurses. To submit a case to the expert committee, nurses filled in a special form, where they specified which risk factors and protective factors women had and which criterion the women did not meet. The members of the committee studied each case independently and based the final decision on weighing up all arguments. They contacted the nurses to inform them about including or excluding the woman from the study.

Women selected by the nurses were appointed as high risk pregnant women and were interviewed by trained female interviewers, which will be described in the next paragraph.

Testing of the selection procedure

Questionnaires

For this part of the study, participants were interviewed two times between 16 and 28 weeks and at 32 weeks of pregnancy. The questionnaires described in this study were used to investigate the presence of nine child abuse risk factors among selected women (no or little social support, a history or present situation of home violence or neglect, psychological symptoms, financial problems, unemployment, housing difficulties, alcohol use, smoking or drug use during pregnancy, having a non-realistic approach about motherhood). In this way we investigated whether participants were correctly appointed as a woman at increased risk of abusing her child (high risk pregnancy). Four items in the checklist used by the nurse were not exactly defined in the same way as the corresponding items in the validated questionnaires (1. no partner vs. no or little social support, 2. depressive complaints vs. psychosocial problems, 3.unwanted pregnancy vs. non-realistic approach about motherhood, 4. receiving help from organization to find a home vs. housing problems)

All interviews were performed by female interviewers, usually at the participant's home. Most interviewers were medical students. We trained all interviewers several times and interviews were conducted in private in order to minimize socially desirable answers. In addition, participants were reassured that all answers would be handled confidentially.

We used four questionnaires:

1. We assessed **Demographic characteristics** of women like ethnical background and whether women received housing assistance. Additionally, we assessed whether they had planned their pregnancy. These questions were translated from the registration forms used in the Nurse-Family Partnership.

2. We obtained whether women were **depressed** with the Edinburgh Postnatal Depression Scale (EPDS), an effective tool to measure postnatal depression [17]. The EPDS is validated for use during pregnancy [18]. If a participant scores higher than 13 on the total EPDS score it indicates she is suffering from depression. A score ≥10 indicates that the participant is possibly suffering from depression.

3. Self-reported domestic violence: To measure whether participants had a history of abuse we asked the following question: "*Have you ever been abused by your partner or a significant other*?" Abuse was defined as being physically maltreated (being hit, punched, kicked, cut, and burned) with or without a weapon and with or without injury. Sexual abuse was defined as forced sexual contact. To determine whether participants had been abused in the present relationship we asked: "*Have you been hit, punched, kicked or in another way abused which resulted in physical injury, this year*?" If a woman answered this question positive, detailed questions were asked about the perpetrator and frequency of the abuse. This questionnaire was from the same as those used by the NFP.

4. Self-reported substance use. At the gestational window of 16 to 28 weeks and at 32 weeks of pregnancy, we asked the women whether they used alcohol or drugs and the quantity of these substances.

Data analysis

We used software SPSS 15.0 for data analysis[19]. For comparing the percentage of women with risk factors selected for the study with those in a reference group we used the Chi-square test. To calculate means and prevalence's we used crosstabs and T-test.

Results

From 2007 to 2009, a total of 460 high risk pregnant women were included in this study by using the two-stage selection procedure. The nurses presented a total of 110 cases to the expert committee because they did not fully meet the selection criteria, and 77 of these were enrolled in the study (figure 1). The expert committee excluded participants because they had too many protective factors or too few risk factors and were therefore not eligible for the study.

The percentage of high risk women selected by the professionals at the first stage was equally distributed over the ten participating regions. Demographic characteristics are shown in Table 1. The mean age of the participants was 19 ± 2.5 years (range from 14 to 27). Approximately 50% of the participants is Dutch; the other 50% has a "non-Dutch" background: Surinamese, Antillean, Moroccan, Turkish or other. Most participants (76%) were single at inclusion. Almost all participants met the first stage inclusion criteria (table 2). 100% of the women met the criteria "no previous live births". The criteria "age" and "gestational age below 28 weeks", were applicable for respectively 99% and 96% of the participants. Participants were included on average at 19.1 ± 5.9 weeks of gestation. 60% of the participants were included before 21 weeks of pregnancy.

Table 3 shows the prevalence of the risk factors obtained from questionnaires conducted by interviewers during 16 to 28 weeks of pregnancy and from an interview by nurses during the second stage of selection. Most participants had financial problems during inclusion (70%). A higher percentage was reported by the nurses (95%), while only 4% of the common population go through financial problems[20]. Fifty percent of the participants had a history of abuse and almost one fifth (18%) of the participants experienced domestic violence during the previous year. The nurses reported percentage of 69% (history of abuse) and 57% (actual domestic violence) among participants. In the general population, 3% experienced domestic violence during pregnancy. One third (31%) of the pregnancies was unwanted, in the general population this prevalence is 11%. Depression (according to the EPDS) occurred in 19% of the participants. The nurses reported that 90% of the participants had psychosocial problems. In the general population this percentage is 12%. From the questionnaires 77% of the participants had more than three risk factors, while nurses reported that 98% of the participants had more than three risk factors.

Discussion

In this manuscript we describe a two-stage selection procedure to select high risk pregnant women and test the selection procedure with validated questionnaires. The first stage is conducted by (health care) professionals and the second stage by trained nurses. Furthermore, an expert committee is involved in the selection procedure. Participants were included at an average age of 19 years and were 19 weeks pregnant at inclusion. The questionnaires show that a high percentage of the participants was single, had domestic violence in the past or in their current relationship, had financial problems or no occupation. Furthermore, most participants had multiple risk factors. These results indicate that by using the two-stage selection procedure women with an increased risk of abusing their child were selected early in pregnancy.

This study showed that a higher prevalence of risk factors was reported during the interview conducted by the nurse, than by using validated questionnaires. A methodological explanation is that not all items were defined the same way in the questionnaires as in the interview by the nurse. For example, the nurse tried to detect if there were psychosocial problems while in the questionnaire the occurrence of depression was measured. More women could be having stress, anxiety and/or depression. Another explanation could be that participants were more open to the nurse than to the interviewers. The nurses are trained to create a trusting relationship and because they have two to three years experience in daily practise as a nurse, they are very capable of conducting such an interview. Furthermore, participants were given the opportunity to discuss their problems. This is also found by Kelly, where he described that women wanted to be asked about their problems if they received help [21]. It is therefore important to consider selecting women with multiple risk factors by a trained nurse.

A limitation of this study is that the recruiters did not register data of women who dropped out at each stage of the selection procedure, because we had insufficient insight into these women. However, from the pilot study of VoorZorg and by personal communication with researchers conducting a similar RCT in Great-Britain, we know that approximately 50% of the women who were initially identified as possible high risk for abusing their child during the first stage were excluded during the second stage. To verify this percentage we conducted a retrospective study among 2,913 women living in Amsterdam who gave birth between January and March 2008. Demographic data of these women were available. A percentage of 1.3% of these women met the first stage selection criteria and was categorized as high risk. Of the total births between January and March 2008 as mentioned before, 0.6% actually received the VoorZorg program and therefore met the second stage selection criteria (Mejdoubi 2010, unpublished data). This indicates that 50% of the participants drop out during the second stage.

Another limitation is that the prevalence of child abuse was not taken into account in this study because participants were still pregnant. Therefore sensitivity and specificity of the two-stage selection procedure were not calculated. On the other hand it is known that families with multiple risk factors have an increased risk of abusing their child. In this study 98% of the women had four or more

risk factors. This indicates that a high prevalence of women with an increased risk of abusing their child were included in the study.

A strength in this study is that the nurses had the possibility to present a case to an expert committee. Approximately 15 percent of this study population is enrolled after consultation of the expert committee. A reason for nurses to consult the committee could be the difficultness of excluding a participant with a high prevalence of risk factors based on one formal criterion. In that case the independent expert committee can make a decision and it is therefore an important part of the selection procedure.

Another strength is that nurses could make a decision based on objective risk factors but also on a subjective factor that is a high suspicion of being at risk for abusing the child in the future (gut feelings). Professionals in the Youth Health Care in the Netherlands are trained and experienced enough to suspect child abuse or whether a patient is at higher risk during a conversation with subjects. Several studies make use of the suspicions of professionals and this factor was also effective in selecting high risk families [22]. A tool that includes this subjective factor is therefore more adequate in screening for families at risk for child abuse than objective factors only.

In this study a very low number of Turkish and Moroccan were included. According to the Dutch Central Bureau of Statistics 14% of the adolescent pregnancies in the Netherlands is of Turkish or Moroccan origin [23]. No data were available on the number of Turkish and Moroccan women who refused to participate in the program. However, other researchers have studied this and noted that these ethnic minorities are less open for outside support. They do not like interference from outside or they feel ashamed about their situation [24]. Ethnic minorities also have strong social networks which provide support [25]. Another explanation could be that these women have the assumption that VoorZorg does not match their cultural standards [24]. Also, it is possible that these women were not including in the study because they did not understand the Dutch language, which was an inlusion criteria of this study. Because the low percentage of Turkish and Moroccan participants, the results of this study might be less generalizable for these women.

Recommendations for future research

A recommendation is to study how more Moroccan and Turkish women can be included in the study. The researchers of the VU University Medical Center are studying this at the moment.

Conclusions

In conclusion, the two-stage selection procedure with five strict inclusion criteria during the first stage, a risk inventory by trained nurses during the second stage, and an expert committee to be consulted, successfully selected young high risk women. Of all selected women, 98% had 4 or more risk factors, indicating a high risk of abusing their child.

Figures

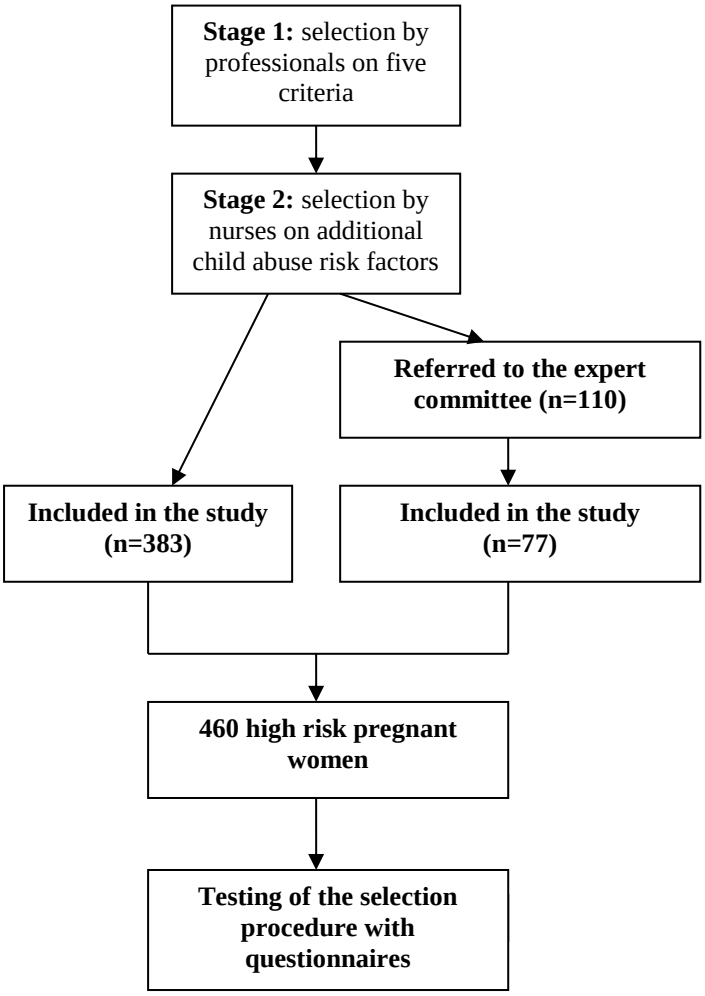

Figure 1: *Flow of participants during the two-stage selection procedure*

TABLES

Table 1:

Demographic Characteristics of the Women at Inclusion (n=460)

Baseline characteristics	VoorZorg women
Age in years	19 ± 2.5[a]
Ethnicity (%)	
Dutch	50
Surinamese/Antillean	27
Moroccan	1
Turkish	4
Other	19
Marital status (%)	
Married/living together	24
Educational Level (%)	
Primary school	5
Pre-vocational secondary education	93
Other	2
Employed (%)	25

[a] Mean ± SD

Table 2:

The Prevalence of the Inclusion Criteria at the First Stage (n=460)

First stage criteria	Prevalence of women
No previous live births	100%
Age ≤ 25 years	99%
Low educational level[a]	92%
Pregnancy ≤ 28 weeks	96%[b]
Understands the Dutch language	100%[c]

[a] Prevocational secondary education
[b]The average gestational age at inclusion was 19 ± 5.9 weeks.
[c]With the exception of one participant.

Table 3:

The Prevalence of the Inclusion Criteria at the Second Stage of VoorZorg Derived from Questionnaires and Interviews by VoorZorg Nurses

		VoorZorg women		General female population
	Inventory items	Interview by VoorZorg nurses	Interview by using questionnaires	
1.	No partner (single)	97%	76%	8% [26]
2.	Alcohol- and/or drug use	45%	25%	15%, 5%[a] [27]
3.	History of abuse and violence	69%	50%	30% [28]
4.	Actual domestic violence	57%	18%	3% [29]
5.	Depressive complaints	90%[b]	20%	12% [30]
6.	Unwanted pregnancy	91%	31%	11% [31]
7.	Housing problems	94%	14%[c]	--
8.	Financial problems	95%	70%	4% [20]
9.	Occupation			
	no education	91%	75%	22% [32]
	no employment	--	74%	12% [33]

Note. References are presented in brackets.
A dash means that no data was available.
[a]The prevalence of alcohol use and drug use are presented separately.
[b]This percentage does not illustrate the prevalence of depression but the prevalence of psychosocial problems.
[c]This is the amount of women who say to get help from organisations and is an underestimation of the actual number.

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CHAPTER 4:
EFFECTS OF NURSE HOME VISITATION ON CIGARETTE SMOKING, PREGNANCY OUTCOMES AND BREASTFEEDING: A RANDOMIZED CONTROLLED TRIAL

Jamila Mejdoubi
Silvia CCM van den Heijkant
Frank JM van Leerdam
Matty Crone
Alfons AM Crijnen
Remy A HiraSing

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Abstract

Objective: antenatal smoking is more prevalent among young women with low socio-economic status. The aim of our study is to assess whether the VoorZorg programme, compared to usual care, is effective in reducing cigarette smoking among young high risk pregnant women. Furthermore, the effect of VoorZorg on pregnancy outcomes and on breast feeding will be described.

Design: a randomised controlled trial of VoorZorg, a nurse home visitation intervention, was undertaken over a 2½ year period from 2007 to 2009. Data were collected between 16 and 28 weeks gestation, 32 weeks gestation and at two months post partum on cigarette smoking status plus six months post-partum for breastfeeding prevalence. Neonatal birth weight and gestation at birth were also collected. Setting: participants living in 20 municipalities in the Netherlands**.**

Participants: 460 pregnant women were recruited by different professionals. Inclusion criteria were age < 26 years, ≤ 28 weeks pregnancy with the first child, low educational level and some knowledge of the Dutch language**.**

Interventions: women in the intervention group received, in addition to usual care, the voorzorg programme which consisted of 40–60 home visits by specialised nurses from pregnancy until two years after birth.

Findings: the percentage of smokers was significantly lower in the intervention group (40%) compared to the control group (48%) during pregnancy (p = 0.03) and at two months post birth (49% and 62%; p = 0.02). During pregnancy the number of daily cigarettes smoked was reduced in both groups. After birth, the intervention group smoked 50% less cigarettes compared to the control group (C: 8 ±10; I: 4 ± 7 (mean ± standard deviation (SD)), p = 0.01). Furthermore, women in the intervention group did not smoke near the baby (C: 2 ± 5; I: 0 ± 0 (mean ± SD) p ¼ 0.03). Birth weight and gestational age were similar in both groups (C: 3147 g, 40 weeks; I: 3144 g, 39 weeks (p =0.94, p = 0.17)). Significantly more women in the intervention group were still breast feeding their baby at six months post -birth (C: 6%; I: 13%, p = 0.04).

Key conclusions: VoorZorg seemed to be effective in reducing cigarette smoking and in increasing breastfeeding duration. No effect was found on pregnancy outcomes.

Introduction

The VoorZorg programme is a home visitation programme translated and culturally adapted from the Nurse Family Partner- ship (NFP) programme. The NFP is an effective programme in the United States (US), designed to address risk factors among young pregnant women with low socio-economic status (SES) that compromise fetal and child development and the main goal is primary prevention of child abuse[1].

Maternal cigarette smoking is one of the most preventable causes of adverse pregnancy outcomes [2]. Women who smoke during pregnancy are at a higher risk for preterm birth, low birth weight and placental complications [3]. In addition, more babies with Sudden Infant Death Syndrome are reported among women who smoked [4]. Complications during birth, like fetal distress or maternal infection, lead to 66% higher medical costs among smokers compared to non-smokers [5,6]. Moreover, the child is at risk of developing behavioural problems such as externalising behaviour, because nicotine expo- sure can affect brain development even after adjustment for other risk factors like socio-economic status [7–9]. To prevent child morbidity and mortality, it is important to reduce maternal cigarette smoking during pregnancy and after birth.

The prevalence of women smoking during pregnancy is high in developed countries [3].In the US, 12% of pregnant women smoke, which is similar to that reported in Sweden [10]. In Australia the percentage of women who smoked during pregnancy is higher (17%) [11]. The prevalence is highest amongst women with low SES [3,12]. Mohsin et al. showed that 43% of young women (< 20 y) with low SES in Australia smoked during pregnancy [11]. Professionals should focus on young women with low SES, by offering them a targeted intervention to stop cigarette smoking.

As far as we know, there is a lack of effective interventions for high risk pregnant women on reducing or quitting cigarette smoking to improve pregnancy outcomes [3]. Lumley et al. described several interventions aiming at smoking cessation among pregnant women. However, only few studies were specifically designed for (young) pregnant women with low SES [13–17]. In these studies, no effect on smoking cessation and pregnancy outcome were reported [3,17].

In the Netherlands midwives use the minimal intervention strategies (V-MIS, "V" stands for midwife in Dutch) for smoking cessation among pregnant women which is based on the Integrated Change model [18]. In brief, the V-MIS is a smoking cessation counselling strategy in which the information is tailored to the motivational stage of the pregnant women. A Randomised Controlled Trial (RCT) by de Vries et al. (2006) showed that the V-MIS was effective on reducing cigarette smoking during pregnancy and six weeks after birth [19]. The effect of the V-MIS among high risk pregnant women was not assessed. We hypothesise that the home visitation programme conducted by specialised nurses will strengthen the effect of the V-MIS to stop or decrease cigarette smoking among high risk pregnant women.

Breastfeeding is also promoted in the VoorZorg programme because of the proven health advantages. Breastfeeding is, among others, associated with better cognitive outcomes of the child and protective against several diseases [20]. And breastfeeding is important for the relationship between

mother and child [21]. The aim of our study is to assess whether the VoorZorg programme, compared to usual care, is effective in reducing cigarette smoking among young high risk pregnant women. Furthermore, the effect of VoorZorg on pregnancy outcomes such as infant birth weight and gestational age plus breastfeeding will be described.

Methods

This study is designed as a single blind, parallel-group, randomised controlled study. The interviewers were blinded from allocation. More detailed descriptions of the design are published elsewhere [22]. This study was approved by the Committee of Ethics on Human Research of the VU University Medical Center (Amsterdam, the Netherlands). All participants signed a written informed consent form.

Participants

Women were actively recruited in 20 municipalities in the Netherlands. A two-stage selection procedure was performed to include all eligible participants [23]. During the first stage, women were selected by general practitioners, midwives and other professionals on the following criteria: (1) maximum age of 25 years, (2) low educational level (primary school or prevocational secondary school), (3) maximum 28 weeks of gestation, (4) no previous live births and (5) understanding of the Dutch language. During the second stage women were interviewed by VoorZorg nurses, and an inclusion criterion was that women reported at least one of the following additional risk factors: no social support, previously or currently experiencing domestic violence, psychosocial symptoms, unwanted and/or unplanned pregnancy, financial problems, housing difficulties, no education and/or employment and alcohol and/or drug use. Out of prior evaluation, it is known that about 50% of the women that were recruited in the first stage were excluded after the interview by the VoorZorg nurses in the second stage because they did not meet the second stage criteria[23].

A total of 460 participants were eligible and randomly assigned into the control or the intervention group after being stratified by region and ethnicity by use of a computer-generated list of random numbers. 223 women were assigned to the control group and received usual care and 237 women were assigned to the intervention group and received the VoorZorg programme. The independent randomisation procedure was performed by a researcher of the VU University Medical Center.

Data collection

In the analyses of this study four data collection moments were included between 16 and 28 weeks and at 32 weeks of pregnancy, at two and six months post birth. Trained female interviewers were available in each region and women were interviewed at home. The interviewers were independent from the VoorZorg nurses. Women were usually interviewed by the same interviewers at each data collecting moment.

We expected a chance that participants could produce socially desirable answers in the presence of others, therefore, the inter- views were conducted in private if possible [24]. Data concerning pregnancy outcomes were extracted from data- bases of Youth Health Care Organizations.

Intervention

All women received usual care provided by the Dutch Youth Health Care Organizations [25]. Every pregnant woman in the Netherlands receives maternal health care by a midwife. The caregiver (midwife or obstetrician) offers health education, performs physical examinations and monitors the development of the fetus. In the Netherlands, every newborn will automatically be registered in a Youth Health Care organization (ambulatory well-baby clinic) to monitor the health and development of the child, and parents are supported in their parenthood. From 2002 onwards the V-MIS was disseminated among all midwives in the Netherlands [18]. The V-MIS aimed at smoking cessation and is based on the '5A'-model and is adjusted for pregnant women. It consists of seven steps (figure 1) described by de Vries et al.[26] Women in the intervention group were offered, in addition to usual care, approximately 10 home visits during pregnancy, 20 during the first year and 20 during the second life year of the child by trained, specialised VoorZorg nurses. In the period that we collected data for the present study (from pregnancy until six months post partum) women received approximately 20 home visits.

The VoorZorg nurses were certified nurses working in Youth Health Care organizations and received specialised training (according to the NFP) in becoming a VoorZorg nurse. The VoorZorg trainings also included training on how to reduce smoking with the V-MIS a nationwide smoking cessation programme, and how to promote breastfeeding. According to the protocol, six domains were discussed during the home visits: (1) the health status of the mother, (2) the child's health and safety, (3) the personal development of the mother, (4) the role of the mother, (5) the mother's relation with her partner, family and friends and (6) the use of (health) care organizations. Furthermore, the VoorZorg nurse inquired about participants' smoking behaviour at each home visit. Participants who declared to smoke were systematically offered the V-MIS. The VoorZorg nurses also discussed whether women were exposed to passive cigarette smoking. After birth, the VoorZorg nurses focused on the negative health effects for the baby and to refrain from smoking in the presence of the baby, as recommended by [27].

Women receiving the VoorZorg intervention were encouraged, already during pregnancy, to initiate and continue breastfeeding after childbirth. The VoorZorg nurse also discussed the problems women encountered when breastfeeding their child and worked together with the mother to seek solutions to continue breastfeed- ing. It is for example known that when babies cry more often, the mother thinks the breastfeeding was not enough to satisfy the baby. Thus, when the baby cries less, chances of breastfeeding might be higher [28].

Outcomes

Primary outcome measures

The first outcome measure was the prevalence of cigarette smoking (percentage of smokers and average number of cigar- ettes smoked a day). Group differences were assessed at baseline, 32 weeks of pregnancy and two months post birth. Also, average numbers of cigarettes smoked a day near the baby were assessed.

Prevalence of cigarette smoking was assessed by asking at baseline whether participants had smoked during their pregnancy. Participants were able to choose from three categories: 'Yes', 'Yes, until I was aware of my pregnancy' and 'No'. The second question was whether they were a current smoker. If participants answered this question positively they were asked about the quantity of cigarettes smoked per day. At 32 weeks of pregnancy participants were asked: 'How many cigarettes do you smoke daily?' The next question was: 'How many cigarettes did you smoke over the past 48 hours?' If a participant answered both questions with '0 cigarettes', she was categorised as a non-smoker. Participants were also asked whether they had smoked during pregnancy before they were aware of their pregnancy.

At two months post birth, these questions were repeated and an additional question was asked regarding the quantity of cigarettes smoked near the baby.

Other primary outcome measures were birth weight, weeks of gestation, adverse pregnancy outcomes (low birth weight (< 2500 g), prematurity (< 37 weeks) and small for gestational age), and breastfeeding. Small for gestational age was defined as a neonate with birth weight below the tenth percentile on the new Dutch reference curves for birth weight by gestational age [29].

In addition, breastfeeding initiation and duration were assessed at six months post birth by asking participants whether they had initiated breastfeeding. When participants answered this question positively, they were asked whether they were still breastfeeding their child. Participants who answered this question negatively were asked more detailed questions about when they quit breast feeding.

Data analyses

We used SPSS 15.0 for regression analyses and MLwiN 2.22 for multi-level analysis (with 95% confidence interval) [30]. Linear regression analyses were used to analyse the number of cigarettes smoked per day, birth weight, weeks of gestation, and duration of breastfeeding. Logistic analyses were used to study cigarette smoking, low birth weight, prematurity and small for gestational age, and breastfeeding. Mean differences (β) and Odds ratios were calculated to measure effect sizes. Last observation carried forward (LOCF) approach was conducted afterwards to replace missing data for dichotomous variables of smoking. Subgroup analyses were conducted to examine the association between smoking and pregnancy outcomes. Multilevel analyses were used to study changes in smoking behaviour in time (base- line assessment, 32 weeks of pregnancy and two months post birth) and to study differences between control and intervention group. It accounts for the hierarchical nature

of the longitudinal data, where level 1 was the measurement in time and level 2 was the individual. Multilevel logistic modelling was performed for dichotomous data (prevalence of smokers) and multilevel linear modelling for continuous data (average number of cigarettes smoked a day). Wald statistics were used to determine significance of the effect. We tested for possible confounders and effect modifiers (age, birth weight, weeks of gestation, gender of new- born, ethnicity and number of risk factors present at baseline).

Findings

Attrition

After randomisation, 20 (8%) of the 237 participants in the intervention group and 35 (16%) of the 223 participants in the control group were excluded from the study (figure 2). Three women in the control group and five women in the intervention group miscarried before receiving any treatment (< 28 weeks of pregnancy). One mother in the control group and four mothers in the intervention group experienced a perinatal death. The difference between both groups, in the prevalence of perinatal deaths, was not significant. The cause of death in the control group was that the baby had a hydrocephalus and in the intervention group that two babies were born premature, one twin died after 29 weeks of pregnancy and one baby died because of a knot of the umbilical cord.

The baseline characteristics of women who were lost to follow up in each measurement were similar to women who remained in the study. Table 1 summarises the baseline characteristics of the participants. At inclusion, participants were on average 19.4 years old and were included on average at 19.8 weeks pregnancy. The difference between control and intervention group was not significant for any of the variables.

Cigarette smoking

Table 2 shows that at 16-28 weeks of pregnancy, an average of 45% of the participants in both conditions are current smokers, smoking on average 7–8 cigarettes per day. At 32 weeks of pregnancy a decrease of the percentage of smokers was measured in both conditions: in the control group, 35% of the women and in the intervention group 33% are currently smoking (OR 0.9; 95% confidence interval (CI) 0.5-1.5, n.s.). After applying the LOCF approach, group differences became significant (p=0.03; OR 0.5; 95% CI 0.3-0.9). At two months post birth, the percentage of smokers was respectively 62% and 49%. LOCF analyses showed a significant difference between control and intervention group (p=0.02; OR 0.5; 95% CI 0.3-0.9).

At two months post birth, the number of cigarettes smoked per day was significantly higher in the control group; in the control group 8 (SD $\pm$10) cigarettes were smoked per day, while in the intervention group 4 (SD $\pm$ 7) cigarettes were smoked per day (mean difference (β) 4; 95% CI 1.0-7.9). The number of cigarettes (cig.) smoked near the baby was also significantly higher in the control group (2 (SD $\pm$ 5) cig. per day) compared to the intervention group (0 (SD $\pm$ 0) cig. per day) (β 1.6; 95% CI 0.2-0.1).

Multilevel analysis showed that over time, cigarette smoking decreased significantly in the intervention group (β 1.7; 95% CI (2.8 to 0.5)). Furthermore, the number of women who smoked was significantly lower in the intervention group (OR 0.5; 95% CI (1.0 to 0.05)).

Pregnancy outcomes

As illustrated in table 3, mean birth weight was similar in both groups (C: 3147; 519 versus. I: 3144; 577 (mean; standard deviation (SD)). No significant difference in mean gestational age was measured (C: 40; 2.1 vs. I: 39; 2 (mean; SD)). The prevalence of babies with low birth weight, being premature or being small for gestational age, was similar in both groups. Subgroup analyses on smoking status (yes, no) showed also no effect on pregnancy outcomes.

Breastfeeding

As table 4 shows, the percentage of women who initiated breastfeeding was similar in both groups (OR 1.3; 95% CI (0.7-2.4) n.s.). Women who quit breastfeeding (> 1 week), quit at on average 10 ± 8 weeks after birth in the control group and 9 ± 7 weeks in the intervention group (β 0.1; 95% CI (3.0-1.5)). At 6 months post birth, significantly more women in the intervention group were still breastfeeding their child (OR 2.6; 95% CI (1.0-6.8)).

Discussion

VoorZorg is a nurse home visiting programme and is the Dutch equivalent of the Nurse Family Partnership in the US. The main focus of VoorZorg is primary prevention of child abuse. Results of VoorZorg on child abuse will be presented elsewhere. In the present study we investigated whether the VoorZorg programme was effective in reducing cigarette smoking, improving pregnancy outcomes and breastfeeding duration among high risk pregnant women. After applying LOCF analyses VoorZorg seemed to be effective in reducing the percentage of smokers during pregnancy and after birth. Women that followed VoorZorg also smoked fewer cigarettes per day after birth and fewer cigarettes in the presence of the baby. Furthermore, a higher prevalence of VoorZorg women breast fed their child at six months. No effect was measured on pregnancy outcomes.

Significantly fewer women in the intervention group started smoking after the child was born compared to women in the control group. Tappin et al. discussed the difficulty of changing smoking behaviour among women with multiple risk factors [31]. An RCT of nurse home visiting in Australia (Kemp et al. 2011) similar to VoorZorg did not find any difference in smoking between the control and intervention group [17]. The difference in the RCT by Kemp et al. was that women of any age and women who already had children as well as first time mothers were enrolled. Because of the result on cessation of smoking, VoorZorg is expected to have a positive effect in this difficult high risk group on other risk behaviours, like drug and/or alcohol abuse and sexual risk behaviour.

The results found in the present study, concerning the similar reduction of the average numbers of cigarettes smoked per day during pregnancy in both groups, were comparable to findings in other studies conducted among low income pregnant women [15,31,32]. However, Olds et al. (1986) showed a positive intervention effect on the numbers of cigarettes smoked per day [1]. We expected the same results in the Netherlands. But we hypothesise that women in our study population had other priorities during pregnancy and VoorZorg nurses possibly gave more attention to these problems. Furthermore, there is already an national intervention programme for smoking cessation offered by midwives to all pregnant women in the Netherlands (the V-MIS) [19]. In the US, the control group received no such intervention during pregnancy. In the present study, after childbirth the message was continued in the VoorZorg intervention that mothers should not smoke in the presence of the child, whereas the control group received no such intervention.

In this study, no significant differences in pregnancy outcomes were found between both groups. These results are consistent with other studies conducted among socially disadvantaged women aiming at improving pregnancy outcomes by reducing smoking [33,34]. However, Olds et al. (1986) found a significant effect in pregnancy outcome in a subgroup of women between 14 and 16 years of age. In the present study the proportion of women in this age group was very low (10 %); we also conducted several subgroup analyses but no effects were measured, probably due to the small sample size in this subgroup. This is in line with the low number of teen pregnancies of this age group in the Netherlands. An unexpected finding regarding pregnancy outcome was that mean birth weight was approximately 3140 g. in both treatment groups. This is low compared to the common Dutch population, where birth weight is on average 3500 g. [35] and also compared to Dutch women with a very low education level where the average birth weight is approximately 3375 g. [36]. Olds et al. (1986) reported on average higher birth weight rates (C: 3262 g. vs. I: 3285g.) [1]. This suggests that in the Netherlands we are dealing with a subgroup of young women with many risk factors associated with adverse pregnancy outcomes.

In the present study significantly more women in the intervention group continued breastfeeding for at least 6 months. According to Milligan et al. (2000), only a few studies found an effect on breastfeeding duration among low income women [37]. In our study the rates of women initiating breastfeeding were comparable to rates in the general female population of the Netherlands (81%). Midwives in the Netherlands promote breastfeeding to all pregnant women. The rates of women in the intervention group continuing breastfeeding for 6 months were comparable to the general female population (13%) and two times higher than in the control group [38]. It is important to encourage breastfeeding for 6 months in young women with low SES. These women experience several barriers associated with breastfeeding duration, like being anxious or depressed or lacking social support [37]. The VoorZorg programme addresses these barriers to support longer breastfeeding duration. VoorZorg builds on the well-established relationship between the mother (to-be) and nurse. Although important improvements are achieved the programme can also be improved in this respect.

A limitation of this study is that self-report questionnaires were used to measure participants' cigarette smoking behaviour instead of biochemical assessments. We chose this method because of financial- and time constraints in our study. Using self-report questionnaires can be done quickly, saving time both for the participants and the researchers. And to increase adherence, it is important to use non-time consuming measurements. In addition, by using cotinine (metabolite of nicotine) measured in blood samples passive smoking is also measured [39]. This could lead to false positive results, especially among this study population who are more likely to be surrounded by smokers [40]. Furthermore a limitation is that we did not report exclusive, full and partial breastfeeding rates because we did not assess these data. Thirdly, a limitation in our study was the relatively high non-response rate in the control group. Because these women did not receive an intervention, they were probably not motivated to participate in the measurements [41]. Furthermore, these women were less traceable for the interviewers than women in the intervention group. Because women in the intervention group had several contact moments with the VoorZorg nurse, they could be easily localised by youth health care organizations. A high non-response rate could bias the results reported in this study, especially when women who are smokers or experience more difficulties were untraceable, but it is likely that we underestimate rather then exaggerate intervention-effects. A recommendation for other researchers is to study how to achieve a higher follow-up rate among young women with low SES.

In conclusion, the VoorZorg intervention seemed to be effective in reducing cigarette smoking during pregnancy and after birth; in the intervention group no cigarettes were smoked in the presence of the baby, which is in contrast to the control group. The VoorZorg intervention had no effect on pregnancy outcomes. Furthermore, significantly more women in the intervention group were still breastfeeding at six months.

Implications for midwives

Midwives are usually the first health care providers (after the general practitioners) to see and examine pregnant women. The women in our study population and their children are at high risk of having several health problems. It is therefore important for midwives to be aware of the problems these women have and also to provide them with information on tailored interventions that are available in their country. Midwives therefore have an ideal position for recruiting and motivating women for a programme, such as the Nurse Family Partnership. Midwives can recruit women for this programme. Furthermore, midwives have a role in counselling pregnant women who smoke on smoking cessation. The V-MIS can support them in this task.

TABLES

Table 1:

Baseline characteristics of participants

	Control (n=223)	**Intervention (n=237)**
Age n(sd)	19.2 (2.6)	19.5 (2.8)
Weeks of gestation n(sd)	19.5 (5.9)	20.1 (6.5)
Married/living with partner	34 (22)	47 (24)
Current education level		
Primary school	7 (4)	11 (6)
Pre-vocational education	150 (96)	179 (94)
Employed	44 (28)	56 (29)
Ethnicity		
Dutch	107 (48)	117 (49)
Moroccan	5 (2)	5 (2)
Turkish	8 (4)	8 (3)
Surinamese/Antillean	60 (27)	65 (27)
Cape Verdean	4 (2)	5 (2)
Other	37 (17)	38 (16)
Attempted to quit smoking	78 (80)	90 (82)
Stopped smoking after aware of pregnancy	25 (20)	21 (13)

Note. In italics the number of participants for whom data were available is described. Numbers are n (%) unless described otherwise.

Table 2:

Percentage of smokers and average numbers of cigarettes smoked a day at baseline, 32 weeks of pregnancy, and at 2 months after birth in control and intervention group and effects of the intervention

	Control N=223 n(%)	Intervention N=237 n(%)	OR / β (95% CI)	Significance level
Smoking at baseline (16-28 wks of pregnancy)				
Current smoker	59 (47%)	71 (43%)	0.7(0.5-1.2)[b]	ns.
Average no. of cigarettes smoked/day	8 (7)	7 (5)	1.4 (-3.3-0.5)[a]	ns.
Smoking at 32 weeks of pregnancy				
Current smoker	34 (35%)	45 (33%)	0.9 (0.5-1.5)[2]	ns.
Current smoker (LOCF)[c]	69 (48%)	75 (40%)	0.5 (0.3-0.9)	p=0.03
Average no. of cigarettes smoked/day	3 (5)	2 (4)	0.5 (-0.6-1.7)[a]	ns.
Smoking at 2 months after birth				
Current smoker	32 (65%)	31 (48%)	0.5 (0.3-1.1)[b]	p=0.08
Current smoker (LOCF)	97 (62%)	96 (49%)	0.5 (0.3-0.9)	p=0.02
Average no. of cigarettes smoked/day n(sd)	8 (10)	4 (7)	4.4 (1.0-7.9)[a]	p=0.01
Average no. of cigarettes smoked/day in presence of the baby n(sd)	2 (5)	0 (0)	1.6 (0.2-0.1)[a]	p=0.03

Note. Numbers are n(%) unless described otherwise.
The control group is the reference group

[a] β value (mean difference)

[b] Odds Ratio

[c] LOCF= Last observation Carried Forward

Table 3:

Birth weight, gestational age and adverse pregnancy outcomes for control- and intervention group and effect sizes

	Control N=223 n(%)	**Intervention N=237 n(%)**	**Corrected β/OR (95% CI)**	**Significance level**
Average birth weight (g) n(sd)	3147 (519)	3144 (577)	-2.4 (-111.1-106.4)[a]	ns.
Average gest. age (wks) n(sd)	40 (2.1)	39 (2)	-0.2 (-0.6-0.1)[a]	ns.
Low birth weight (< 2500g)	20(11.3)	25(12.3)	1.1 (0.5-2.5)[b]	ns.
Preterm gestation (< 37 wks)	10(7.0)	16(8.6)	0.9 (0.3-2.7)[b]	ns.
Small for gestational age	31(18)	34(16)	0.8 (0.4-1.6)[b]	ns.

Note. Numbers are n(%) unless described otherwise.
The control group is the reference group

[a] β value

[b] Odds Ratio

Table 4: *Breastfeeding initiation and duration at 6 months after birth in control and intervention group*

	Control N=223 n (%)	**Intervention N=237 n (%)**	**OR (95% CI)**	**Significance level**
Initiated breastfeeding	85(78)	130(82)	1.3 (0.7-2.4)	ns.
Ended < 1 week	6(8)	5(5)	0.6 (0.2-2.0)	ns.
Ended > 1 week*	73(92)	103(95)	1.7 (0.5-5.8)	ns.
Breastfeeding at 6 months	6(6)	21(13)	2.6 (1.0-6.8)	p=0.04

Note. No confounders or effect modifiers were found.
The control group is the reference group

* C: on average 10 ± 8 weeks
I: on average 9 ± 7 weeks

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CHAPTER 5:
EFFECT OF NURSE HOME VISITS VS. USUAL CARE ON REDUCING INTIMATE PARTNER VIOLENCE IN YOUNG HIGH-RISK PREGNANT WOMEN: A RANDOMIZED CONTROLLED TRIAL

Jamila Mejdoubi
Silvia CCM van den Heijkant
Frank JM van Leerdam
Martijn Heymans
Remy A HiraSing
Alfons AM Crijnen

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Abstract

Background

Expectant mothers and mothers of young children are especially vulnerable to intimate partner violence (IPV). The Nurse-Family Partnership (NFP) is a home visitation program in the United States effective for the prevention of adverse child health outcomes. Evidence regarding the effect of nurse home visiting on IPV is inconsistent. This study aims to study the effect of VoorZorg, the Dutch NFP, on IPV.

Methods

A random sample of 460 eligible disadvantaged women <26 years, with no previous live births, was randomized. Women in the control group (C; n=223) received usual care; women in the intervention group (I; n=237) received usual care plus nurse home visits periodically during pregnancy and until the child's second birthday.

Results

At 32 weeks of pregnancy, women in the intervention group self-reported significantly less IPV victimization than women in the control group in: level 2 psychological aggression (C: 56% vs. I: 39%), physical assault level 1 (C: 58% vs. I: 40%) and level 2 (C: 31% vs. I: 20%), and level 1 sexual coercion (C: 16% vs. I: 8%). Furthermore, women in the intervention group reported significantly less IPV perpetration in: level 2 psychological aggression (C: 60% vs. I: 46%), level 1 physical assault (C: 65% vs. I: 52%), and level 1 injury (C: 27% vs. I: 17%). At 24 months after birth, IPV victimization was significantly lower in the intervention group for level 1 physical assault (C: 44% vs. I: 26%), and IPV perpetration was significantly lower for level 1 sexual assault (C: 18% vs. I: 3%). Multilevel analyses showed a significant improvement in IPV victimization and perpetration among women in the intervention group at 24 months after birth.

Conclusion

VoorZorg, compared with the usual care, is effective in reducing IPV during pregnancy and in the two years after birth among young high-risk women.

BACKGROUND

Expectant mothers and young mothers are vulnerable to intimate partner violence (IPV)[1–3]. IPV is associated with physical injury, heart problems, gastrointestinal diseases, psychosocial problems, substance abuse, sexual risk behavior, suicide attempts, and mortality [4,5]. IPV during pregnancy increases a mother's risk of adverse pregnancy outcomes and the likelihood that her children will develop conduct problems[6,7]. Parents involved in an aggressive relationship are more likely to abuse their child [8]. For children, both experiencing abuse and witnessing abuse are forms of child abuse. It is estimated that among young adult women, IPV is more prevalent than it is among adult women. Pregnant adolescents are approximately six times more likely to be victim of violence by a dating partner compared with their non-pregnant peers[9]. Among pregnant adolescents the prevalence of IPV ranges from 5% to 38%[10]. To protect at-risk mothers and their children from the health and developmental risks of IPV, early intervention is important, if possible, during pregnancy.

Targeted interventions designed to prevent or reduce IPV victimization and perpetration are scarce[11,12]. The Nurse-Family Partnership (NFP), developed by D. Olds et al., is a well-known nurse home visitation program that has been tested in three randomized controlled trials (RCT) with young high-risk pregnant women[13]. The trials were conducted in three distinct populations in the United States (US): Elmira (New York), Memphis (Tennessee) and Denver (Colorado)[14–17]. The NFP has proven effective for the prevention of adverse child health outcomes including child abuse. The Denver trial detected program effects on IPV at four year follow-up [18,19]. The Elmira trial also reported program effects on IPV [13]. Olds et al. showed that home visitation programs designed to prevent child abuse and neglect have limited effectiveness if the mother is currently experiencing IPV[20]. Because of the strong links between IPV and child abuse and neglect it is important to study whether nurse home visiting is effective at reducing IPV. Langhinrichsen-Rohling et al. conducted a preliminary test of an IPV prevention program among a small group of high-risk inner-city pregnant adolescent girls in which they found an effect on IPV perpetration and victimization[21].

In the Netherlands, the NFP was translated into the Dutch language and adapted to be integrated into the Dutch health care system. Although the adapted program, VoorZorg, is the first evaluation of the NFP outside the US, other adaptations of the program are currently being evaluated in England, Canada and Australia. VoorZorg consists of 40-60 structured home visits with young pregnant women by well-trained nurses, from pregnancy until the child is two years of age. Primary outcome measures of the Dutch RCT are smoking cessation, birth outcomes (birth weight and pregnancy duration), breast feeding, child development, IPV and child abuse [22]. The objective of the current study is to assess the effect of VoorZorg on addressing self-reported IPV victimization and perpetration among young, low-educated pregnant women and mothers compared with young mothers receiving the usual care in the Netherlands.

METHODS

The protocol for this trial and supporting CONSORT checklist are available as supporting information; see Checklist S1 and Protocol S1. Prior to this study, the NFP was translated into Dutch and culturally adapted to accommodate the needs of pregnant women in the Netherlands and to be integrated into the Dutch child health care system[22]. The most important adaptations were placing more emphasis on home delivery, instructing women to stop smoking during pregnancy, offering more information about breastfeeding and emphasizing the advantages of breastfeeding, adjusting program practices to avoid overlapping duties with midwifes or youth health care professionals, organization of pregnancy classes, ultrasounds and other educational opportunities; these files are available as supporting information; see Adjustments in the Dutch version of Pregnancy Guidelines version S1 and Adjustments in the Dutch version of Infancy Guidelines S1[23,24]. The intervention and implementation were tested in a pilot study.

Ethics Statement

This study was approved by the Medical Ethical Committee of the VU University Medical Center (VU MC). Women who declined to participate were not disadvantaged in any way by refusing to participate in this study. They received the usual standard of care.

The informed consent procedure was conducted by a specialized VoorZorg nurse during the selection process, which is described in the next paragraph. The VoorZorg nurse informed the pregnant woman about the content of the VoorZorg program and the RCT, and explained the 50% chance to be assigned to the control group. If the woman agreed to participate, a written informed consent was signed after explaining the aim of signing this form. These steps were all written in a protocol designed for VoorZorg nurses. All participants signed forms acknowledging informed consent.

Participants and setting

From 2007 to 2009, 460 participants were recruited for the RCT based on a sample size calculation. A two-stage selection procedure was performed (Unpublished data). During the first stage, midwives, general practitioners, gynecologists, and others actively recruited women in 20 municipalities in the Netherlands. Inclusion criteria for the first stage were: (1) maximum age of 25 years, (2) low educational level (pre-vocational secondary education), (3) maximum 28 weeks of gestation, (4) no previous live birth and (5) some understanding of the Dutch language. These women were routed to the second stage, in which VoorZorg nurses interviewed women to ensure they had at least one additional risk factor (being single, a history or present situation of domestic violence, psychosocial symptoms, unwanted pregnancy, financial problems, housing difficulties, no employment and/or education, alcohol and/or drug use). When a potential participant did not meet all of the inclusion criteria for the first stage, but had multiple risk factors, the VoorZorg nurse presented the case to an

independent expert committee, which decided on inclusion or exclusion. The number (%) of participants recruited in this manner was 77 (16,7%).

All eligible women were randomized into the control or intervention group after stratification by region and ethnicity (Dutch, Surinamese/Antillean, Turkish, Moroccan, Cape Verdean or other). Ethnicity classification was performed by the VoorZorg nurse 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 particular country. Finally, 223 women were assigned to the control group and 237 women to the intervention group.

Intervention

Women in the control group received the usual care [22]. The usual care consists of maternal health care during pregnancy offered by a midwife or obstetrician to gain optimal pregnancy outcomes. The midwife or obstetrician offers health education, performs physical examinations and monitors the development of the fetus. After birth, a maternity care helper visits the mother at home to take care of the mother, the newborn and the household, and advises the mother about taking care of her baby. Furthermore, every newborn is registered in a child health care organization (ambulatory well-baby clinic) to monitor the health and development of the child and to support parents in their new role. In total, nine to eleven check-ups are performed until the child's second birthday. Families with special needs can receive support from (child) welfare organizations and mental health services established in different regions in the Netherlands.

Women in the intervention group were offered approximately 10 nurse home visits during pregnancy, 20 during the first year and 20 during the second life of the child's life by trained and experienced VoorZorg nurses, in addition to the usual care. Text messaging, telephone and social media were also used to contact the mothers. Home visits are well-structured and described in manuals; each of six domains (health status of the mother, child's health and safety, personal development of the mother, the mother as a role model, relation of the mother with her partner, family and friends, and use of institutions) were addressed during each visit. The participant's partner and/or father of the baby was included during each home visit, if possible.

Ultimate goals of this structured nurse home visitation program are: to improve the outcomes of pregnancy by improving a mother's health during pregnancy, to improve the child's health and development by helping parents provide more competent care to their children, and to improve the mother's own personal development.

Within the context of these well-structured visits, several elements are considered to address IPV. The VoorZorg nurses attempted to mitigate risk factors for IPV by reducing stress, by trying to make women financially independent, or by providing housing assistance. Nurses helped women (and their partners) during home visits to be aware of IPV, to identify abusive relationships by use of the Power and Control Wheel and to make them aware of the consequences of abuse for the child [25]. The Power and Control Wheel demonstrates the different types of abuse that perpetrators use to

control their victims. For safety reasons, this tool was discussed with the mother alone. Moreover, VoorZorg nurses supported women and their partners with strategies for emotional regulation and communication. The nurses also helped both partners to make safer decisions for the sake of themselves and their child, such as preventing arguments from escalating to a physical fight by teaching them how to address these situations, and by teaching them how to negotiate and to listen to each other. In families where IPV was present, these topics were repeated at each home visit. These elements match largely with the essential elements for effective programs on IPV for high-risk adolescent pregnant girls as identified by Langhinrichsen-Rohling and Turner (2012) [21].

VoorZorg nurses strive to establish a trusting relationship with mothers-to-be at a sensitive time in their development. Because it takes time to establish such a relationship, risk factors for IPV and child safety were addressed over a prolonged period of time during pregnancy and first years of life.

Measurements

The RCT measured the following outcomes[22]:

1. 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;
2. Adverse pregnancy outcomes, birth weight and gestational age;
3. 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];
4. Child abuse reports;
5. Intimate Partner Violence.

This manuscript specifically addresses self-reported IPV.
The primary outcome measure was self-reported psychological, physical or sexual violence, and injury towards the participant (victim) as well as towards her partner (perpetrator). Secondary outcomes were a summation of forms of violence, and both experiencing and perpetrating IPV. All outcomes were measured with the revised Conflict Tactics Scale. Psychometric properties are described by Straus et al. [28]

All women were interviewed three times at their home, at 16-28 and 32 weeks of pregnancy and 24 months after birth, by trained female interviewers. To prevent socially desirable answers and for safety reasons, the interviewers conducted the interviews in private.

Interviewers collected demographic information including age, ethnicity and education level at 16 to 28 weeks of pregnancy (baseline)[22]. At this baseline, the interviewers used the Abuse Assessment Screen to measure physical and sexual violence in the past[29]. At 32 weeks of pregnancy and 24 months after birth, the revised Conflict Tactics Scale (CTS2) was used to measure prevalence

of IPV victimization and perpetration[28]. The CTS2 questionnaire includes four scales: physical assault, psychological aggression, injury and sexual coercion. The CTS2 also takes into account the severity of violence (level 1 and level 2) as shown in **figure 1**. Annual prevalence was measured by indicating whether one or more of the acts in each scale were present in the past year. The variable "Combination of IPV forms" indicates whether more than one form of violence (psychological, physical, sexual violence and injury) was present. [28,30] Interviewers did not administer the CTS2 at baseline because the CTS2 measures IPV during a current or most recent relationship rather than relationships in the past.

Power Calculation

The sample size calculation was based on finding an effect in smoking reduction or cessation at the time of birth, at 12 months and at 24 months postpartum and was based on findings from the effects of the NFP study [15]. To detect an average improvement or a decrease in smoking by four cigarettes a day with a standard deviation of eight cigarettes, a power of 80% and an alpha of 5% were used. This resulted in a sample size of 57. Given that 25% of all women smoke at the start of pregnancy in the Netherlands, 228 participants in the control group and 228 participants in the intervention group were needed to detect a statistically significant effect.

Statistical analyses

Data were analyzed with the statistical package SPSS 15.0 for Windows. Multivariable logistic regression analyses were performed to compare differences in dichotomous outcomes between the control and intervention groups. Numbers needed to treat (NNT) and odds-ratios and their corresponding 95% confidence intervals were calculated. NNT is defined as the estimated number of participants who need to be treated with VoorZorg rather than the usual care for one additional participant to benefit over a time period of two years[31]. Multivariable Linear regression analyses were used to compare continuous outcomes.

We applied additional imputation techniques only for data from 24 months after birth because a completers/non-completers analysis was performed and indicated that we had enough data at 32 weeks for our analyses. In the control group, 110 CTS2 questionnaires were completed at T=32 weeks and 74 at T=24 months. Of these, 36 observations were carried forward, which is 33%. In the intervention group, 156 CTS2 questionnaires were completed at T=32 weeks and 110 at T=24 months. Of these, 29 observations were carried forward, which is 30%. First, we analyzed the data from 24 months after birth without imputation techniques. Then, last observation carried forward analyses and multiple imputation (MI) analyses were applied to impute missing values with Stata 12 (Stata Statistical Software: Release 12.0. College Station, Tex: Stata Corp;2001). Only results from the MI analyses were reported because this procedure results in more power, generates valid missing value

imputations under a variety of missing data scenarios and is currently the most recommended missing data method.

Multilevel Regression Analysis (MLwiN 2.24, Centre for Multilevel Modelling, Bristol, UK) was performed to measure the longitudinal relationship between the VoorZorg intervention and IPV victimization or perpetration. The dependency in the outcome variable being victim or perpetrator within the same person due to repeated measurements over time was accounted for by using multilevel models. In these models the time and intervention variable are included. Furthermore, the increase or decrease of the intervention effect over time was studied by introducing interaction terms between the intervention and time variable. Differences were considered significant if p-values were <0.05 (2-sided). All analyses were adjusted for possible confounders and effect modifiers.

Attrition analysis was conducted to evaluate the differences on baseline characteristics and lifetime prevalence of IPV between participants who remained in the study versus those who did not.

RESULTS

Baseline characteristics

The flow of participants throughout the study is shown in **figure 2.** There were no significant differences in the reasons for loss to follow-up between the two groups. In the control group, 214 of the 223 participants received the allocated condition, 26 were lost to follow-up, 29 did not want to participate in the measurement of T=32 weeks, and 21 did not participate due to design constraints. Of the 138 measurements, there were 110 complete CTS2 questionnaires. In the intervention group, 218 of the 237 participants received the allocated condition; 12 were lost to follow-up, 15 did not want to participate in the measurement of T=32 weeks, and eight did not participate due to design constraints. Of the 185 measurements, there were 156 complete CTS2 questionnaires. **Table 1** describes baseline characteristics. No significant differences in demographic characteristics or in the number of risk factors between the control and intervention groups were found at baseline. Of the two groups, 18% (n=40) of women in the control group and 19% (n=46) in the intervention group were physically abused during the past year, and 4% (n=9) in the control group and 5% (n=12) in the intervention group were sexually abused. Attrition analysis showed that participants who were lost to follow-up did not differ significantly from participants who remained in the study with regard to baseline characteristics displayed in table 1.

Intervention delivery

The intervention is a structured program, in which the frequency of home visits is greater in the beginning during pregnancy and the first months after delivery. Women are included in the program at 20 ± 6 (mean ± SD) weeks of pregnancy. The number of home visits during pregnancy was 9 ± 4

(mean ± SD). Only two women were included late and gave birth early, in which case they received less home visits during pregnancy. There were no women included after 28 weeks of pregnancy. The majority of participants received between six and 13 home visits during pregnancy.

IPV

Participant is victim

At 32 weeks of pregnancy, all participants reported experiencing level 1 psychological aggression, as shown in **table 2**. Reports of level 2 psychological aggression were significantly lower in the intervention group than in the control group (OR 0.55; 95% CI 0.32 to 0.94). Significantly fewer women in the intervention group experienced level 1 physical assault (OR 0.38; 95% CI 0.22 to 0.66) and level 2 assault (OR 0.57; 95% CI 0.32 to 0.99). Experiences of level 1 sexual coercion were significantly lower in the intervention group (OR 0.47; 95% CI 0.19 to 0.90). The prevalence of level 2 sexual coercion (OR 1.09; 95% CI 0.41 to 2.92) and the prevalence of injuries experienced after a fight (OR 1.13; 95% CI 0.36 to 3.56) did not differ significantly in both groups. Significantly fewer participants in the intervention group were victims of more than two forms of violence compared with participants in the control group (OR 0.49; 95% CI 0.28 to 0.86).

At 24 months after birth, multiple imputation analysis revealed that the prevalence of level 2 physical assault was significantly lower among women in the intervention group (OR 0.46; 95% CI 0.24 to 0.89). Other forms of violence were not significantly different at 24 months.

Multilevel logistic regression analyses revealed that reports of level 2 psychological aggression and level 1 physical assault among women in the intervention group reduced significantly more over the course of the intervention than reports among women in the control group.

Participant is perpetrator

The percentage of participants who reported abusing their partner is illustrated in **table 3**. At 32 weeks of pregnancy, participants in the intervention group reported using significantly less level 2 psychological aggression (OR 0.57; 95% CI 0.34 to 0.95) and level 1 physical assault (OR 0.57; 95% CI 0.34 to 0.95), and inflicted significantly less level 1 injuries to their partners (OR 0.53; 95% CI 0.29 to 0.96) than participants in the control group. Sexual coercion was the least common form of violence used by participants in both groups. Significantly fewer participants in the intervention group used more than two forms of violence towards their partner compared with participants in the control group (OR 0.53; 95% CI 0.30 to 0.94).

Multiple imputation analyses revealed that at 24 months after birth, the prevalence of level 1 sexual coercion was significantly lower in the intervention group than in the control group (OR 0.10; 95% CI 0.02 to 0.56). The prevalence of psychological aggression, physical assault, level 2 sexual coercion, and injuries inflicted on partner were similar in both groups.

Multilevel logistic regression analyses showed that level 1 physical assault decreased significantly over time among participants in the intervention group and was significantly lower than in the control group.

Participant is both victim and perpetrator

The majority of the victims of psychological aggression or physical assault reported perpetrating abuse as well (approximately 85%). At 32 weeks of pregnancy, the prevalence of women being both victim and perpetrator was significantly lower in the intervention group for level 2 psychological aggression (OR 0.48; 95% CI 0.29 to 0.80) and level 1 physical assault (OR 0.44; 95% CI 0.27 to 0.72), as compared with the prevalence within the control group. At 24 months after birth, women in the intervention group had a statistically significant lower odds of being both victim and perpetrator of level 1 physical assault compared with women in the control group (OR 0.48; 95% CI 0.25 to 0. 93).

DISCUSSION

The current study shows that the VoorZorg program is effective in reducing victimization and perpetration of self-reported IPV during pregnancy and two years after birth among low-educated pregnant young women. Through nurse home visits, a trusting relationship is established between patient and nurse. By addressing factors that may increase the risk for IPV in general (e.g., a reduction in stress), as well as factors that may increase the risk for IPV in relation to a specific person (e.g., identifying an abusive relationship), victimization and perpetration due to IPV was significantly lower during pregnancy and two years after birth in a sample of low-educated pregnant women compared with women in a control group. The reduction in IPV means that an important risk factor for compromised fetal development is mitigated through these nurse home visits. Furthermore, because the program works to proactively prevent IPV, it may have longer-term positive health effects on parents and their children.[32] VoorZorg is the Dutch equivalent of the NFP, which is widely recognized as an evidence-based preventive intervention that targets child abuse and neglect in the United States. We are the first researchers outside of the US to assess the effect of the NFP and to report the results of an RCT studying the effectiveness of VoorZorg on children's health and development.

Olds and other researchers have found that the NFP is associated with many positive and long-lasting effects of the NFP on mother and child development. Our findings regarding the positive effects that the program has on IPV victimization and perpetration among young pregnant mothers adds to this evidence. However, Olds et al. did not find that the NFP has an effect on IPV during pregnancy and after birth.[18] Some researchers have argued that participants are reluctant to report violence in families with young children because nurses in the United States are obliged mandated to report child abuse and participants might risk to lose losing their child to Child Protection Services[33]. In the Netherlands, nurses are not required to report child abuse, which may explain the differences between our findings and previous studies. Another explanation might be that, in the Netherlands, it is more

socially accepted to speak about non-marital sex and IPV than in the US[34]. Therefore, VoorZorg nurses can address IPV more effectively. Eckenrode et al. showed that the presence of IPV moderated the impact of the program on the prevention of child abuse and neglect[20] with smaller effects on abuse and neglect at higher levels of IPV. The current study reveals that home visits reduce incidents of intimate partner violence in a sample of high-risk young pregnant women; future analyses will reveal whether an additional impact on child abuse and neglect will be found which should be in line with the findings of Eckenrode et al.

In this high-risk sample of low-educated young pregnant women, 100% reported experiencing psychological violence, 58% reported experiencing physical violence, 26% reported experiencing injuries after a fight and 16% experienced sexual violence during pregnancy. All women in this sample reported experiencing psychological violence, which indicates that it may well be a situational couple violence which may be present in many couples relationships.[35] Similarly, our study found that women reported high levels of psychological aggression at 24 months. A potential explanation for this finding is that the mothers experienced a high level of stress because the baby developed into a toddler and needs much more attention. Toddlers want to explore their limits through new experiences and are therefore more prone to encountering hazards, such as falling on the stairs. For the high-risk young mothers in this study, this stage in their child's development is a very stressful period. This is exacerbated by the fact that their children often exhibit more externalizing behavior and listen less carefully compared with children in families where there is more structure and calm. Mc Farlane et al. reported that 17% of low income, pregnant women experienced physical or sexual violence [29]. The prevalence of these forms of abuse reported in the current study are also high, even when compared with pregnant adolescents living below the poverty level, who already are at an elevated risk of experiencing violence (21%)[36]. Moreover, a high percentage of women (69%) in the VoorZorg study revealed a history of violence earlier in life (unpublished data). These findings emphasize the importance for health care workers to focus on this vulnerable group. In addition to the effect that violence has on a mother, a child that grows up in a violent environment is more likely become involved in a violent relationship later in life[37]. It is important to break this cycle of violence.

A major benefit of home-visiting interventions is that they succeed in reaching high-risk young pregnant women, who are notoriously hard to reach for regular services, during a vulnerable stage in life over a prolonged period of time. In our study, female participants received between six and 13 home visits during pregnancy. These home visits were standardized and the intervention delivery was comparable with the work of Olds et al. in terms of timing and intensity of the home visits. The intervention successfully addresses multiple risk factors that can compromise the development of a young mother and child. As a result, participants receive a myriad of benefits; mothers become better able to raise their child, and children become less exposed to stress[38]. By reducing a child's exposure to violence and thereby reducing exposure to stress, the child's brain development can improve. An elevated cortisol level, a hormone released during stress, can affect brain development and can lead to conduct disorders, increasing the risk of having stress-related

psychiatric disorders in later life[39]. Women receiving the VoorZorg program reported using less physical violence towards their partner than women receiving the usual care. Generally, less attention is paid to female perpetrators and almost no evidence exists about effective strategies to reduce female perpetration of physical violence[40]. In the current study, we did not measure the reasons that women use violence, but previous studies have suggested that women use physical force because they feel emotionally hurt and want to express their feelings[40]. This suggests that women receiving the VoorZorg program have developed a different strategy for expressing themselves rather than using violence. Women also use violence to defend themselves, which may imply that women receiving the VoorZorg program feel less threatened by their partners[41]. According to Johnson's typologies IPV, our study population could be categorized as "violent resistant", which means that the woman is violent but her partner is both violent and controlling. This form of violence is almost exclusively common among women[35,42]. Future research should determine what causes women to use physical force and the mechanisms by which VoorZorg reduces their use of force, taking in account that many women are "violent resistant".

This study also reveals some key factors that intervention programs should integrate to reduce IPV and its impact on health. Firstly, it is important to screen at-risk groups and address IPV risk factors, such as alcohol consumption and financial dependency. Home visiting programs seem to be promising in addressing these risk factors. Nurses see the home environment and can detect risk factors for IPV and observe whether IPV is present[43]. Secondly, an important factor is creating an open and nonjudgmental dialogue between nurse and patient to make it easier for women to admit that IPV is present[44]. Nicolaidis et al. showed that victims of abuse find it very important that their relationship with health care professionals is based on trust and respect[45]. When patients have a trusting and respectful relationship with their health care provider, a safe space is created in which women can speak about their experiences with violence. Thirdly, when IPV is present in a family it's important to reduce its impact. Social support and an increase in one's self-efficacy appear to have a substantial effect on reducing the impact of IPV[46]. Lastly, it is important to address violent and controlling behavior among perpetrators, when perpetrators use controlling behavior, their partners may feel forced to use violence.

A strength of this study is that VoorZorg is designed for low-educated, young pregnant women. This young population requires special attention because they have multiple risk factors associated with IPV and many of them do not see violence as a reason to end their relationship[47]. IPV could therefore have a greater impact on their life compared with adult women. Given our results, we expect that many women in our study population have post-traumatic stress disorder (PTSD) because of current and past IPV. VoorZorg does not, however, focus on treating PTSD. Women with PTSD complaints are referred to mental health services when possible. Another limitation of this study was the high loss to follow-up at the 24 month measurement as this could limit the generalizability and the integrity of our results. Two main reasons for loss to follow-up are: 1) women, especially in the control group, were not traceable and 2) participants declined to participate in the interviews despite

informed consent. To diminish these problems, the researchers instructed the interviewers on how to address untraceable women. Methods included using social media and youth health care organizations or General Practitioners to restore the contact and obtain the most recent contact information. Child Health Care professionals and GP's often could not trace women in the control group, which underscores their inaccessibility. Because the VoorZorg nurse regularly visited women in the intervention group, they were easier to contact throughout the study. Another limitation was the use of self-report questionnaires to measure IPV. Self-reports were not confirmed by other informants. The CTS2 is criticized because of methodological shortcomings, such as not addressing coercion, control or motives, and no measurement of the different types of partner violence[30,48]. However, we used the CTS2 because we wanted to measure the frequency and nature of the different types of IPV. We also use the CTS2 because it is the most widely used instrument and has been successfully used to identify intervention effects in other studies about IPV [21,49]. We measured the context and consequences of IPV with other variables .

We recommend that further research examine how to decrease loss to follow-up among low-income pregnant young women. We also recommend that future interventions should address IPV perpetration by women. Care providers should be aware that perpetration is prevalent among high-risk women and should address the reasons that women use violence. For violence, even if it is for self-defense, has many health consequences for the parents and their children.

CONCLUSION

Overall, both the control and intervention group reported a high prevalence violence during pregnancy. At 32 weeks of pregnancy, significantly fewer women in the intervention group were violated by their partner and used significantly less violence toward their partner. At 24 months after birth, women receiving home visits experienced less physical violence. They also used less sexual violence towards their partner. In conclusion, the VoorZorg intervention is effective in reducing IPV during pregnancy and up to two years after birth. Further research is needed to investigate the long-term effects of VoorZorg on IPV and children's development.

TABLES

Table 1 : *Baseline characteristics of participants*

	Control (n=223)	**Intervention (n=237)**
Mean age, years mean(sd)	19.2 (2.6)	19.5 (2.8)
Weeks of gestation mean(sd)	19.6 (5.9)	20.1 (6.5)
Region		
Urban	147 (66)	158 (67)
Rural	76 (34)	79 (33)
Ethnicity		
Dutch	110 (49)	115 (49)
Turkish/Moroccan	13 (6)	13 (6)
Surinamese/Antillean	58 (26)	64 (27)
Other	42 (19)	45 (19)
Education level		
Primary school	7 (5)	11 (6)
Pre-vocational Secondary education	150 (96)	179 (94)
Married/living together	36 (16)	46 (19)
Having a boyfriend	49 (22)	70 (30)
Living with boyfriend	40 (18)	58 (24)
Lifetime prevalence of IPV	74 (33)	84 (35)
Victim of physical abuse during past year	40(18)	46(19)
Victim of sexual abuse during past year	9(4)	12(5)

Note. The information in Table 1 describes only those participants for whom data were available. Numbers are n (%) unless noted otherwise.

Table 2:

Prevalence of IPV by treatment condition at 32 weeks of pregnancy and 24 months after birth

Participant is victim	**Control %(n)** ***(n=110)***	**Intervention %(n)** ***(n=156)***	**NNT**	**Odds ratio (95% CI)**
32 weeks of pregnancy				
Psychological Aggression[#]				
Level 1	100% (110)	100% (156)	-	-
Level 2	56% (61)	39% (61)	6	0.55 (0.32 to 0.94)**[1]
Physical assault				
Level 1	58% (64)	40% (62)	6	0.38 (0.22 to 0.66)****[2]
Level 2	31% (34)	20% (31)	9	0.57 (0.32 to 0.99)**
Sexual coercion				
Level 1	16% (18)	8% (12)	13	0.47 (0.19 to 0.90)**
Level 2	6% (7)	7% (11)	-	1.09 (0.41 to 2.92)
Injury				
Level 1	26% (28)	16% (25)	10	0.57(0.31 to 1.05)
Level 2	5% (5)	5% (8)	-	1.13 (0.36 to 3.56)
Combination of IPV forms				
mean[†]	1.9; 1.06	1.7; 0.96		-0.07 to 0.42
>2 forms	31% (35)	19% (29)	8	0.49 (0.28 to 0.86)**
24 months after birth	***(n=223)***	***(n=237)***		
Psychological aggression				
Level 1	73% (162)	74% (175)	-	0.99 (0.50 to 1.95)
Level 2	47% (105)	35% (83)	8	0.63 (0.34 to 1.14)
Physical assault				
Level 1	44% (98)	26% (62)	6	0.46 (0.24 to 0.89)**
Level 2	25% (56)	17% (40)	12.5	0.63 (0.29 to 1.39)
Sexual coercion				
Level 1	15% (33)	8% (19)	14	0.49 (0.19 to 1.27)
Level 2	5% (11)	8% (19)	-	1.61 (0.38 to 6.68)
Injury				
Level 1	23% (51)	16% (38)	14	0.63 (0.25 to 1.54)
Level 2	9% (20)	2% (8)	14	0.22 (0.03 to 1.57)

Combination of IPV forms				
mean[†]	1.6;0.19	1.3;0.12		0.32 (-0.70 to 0.06)
>2 forms	36% (80)	23% (55)	8	0.51 (0.21 to 1.25)

Note. Multiple imputation analysis was conducted at 24 months after birth

NNT = numbers needed to treat over a 2-year time period

[†] Numbers are presented as the mean; Standard deviation

** p<0.05; *** p<0.005; **** p<0.001

[#] For explanation of levels 1 and 2: see Measurements in the Methods section

[1] Adjusted for age and number of Sexually transmitted disease (STD) treatments

[2] Adjusted for number of risk factors at baseline and number of STD treatments.

Table 3:

Prevalence of IPV by treatment condition at 32 weeks of pregnancy and 24 months after birth when participant is perpetrator

Participant is perpetrator	**Control %(n) *(n=110)***	**Intervention %(n) (n=156)**	**NNT**	**Odds ratio (95% CI)**
32 wks of pregnancy				
Psychological aggression				
Level 1	87% (95)	89% (139)	-	1.59 (0.69 to 3.62)
Level 2	60% (66)	46% (72)	7	0.57 (0.35 to 0.94)**
Physical assault				
Level 1	65% (71)	52% (81)	8	0.57 (0.34 to 0.95)**
Level 2	33% (36)	28% (43)	20	0.78 (0.46 to 1.33)
Sexual coercion				
Level 1	6% (7)	7% (11)	-	1.10 (0.42 to 2.95)
Level 2	3% (3)	1% (2)	50	0.47 (0.08 to 2.84)
Injury				
Level 1	27% (30)	17% (26)	10	0.53 (0.29 to 0.96)**
Level 2	8% (9)	10% (15)	-	1.19 (0.51 to 2.85)
Combination of IPV forms				
mean[†]	2.0; 0.97	1.7; 0.90		0.06 to 0.52**
>2 forms	31% (34)	19% (30)	8	0.53 (0.30 to 0.94)**
24 months after birth	***(n=223)***	***(n=237)***		
Psychological aggression				
Level 1	80% (178)	76% (180)	25	0.89 (0.38 to 2.09)
Level 2	39% (87)	38% (90)	100	0.97 (0.50 to 1.89)
Physical assault				
Level 1	48% (107)	33% (78)	7	0.54 (0.28 to 1.03)
Level 2	25% (56)	14% (33)	9	0.48 (0.22 to 1.05)
Sexual coercion				
Level 1	18% (40)	3% (7)	7	0.10 (0.02 to 0.56)***
Level 2	5% (11)	3% (7)	50	0.60 (0.06 to 6.16)
Injury				
Level 1	24% (54)	17% (40)	14	0.63 (0.28 to 1.43)
Level 2	9% (20)	8% (19)	100	0.81 (0.29 to 2.31)

Combination of IPV forms				
mean[†]	1.7;0.16	1.3;0.1	-	0.40 (-0.07 to -0.03)**
>2 forms	33% (74)	21% (50)	8	0.56 (0.25 to 1.28)

Note. Multiple imputation analysis was conducted at 24 months after birth

NNT = numbers needed to treat over a 2-year time period

[†] Numbers are presented as the mean; Standard deviation

** $p<0.05$; *** $p<0.005$

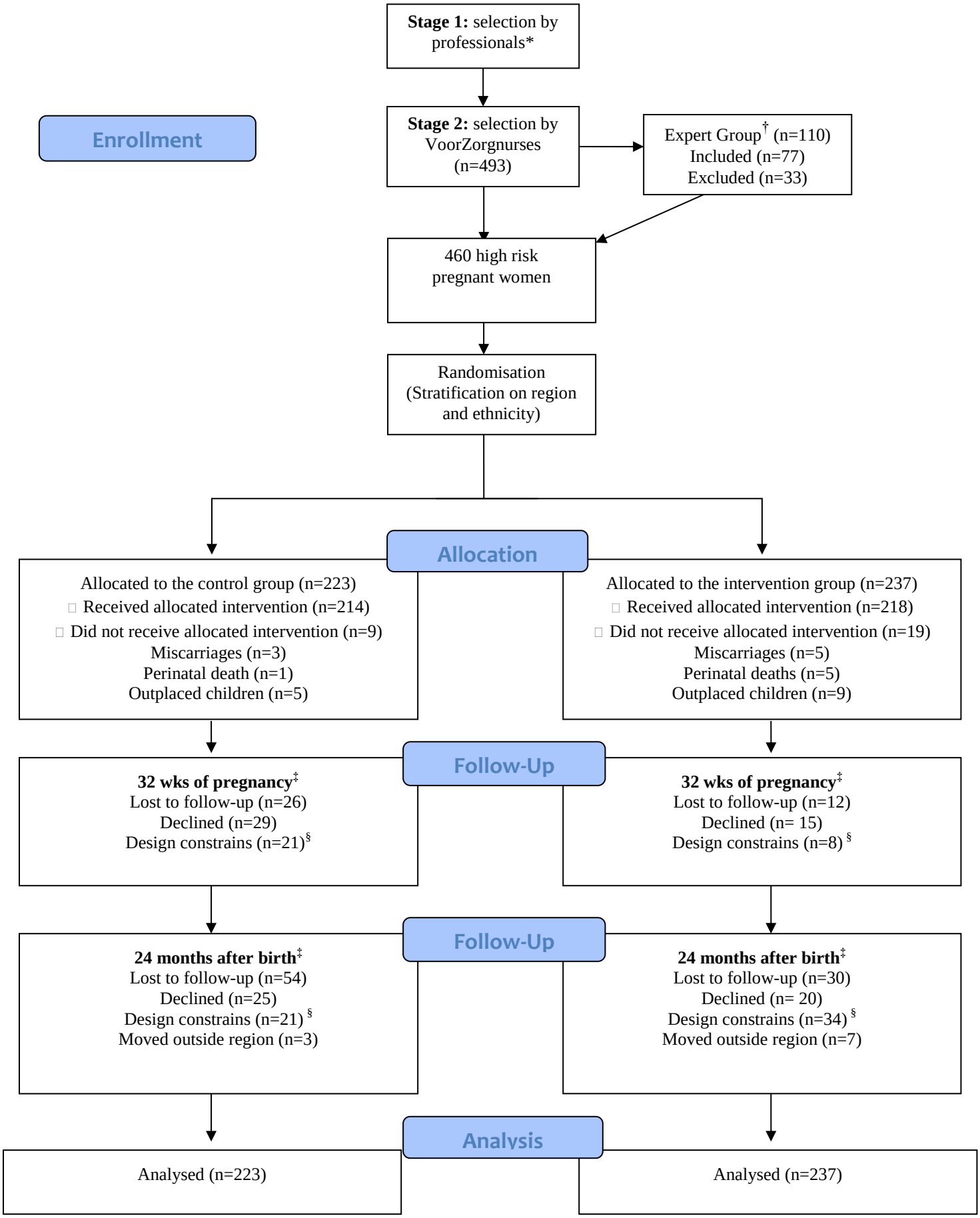
[#] For explanation of levels 1 and 2: see Measurements in the Methods section.

FIGURES

Figure 1: Items and subscales of the Revised Conflict Tactics Scale.

Psychological aggression	Level 1	Insulted or swore at partner, shouted at partner, stomped out of room during a disagreement, said something to spite partner
	Level 2	Called partner fat or ugly, destroyed something belonging to my partner, accused my partner of being a lousy lover, threatened to hit or throw something at my partner
Physical assault	Level 1	Threw something at partner that could hurt, twisted partner's arm or hair, pushed or shoved partner, grabbed partner, slapped partner
	Level 2	Used knife or gun on partner punched or hit partner with something that could hurt, choked partner, slammed partner against wall, beat up partner, burned or scalded partner on purpose, kicked partner
Sexual coercion	Level 1	Made partner have sex without a condom, insisted on (oral or anal) sex when partner did not want to (but did not use physical force)
	Level 2	Used force to make partner have (oral or anal) sex, used threats to make my partner have (oral or anal) sex
Injury	Level 1	Had a sprain, bruise, or small cut because of a fight with my partner, felt physical pain that still hurt the next day because of a fight with my partner
	Level 2	Passed out from being hit on the head with my partner in a fight, went to a doctor because of a fight with my partner, needed to see a doctor because of a fight with partner, had a broken bone from a fight with my partner

Figure 2: Flow of the participants through the study



*General practitioners, gynecologists, midwives, street corner workers (comparable to social workers) etc. The number of women for stage 1 is unknown; the pilot studies indicate that the VoorZorg nurses selected approximately 50% of them.

† Only VoorZorg nurses could refer to the expert group, which settles arguments around inclusion

§ No interviewer available, start-up problems RCT

‡ Numbers were only used for the 24-month analyses with imputated values.

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CHAPTER 6:

THE EFFECT OF VOORZORG, THE DUTCH NURSE FAMILY PARTNERSHIP, ON CHILD MALTREATMENT AND DEVELOPMENT: A RANDOMIZED CONTROLLED TRIAL.

Jamila Mejdoubi
Silvia CCM van den Heijkant
Frank JM van Leerdam
Martijn Heymans
Alfons AM Crijnen
Remy A HiraSing

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.

Funding

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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). The participants signed an informed consent statement. 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 care-givers 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 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 considered to exhibit internalizing or externalizing behaviors if they scored ≥ 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 primary outcome, we conducted moderation analyses to test for differences between subgroups (sex and ethnicity).[17] 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 analyzed with mixed model analyses to measure the longitudinal relationship between the VoorZorg intervention and the IT-HOME score over the three measurements. Differences were considered significant when the p-values were <0.05 (2-sided). All analyses were adjusted for possible confounders and effect modifiers.

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. 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). Subgroup analyses stratified by the sex or ethnicity of the child revealed no significant differences in the primary outcome (data not shown).

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.

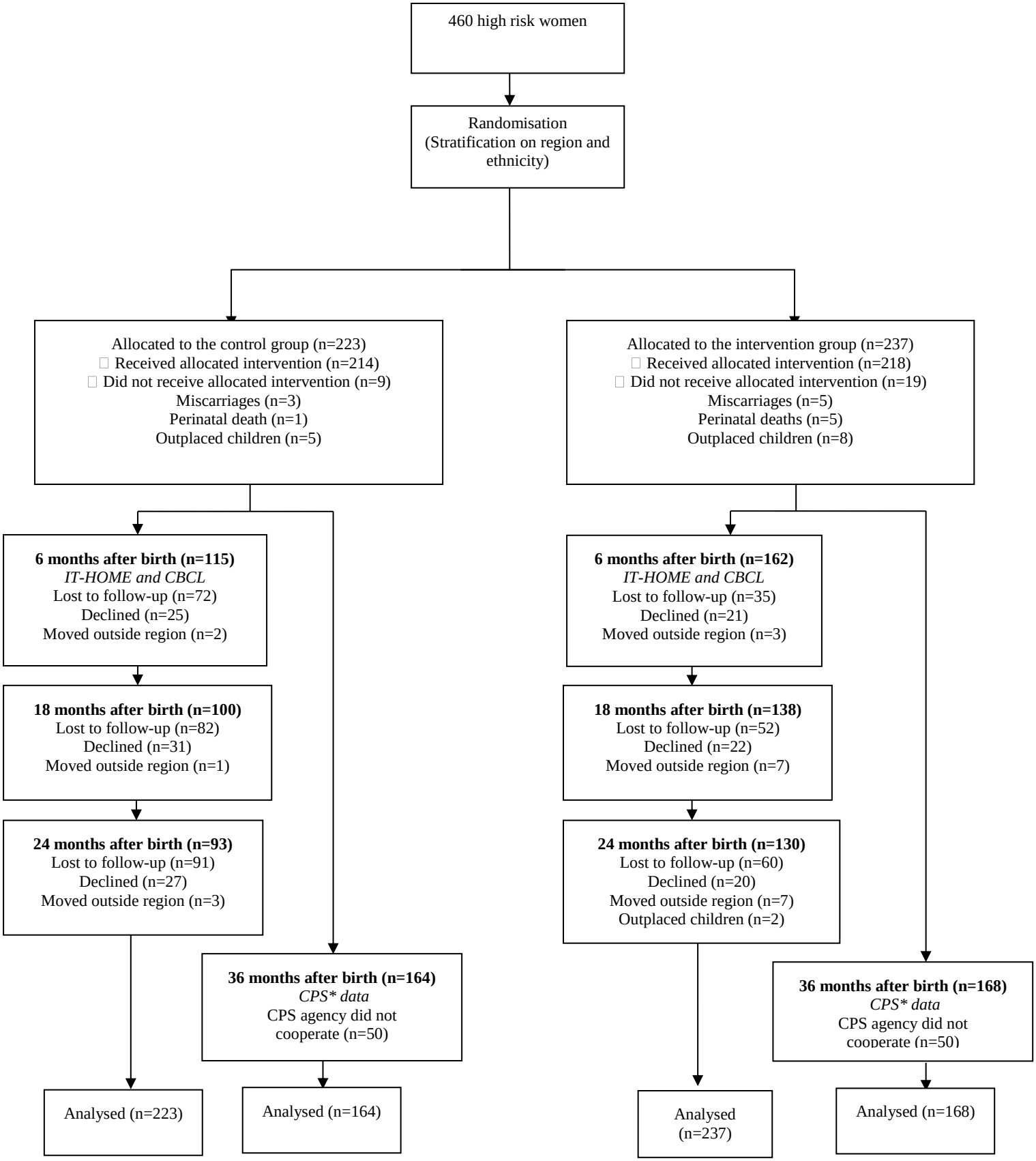
The validity of the use of the prevalence of CPS reports to indicate a reduction in child maltreatment due to home visitations is further supported by the observed improvements in the relevant risk factors for maltreatment, such as the home environment and the children's behaviors. The reduced prevalence 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 interactional 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). 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 and the NFP are evidence-based programs 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.

Flow chart VoorZorg study



* 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.

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CHAPTER 7:
GENERAL DISCUSSION

General Discussion

Introduction

Pregnancy and the first two years of life are sensitive periods in a young life. In these periods, we are susceptible to environmental factors, especially in interaction with others. Children who grow up in families with a low socioeconomic status are more commonly exposed to several negative environmental risk factors, like stress and substance abuse that compromise fetal and early child development. Furthermore, these children are at increased risk of child maltreatment. Child maltreatment is a major public-health problem which is associated with negative (mental) health as well as developmental consequences. Child maltreatment is linked with physical injury, growth retardation, obesity and can lead to anxiety, depression, posttraumatic-stress disorder, and is associated with long-term deficits in educational achievement. Children who are victims of abuse are more likely to engage in risky health behavior during adolescence. And by the time they reach adulthood, these children have an increased risk to develop chronic diseases and of reduced life expectancy[1]. Therefore, it is important to intervene at an early stage of life to address environmental risk factors for child maltreatment and to contribute to better health and development of the child.

The Nurse-Family Partnership (NFP) is an evidence-based nurse home visiting program to prevent child abuse and neglect starting during pregnancy until the child's second birthday. NFP has been developed and studied in the United States and was found to be effective in addressing risk factors for child maltreatment among high risk families, as well as primary prevention of child abuse[2]. Because there are no evidence-based programs for the primary prevention of child maltreatment in the Netherlands, and studies on the effectiveness of NFP were all conducted in the US, we translated and culturally adapted NFP into VoorZorg for use in the Netherlands and to study its effectiveness. VoorZorg is an intensive program; high risk women receive 40 to 60 nurse home visits during pregnancy until the child's second birthday by trained and experienced VoorZorg nurses. These visits are well structured and address six domains: health status of the mother, child's health and safety, personal development of the mother, the mother as a role model, relation of the mother with her partner, family and friends and use of institutions. Before implementing VoorZorg on a large scale in the Netherlands we assessed the effectiveness through a Randomized Controlled Trial (RCT).

The overall aim of this thesis was to assess the effectiveness of VoorZorg in addressing risk factors during pregnancy and early childhood compromising fetal and early child development in high risk families. This aim was further operationalized as follows:

1. To describe the phases of implementation of VoorZorg and the design of the effect study (Chapter 2);

2. To describe the two-stage selection procedure to select women at increased risk for child maltreatment and to test whether this selection procedure was effective in including high risk women (Chapter 3);
3. To study the effect of VoorZorg on cigarette smoking, (adverse) pregnancy outcomes and breastfeeding (Chapter 4);
4. To assess the effect of VoorZorg on intimate partner violence perpetration and victimization during pregnancy and the first two years of life (Chapter 5);
5. To study the effect of VoorZorg on child maltreatment, home environment and children's externalizing and internalizing behavior (Chapter 6).

In this final chapter, we will present the main findings of this study and discuss methodological considerations of the VoorZorg study. In addition, implications for implementation and future research will be described. This chapter will end with key recommendations and concluding remarks.

Main Findings

The VoorZorg study consists of two parts: Part 1. The translation and cultural adaption of VoorZorg and developing the design of the effect study, and Part 2. the Randomized Controlled trial (RCT) to study the effectiveness of VoorZorg in a sample of high risk pregnant woman.

Part I: Design of the VoorZorg program

In **chapter two** the study protocol of the VoorZorg program is described. The implementation of VoorZorg consisted of three partly overlapping phases. Phase 1 was the translation and cultural adaptation of the Nurse-Family Partnership and the design of a two-stage selection procedure to select women at an increased risk for child maltreatment. Phase 2 was a pilot study to examine the conditions for implementation of the VoorZorg program including the training of nurses. Phase 3 was the evaluation of VoorZorg in an RCT to assess the effect of this program in a sample of high risk women and compared to usual care.

The two-stage selection procedure

In **chapter three** we discussed the necessity to start a selective intervention targeting child maltreatment as early as possible in families who are at increased risk for abusing their child. For this purpose it is necessary to use the appropriate selection procedure to identify those families at risk for whom the intervention was developed. We constructed a two-stage selection procedure to identify young, high risk women early in pregnancy who are eligible for inclusion in the VoorZorg program. The first stage of the selection procedure was conducted by professionals, such as midwives, gynecologists, general practioners and street corner workers. These professionals use the following five criteria: 1. low education level, 2. age ≤25 years, 3. maximum gestational age of 28 weeks, 4. pregnant with the first child, and 5. able to understand the Dutch language. Women who met these five

criteria went through the second stage selection performed by a trained VoorZorg nurse. The VoorZorg nurse interviewed women at their homes and checked whether women had at least one of the following additional risk factors: 1. no or little social support, 2. a history or 3. present situation of domestic violence or neglect, 4. psychological symptoms, 5. financial problems, 6. unemployment 7. housing difficulties, 8. alcohol use, smoking or drug use during pregnancy, 9. having a non-realistic approach about motherhood. As part of the selection procedure nurses had to consult an expert committee in case of doubt on whether to include a woman.

In this chapter we also tested with validated questionnaires whether participants were at increased risk for child maltreatment. Participants were included at an average age of 19 years. A high percentage of the participants was single, had a history of domestic violence or in their current relationship, had financial problems, or had no occupation. 98% had more than three risk factors, which increases their risk for abusing their child significantly. We conclude that with the two-stage selection procedure women with an increased risk of abusing their child were selected early in pregnancy.

Part II: Evaluation of the VoorZorg program

In Part II of this thesis the results of the effect study of VoorZorg in addressing risk factors for early child maltreatment compared to usual care are described.

Cigarette smoking, pregnancy outcomes and breastfeeding

In **chapter four** we described the short-term effects of VoorZorg during pregnancy and the first 6 months of life of the child on maternal cigarette smoking, pregnancy outcomes, and breastfeeding. Maternal cigarette smoking is one of the most preventable causes of adverse pregnancy outcomes. The V-MIS, a set of Minimal Intervention Strategies for midwives based on the Integrated Change model was shown to be effective in reducing cigarette smoking during pregnancy and the first six weeks after birth in a general population sample of pregnant woman [3]. Although V-MIS was incorporated in the VoorZorg intervention, the effectiveness of V-MIS in reducing cigarette smoking among high risk pregnant women was not yet determined. Therefore, and because Olds had found important intervention effects for mothers who reduced smoking during pregnancy, we wanted to determine whether VoorZorg is effective in addressing cigarette smoking among high risk pregnant women[4]. The current study showed that VoorZorg is effective in reducing the number of women who smoked during pregnancy and during the first two years after birth. The number of cigarettes smoked a day during pregnancy was also reduced in both groups compared to the start of pregnancy but not significantly different in VoorZorg compared to control condition. During the first two months of life of the child, participants receiving VoorZorg smoked significantly fewer cigarettes a day and did not smoke in the presence of the baby.

In this chapter we also assessed the effect of VoorZorg on pregnancy outcomes. There were no intervention effects on mean birth weight and gestational age. Furthermore, VoorZorg was not

different in addressing adverse pregnancy outcomes, like low birth weight or babies being small for gestational age, compared to the control condition.

The third aim of this chapter was to measure whether more mothers receiving VoorZorg initiated breastfeeding after childbirth and had longer breastfeeding duration as it has many health benefits for the child and facilitates the mother-child interaction. The current study showed that the prevalence of women who initiated breastfeeding was similarly high in both control and intervention group. At six months after birth, the prevalence of women who still breastfed their child was significantly higher among women in the intervention group compared to the control group, and was similar to the general Dutch population.

In conclusion, VoorZorg is effective on reducing cigarette smoking during pregnancy and the two months after birth, and the duration of breastfeeding compared to the control group was longer. No effect was found on pregnancy outcomes.

Intimate partner violence (IPV)

Chapter five describes the effect of VoorZorg on IPV victimization and perpetration at 32 weeks of pregnancy and 24 months after birth. IPV is considered as a form of child maltreatment and is known to affect the health and development of the child. Furthermore, in families where IPV is present, children are at increased risk to be abused.

IPV victimization

We studied whether VoorZorg is effective on reducing IPV victimization. IPV victimization occurs when the participating mother is the victim of violence and her partner is the violator. Four different types of IPV were measured. These analyses showed that at 32 weeks of pregnancy all participants in control and intervention condition were victims of level 1 psychological aggression, which indicates that it can be a situational couple violence, which may be present in many relationships. However, women in the intervention condition reported significantly less level 2 psychological aggression, which is a more severe form of psychological aggression. In addition, physical assault and level 1 sexual coercion were significantly lower in the intervention group. The prevalence of level 2 sexual coercion and the prevalence of injury after a fight were equal in both groups. The results showed also that in the intervention group significantly fewer participants were victims of more than two forms of violence compared to the control group.

At 24 months after birth the prevalence of women experiencing level 2 physical assault was significantly lower in the intervention condition.

IPV perpetration

IPV perpetration is when the participant uses violence towards her partner. At 32 weeks of pregnancy, women in the intervention group reported using significantly less psychological aggression and physical assault. Furthermore, they inflicted significantly fewer injuries to their partners. Sexual

coercion was the least common form of violence used by participants. There was no significant difference between the groups. Furthermore, in the intervention group significantly fewer participants used more than two forms of violence towards their partner compared to the control group. At 24 months, after applying multiple imputation analyses, we found that the prevalence of sexual coercion was significantly lower amongst women receiving the VoorZorg program. Multilevel logistic regression analyses showed that physical assault decreased significantly over time in the intervention group and was significantly lower than in the control group.

Child maltreatment reports, home environment and child behavior

In **chapter 6** we presented results of VoorZorg compared to the usual care on the following child related outcome measures: child maltreatment, home environment and children's internalizing and externalizing behavior. The primary outcome measure in this study was whether a child was reported to Child Protective Services (CPS) during pregnancy until three years after birth. A high percentage of children were reported to child protective services during this period. The percentage of children of mothers receiving the VoorZorg program with a CPS report of abuse was significantly lower compared to the control group (C: 19%, I: 11%). According to additional information by the CPS agencies, 93% of these reports were valid cases of child maltreatment substantiated by independent evaluations of CPS. This result indicates that child maltreatment and neglect is prevented by VoorZorg during pregnancy and early life.

Secondary outcome measures in this chapter were measured at 6, 18 and 24 months after birth. We assessed the home environment of the child measured with the Infant Toddler-Home Observation Measurement of the Environment (IT-HOME) inventory and children's internalizing and externalizing behaviour measured with the Child Behaviour Checklist (CBCL/1.5-5). The analyses showed that at 6 and 18 months after birth, VoorZorg had no effects on total HOME score. However, at 24 months after birth, total HOME score was significantly higher for women receiving VoorZorg, indicating a more enriched and more supportive home environment. We also applied secondary analyses for the HOME where we corrected for the time variable. These results showed no significant difference on total HOME score between both groups over the three measurements (6, 18 and 24 months after birth). For the CBCL/1.5-5 outcome we found that at 24 months after birth, the prevalence of children having externalizing behaviour was not statistically different between both groups. However, the prevalence of internalizing behaviour was significantly lower in the intervention group. The difference between control and intervention group was especially visible on the subscales somatic complaints and withdrawn behaviour.

Summary of the results of the RCT

In conclusion, our study showed that VoorZorg, the first translated and culturally adapted Nurse-Family Partnership outside the US evaluated by independent researchers, identifies the appropriate population of pregnant women at risk for child maltreatment. Furthermore, VoorZorg effectively

improves the conditions for a favorable child development and growth through effects on cigarette smoking, breastfeeding duration, intimate partner violence (a form of child maltreatment), child maltreatment, long-term home environment and internalizing behavior. VoorZorg is not different on pregnancy outcomes and externalizing behavior in early life compared to the control condition. With these results we can conclude that VoorZorg is an evidence-based program for the primary prevention of child maltreatment as well as for associated risk factors for maltreatment among young high risk pregnant women.

Methodological considerations

We conducted a single blind, parallel-group, randomized controlled study. In these paragraphs we will discuss methodological issues in our study.

Participants: recruitment of high risk pregnant women

A two-stage selection procedure was used to recruit women in our study. A shortcoming of our study is that the professionals conducting the first stage of selection did not document how many women were approached, how many declined to participate in the trial, and their reasons for declining. Although we used personal interaction to recruit women, which is known to increase response rates, it is important to measure how many women refused to participate or were excluded by the professionals at each stage and why they declined[5]. In a separate pilot study amongst pregnant women in Amsterdam, approximately 50% of all women who met the first stage criteria were included in the trial. This percentage is confirmed by colleague-researchers in the United Kingdom who are also evaluating NFP. Information about the reasons for non-participation should be examined to enhance the feasibility of the program. Another limitation regarding recruitment is that a relatively low percentage (6%) of Turkish and Moroccan women, the main immigrant populations in the Netherlands, were included in the intervention. We do not know why the number of these ethnic groups is low in our study. One reason might be that those young – unwanted – pregnant women marry within their cultural minority and are supported by other extended family members. Additionally, it is possible that women from these ethnic backgrounds were less often recruited by the professionals. Again, this issue should be addressed in a future study to enhance the feasibility for minority populations. These limitations can have an influence on the external validity and generalizability of the study.

Participants: follow-up rate

The percentage of participants lost to follow-up was high in our study, especially at 24 months (50%), a finding common in these high risk populations. The most important reasons for the high loss to follow-up are: 1. Women, especially in the control group, were not traceable by the interviewers, and some of them even not traceable by Youth Health Care organizations in their region. We always tried to update their contact details by letting them fill in a form with contact information and their social

network, but even this strategy was not effective. 2. Participants declined to participate in the entire interview. 3. Participants were hard to reach for interviewers and it was laborious to make appointments for an interview. Even when clear appointments were made, there was a chance that participants were not at home. The high loss to follow-up is a further indication of the level of disorganization in this high- risk population. By applying attrition analysis we observed that attrition was at random and that results are thus still representative for the study population. However, we corrected for the high loss to follow-up by imputing missing data. For sensitivity analyses we applied different imputation techniques (last observation carried forward, multiple imputation analysis) to assess if different missing data handling methods yielded different results. We chose Multiple Imputation as the primary analysis as this technique resulted in a higher power and valid estimates.

Measurements: Self-reported questionnaires

In our study we used validated questionnaires and official records to assess the outcome measures. The data regarding child maltreatment and pregnancy health outcomes were obtained from independent official and medical records. However, a number of outcomes were based on self-reports, which can be prone to different forms of bias, such as recall bias and social desirability bias[6]. Furthermore, women in the intervention group could be aware of the consequences of the risk factors and therefore may report less risk behavior. However, Olds et al. concluded in their study on the effectiveness of the Nurse-Family Partnership (NFP) that women in the intervention group were more likely to report the actual number of cigarettes they smoked a day which he verified with biochemical parameters[2]. In the current study we did not verify cigarette smoking with biochemical parameters because of time and financial constraints, and because cotinine in blood samples is not a reliable method as it may also measure passive smoking which would lead to false positive results, especially among this study population who are more likely to be surrounded by smokers[7]. We hypothesize that the findings in Olds' study are also applicable for our study and assume that the reported cigarette smoking behavior is similar to actual smoking behavior (chapter 4).

Measurements: Breastfeeding

We have measured breastfeeding initiation and duration, but did not assess whether women were giving exclusive or partial breastfeeding. WHO standards emphasize to differentiate between types of breastfeeding, but a recent study by Kramer et al showed that exclusive breastfeeding compared to partial breastfeeding had no additional effect on long term obesity and cognitive development[8]. Furthermore, we did not assess reasons for women to stop breastfeeding their child. If the reasons for stopping would have been known the VoorZorg program could be enhanced by addressing this subject more specifically. However, for the aim of the RCT, which is to study the effectiveness of the intervention, the measures were sufficient.

Measurements: Intimate partner violence

The revised Conflict Tactics Scale (CTS2) was used to measure Intimate Partner Violence (IPV). Although this questionnaire is the most used to measure IPV, some researchers have criticized the CTS2[9]. Reasons for critique are, among others, that the CTS2 asks for specific types of abuse, and women would therefore not report other types of violence. However, our measurement of four types of abuse at two levels of severity is a valid procedure to determine the effectiveness of the intervention[10]. A strength of the CTS2 is that in addition to victimization also perpetration of acts of abuse by the mothers is measured. Also, some argue that the CTS2 does not include questions addressing coercion, control or motives for conflict tactics, and does not measure exposure to sexual assault or violence from ex-partners. Although we think that this information is important to assess, it is not necessary for the aim of our RCT and was partly already assessed with other measures. Psychometric properties of this questionnaire are discussed in chapter 5.

Measurements: Child maltreatment

The occurrence of child maltreatment can be measured in different ways[11]. In the current study we used child maltreatment reports from Child Protecting Services in the Netherlands (Advies en Meldpunt Kindermishandeling). According to Shlonsky et al. this is the gold standard to measure the occurrence of child maltreatment[11]The benefit of those reports is that professionals and concerned non-professionals reported maltreatment independently of the intervention. However, a limitation of using CPS data is that it may be prone to surveillance bias, because mothers and children receiving VoorZorg are under more scrutiny, and liberal bias, when professionals tend to report less incidents or only more severe incidents of maltreatment. Nevertheless, although the validity of these reports may be hampered by surveillance bias, as well as liberal bias Chaffin and Bard (2006) and Reynolds (2009) concluded that the effect of these biases differed little in terms of reported incidents, severity and confirmation.

A second limitation is that although reports are a reliable and verified data source it is recommended to collect data from additional sources to detect cases of child maltreatment. This is called triangulation and provides more reliable data, also because only 13% of cases of child maltreatment reached CPS[12,13]. This is especially necessary in prevalence studies rather than in RCTs [14]. Olds et al. used CPS reports and included data from emergency room visits and injuries. In the current study, inclusion of emergency room visits as an indicator of abuse and neglect was not feasible given the wide geographical distribution of participating subjects and hospitals. Euser et al. assessed child maltreatment by combining data from CPS with those of schools, well baby clinics, and General Practioners. Because of time constraints we were not able to use different sources to assess child maltreatment. The percentage of child maltreatment presented in our study may therefore be an underestimation of the actual prevalence of child maltreatment with only the more severe cases being reported to CPS. In addition, at the time of conducting this study it was not mandatory to report cases

of suspected child maltreatment to CPS. However, professionals in institutions were requested to follow-up on guidelines in which they reported suspected cases to supervisors and discussed the consequences to increase awareness on this subject.

A third limitation is that we assumed that a CPS report is actually a case of child maltreatment. This assumption was based on additional information by CPS that 93% of CPS reports in the current study resulted in substantiated cases of maltreatment in independent CPS analyses, a finding which is generally also observed at the national level[15]. Furthermore, we checked this in a subgroup of children in our study population with a CPS report, this study showed that 96 % was indeed a valid case of child maltreatment.

Sample size calculation

Our primary outcome measure in this study is the prevention of child maltreatment. However, a-priori sample size calculation was based on finding an effect in smoking reduction or cessation, a precursor of effects of intervention on child maltreatment in Olds' study[4]. This might have led to miscalculation of the sample size where the power is underestimated or overestimated. This could bias the results. When the sample size is underestimated, the treatment effect would be smaller. In contrast, when sample size is overestimated and VoorZorg proves effective, some subjects unnecessarily received usual care instead of VoorZorg. We did a post-calculation of the sample size with intimate partner violence as outcome measure (unpublished data). These analyses showed that the sample size calculated a-priori on smoking was similar to the post-calculation on intimate partner violence. However, it is important to conduct a-priori sample size calculation on the primary outcome measure.

Reflections and future research

Recommendations

Recommendations for future interventions for young high risk families based on the findings of this study are described below.

For practice

The main question in this thesis is: *Should VoorZorg be implemented in the Netherlands to address risk factors during pregnancy and early childhood that compromise fetal and early child development among high risk pregnant women?* With the results described in this thesis we can say that the VoorZorg program, an intensive program from pregnancy until the child's second birthday, has showed to be effective on important outcomes like child maltreatment which is the main aim of the VoorZorg program. These results, together with results gained in the NFP study, show that nurse home visitations are effective in addressing problems prevalent in high risk families[2]. As David Olds pointed out: "*This pattern of results challenges the position that these kinds of intensive programs for targeted at-risk groups ought to be made available on a universal basis."[16]* VoorZorg should be

implemented troughout the Netherlands. Even before the RCT results were published, several municipalities in the Netherlands released financial resources to appoint VoorZorg nurses in their region. The Netherlands Youth Institute, responsible for the implementation of VoorZorg, and municipalities which already participated under trial conditions, are very enthusiastic about the program.

We have studied a very complex population and observed several positive behavioral changes for participating mothers, but also for their children. With these results we have proved that a positive behavioral change is possible among this population of high risk women favoring the development of their children. However, the right intervention and the right tools are necessary for succeeding. With VoorZorg, these women are receiving an intervention in a sensitive period during pregnancy and the first two years of the child's life. Also important is that these women are approached in a positive way to empower them and that a trusting relationship is created between the VoorZorg nurse and the woman. These women are made aware of their own strength by supporting them and by increasing their self-efficacy. In addition, the VoorZorg nurse learned them that their positive behavioral change will affect their child in a positive way through their entire lifespan. Health care professionals should build on these key elements when reaching out to these vulnerable families.[17]

Early intervention

Health care professionals should be aware that primary prevention is more (cost-) effective than treatment at later age. Early intervention is important to address adverse childhood experiences and to prevent health and behavioral problems throughout the lifespan[1,2]. In this way professionals will contribute to a better future for the child and for the next generations. Furthermore, by reducing health problems, health related costs throughout the lifespan are reduced. In a study on the cost effectiveness of VoorZorg, it was concluded that VoorZorg was indeed cost-effective[18]. Therefore, early intervention should remain the focus of Youth Health Care for the prevention of adverse childhood experiences.

High- risk group

In this study we have identified a group of women with multiple risk factors. We did not expect that these women would have so many complex problems; 98 % had more than three risk factors (chapter 2). Their own history of growing up with low SES and abuse and/or neglect increases to the risk that they will abuse their children[19]. Furthermore, their current situation of poverty and intimate partner violence means that their child is at higher risk to be exposed to violence. Health care providers should be aware of this problem. These women need help tailored to their problems, and usual care alone is often not sufficient for this high risk population[20]. VoorZorg is an effective intervention that addresses these issues. Therefore, VoorZorg should be made available for all high risk pregnant women.

Untraceable women

In our study we came across a serious issue in terms of research and health services which is that a number of women were untraceable, not only for the researchers but also for Child Health Services. Because these services are well organized and families are usually highly compliant, it is hard to understand that so many mothers and children at high risk for abuse are untraceable. Tracing their whereabouts and monitoring children's health and mental development are prerequisite to the prevention of child maltreatment. The current study shows that in VoorZorg a higher retention is achieved, meaning that the nurses have a lasting relationship with these mothers at risk, enabling them to deal with the many challenges of raising a young child. We recommend that it should be made legally possible to track more of these mothers and children by Child Health Services, for example through their Citizen Service Number (Burger Service Nummer, BSN).

For research

Follow-up research

Although we have studied many outcome measures in this thesis, more research is needed to study long-term effects of the VoorZorg intervention Study. In the ACE study, Felitty et al showed that early intervention may have positive results during lifetime[21] whereas Olds et al. demonstrated that even in children whose fathers and mothers received intervention as a young child, positive effects were measured [2,22]. So far, we can conclude from the current study that VoorZorg is effective in the first three years of life, which is an important phase for the health and (later) development of the child and for the prevention of child maltreatment. Positive results are also expected at older ages of the child. So it is important to continue following this population of mothers and their children to demonstrate future effects of VoorZorg.

Address loss to follow-up

A high loss to follow-up among young high risk women and their children was observed[23]. Several researchers acknowledged this to be a limitation in their study, but - to the best of our knowledge - no researchers came up with an effective solution to remedy this issue. Little et al. described solutions for limiting loss to follow up, but these solutions do not always apply for high risk families[24]. An effective solution for this high risk population is needed, because a high loss to follow up can be detrimental as it may affect the outcomes and generalizability of the study, especially when attrition is not at random. In our study, we encountered a high loss to follow up several times. Solutions for the VoorZorg study were: first, to train the interviewers to motivate the participants to stay in the study by using motivational interviewing. A second solution was that we contacted the participants at each follow up moment even if they declined to be interviewed at an earlier moment. A third solution was that we let them fill in a contact form with contact details of themselves and their social network. A fourth solution was that we had a bonus for the interviewers if they interviewed all women in their

region, to increase the interviewers' motivation. This resulted in more women willing to participate. We did not study other solutions because of time and financial constraints. One idea was to create a website where participants could exchange information or tips with other participants. Social media can play an important role as they are often used by adolescents. Furthermore, we thought about an increase of incentives, such as a present for the child at their birthday to increase involvement with the research program and decrease attrition. Further research on this issue as well as exchange between researchers is recommended to address reasons for drop out and enhance the involvement of participants.

Recruitment of common ethnic groups

We observed that the percentage of Turkish and Moroccan women participating in the study is relatively low. Although the prevalence of teen mothers in this population is lower compared to other ethnicities in the Netherlands, there is a need for intervention in this population[25]. At the moment we are conducting qualitative research to study determinants of Moroccan and Turkish women to participate in the VoorZorg study. A possible solution to recruit Moroccan and Turkish is to create a trust relationship between the VoorZorg nurses and the woman already during the selection procedure and give more specific information. In addition, because the family is very important in this culture we have to study if and how we can involve the parents in the selection procedure. This subject should be investigated.

Evidence-based research

It is important to promote evidence based research in the Dutch Youth Health Care. Prinsen has described several interventions in the Netherlands that aimed at supporting parents in raising their child. However, most of these interventions were practice-based, rather than evidence-based[26]. Therefore, Prinsen concluded that we need more evidence-based programs in the Netherlands. These interventions are known to increase patient adherence to a program. Furthermore, it is better for the government to invest in evidence-based interventions [27]. The Academic Collaborative Centers in Child Health Care, collaboration between University Medical Centers and Youth Health Care Centers, can contribute to generate evidence-based research that can be implemented in daily care.

Pre-VoorZorg

More research is needed on how to improve pregnancy health outcomes among high risk families, because in the current study no effect was found of VoorZorg on pregnancy related health outcomes. In the NFP study, Olds et al. observed positive results only among a subgroup of young adolescents[28]. It is therefore necessary to enhance NFP and VoorZorg with results of other studies in community health.

One suggestion is to start before the onset of pregnancy because starting during pregnancy may be too late to change certain behavior affecting pregnancy outcomes, like infections, cigarette smoking and

alcohol use. In the Netherlands there is a growing interest in preconception care for - well-organized - families who would like to have a child.[29] But for this poorly organized high risk population who usually do not plan their pregnancy, we could introduce "Pre-VoorZorg" where high risk women are targeted in secondary school before they are pregnant. Such a program should not only address "safe sex" and contraception, but also educate these youngsters on the effect of risky health behavior on pregnancy outcomes and how it may affect the mental and physical health of their future child. With Pre-VoorZorg we can cover two important periods: 1) the preconception period and 2) pregnancy and the first two years of life.

International platform

The NFP intervention is at the moment evaluated in several countries. And with the positive results already shown in NFP and further substantiated in VoorZorg, it is to be expected that even more countries will start to evaluate this program. The Netherlands has organized a platform together with England and Germany to exchange information on NFP. And, an international platform has been established with the US, Canada and Australia, and European countries that are implementing the NFP. This platform can be expanded to all countries who are (willing to) implement(ing) this program. Together, these countries can learn about implementation of the program and what is needed to adapt the program to fit in their country. Furthermore, all countries evaluating the NFP can pool together their data to learn from each other and improve the program.

Key recommendations for implementing the Nurse Family Partnership

In the years that the VoorZorg study was conducted we have learned that if an intervention is being studied on a large scale it is important to consider the following key points:

- Sufficient financial resources are required for the implementation of the program and the effect study
- Communication between stakeholders is a must (also for obtaining data for monitoring the program)
- A platform is required for international partners who are evaluating the NFP
- Trained and qualified staff are necessary for the implementation of the program and the effect study
- Regular monitoring and improving the NFP program is required
- A trusting relationship between the mother and nurse are required
- It is key to stay in contact with the target population to address their needs and to improve the program where and if necessary
- And - most important - that there is a well-organized plan for adaptation, implementation and RCT about which stakeholders have expressed a commitment which they hold for a prolonged period of time.

General Conclusion

VoorZorg, a theory and practice-based nurse home visiting program, starting early in pregnancy until the child's second birthday, is effective in addressing risk factors operating during pregnancy and early childhood that compromise fetal and early child development. High risk women that received VoorZorg smoked fewer cigarettes, breastfed longer, and were less often victims and perpetrators of violence. In addition, child maltreatment was lower among women receiving VoorZorg and children were less likely to have internalizing behavior, which might be the first indication of a reduction in anxiety and stress in these young children due to the decline in IPV and child maltreatment. Furthermore, their home environment appeared to be enriched and better attuned to their needs. With these results we can conclude that VoorZorg is an evidence-based program for the primary prevention of child maltreatment as well as for associated risk factors for maltreatment among young high risk pregnant women and should be implemented throughout the Netherlands and should be extended to other countries as well.

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SUMMARY

Summary

Introduction

Children who grow up in families with low socioeconomic status combined with other risk factors are exposed to several negative environmental risk factors, like stress and substance abuse, that compromise fetal and early child development. Furthermore, these children are at increased risk of child maltreatment and witnessing intimate partner violence, itself a form of child maltreatment. Child maltreatment has many consequences on the mental and physical health of the young child with repercussions throughout the whole lifespan. Child maltreatment is, for example, an important determinant for risky health behavior, for criminal behavior and for intimate partner violence. The impact on society of growing up in a high risk family is high as the costs of child maltreatment are enormous, not only in healthcare and welfare costs, but also due to lower participation in school and paying jobs, and the (im)material costs of criminal behavior. The consequences of growing up in a high risk family also affects the next generations as risk factors are transmitted from generation to generation. Therefore, it is important to break this circle and to prevent these health risks and societal costs by intervening early.

The Nurse-Family Partnership (NFP) in the United States addresses risk factors among high risk pregnant women for the primary prevention of child maltreatment. As far as we know, NFP is the only effective intervention on the primary prevention of child maltreatment. The NFP is a home visiting program for pregnant high risk women by trained nurses. High risk women receive 40 to 60 home visits during pregnancy and the first two years of life of the child. These visits address six domains: 1) health status of the mother, 2) child's health and safety, 3) personal development of the mother, 4) the mother as a role model, 5) relation of the mother with her partner, family and friends and 6) use of institutions. Visits are well-structured and described in two manuals, but nurses are able to improvise when needed. It is important that nurses develop and maintain a trusting relationship with the mother throughout the program.

Although NFP has been proven to be an evidence-based intervention for the primary prevention of child maltreatment, the program has not yet been studied outside the US. If the effectiveness of NFP in reducing child maltreatment could be proved outside the US this would further validate the program. Because of the many positive results of the NFP in the US, we translated and culturally adapted this program in the Netherlands into VoorZorg. Before implementing this program in the Netherlands on a larger scale we evaluated it in a Randomized Controlled Trial from 2007 in ten (sub) urban regions in the Netherlands. This is the first study on the NFP outside the US. In this thesis we describe the effectiveness of the VoorZorg program among high risk pregnant women compared to the usual care in the Netherlands.

Main Findings

Chapter 2 of this thesis describes the design of VoorZorg. The evaluation of VoorZorg consisted of three (partly overlapping) phases: in phase 1, the NFP was translated and culturally adapted to accommodate the needs of pregnant women in the Netherlands and to address risk factors in the Dutch population. Additionally, a screening procedure was developed and evaluated to identify high risk women. Phase 2 aimed at assessing whether this intervention meets the needs of the at-risk mothers and their yet-to-be-born children. Phase 2 also aimed at assessing whether the nurses visiting the mothers are capable of conducting the intervention as described in their protocols. This phase included an assessment of treatment integrity, and of the feasibility and adequacy of the intervention. Phase 3 aimed at studying the effectiveness of VoorZorg in addressing risk factors during pregnancy and early childhood that compromise fetal and early child development through a Randomized Controlled Trial.

Chapter 3 describes the selection procedure developed to identify pregnant women with an increased risk of child maltreatment. This selection procedure consists of two stages with (1) formal criteria and (2) an interview with a VoorZorg nurse. We also assessed the feasibility of the two-stage selection procedure with validated questionnaires. This study revealed that 98% of the women in our study had more than three risk factors of child maltreatment. This indicates an increased risk of child maltreatment. We can conclude that the two-stage selection procedure identifies high risk pregnant women at an early stage of pregnancy.

Chapter 4 describes the first results of the effect study of VoorZorg. This study revealed that VoorZorg was effective on addressing cigarette smoking and also on smoking in the presence of the baby. Furthermore, the number of women that still breastfed their child at six months after birth was significantly higher among women receiving VoorZorg and comparable to the general population. VoorZorg showed no significant effect on (adverse) pregnancy outcomes.

Chapter 5 describes the results of VoorZorg on intimate partner violence (IPV) during pregnancy and 24 months after birth. IPV is a form of child maltreatment. This study revealed that women receiving VoorZorg reported significantly less IPV victimization compared to the usual care during pregnancy. Furthermore, these women reported significantly less IPV perpetration. At 24 months after birth, women receiving VoorZorg reported significantly less physical violence. In addition, they reported significantly less perpetration of sexual assault towards their partners. At 24 months, other forms of violence were not significantly lower for the VoorZorg group compared to the usual care.

Chapter 6 describes the effect of VoorZorg on child maltreatment, home environment and child behavior. This study showed that children of mothers receiving VoorZorg had significantly less child protective services reports (AMK) during pregnancy and the first three years of life of the child. This

indicates that there is less child maltreatment in this group. VoorZorg had no short-term effects on the home environment of the child. However, at 24 months after birth, total HOME score was significantly higher for women receiving VoorZorg, indicating a more enriched and more supportive home environment. Also, at 24 months after birth, children of women receiving VoorZorg exposed significantly less internalizing behavior compared to the usual care. However, no significant difference between both conditions was measured on externalizing behavior.

In **chapter 7** the main findings from this thesis are described and discussed. Based on the results, we can firmly conclude that the VoorZorg program, an intensive nurse home visiting program lasting from pregnancy until the child's second birthday, is effective at reducing child maltreatment and domestic violence. These results, together with results gained in the NFP study, reveal that nurse home visitations successfully address important risk factors prevalent in high risk families. Therefore, VoorZorg /NFP should be implemented not only in the Netherlands and the US, but should be extended to other countries as well.

SAMENVATTING

Introductie

De foetale en vroege ontwikkeling kan negatief beïnvloed worden bij kinderen die opgroeien in gezinnen met een lage sociaaleconomische status. Deze kinderen worden blootgesteld aan verschillende negatieve omgevingsfactoren, zoals stress en drugsmisbruik. Ze hebben een verhoogd risico om slachtoffer van kindermishandeling te worden en om getuige te zijn van huiselijk geweld, wat ook een vorm van kindermishandeling is. Kindermishandeling heeft vele negatieve gevolgen voor de mentale en lichamelijke gezondheid van het jonge kind die de levensloop van het kind kunnen bepalen. Zo is kindermishandeling een belangrijke determinant voor negatief gezondheidsgedrag, en voor crimineel gedrag en partnergeweld (IPV). De gevolgen van het opgroeien in een hoog-risico gezin hebben ook invloed op de volgende generaties, omdat risicofactoren van generatie op generatie worden doorgegeven. De maatschappelijke impact van het opgroeien in een hoog-risico gezin is hoog; de kosten van kindermishandeling zijn enorm, niet alleen in zorg en welzijn, maar ook door lage opleiding, minder participatie op de arbeidsmarkt en de (im-) materiële kosten van criminaliteit. Het is daarom van belang vroeg in te grijpen en de intergenerationele cirkel van problematiek in deze gezinnen te doorbreken om zodoende gezondheidsrisico's en maatschappelijke kosten te voorkomen.

Het Nurse-Family Partnership (NFP) in the Verenigde Staten (VS) heeft als doel om risico factoren bij hoog-risico zwangeren aan te pakken om daarmee kindermishandeling te voorkomen. Voor zover wij weten, is het NFP programma de enige effectieve interventie voor de primaire preventie van kindermishandeling. Het NFP is een huisbezoekprogramma waarbij hoog risico zwangeren thuis worden bezocht door getrainde verpleegkundigen. Hoog-risico zwangeren ontvangen 40 tot 60 huisbezoeken tijdens de zwangerschap en de eerste 2 levensjaren van het kind. Deze huisbezoeken richten zich op zes domeinen: 1) de gezondheid van de moeder, 2) de gezondheid en veiligheid van het kind, 3) de persoonlijke ontwikkeling van de moeder, 4) de rol van de moeder als opvoeder van haar kind, 5) de relatie van de moeder met familie en vrienden, en 6) het gebruik van gemeenschapsvoorzieningen door de moeder. De huisbezoeken zijn gestructureerd en beschreven in twee handleidingen. Verpleegkundigen zorgen ervoor dat relevante onderwerpen, zoals middelengebruik of relationeel geweld en huiselijk geweld, regelmatig terugkomen tijdens de huisbezoeken indien daar aanleiding toe is. Het is belangrijk dat de verpleegkundigen gedurende het programma een vertrouwensband met de moeders ontwikkelen en deze behouden.

Het NFP programma is uitvoerig onderzocht en effectief bevonden voor de primaire preventie van kindermishandeling. Het programma is nog niet onderzocht buiten de VS. Als de effectiviteit van NFP op het voorkomen van kindermishandeling kan worden bewezen in studies buiten de VS zal dit de validiteit van het programma versterken.

Vanwege de positieve resultaten van het NFP in de VS is besloten om het programma naar Nederland te halen in nauwe samenwerking met David Olds. Hiertoe is allereerst het programma vertaald en cultureel aangepast aan Nederland (VoorZorg) waarbij ook aandacht is geweest voor de implementatie. Vanaf 2007 werd de effectiviteit van VoorZorg onderzocht door middel van een

gerandomiseerde trial (RCT) in tien regio's in Nederland. Dit is de eerste effectstudie buiten de VS waar de effectiviteit van NFP/VoorZorg op het voorkomen van risicofactoren voor alsmede van feitelijke kindermishandeling en verwaarlozing wordt onderzocht. In dit proefschrift wordt de effectiviteit van VoorZorg bij hoog risico zwangeren in vergelijking met de gebruikelijke zorg in Nederland beschreven.

De belangrijkste bevindingen

Hoofdstuk 2 van dit proefschrift beschrijft de design van VoorZorg . De evaluatie van VoorZorg bestaat uit drie fasen die elkaar dakpansgewijs opvolgen: in fase 1 werd het NFP vertaald en cultureel aangepast om te voldoen aan de behoeften van de zwangere vrouwen in Nederland en om risicofactoren die specifiek aanwezig zijn in de Nederlandse bevolking aan te pakken. Daarnaast is een screeningsprocedure ontwikkeld en op kleine schaal geëvalueerd om hoog-risico vrouwen te werven. Fase 2 was erop gericht om te beoordelen of VoorZorg voldoet aan de behoeften van hoog-risico moeders en hun ongeboren kind. Fase 2 had ook als doel beoordelen of de verpleegkundigen de interventie konden uitvoeren zoals beschreven in het protocol. Deze fase omvatte een beoordeling van "treatment integrity", en van de haalbaarheid en de toepasbaarheid van de interventie. Fase 3 had als doel met een Randomized Controlled Trial (RCT) onderzoeken of VoorZorg effectief is op het aanpakken van risicofactoren tijdens de zwangerschap en de vroege kinderjaren die de foetale en vroege ontwikkeling van het kind negatief kunnen beïnvloeden.

Hoofdstuk 3 beschrijft de selectieprocedure die is ontwikkeld om zwangeren die een verhoogd risico hebben op kindermishandeling te identificeren en te selecteren. Deze selectieprocedure bestaat uit twee stappen met (1) formele criteria en (2) een interview met een VoorZorgverpleegkundige. Onderzocht werd met gevalideerde vragenlijsten of deze selectieprocedure geschikt is om hoog risico zwangeren te selecteren. Deze studie toonde aan dat 98% van de onderzochte vrouwen meer dan drie risicofactoren voor kindermishandeling had. Dat wil zeggen dat deze vrouwen een verhoogd risico hebben op kindermishandeling. We kunnen hieruit concluderen dat met de twee-staps selectieprocedure de juiste groep van hoog-risico vrouwen vroeg in de zwangerschap geselecteerd kan worden.

Hoofdstuk 4 beschrijft de eerste resultaten van het onderzoek naar het effect van VoorZorg. Deze studie toonde aan dat VoorZorg effectief is in het verminderen van het roken tijdens de zwangerschap en ook op het roken in bijzijn van de baby. Bovendien is het aantal vrouwen, dat bij zes maanden na de geboorte nog borstvoeding geeft significant hoger bij vrouwen die VoorZorg ontvingen. Dit was vergelijkbaar met de algemene bevolking. VoorZorg had geen significant effect op de (nadelige) zwangerschapsuitkomsten.

Hoofdstuk 5 beschrijft de resultaten van VoorZorg op partnergeweld (IPV) tijdens de zwangerschap en 24 maanden na de geboorte. IPV is een vorm van kindermishandeling. Deze studie toonde aan dat vrouwen die VoorZorg ontvingen significant minder IPV slachtofferschap tijdens de zwangerschap rapporteerden in vergelijking met vrouwen die de gebruikelijke zorg ontvingen. Bovendien rapporteerden deze VoorZorgvrouwen significant minder IPV daderschap. Bij 24 maanden na de geboorte, rapporteerden vrouwen die VoorZorg ontvingen significant minder slachtoffer te zijn van fysiek geweld. Daarnaast waren ze significant minder vaak dader van seksuele agressie ten opzichte van hun partners. Bij 24 maanden waren andere vormen van geweld niet significant lager voor de VoorZorg groep in vergelijking met de gebruikelijke zorg groep.

Hoofdstuk 6 beschrijft het effect van VoorZorg op kindermishandeling, leefomgeving en het gedrag van het kind. Deze studie toonde aan dat kinderen van moeders die VoorZorg ontvingen statistisch significant minder (40%) AMK meldingen hadden tijdens de zwangerschap en de eerste drie jaar van het leven van het kind. Dit geeft aan dat er minder kindermishandeling is in deze groep. VoorZorg had ook een effect op de leefomgeving van het kind: op 24 maanden na de geboorte was de leefomgeving beter. Dit kan betekenen dat vrouwen die VoorZorg ontvingen een meer verrijkte en ondersteunende leefomgeving hebben gecreëerd. Op 24 maanden na de geboorte toonden kinderen van vrouwen die VoorZorg ontvingen significant minder internaliserend gedrag in vergelijking met de gebruikelijke zorg, hetgeen kan duiden op dat deze kinderen significant minder stress ervaren. Echter was er geen significant verschil tussen beide groepen op externaliserend gedrag.

In **hoofdstuk 7** worden de belangrijkste bevindingen van dit proefschrift beschreven en besproken. Op basis van de resultaten concluderen we dat het VoorZorg programma, een intensieve verpleegkundige huisbezoekprogramma gedurende de zwangerschap tot het tweede levensjaar van het kind, effectief is in het verminderen van kindermishandeling en huiselijk geweld. Deze resultaten, samen met de resultaten behaald in de NFP studie, tonen aan dat VoorZorg huisbezoeken door getrainde VoorZorg verpleegkundigen effectief zijn in de aanpak van risicofactoren bij hoog risico gezinnen. VoorZorg en het NFP dienen te worden geïmplementeerd, niet alleen in Nederland en de VS, maar ook in andere landen.