PROTOCOL

Innovative postnatal risk assessment in preventive child health Care: A study protocol

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Abstract

Aim: To introduce the rationale and design of a postnatal risk assessment study, which will be embedded in Preventive Child Health Care. This study will evaluate: (a) the predictive value of an innovative postnatal risk assessment, meant to assess the risk of growth and developmental problems in young children; and (b) its effectiveness in combination with tailored care pathways.

Design: This study concerns a historically controlled study design and is designed as part of the Healthy Pregnancy 4 All-2 program. We hypothesize that child growth and developmental problems will be reduced in the intervention cohort due to the postnatal risk assessment and corresponding care pathways.

Methods: The study was approved in August 2016. Children and their parents, visiting well-baby clinics during regular visits, will participate in the intervention ($N = 2,650$). Additional data of a historical control group ($N = 2,650$) in the same neighbourhoods will be collected. The intervention, consisting of the risk assessment and its corresponding care pathways, will be executed in the period between birth and 2 months of (corrected) age. The predictive value of the risk assessment and its effectiveness in combination with its corresponding care pathways will be assessed by Preventive Child Health Care nurses and physicians in four Preventive Child Health Care organisations in three municipalities with adverse perinatal outcomes. A total risk score above a predefined threshold, which is based on a weighted risk score, determines structured multidisciplinary consultation.

Discussion: The successful implementation of this innovative postnatal risk assessment including corresponding care pathways has potential for further integration of risk assessment and a family-centred approach in the work process of Preventive Child Health Care nurses and physicians.

Impact: This study introduces a systematic approach in postnatal health care which may improve growth and developmental outcomes of children and even future generations.

KEYWORDS
care pathway, child growth and development, interdisciplinary collaboration, preventive child health Care nurses, preventive child health Care physicians, preventive nursing, risk assessment

1 | INTRODUCTION

Prenatal, perinatal and neonatal health influence a child's growth and development and their well-being until adulthood (Barker, 2007). Health problems such as obesity, diabetes, coronary heart disease, and psychological disorders may partly originate during embryonic and foetal development (Barker, 2007; Calkins & Devaskar, 2011; Gillman, 2015; Heindel & Vandenberg, 2015). Vulnerable women (Grabovschi, Loignon, & Fortin, 2013) have an increased risk of preterm delivery, a child who is born small for gestational age (SGA), has congenital anomalies, or is born with a low Apgar score (<7 after 5 min). These four adverse pregnancy outcomes are also called the Big4 (Bonsel & Steegers, 2011). The Big4 outcomes account for 85% of perinatal death and are related to growth and developmental problems in children in the Netherlands (Vos, van Voorst, Steegers, & Denktas, 2016). These children are more likely to grow up in poverty or experience child abuse, which may have an impact on their cognitive, psychosocial, and/or physical development (Gershoff, Aber, Raver, & Lennon, 2007; Gilbert, Bauer, Carroll, & Downs, 2013; Gilbert et al., 2009; Yeung, Linver, & Brooks-Gunn, 2002). In addition, the burden of disease for Big4 survivors is high, often due to complications in their growth and development (Poeran et al., 2013; Scholmerich et al., 2014; Vos, Posthumus, Bonsel, Steegers, & Denktas, 2014).

1.1 | Background

The Dutch child health care system is unique in its design and approach. In the Netherlands, preventive and curative medicine have separate care systems. For children aged 0–4 years Preventive Medicine or Preventive Child Health Care (PCHC) is delivered by well-baby clinics. At fixed ages infants and children are offered check-ups to assess health, growth, and development; this is a national program imposed by the government free of charge. The attendance rate is approximately 95%. At every check-up, weight and length/height are measured and plotted in growth charts (Talma, Bakker, HiraSing, & Buuren, 2010). Development of a child is recorded using the 'Van Wiechen' developmental test (VWDT; Laurent de Angulo & Brouwers-de Jong, 2015).

In Dutch PCHC, risk selection of children with increased risk of growth and developmental problems (such as the increased risk in preterm born children) and early detection of problems (e.g., psychosocial problems) are supported by guidelines and the use of measuring instruments. PCHC professionals use growth charts, which have been developed for different ethnicities living in the Netherlands (van Buuren, 2014; van Dommelen & van Buuren, 2014; Schonbeck, van Dommelen, HiraSing, & van Buuren, 2015; Schonbeck et al., 2011) and other instruments, such as (validated) questionnaires. These instruments are incorporated in guidelines, which are developed under the responsibility of the Dutch Centre for Child Health Care (NCJ).

Table 1 highlights in short HP4All-1 and the antenatal R4U. HP4All-2 focuses on pre-conception, antenatal, and postnatal risk assessment in combination with tailored care pathways by maternity care and PCHC. Consequently, this program consists of three studies concerning interconception care, maternity care, and risk assessment in PCHC organizations. This paper focuses on the latter.

1.2 | Aim

We aim to describe the rationale and design of a postnatal risk selection study, which is embedded in PCHC. This study is designed to evaluate: (a) the predictive value of the innovative postnatal R4U, meant to assess the risk of growth and developmental problems in early life; and (b) its effectiveness in combination with tailored care pathways.

2 | METHODS

2.1 | Design

In this study we aim to use a historically controlled study design, where the outcomes in the intervention cohort will be evaluated and compared with the outcomes of a historical cohort in the same four-digit postal code areas. The historical control group will consist of children who visited the participating PCHC organization prior to the study and were of the same age as the intervention cohort at time of growth and developmental assessments. The intervention and control group will be matched for heritage and the four-digit postal code area of their neighbourhood, to make sure that individual differences in the two groups cannot confound the results. We presume that the above-mentioned variables correlate highly with our outcomes: a child's ethnicity influences its growth and development (Reeske et al., 2013; Rijlaarsdam et al., 2013) and environmental inequalities such as socio-economic status (Marmot, 2005) and neighbourhood deprivation affect health

TABLE 1 Summary of the Healthy Pregnancy 4 All program and the antenatal R4U

Healthy Pregnancy 4 All and the antenatal R4U
The risk of Big4 outcomes and adverse perinatal health is high, especially in socially deprived neighbourhoods [Vos at el., Acta Obset Gynecol Scand, 2014; Poeran et al., J Matern Fetal Neonat Med, 2011]. Therefore, Dutch municipalities and health scientists of the Erasmus Medical Centre initiated the Healthy Pregnancy 4 All (HP4All) program in 2011 [Vos et al., Acta Obset Gynecol Scand, 2014; Denktas et al., Maten Child Health J, 2012]. A scorecard-based risk screening, the antenatal Rotterdam Reproductive Risk Reduction checklist (antenatal R4U) has been implemented in antenatal health care. Corresponding care pathways were developed and piloted [Van Veen et al., Midwifery, 2015]. These experiences were used to further improve and implement these tools in other municipalities with high perinatal mortality and morbidity. The sequel of the HP4All program is the HP4All-2 program, with the aim to endorse and facilitate continuous care for families at risk after birth [Waelput et al., BMC Pregnancy & Childbirth, 2017].

(Rajaratnam, Burke, & O'Campo, 2006). We chose to define neighbourhoods by the four-digit postal code area. Growth and development will be assessed at the PCHC during regular scheduled consultations in a certain timeframe. Gender adjustment will be applied during the time of analysis. Figure 1 represents an overview of the study design.

2.2 | Sample/participants

The study will be executed in three municipalities in the Netherlands; Amsterdam, Rotterdam, and Dordrecht. All three are included in the ranking of high perinatal mortality, high prematurity and high SGA rates, and high frequencies of children living in deprivation (Waelput, 2017). All newborns in these municipalities, aged 0–8 weeks of age, will be eligible for inclusion in this study, during a maximum of 18 months. For children born preterm, their corrected age will be used (Lems, Hopkins, & Samson, 1993). In Table 2 the study is presented according to the TIDieR checklist.

2.3 | Outcomes

2.3.1 | Primary outcomes

The primary outcomes will be overweight (>1 standard deviation score (SDS) for length) or obesity (>2 SDS for length), catch-up growth (change in length/weight > 0.67 SDS) in the first 6 months of

life (Schonbeck et al., 2011) and developmental problems (based on the D-score of the VWDT, reflecting an overall assessment of motor, cognitive, psychosocial, and language problems in total; Jacobusse, van Buuren, & Verkerk, 2006, 2008).

2.3.2 | Secondary outcomes

Secondary outcomes will be the use of the 'postnatal R4U scorecard' and the referral to care pathways by the PCHC nurses and physicians and their knowledge, attitude, and intention after implementation.

2.4 | Independent variables

Independent variables are the intervention itself (including the assessment of risk factors in six domains: social, ethnic, health care, lifestyle, general medical, and obstetric) and several other covariates, collected from the digital patient files including ethnicity, gender, age of the child in days, age of the parent(s) in years, the four-digit postal code area, and weight and height of the mother.

2.5 | Data collection

Data will be collected during the first home visit by the PCHC nurse and regular visits to the participating well-baby clinics starting at the
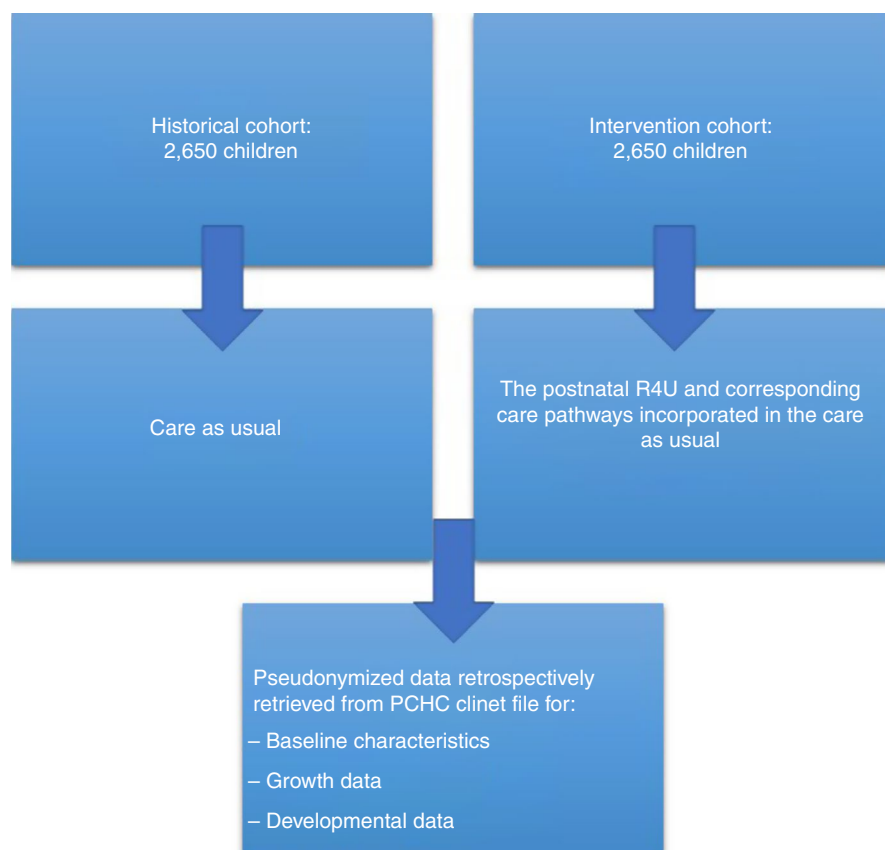
FIGURE 1 Design of the study [Colour figure can be viewed at wileyonlinelibrary.com]

TABLE 2 Items included in the Template for Intervention Description and Replication (TIDieR) checklist

Item	Description
Brief name	An innovative postnatal risk assessment study.
Rationale/ theory/goal	This study is designed to evaluate (1) the predictive value of the innovative postnatal R4U, meant to assess the risk of growth and developmental problems in early life, and (2) its effectiveness in combination with tailored care pathways.
Materials	• Posters for the well-baby clinics to inform parents about the study • Flyers for the well-baby clinics to inform parents about the study. • Educational booklet for the PCHC nurses and physicians about the background of the risk factors assessed and effective communication skills. • Educational pocketbook with a summary of all risk factors included in the postnatal R4U. • The postnatal R4U risk assessment embedded in the PCHC digital file
Procedures	• A pre-training will be delivered by a professional training company for PCHC nurses and physicians on the background of the study and effective communication skills. • Regular well-baby clinic visits by one of the researchers to offer support, assess the progress, and answer questions.
Intervention provider	The intervention will be provided by PCHC nurses and PCHC physicians who deliver care as usual. If applicable (in case of a care pathway or multidisciplinary consultation) they will refer to other healthcare providers such as social workers, physiotherapists, dieticians who will also deliver care as usual.
Modes of delivery	The postnatal R4U will be assessed face to face by PCHC nurses and physicians during care as usual.
Types of location	The postnatal R4U will be assessed at the parents' home during the regular PCHC home visit or during regular well-baby clinic consultations.
Delivery of the intervention	We aim to include 3,120 children.

age of 2 or 3 weeks until the age of 18 months. No additional visits to the PCHC will be necessary or planned for this study. An opt-out methodology will be applied (Vellinga, Cormican, Hanahoe, Bennett, & Murphy, 2011); all newborns will be included unless parents object to the use of their data for anonymous scientific research. We will be able to use this methodology because the study uses data which are already being recorded in the digital patient files by the PCHC nurses and physicians when they will provide care as usual.

2.6 | Intervention

The intervention will consist of the assessment of the risk of future growth and developmental problems by the postnatal R4U in combination with corresponding care pathways (if applicable), delivered during care as usual. The development of the 41-item postnatal R4U scorecard resembled the development of the antenatal R4U (Vos et al., 2015). While the antenatal R4U is applied during the first trimester of pregnancy, the postnatal R4U will be applied during the first 8 weeks of life. In case of preterm birth, the postnatal R4U can be applied until the corrected age of 8 weeks (Lems et al., 1993). It focuses on risk factors associated with growth and developmental problems, based on reviewed literature and focus group discussions with healthcare nurses, physicians, and researchers. These risk factors originate from both medical and non-medical domains. The design of the postnatal R4U has been published in more detail, separately (van Minde, Blanchette, Raat, Steegers, & Kroon, 2019).The postnatal R4U will be integrated in the digital PCHC patient files, automatically transferring data of relevant risk to the postnatal R4U

(van Minde et al., 2019). Figure 2 presents the previously developed postnatal R4U.

Tailored care pathways will be developed in collaboration with PCHC organisations, municipalities, and other care providers in the participating neighbourhoods, such as social services. Every care pathway will be developed to reflect the actual situation in a participating neighbourhood. PCHC nurses and physicians will have a single overview of the care available for their clients in their neighbourhood. Care pathways are related to psychosocial problems, financial problems, smoking, substance abuse, weight, chronical illness, psychiatry, preterm birth/SGA, and congenital anomalies (van Minde et al., 2019). Examples of care pathways that will be designed can be found in Supplement 1.

2.7 | Statistics

2.7.1 | Power calculation and sample size

Power calculation took place in June and July 2015 by an independent statistician who was not involved in executing the study. Calculation was based on the prevalence of catch-up growth in the Netherlands, defined as a change in height standard deviation scores of >0.67 standard deviation (*SD*) from birth to 6 months of age (Taal, Vd Heijden, Steegers, Hofman, & Jaddoe, 2013) and the D-score derived from the Van Wiechen developmental research (Laurent de Angulo & Brouwers-de Jong, 2015). The prevalence of catch-up growth in the Netherlands was estimated at 20% on the basis of analyses of Generation R cohort data (Taal et al., 2013). The VWDT

Script	Home environment	SCORE YES	NO	PATHWAY
	Social situation parents	YES	NO	
P1	Single parent	1	0	Social
P2	Lack of social support	1	0	Social
P3	Presence of domestic violence	2	0	Social
P4	Child Social Services involved with bothers/sisters	2	0	Social
P5	Child Social Services involved during pregnancy or after birth	3	0	Social
	Work and income parents	YES	NO	
P6	Unemoloyed (> 3 months)	1	0	Social
P7	Family living on low income (< 1000 Euros a month)	2	0	Financial
P8	Financial problems	1	0	Financial
	Education parents	YES	NO	
P9	Low educated /iliterate	2	0	Social
	Living environment of the family	YES	NO	
P10	Unsafe living environment	1	0	Housing
P11	Living in deprived neighborhood (based on 4 digit zipcode)	2	0	Social
	Script: 4 digit zipcode for deprived neighborhoods			
	ETHNICITY			
	Ethnicity father/mother	YES	NO	
P12	Surinam-Creole	1	0	Weight
	Surinam-Hindu	1	0	Weight
	Surinam-Indonesian	1	0	Weight
	Antillian-Aruban	1	0	Weight
	Capeverdian	1	0	Weight
	Turkish	1	0	Weight
	Maroccan	1	0	Weight
	Other non-western	1	0	Weight
	Language/communication	YES	NO	
P13	Doesn't speak Dutch or English	1	0	Social
P14	Mentally disabled parents(s)	1	0	Social
	CARE			
	General	YES	NO	
P15	No (healthcare insurance)	1	0	Social
	Family planning	YES	NO	
P16	Mother age < 20 years	2	0	Finances
	LIFESTYLE			
	Intoxications	YES	NO	
P17	Smoking in pregnancy	1	0	Smoking
P18	Mother smokes	1	0	Smoking
P19	Father smokes	1	0	Smoking
P20	Alchol in pregnancy	1	0	Toxic
P21	Alchol abuse by mother	1	0	Toxic
P22	Alchol abuse by father	1	0	Toxic
P23	Drug use in pregnancy	3	0	Toxic
P24	Drug abuse mother	3	0	Toxic
P25	Drug abuse father	3	0	Toxic
	Weight of the mother	YES	NO	
P26	BMI < 18,5	1	0	
	BMI > 25	2	0	Weight
R4U©Erasmus MC	version: postnatal			

Script	MEDICAL	SCORE YES	NO	PATHWAY
	Health of the parents	YES	NO	
P27	One or more chronical illness of the parents(s)	0	0	Chronic
P28	Diabetes of the mother	1	0	
P29	Epilepsie with medication of the mother	2	0	
	PSYCHIATRY	YES	NO	
P30	Psychiatric problems parent(s) in history or present	1	0	Psychiatry
P31	Psychiatric drugs during pregnancy by the mother	1	0	Psychiatry
P32	Psychiatric problems in the family (1st and 2nd degree)	1	0	Psychiatry
	OBSTETRIC			
	During pregancy	YES	NO	
P33	Insulin or diet because of diabetes gravidarum	2	0	Weight
P34	Gained more than 16 kg in weight	1	0	Weight
P35	Untreated hypothyroid in first trimester	1	0	
	Birth outcomes	YES	NO	
P37	Birth weight < P10	1	0	Weight/dys
	Birth weight > P90	2	0	Weight
P38	Prematurity (< 37 weeks of gestation)	2	0	Premature
P39	Low Apgar score (<7 after 5 min)	1	0	
P40	Congential anomalies	1	0	Congenital
P41	Formula feeding directly after birth	1	0	Weight

RESULT		
Domain	*Max. score*	*Score*
SOCIAL	18	
ETHNICITY	3	
CARE	3	
LIFESTYLE	18	
MEDICAL	6	
OBSTETRIC	11	
Total	59	

DIRECTED CARE	YES	NO	ACTION
Use of care pathways			
Multidisciplinary consultation			
Interconception advice			
Consult of the General Practitioner			
Consult at General Practitioner			
Other: ...			

FIGURE 2 The postnatal R4U [Colour figure can be viewed at wileyonlinelibrary.com]

is a 75-item survey on motor, speech/language, psychosocial, and cognitive domains. The D-score is a summary of the development of a child at a certain age point, which is a summarizing objective measure of the VWDT (Jacobusse et al., 2006). The average outcome of the D-score and the standard deviation score (SDS) at the age of 6 months is 35.5 with a SDS of 2.93 (Dusseldorp, Boere-Boonekamp, & Coenen-van Vroonhoven, 2011).

We hypothesize that growth and developmental problems will be reduced in the intervention cohort due to the postnatal R4U risk assessment and corresponding care pathways. For catch-up growth we assumed a relevant decrease in the intervention group from 20%–17% and for development a relevant increase of the D-score of 0.41 points at the age of 6 months. Aiming at a power of 80% and an alpha of 0.05 both outcomes warrant 2,650 children in both the intervention group and the historical control group until the end of the follow-up period. Considering a loss

to follow-up of 15% of the children, 3,120 children should be included at starting point.

2.8 | Statistical analysis

Data will be collected anonymously using pseudonyms instead of PCHC client numbers. Hence, data will be analysed anonymously. To guarantee anonymity of the PCHC organisations, we will not analyse the data on PCHC organisational level. Study participants, municipalities or PCHC organisations will not be traceable.

The effectiveness of the postnatal R4U, corresponding care pathways, and multidisciplinary consultation versus the conventional care as usual in PCHC will be assessed by univariable and multivariable linear and logistic regression analysis with random effects. Results will be presented as effect estimates or odds ratios with a measure

of precision (95% confidence interval). Backward logistic regression analysis and ROC analysis will be used for prediction modelling; the prediction models will be internally validated by bootstrapping.

2.9 | Rigour

Several actions will be taken to ensure rigour in quantitative data collection and analysis. The data collected will be protected and stored according to Dutch law (College Bescherming Persoonsgegevens, 2013, translation: Data Protection Board). Data will be retrieved from the digital files of the PCHC organisations and will be sent to a secured application which uses pseudonymization. Pseudonymization is a procedure by which most identifying fields in a data record are replaced by one or more artificial identifiers, or pseudonyms. There can be a single pseudonym for a collection of replaced fields or a pseudonym per replaced field. The purpose is to render the data record, not identifying and not traceable to a single person. After the pseudonymization process, the data will be sent to the researchers who have a secured application.

3 | DISCUSSION

This study provides the evaluation of an innovative postnatal risk selection method combining medical and non-medical risk factors influencing a child's growth and development, the postnatal R4U. To support the nurses and physicians during the implementation of the risk assessment, a training is offered at starting point, which has been developed in collaboration with a professional training company. During this training, PCHC nurses and physicians will be able to practice and improve their communication techniques in addressing delicate subjects to parents (van Minde et al., 2019).

3.1 | Strengths and limitations of this study

This study may result in improved perinatal health and long-term health of newborns by enhancing the role of PCHC in the continuous care of vulnerable families, postnatally. Consequently, this may strengthen PCHC collaboration with other healthcare professionals, such as midwives, obstetricians, gynaecologists, paediatricians, and social workers.

Often a randomized controlled trial (RCT) is the preferred study design, as it is supposed to minimize the effect of confounders. Nevertheless, an RCT has its own limitations, such as the possibility of contamination between the intervention and control groups. For example, caregivers/PCHC nurses and physicians might hear about the intervention and adopt it themselves. With this historical design the intervention cannot be implemented in the control group.

The postnatal R4U will enable a systematic and profound assessment and summary of medical and non-medical risk factors. Therefore, this method could reveal risks at an earlier stage of life. This could enable nurses and physicians in offering timely, adequate and tailored interventions. At start, this may result in consulting other healthcare professionals more frequently, which could be more time-consuming. However, in the long run this possibly results in a benefit for families at risk, who receive care at an earlier stage, preventing the further increase or accumulation of problems. Hence, this approach may aid healthcare/PCHC nurses and physicians and health care in general, by avoiding the necessity of crisis management at a later stage.

PCHC nurses and physicians will apply a new working strategy, implementing the postnatal R4U and possible care pathways in their daily working routine. During the initial phase of the implementation, items could be misinterpreted or scored erroneously. To optimize implementation and prepare PCHC nurses and physicians adequately, a training is therefore offered concerning the development and content of the postnatal R4U and its incorporated risk factors. By doing so, we intend to increase knowledge and the use of the instrument and knowledge on perinatal risk factors and their influences on health.

4 | CONCLUSION

Through early detection of risk factors and early deployment of care pathways we aim to achieve a decrease of growth and developmental problems in childhood. This intervention may result in healthier lifestyles and additionally, in the long run, in a healthier life for future generations.

STUDY STATUS
Ongoing.

RELATED ARTICLES
Van Minde et al, 'Reducing growth and developmental problems in children: Development of an innovative postnatal risk assessment.' PLoS One, 2019 Oct 15.

Van Minde et al, 'Postnatal screening and care for non-medical risk factors by preventive child health Care in deprived and non-deprived neighbourhoods.' BMC Health Services Research, 2018 June 8.

Waelput et al, 'Geographical differences in perinatal health and child welfare in the Netherlands: rationale for the healthy pregnancy 4 all-2 program.' BMC Pregnancy & Childbirth, 2017 August 1.

No publications containing the results of this study have been published or submitted.

PATIENT AND PUBLIC INVOLVEMENT
Patients or the public were not involved in the design, or conduct, or reporting, or dissemination of our research.

ETHICAL CONSIDERATIONS
This study has been approved by the Ethics Committee of the Erasmus Medical Centre Rotterdam (Ref. No. MEC- OZBS72.15107). As a result of this review, the Board declared that the rules laid down in the Medical Research Involving Human Subjects Act (also known by its Dutch abbreviation WMO) do not apply to the study. Oral informed

consent will be obtained from the parents through an opt-out methodology.

CONSENT TO PUBLISH

Parental consent will be obtained through an opt-out methodology. The parents will verbally decline or accept participation to the study and the PCHC nurses and physicians will register the declined or accepted participation to the study in the PCHC client file of the child. After oral informed consent by the parents the postnatal R4U will be automatically generated.

ACKNOWLEDGEMENTS

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CONFLICTS OF INTEREST

The authors declare that they have no competing interest.

AUTHORS' CONTRIBUTIONS

ES conceived the HP4All and HP4All-2 program. MM and MK were responsible of the study design. MM has drafted the first version of the manuscript. ES, HR, and MR participated in the design of the study. MK supervises the study and has contributed to the first version of the manuscript. All the authors have contributed to the final version of the manuscript and have given approval of the version to be published.

All the authors agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately and resolved.

PEER REVIEW

The peer review history for this article is available at https://publons.com/publon/10.1111/jan.14547.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from PCHC organizations participating in this study, but restrictions apply to the availability of these data, which were used under licence for the current study and thus are not publicly available. Data are however available from the authors on reasonable request and with permission of the participating PCHC organizations.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.