Research Square

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Early outcomes of prenatal and infancy home visiting in Germany: a secondary analysis of a randomised controlled trial

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Research Article

Keywords: Home visiting, Nurse-Family Partnership, Early childhood intervention, Randomised controlled trial, Feto-infant mortality, Child development, Socioeconomic disadvantage

Posted Date: November 18th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-11130154/v1

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Additional Declarations: No competing interests reported.

Abstract

Background

Home visiting may improve maternal and child outcomes in socially disadvantaged families, but evidence on outcomes during the first year and across delivery models is limited. We assessed the early effects of ProKind, the German adaptation of the Nurse-Family Partnership programme, on feto-infant mortality and maternal and child outcomes from pregnancy through 12 months postpartum, with separate analyses of two delivery models.

Methods

This secondary analysis of a multicentre randomised controlled trial included 755 socially disadvantaged first-time pregnant women recruited from November 2006 to December 2009 in 15 German municipalities. Intervention participants received structured home visits until the child's second birthday, delivered by the same midwife (continuous model, CM) or a midwife followed by a social worker (tandem model, TM). Control participants received usual services. Primary outcomes were feto-infant mortality and child cognitive and motor development at 6 and 12 months. Average treatment effects (ATEs) were estimated using augmented inverse probability weighting, pooled and by model.

Results

Among 394 intervention and 361 control participants, feto-infant mortality was lower with intervention (0.5% vs 3.1%; ATE − 0.026, 95% CI − 0.046 to − 0.006; $p = 0.01$). At 6 months, neither model showed significant effects on child development. At 12 months, the CM showed a higher Psychomotor Development Index raw score (ATE 4.10, 95% CI 2.57 to 5.64; $p < 0.001$) and fewer motor (ATE − 0.09, 95% CI − 0.14 to − 0.03; $p = 0.002$) and cognitive (ATE − 0.09, 95% CI − 0.14 to − 0.03; $p = 0.002$) developmental delays. The TM showed no consistent effects.

Conclusions

ProKind was associated with lower feto-infant mortality, and the continuous midwife model showed early benefits in child development and parenting-related outcomes, supporting the importance of relational continuity in early home visiting.

Trial registration

This trial has been registered with the German Clinical Trials Register (https://www.drks.de/drks_web/setLocale_EN.do). DRKS00007554 was registered on 11 June 2015 and DRKS00025962 on 8 October 2021.

Background

Early socioeconomic and psychosocial adversity is associated with poorer health, cognitive and developmental outcomes throughout childhood [1–6]. These risks may emerge during pregnancy and infancy, when cumulative adversity, maternal stress, and limited caregiving resources affect maternal functioning and child development [7–13]. In the most severe cases, socioeconomic disadvantage is associated with adverse perinatal outcomes and neonatal mortality [14–16]. Home visiting programmes beginning during pregnancy may buffer these risks by strengthening maternal health, parenting capacities, and early child development [17–22].

Systematic review and meta-analytic evidence suggests that sustained home visiting can improve maternal and child outcomes, although effects vary across programmes and outcomes [20–22]. Among the most extensively evaluated programmes is the US Nurse-Family Partnership, which has one of the strongest evidence bases for long-term effects in disadvantaged families [20, 23–29]. It has been evaluated in three randomised controlled trials and has shown effects across pregnancy, parenting, child development and long-term maternal and child outcomes [23–29]. ProKind is the German adaptation of this programme. Trials of international adaptations have reported mixed findings, potentially reflecting differences in usual care, participant risk and implementation [30–34].

ProKind was adapted to the German health and welfare system, in which the national early childhood intervention framework [*Frühe Hilfen*], including long-term home visiting by family midwives, was established from 2006 onwards [35]. The programme was implemented using two delivery models. In the continuous model (CM), the same midwife provided visits from pregnancy through the child's second birthday. In the tandem model (TM), a midwife provided visits during pregnancy and early postpartum, followed by a social worker approximately two months after birth. The CM was structurally closer to the original programme, whereas the TM reflected German funding structures and the division of responsibilities between midwifery care and social welfare support [36–39].

Evidence from the NFP suggests that programme effects may vary according to characteristics of intervention delivery, including the professional background of home visitors [40, 41]. This is particularly relevant to ProKind because the two delivery models differed in both professional continuity and the type of professional providing visits after the early postpartum period. Previous ProKind analyses showed beneficial effects on maternal self-efficacy, child development, mental health, parenting, child behavioural problems and child welfare outcomes [37, 39, 42–45]. Effects were more consistent within CM than TM sites [39, 44, 45].

Whether ProKind affected feto-infant mortality remains unknown. No model-specific analysis has examined maternal and child outcomes across the early phase from pregnancy through 12 months postpartum, when visit frequency was highest and pathways underlying later effects may have been established. This secondary analysis assessed feto-infant mortality primarily in the pooled sample because both models were delivered by midwives during pregnancy. Early maternal and child outcomes were assessed separately within CM and TM sites.

Methods

This study is a secondary analysis of the early phase of the ProKind multicentre randomised controlled trial, the German adaptation of the Nurse-Family Partnership programme. The trial was conducted in 15 municipalities in Bremen, Lower Saxony, and Saxony and used data from baseline through 12 months postpartum. The study was approved by the ethics committees of the German Society for Psychology, the University of Leipzig, and University Hospital Jena (SK 122014; 406-14-15,122,014; 2021-2372-Bef). The trial was registered in the German Clinical Trials Register (DRKS00007554/DRKS00025962) and conducted in accordance with the Declaration of Helsinki. All participants provided informed consent, and the report follows the CONSORT 2025 reporting guideline [46] (Additional file 1).

Design and participants

Participants were recruited between November 2006 and December 2009 if they had no previous live birth and were between 12 and 28 weeks' gestation. Of 1157 women assessed for eligibility, 402 were excluded, 263 did not meet eligibility criteria and 139 declined participation. The remaining 755 participants were randomised to the intervention group (n = 394) or control group (n = 361). Eligibility required at least one financial risk factor, such as receipt of social welfare benefits or over-indebtedness, and at least one additional social or personal risk factor, such as being younger than 18 years, lacking a school leaving certificate, or a personal history of abuse or neglect [39]. Women with severe substance dependence were excluded [47]. Recruitment occurred mainly through gynaecologists, psychosocial counselling centres and employment agencies. Baseline randomisation was conducted by the research team. Randomisation used Efron's biased coin design within sites and was stratified by implementation site, maternal age (≤ 18 vs > 18 years), and maternal nationality (German vs non-German) [48]. Before randomisation, participants were assigned to a delivery model according to residence. Five strata implemented the CM, seven the TM, and one both. At the site implementing both, control group (CG) participants were matched to CM or TM intervention group (IG) participants by date of affiliation. Interviewers masked to group assignment collected Phase I data through face-to-face assessments in families' homes, developmental tests, and telephone interviews. At baseline, participants had a mean age of 21.7 years, approximately 88% were unmarried, and approximately 12% had an immigrant background [38].

Intervention and control conditions

The intervention aimed to improve maternal and child health by strengthening maternal self-efficacy, attachment, parenting capacities, and social support, and to support maternal life-course development through family planning, continued education, and financial autonomy. ProKind retained the core Nurse-Family Partnership components, including target-group criteria, structured visit guidelines, documentation, and supervision, with home visits from the 12th to 28th week of pregnancy until the child's second birthday, delivered weekly to monthly and most frequently during pregnancy and early postpartum. In the CM, the same midwife delivered all visits. In the TM, the midwife delivered most pregnancy visits, and the social worker assumed primary responsibility approximately 2 months after birth. Joint visits during the transition introduced both professionals, and families were informed of the planned handover from the outset. Families received a mean (*SD*) of 32.4 (18.1) visits in the CM and 33.0 (19.4) visits in the TM. Mean (*SD*) visit duration was 82.6 (12.4) minutes and 79.6 (14.3) minutes, respectively. The control group had access to standard local health and social services.

Characteristics and training of home visitors

In total, 62 home visitors delivered the intervention, including 37 midwives, 24 social workers, and one paediatric nurse. Their mean (*SD*) age was 40.0 (7.8) years at intervention onset. All were female and of German nationality. Each received approximately 16 days of in-service training aligned with the Nurse-Family Partnership curriculum and early child development training [38]. Apart from profession-specific modules, such as client-centred communication for midwives and feeding practices for social workers, the curriculum was generally the same for both delivery models. Weekly clinical supervision lasted approximately one hour.

Outcomes

Outcomes were organised into two categories (Additional file 2: Table S1). Primary outcomes were feto-infant mortality and child development. Feto-infant mortality was defined as stillbirth from the 24th week of pregnancy onward and perinatal death within the first days following birth; it was coded as an adverse event, so that a lower rate indicates a more favourable outcome. Ascertainment was based on project documentation including reports from programme midwives and social workers as well as programme-accompanying records. Child development was assessed objectively at t2 and t3 using the Bayley Scales of Infant Development (BSID-II) [49], yielding the Mental Development Index (MDI) and Psychomotor Development Index (PDI) as raw scores, for which higher scores indicate better development, as well as a classification of developmental delays (index score < 85), for which a higher proportion indicates less favourable development. Secondary outcomes comprised survey-based measures of maternal mental health, parenting behaviour, and mother-infant attachment. Maternal mental health was assessed using the Depression, Anxiety, and Stress subscales and total score of the DASS-21 [50], on which higher scores indicate a greater mental health burden. Parenting behaviour was operationalised through the Parenting Stress Index (PSI/EBI) [51, 52], on which higher scores indicate greater parenting stress, and the Parental Expectations Survey for maternal self-efficacy [53], on which higher scores indicate

greater self-efficacy. Mother-infant attachment was measured with the Maternal Attachment Questionnaire (MAQ) [54], on which higher scores indicate stronger attachment. Maternal health behaviour was assessed by self-reported daily cigarette consumption and breastfeeding behaviour, with daily smoking and never breastfeeding coded as adverse behaviours. Child-rearing knowledge was measured with a scale assessing mothers' experiences and knowledge about children [42], on which higher scores indicate greater knowledge. Maternal empathy was assessed using a subscale of the Interpersonal Reactivity Index (IRI) [47], on which higher scores indicate greater empathy.

Sociodemographic variables and psychosocial adversities

Baseline demographic information included maternal age, marital status, nationality, education, income, and additional indicators of socioeconomic disadvantage and psychosocial adversity. Cumulative risk burden was assessed using a sum index of dichotomised demographic, psychosocial, and health-related adversities, including socioeconomic disadvantage, unplanned pregnancy, mental health problems, experiences of violence, and history of foster care experience [55]. Families with 6 or more risk factors were classified as high risk. Demographic characteristics, psychosocial adversities, and clinical characteristics of the assessment samples are shown in Table 1.

Table 1
Sociodemographic characteristics, psychosocial adversities and clinical characteristics by assessment sample

Characteristic	Model, No. (%)					Model, No. (%)					Model, No. (%)				
	Pregnancy					6 months postpartum					12 months postpartum				
	Continuous model		Tandem model			Continuous model		Tandem model			Continuous model		Tandem model		
	IG (n = 156)	CG (n = 137)	IG (n = 116)	CG (n = 110)	Total (n = 523)	IG (n = 154)	CG (n = 133)	IG (n = 107)	CG (n = 105)	Total (n = 503)	IG (n = 136)	CG (n = 121)	IG (n = 87)	CG (n = 84)	Total (n = 432)
Demographic characteristics															
Mother's age at baseline, mean (SD), y	21.4 (4.1)	21.5 (4.4)	21.5 (5.0)	21.3 (4.3)	21.4 (4.4)	21.3 (3.9)	21.9 (4.8)	22.2 (5.2)	21.6 (4.6)	21.7 (4.6)	21.7 (4.1)	22.4 (4.8)	22.7 (5.5)	21.9 (4.8)	22.1 (4.7)
Week of pregnancy at affiliation	19.7 (5.6)	20.3 (5.7)	19.7 (5.2)	21.2 (5.4)	20.2 (5.5)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Child´s age at assessment, mean (SD), mo	NA	NA	NA	NA	NA	6.9 (0.8)	6.9 (0.7)	7.2 (1.5)	6.9 (1.5)	7.0 (1.1)	13.2 (1.4)	13.2 (1.0)	13.4 (0.9)	13.2 (0.9)	13.3 (1.1)
Child sex[a]															
Female	NA	NA	NA	NA	NA	76 (49.4)	67 (50.4)	61 (57.0)	60 (57.1)	266 (52.9)	67 (49.3)	62 (51.2)	52 (59.8)	49 (58.3)	232 (53.7)
Male	NA	NA	NA	NA	NA	78 (50.6)	66 (49.6)	46 (43.0)	45 (42.9)	237 (47.1)	69 (50.7)	59 (48.8)	35 (40.2)	35 (41.7)	200 (46.3)
No partnership	48 (30.8)	36 (26.3)	34 (29.3)	27 (24.5)	146 (27.9)	45 (29.2)	40 (30.1)	29 (27.1)	25 (23.8)	140 (27.8)	41 (30.1)	38 (31.4)	28 (32.2)	16 (19.0)	124 (28.7)
Lives alone	44 (28.2)	41 (30.4)	24 (21.6)	31 (29.2)	142 (27.7)	45 (29.2)	40 (30.3)	25 (23.8)	31 (31.0)	143 (28.9)	37 (27.2)	41 (34.2)	23 (27.1)	25 (30.9)	128 (30.0)
Lives with partner or husband	59 (37.8)	50 (37.0)	49 (44.5)	39 (36.8)	198 (38.7)	59 (38.3)	49 (37.4)	45 (43.3)	39 (39.0)	193 (39.1)	55 (40.4)	46 (38.7)	32 (38.1)	31 (38.3)	165 (38.9)
Married	16 (10.3)	9 (6.6)	11 (9.5)	10 (9.1)	46 (8.8)	18 (11.7)	8 (6.0)	9 (8.4)	9 (8.6)	44 (8.7)	19 (14.0)	8 (6.6)	7 (8.0)	9 (10.7)	43 (10.0)
Non-German nationality	13 (8.3)	16 (11.7)	6 (5.2)	3 (2.7)	38 (7.3)	13 (8.4)	14 (10.5)	6 (5.6)	5 (4.8)	38 (7.6)	11 (8.1)	14 (11.6)	5 (5.7)	3 (3.6)	33 (7.6)
Household size, mean (SD)	2.6 (1.9)	2.4 (1.5)	2.6 (1.4)	2.6 (1.5)	2.5 (1.6)	2.6 (1.9)	2.6 (1.6)	2.6 (1.5)	2.5 (1.4)	2.5 (1.6)	2.5 (1.7)	2.4 (1.5)	2.6 (1.5)	2.4 (1.4)	2.5 (1.5)
Social class index, mean (SD)	4.3 (1.7)	4.2 (1.8)	4.2 (1.9)	4.3 (1.6)	4.2 (1.7)	4.3 (1.7)	4.4 (1.9)	4.3 (1.9)	4.5 (1.9)	4.3 (1.8)	4.3 (1.8)	4.5 (1.9)	4.5 (2.0)	4.8 (2.1)	4.5 (1.9)
Psychosocial adversities															
Underage	30 (19.2)	26 (19.0)	27 (23.3)	22 (20.0)	105 (20.1)	29 (18.8)	21 (15.8)	20 (18.7)	22 (21.0)	92 (18.3)	23 (16.9)	14 (11.6)	15 (17.2)	18 (21.4)	70 (16.2)
Low social support	8 (5.1)	10 (7.3)	5 (4.3)	5 (4.5)	28 (5.4)	8 (5.2)	10 (7.5)	7 (6.5)	8 (7.6)	33 (6.6)	10 (7.4)	9 (7.4)	6 (6.9)	6 (7.1)	31 (7.2)
Unwanted pregnancy	33 (21.2)	23 (16.8)	22 (19.0)	20 (18.2)	98 (18.7)	29 (18.8)	18 (13.5)	17 (15.9)	19 (18.1)	83 (16.5)	27 (19.9)	16 (13.2)	16 (18.4)	14 (16.7)	73 (16.9)
Alcohol misuse	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.8)	0 (0.0)	1 (1.0)	2 (0.4)	0 (0.0)	1 (0.8)	0 (0.0)	1 (1.2)	2 (0.5)
Drug misuse	1 (0.6)	3 (2.2)	4 (3.4)	2 (1.8)	10 (1.9)	1 (0.6)	1 (0.8)	2 (1.9)	1 (1.0)	5 (1.0)	1 (0.7)	1 (0.8)	2 (2.3)	1 (1.2)	5 (1.2)
Experience of custodial care	38 (24.4)	31 (22.6)	24 (20.7)	17 (15.5)	111 (21.2)	35 (22.7)	28 (21.1)	18 (16.8)	14 (13.3)	96 (19.1)	31 (22.8)	24 (19.8)	14 (16.1)	8 (9.5)	78 (18.1)

[a] Missing data for 4 children. BMI body mass index, CG control group, IG intervention group, NA not applicable, SD standard deviation. After Benjamini-Hochberg correction [57], there were no statistically significant between-group differences at any assessment point

Characteristic	Model, No. (%)					Model, No. (%)					Model, No. (%)				
	Pregnancy					6 months postpartum					12 months postpartum				
	Continuous model		Tandem model			Continuous model		Tandem model			Continuous model		Tandem model		
Loss of important attachment figure during childhood	88 (56.4)	78 (56.9)	53 (45.7)	53 (48.6)	274 (52.5)	82 (53.2)	77 (57.9)	47 (43.9)	51 (49.0)	259 (51.6)	69 (50.7)	71 (58.7)	40 (46.0)	36 (42.9)	218 (50.5)
Neglect or maltreatment during childhood	53 (34.0)	59 (43.1)	47 (40.5)	36 (32.7)	197 (37.7)	51 (33.1)	56 (42.1)	44 (41.1)	31 (29.5)	184 (36.6)	46 (33.8)	52 (43.0)	36 (41.4)	24 (28.6)	160 (37.0)
Violence during pregnancy	10 (6.4)	16 (11.7)	3 (2.6)	5 (4.5)	34 (6.5)	13 (8.4)	13 (9.8)	4 (3.7)	5 (4.8)	35 (7.0)	10 (7.4)	12 (9.9)	3 (3.4)	5 (6.0)	30 (6.9)
Lifetime violence	89 (57.1)	80 (58.4)	64 (55.2)	58 (52.7)	293 (56.0)	84 (54.5)	80 (60.2)	58 (54.2)	53 (50.5)	277 (55.1)	74 (54.4)	75 (62.0)	44 (50.6)	43 (51.2)	238 (55.1)
Lifetime mental illness	17 (10.9)	19 (13.9)	16 (13.8)	25 (22.7)	77 (14.7)	15 (9.7)	22 (16.5)	14 (13.1)	24 (22.9)	75 (14.9)	14 (10.3)	22 (18.2)	14 (16.1)	17 (20.2)	67 (15.5)
Potential for aggression	19 (12.2)	24 (17.5)	17 (14.7)	17 (15.5)	77 (14.7)	18 (11.7)	26 (19.5)	16 (15.0)	18 (17.1)	78 (15.5)	18 (13.2)	23 (19.0)	10 (11.5)	15 (17.9)	66 (15.3)
Depressive symptoms	20 (12.8)	11 (8.0)	8 (6.9)	14 (12.7)	53 (10.1)	17 (11.0)	14 (10.5)	8 (7.5)	12 (11.4)	51 (10.1)	18 (13.2)	10 (8.3)	8 (9.2)	8 (9.5)	44 (10.2)
Anxiety symptoms	33 (21.2)	21 (15.3)	13 (11.2)	17 (15.5)	85 (16.3)	32 (20.8)	21 (15.8)	13 (12.1)	15 (14.3)	82 (16.3)	29 (21.3)	20 (16.5)	10 (11.5)	10 (11.9)	70 (16.2)
Stress symptoms	54 (34.6)	34 (24.8)	33 (28.4)	29 (26.4)	151 (28.9)	50 (32.5)	39 (29.3)	32 (29.9)	28 (26.7)	150 (29.8)	44 (32.4)	35 (28.9)	27 (31.0)	22 (26.2)	129 (29.9)
Low education	121 (77.6)	105 (76.6)	85 (73.3)	80 (72.7)	395 (75.5)	118 (76.6)	96 (72.2)	77 (72.0)	75 (71.4)	370 (73.6)	103 (75.7)	84 (69.4)	59 (67.8)	54 (64.3)	304 (70.4)
High-risk pregnancy (maternity record)	13 (8.7)	14 (10.6)	18 (15.8)	10 (9.1)	55 (10.8)	12 (8.0)	14 (11.0)	17 (16.5)	12 (11.7)	55 (11.3)	11 (8.3)	11 (9.6)	14 (16.7)	12 (14.6)	48 (11.5)
Overall self-efficacy, mean (SD)	2.9 (0.5)	2.9 (0.4)	2.9 (0.5)	2.9 (0.5)	2.9 (0.5)	2.9 (0.4)	2.9 (0.4)	2.9 (0.5)	2.9 (0.5)	2.9 (0.4)	2.9 (0.5)	2.9 (0.4)	2.9 (0.5)	2.9 (0.4)	2.9 (0.5)
Parental self-efficacy, mean (SD)	3.4 (0.3)	3.4 (0.3)	3.3 (0.4)	3.4 (0.5)	3.4 (0.4)	3.4 (0.3)	3.4 (0.3)	3.4 (0.4)	3.4 (0.5)	3.4 (0.4)	3.4 (0.3)	3.4 (0.3)	3.3 (0.5)	3.4 (0.5)	3.4 (0.4)
Attachment, mean (SD)	3.5 (0.3)	3.5 (0.3)	3.4 (0.4)	3.5 (0.3)	3.5 (0.3)	3.5 (0.3)	3.5 (0.3)	3.5 (0.3)	3.4 (0.3)	3.5 (0.3)	3.5 (0.3)	3.5 (0.3)	3.4 (0.4)	3.5 (0.3)	3.5 (0.3)
Risk factors Total, mean (SD)	5.8 (2.6)	5.9 (2.5)	5.5 (2.1)	5.5 (2.3)	5.7 (2.4)	5.7 (2.6)	5.8 (2.4)	5.3 (2.1)	5.4 (2.2)	5.6 (2.4)	5.7 (2.6)	5.8 (2.5)	5.3 (2.0)	5.1 (2.1)	5.5 (2.4)
Clinical baseline characteristics															
BMI, mean (SD)	23.7 (5.6)	23.5 (5.6)	23.2 (5.8)	22.9 (5.3)	23.4 (5.5)	23.6 (5.6)	23.9 (5.7)	23.5 (6.1)	22.8 (5.0)	23.5 (5.6)	24.0 (5.8)	23.8 (5.8)	23.5 (5.3)	22.7 (5.2)	23.6 (5.6)
Severe obesity (BMI > = 30)	21 (13.5)	14 (10.2)	14 (12.2)	10 (9.3)	59 (11.3)	20 (13.0)	17 (12.8)	14 (13.2)	7 (6.7)	58 (11.6)	21 (15.6)	15 (12.4)	13 (15.1)	7 (8.3)	56 (13.0)
Severe underweight	5 (3.2)	4 (2.9)	5 (4.3)	7 (6.5)	21 (4.0)	5 (3.2)	3 (2.3)	4 (3.8)	6 (5.8)	18 (3.6)	3 (2.2)	3 (2.5)	4 (4.7)	5 (6.0)	15 (3.5)
Smokes	73 (46.8)	57 (41.6)	55 (47.4)	53 (48.2)	239 (45.7)	66 (42.9)	59 (44.4)	45 (42.1)	50 (47.6)	221 (43.9)	62 (45.6)	51 (42.1)	38 (43.7)	34 (40.5)	186 (43.1)
Smokes daily	56 (35.9)	44 (32.1)	37 (31.9)	33 (30.0)	170 (32.5)	51 (33.1)	45 (33.8)	30 (28.0)	35 (33.3)	161 (32.0)	46 (33.8)	38 (31.4)	28 (32.2)	22 (26.2)	134 (31.0)

[a] Missing data for 4 children. BMI body mass index, CG control group, IG intervention group, NA not applicable, SD standard deviation. After Benjamini-Hochberg correction [57], there were no statistically significant between-group differences at any assessment point

Statistical analysis

Post hoc minimum detectable effect calculations were conducted to contextualise model-specific analyses. Assuming two-sided $\alpha = 0.05$ and 80% power, detectable standardised effects were $d = 0.18$ in the full sample, $d = 0.28$ in the CM, $d = 0.30$ in the TM. All analyses followed the intention-to-treat principle (ITT) and were conducted for the full sample where applicable and separately for CM and TM sites. Within each model, intervention effects represent comparisons between the model-specific intervention group and control group (CM-IG vs CM-CG and TM-IG vs TM-CG). Intervention effects were estimated using augmented inverse probability weighting (AIPW) combined with LASSO [56]. AIPW was preferred over complete-case ITT analysis to reduce selection bias under the missing-at-random assumption. LASSO provided data-adaptive selection of attrition predictors for variance reduction, not confounding control. Stratification variables from the randomisation were always included as covariates, standard errors were clustered at the site level. Average treatment effects (ATEs) are reported with 95% confidence intervals (CIs) and two-sided p values. Baseline differences between groups in the characteristics shown in Table 1 were assessed with correction for multiple comparisons using the Benjamini-Hochberg procedure [57]. All statistical analyses were performed with Stata version 17. Data analysis was conducted in March 2026. The authors used ChatGPT (Version 5.6 Sol, OpenAI) to improve the readability of the manuscript. All content was reviewed and verified by the authors, who take full responsibility for the work.

Results

Of the 755 families enrolled, 752 were included in the pooled feto-infant mortality analysis after excluding three women who discontinued before intervention onset, and 748 in the model-separated feto-infant mortality analyses after additionally excluding four women who changed delivery model (Fig. 1). Feto-infant mortality was also analysed descriptively within the CM and TM subsamples to assess directional consistency across models; because both models were midwife-delivered during pregnancy and early postpartum, these estimates were interpreted as exploratory subgroup analyses. Model-separated analyses of all other outcomes included 751 participants after excluding the four who changed delivery model. Outcome-specific analytic samples varied by follow-up participation and available outcome data. Retention was 71% at 36 weeks of gestation, 67% at 6 months postpartum, and 57% at 12 months postpartum, with no significant between-group differences. Participants included in follow-up tended to have a lower baseline psychosocial risk burden than those lost to follow-up, although differences varied across delivery models and assessment points (Additional file 2: Table S2). Analytic samples comprised 523 participants at 36 weeks of gestation, 503 at 6 months, and 432 at 12 months postpartum. Sample characteristics are shown in Table 1.

Pregnancy (t1)

For the primary outcome, feto-infant mortality was lower in the IG than in the CG in the pooled analysis (0.5% vs 3.1%; ATE − 0.026, 95% CI − 0.046 to − 0.006; $p = 0.01$). Model-specific estimates were directionally similar but imprecise because of the small number of events, with lower feto-infant mortality in the CM (0.5% vs 3.5%; ATE − 0.030, 95% CI − 0.060 to 0.001; $p = 0.06$) and TM (0.6% vs 2.5%; ATE − 0.020, 95% CI − 0.049 to 0.009; $p = 0.18$; Table 2; Additional file 2: Table S3).

Table 2
Intervention effects on outcomes at 36 weeks of gestation (t1)

Outcome	Pooled				Continuous Model				Tandem Model			
	IG No.	CG No.	ATE (95% CI)	*p* value	IG No.	CG No.	ATE (95% CI)	*p* value	IG No.	CG No.	ATE (95% CI)	*p* value
Primary outcome												
Feto-infant mortality	392	360	-0.026 (-0.046 to -0.006)	0.01	212	199	-0.030 (-0.060 to 0.001)	0.06	176	161	-0.020 (-0.049 to 0.009)	0.18
Secondary outcomes												
Daily smoking	276	247	-0.01 (-0.06 to 0.05)	0.76	156	137	-0.03 (-0.07 to 0.02)	0.21	116	110	0.01 (-0.08 to 0.11)	0.80
DASS-21 total score	276	247	-1.61 (-3.14 to -0.08)	0.04	156	137	-2.22 (-3.94 to -0.50)	0.01	116	110	0.09 (-1.47 to 1.66)	0.91
DASS-21 (Depression)	276	247	-0.05 (-0.13 to 0.02)	0.14	156	137	-0.10 (-0.16 to -0.04)	< 0.001	116	110	0.03 (-0.03 to 0.09)	0.35
DASS-21 (Anxiety)	276	247	-0.09 (-0.18 to -0.01)	0.04	156	137	-0.13 (-0.22 to -0.03)	0.01	116	110	-0.04 (-0.14 to 0.07)	0.52
DASS-21 (Stress)	276	247	-0.06 (-0.14 to 0.01)	0.09	156	137	-0.06 (-0.12 to 0.01)	0.09	116	110	-0.02 (-0.13 to 0.09)	0.71
Mother-infant attachment	276	247	0.00 (-0.04 to 0.04)	0.92	156	137	0.02 (-0.02 to 0.07)	0.34	116	110	-0.01 (-0.06 to 0.03)	0.62
Parenting stress	276	247	0.11 (-0.54 to 0.76)	0.75	156	137	0.11 (-0.61 to 0.83)	0.76	116	110	-0.18 (-1.28 to 0.93)	0.75
Maternal self-efficacy	276	247	-0.01 (-0.05 to 0.04)	0.79	156	137	-0.01 (-0.04 to 0.02)	0.57	116	110	-0.03 (-0.12 to 0.06)	0.52
Maternal empathy	276	247	0.02 (-0.03 to 0.08)	0.38	156	137	0.02 (-0.04 to 0.08)	0.46	116	110	0.02 (-0.08 to 0.12)	0.73
Child-rearing knowledge	276	246	0.00 (-0.08 to 0.08)	0.93	156	136	0.02 (-0.08 to 0.12)	0.68	116	110	-0.05 (-0.14 to 0.03)	0.23

ATE average treatment effect, CG control group, CI confidence interval, DASS-21 Depression Anxiety Stress Scales, IG intervention group. *p* values are two-sided

For secondary outcomes during pregnancy, most pooled effects were not significant. Significant effects were observed for maternal mental health, with lower DASS-21 total scores (ATE − 1.61, 95% CI − 3.14 to − 0.08; $p = 0.04$) and lower anxiety scores (ATE − 0.09, 95% CI − 0.18 to − 0.01; $p = 0.04$) in the intervention group, indicating a lower mental health burden. In model-specific analyses, significant effects were limited to the CM, with lower DASS-21 total scores (ATE − 2.22, 95% CI − 3.94 to − 0.50; $p = 0.01$), depression (ATE − 0.10, 95% CI − 0.16 to − 0.04; $p < 0.001$), and anxiety (ATE − 0.13, 95% CI − 0.22 to − 0.03; $p = 0.01$). No significant secondary outcome effects were observed in the TM.

Six months postpartum (t2)

At 6 months postpartum, no significant intervention effects were found for the primary child development outcomes in either delivery model. For secondary outcomes, most measures showed no significant intervention effects in either model. In the CM, daily smoking was higher in the IG than in the CG (ATE 0.05, 95% CI 0.002 to 0.100; $p = 0.04$), contrary to the expected direction. In the TM, child-rearing knowledge was higher in the IG than in the CG (ATE 0.10, 95% CI 0.02 to 0.17; $p = 0.01$; Table 3; Additional file 2: Table S4).

Table 3
Intervention effects on outcomes at 6 months postpartum (t2)

Outcome	Continuous Model				Tandem Model			
	IG No.	CG No.	ATE (95% CI)	*p* value	IG No.	CG No.	ATE (95% CI)	*p* value
Primary outcomes								
PDI raw score	149	126	0.52 (-1.06 to 2.11)	0.52	103	99	1.90 (-2.21 to 6.01)	0.37
PDI delay < 85	149	126	-0.03 (-0.09 to 0.03)	0.38	103	99	-0.07 (-0.18 to 0.05)	0.28
MDI raw score	148	126	0.59 (-0.53 to 1.72)	0.30	95	91	1.53 (-0.13 to 3.18)	0.07
MDI delay < 85	148	126	0.01 (-0.01 to 0.04)	0.33	95	91	-0.08 (-0.19 to 0.04)	0.20
Secondary outcomes								
Daily smoking	151	132	0.05 (0.002 to 0.100)	0.04	107	105	-0.08 (-0.18 to 0.02)	0.12
DASS-21 total score	153	133	-0.33 (-2.10 to 1.44)	0.72	106	105	-1.57 (-4.09 to 0.95)	0.22
DASS-21 (Depression)	153	133	0.02 (-0.10 to 0.14)	0.74	106	105	-0.07 (-0.20 to 0.06)	0.29
DASS-21 (Anxiety)	153	133	0.00 (-0.08 to 0.07)	0.91	106	105	-0.08 (-0.22 to 0.06)	0.25
DASS-21 (Stress)	153	133	-0.08 (-0.17 to 0.00)	0.06	106	105	-0.12 (-0.26 to 0.02)	0.09
Mother-infant attachment	154	133	0.03 (0.00 to 0.06)	0.07	107	105	0.00 (-0.08 to 0.07)	0.96
Parenting stress	153	131	-0.42 (-1.41 to 0.58)	0.41	107	105	-0.63 (-2.44 to 1.19)	0.50
Maternal self-efficacy	154	133	0.03 (0.00 to 0.06)	0.06	107	105	0.00 (-0.06 to 0.06)	0.92
Child-rearing knowledge	154	133	0.04 (-0.07 to 0.15)	0.49	107	105	0.10 (0.02 to 0.17)	0.01

ATE average treatment effect, CG control group, CI confidence interval, DASS-21 Depression Anxiety Stress Scales, IG intervention group, MDI Mental Development Index, PDI Psychomotor Development Index. *p* values are two-sided

Twelve months postpartum (t3)

At 12 months postpartum, significant child development effects were observed in the CM. The IG had higher PDI raw scores than the CG (94.14 vs 90.35; ATE 4.10, 95% CI 2.57 to 5.64; $p < 0.001$) and a lower prevalence of motor developmental delays (32.2% vs 39.4%; ATE − 0.09, 95% CI − 0.14 to − 0.03; $p = 0.002$). Cognitive developmental delays were also less frequent in the IG (15.6% vs 24.1%; ATE − 0.09, 95% CI − 0.14 to − 0.03; $p = 0.002$), whereas the MDI raw score estimate was in the same direction but imprecise. No significant child development effects were observed in the TM (Table 4; Additional file 2: Table S5).

Table 4
Intervention effects on outcomes at 12 months postpartum (t3)

Outcome	Continuous Model				Tandem Model			
	IG No.	CG No.	ATE (95% CI)	*p* value	IG No.	CG No.	ATE (95% CI)	*p* value
Primary outcomes								
PDI raw score	121	104	4.10 (2.57 to 5.64)	< 0.001	78	68	-3.49 (-8.97 to 1.99)	0.21
PDI delay < 85	121	104	-0.09 (-0.14 to -0.03)	0.002	78	68	0.11 (-0.03 to 0.25)	0.13
MDI raw score	122	112	2.69 (-0.23 to 5.61)	0.07	77	78	3.00 (-1.40 to 7.41)	0.18
MDI delay < 85	122	112	-0.09 (-0.14 to -0.03)	0.002	77	78	-0.11 (-0.28 to 0.05)	0.19
Secondary outcomes								
Daily smoking	135	121	0.09 (0.00 to 0.17)	0.05	87	84	0.02 (-0.05 to 0.10)	0.53
Mother-infant attachment	134	121	0.09 (0.04 to 0.13)	< 0.001	87	84	0.05 (-0.01 to 0.11)	0.11
Parenting stress	135	121	-1.48 (-2.19 to -0.77)	< 0.001	87	84	-0.64 (-1.39 to 0.11)	0.09
Maternal self-efficacy	135	121	0.06 (0.002 to 0.128)	0.04	87	84	0.01 (-0.05 to 0.08)	0.75
Never breastfed	136	120	-0.03 (-0.08 to 0.02)	0.22	87	82	0.05 (-0.06 to 0.16)	0.39

ATE average treatment effect, CG control group, CI confidence interval, IG intervention group, MDI Mental Development Index, PDI Psychomotor Development Index. *p* values are two-sided

For secondary outcomes, the CM showed stronger mother-infant attachment (ATE 0.09, 95% CI 0.04 to 0.13; $p < 0.001$), lower parenting stress (ATE − 1.48, 95% CI − 2.19 to − 0.77; $p < 0.001$), and higher maternal self-efficacy (ATE 0.06, 95% CI 0.002 to 0.128; $p = 0.04$). Daily smoking estimates were in the opposite direction of the expected effect but imprecise, and breastfeeding did not differ between groups. No significant secondary outcome effects were observed in the TM.

Discussion

In this secondary analysis of the ProKind randomised controlled trial, we examined intervention effects during the early programme phase from pregnancy through 12 months postpartum, with separate analyses for the continuous model (CM) and tandem model (TM). The pooled analysis showed lower feto-infant mortality in the intervention group than in the control group. The control-group rate of 3.1% far exceeds the national perinatal mortality rate for Germany, where stillbirths (4.0 per 1000 total births) and early neonatal deaths (1.8 per 1000 live births) together amounted to approximately 6 per 1000 births in 2010 [58], underscoring the health vulnerability of this population. Given the small number of events, this finding should be interpreted cautiously but is clinically important.

The most consistent effects were observed in the CM at 12 months postpartum. Children in the CM-IG showed better motor development and lower rates of motor and cognitive developmental delay. These findings are noteworthy because early developmental delays are associated with later educational, psychosocial, and health outcomes [21, 26, 59–62]. The pattern is broadly consistent with the Memphis Nurse-Family Partnership trial, although direct comparison is limited by differences in sample composition and context [24].

For secondary outcomes, CM effects were observed for maternal mental health during pregnancy and for mother-infant attachment, parenting stress, and maternal self-efficacy at 12 months postpartum. This pattern is consistent with the Nurse-Family Partnership model, in which improvements in prenatal health, maternal self-efficacy, parental caregiving, and the parent-child relationship are expected to support child health and development [63, 64]. The higher rate of daily smoking at 6 months postpartum in the CM-IG was isolated and opposite to the expected direction and should be interpreted cautiously.

In contrast, the TM showed no consistent pattern of intervention effects, apart from higher child-rearing knowledge at 6 months postpartum. The stronger CM findings may reflect the importance of continuity in the working alliance between mother and home visitor [65], which is closely linked to engagement and therapeutic mechanisms in home visiting programmes [66–68]. Consistent with this, model differences were minimal during pregnancy but most pronounced at 12 months, when the models had diverged most in continuity of care. In the TM, the midwife-to-social-worker transition occurred approximately 2 months after birth, a potentially sensitive period. Differences in engagement or dropout cannot be excluded, although earlier analyses found no meaningful differences in programme content between models [39].

The German care context may also have attenuated effects. Standard care already includes antenatal and postpartum services, and approximately 70% of mothers in both groups used at least one statutory midwifery visit [69], which may explain the absence of effects on outcomes such as breastfeeding.

These findings suggest that relational continuity may be important when adapting home visiting programmes to existing service structures. Scaling the CM to routine practice would require maintaining the demonstration project's structural conditions, including intensive training, regular supervision, clear inclusion criteria, and standardised case management. Its real-world effectiveness should be evaluated in future pragmatic trials [70].

Strengths and limitations

This study has several strengths and limitations. This is one of the few randomised controlled trials examining early, model-separated effects of a home visiting intervention for socially disadvantaged families in Europe. The findings may inform future adaptations of home visiting programmes and the design of services for high-risk families. However, some limitations need to be addressed. First, model-separated analyses reduced statistical power, particularly after attrition at later assessments; nonsignificant subgroup findings should therefore be interpreted as absence of evidence rather than evidence of no effect. Second, selective dropout may have introduced bias because younger mothers and those with higher risk burden and lower socioeconomic status were more likely to withdraw from follow-up [37, 55]. We addressed this using augmented inverse probability weighting combined with LASSO, but this approach relies on the missing-at-random assumption. Third, several secondary outcomes relied on maternal self-report and may be affected by socially desirable responding.

Conclusions

In this secondary analysis of the ProKind randomised controlled trial, early home visiting was associated with lower feto-infant mortality in the pooled sample and with improved developmental and maternal outcomes in the CM. Effects were less consistent in the TM. These findings support further evaluation of continuous, needs-based home visiting for socially disadvantaged first-time mothers in Germany and other European welfare-state contexts.

Abbreviations

AIPW
augmented inverse probability weighting
ATE
average treatment effect
BMI
body mass index
BSID-II
Bayley Scales of Infant Development, second edition
CG
control group
CI

confidence interval
CM
continuous model
CONSORT
Consolidated Standards of Reporting Trials
DASS-21
Depression Anxiety Stress Scales
EBI
Eltern-Belastungs-Inventar
IG
intervention group
IRI
Interpersonal Reactivity Index
ITT
intention-to-treat
LASSO
least absolute shrinkage and selection operator
MAQ
Maternal Attachment Questionnaire
MDI
Mental Development Index
NA
not applicable
NFP
Nurse-Family Partnership
PDI
Psychomotor Development Index
PSI
Parenting Stress Index
SD
standard deviation
TM
tandem model

Declarations

Ethics approval and consent to participate

The study was approved by the ethics committees of the German Society for Psychology, the University of Leipzig, and University Hospital Jena (SK 122014; 406-14-15,122,014; 2021-2372-Bef). The trial was registered in the German Clinical Trials Register (DRKS00007554/DRKS00025962) and conducted in accordance with the Declaration of Helsinki. All participants provided informed consent.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Authors' information

Not applicable.

Funding

ProKind was funded across three project phases. Phase 1, from the 12th week of pregnancy through 36 months postpartum, was supported by the Federal Ministry for Family Affairs, Senior Citizens, Women and Youth (BMFSFJ; grant IIA6-25080820V6), the Günter-Reimann-Dubbers Foundation, the Dürr Foundation, and the TUI Foundation. Phase 2, the 7-year follow-up, was supported by the Federal Ministry of Education and Research (BMBF; grants 01EL1408A, 01EL1408B, and 01EL1408C). Phase 3, the 18-year follow-up, was supported by the BMBF (grants 01EL2013A/D, 01EL2013B, and 01EL2013C). No specific funding was received for the present analysis. The funders had no role in the design and conduct of the present analysis; collection,

management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Author Contribution

SK conceptualised and designed the study and drafted the initial manuscript. MS conducted the statistical analyses and contributed to the interpretation of the data. SF contributed to the data interpretation and drafted portions of the manuscript. TB, GC and DB contributed to the conception and design of the study, and DB supervised the project. All authors critically reviewed and revised the manuscript for important intellectual content and approved the final manuscript as submitted, and agree to be accountable for all aspects of the work.https://submission.springernature.com/new/submission/ea6544d5-289b-4913-98be-b652b54984eb/declarations

Acknowledgements

We thank the ProKind staff for their contributions to this research. Additionally, we extend our gratitude to all participating families whose cooperation made this study possible. The authors declare that Gen AI was used in the creation of this manuscript. The authors used ChatGPT (Version 5.6 Sol, OpenAI) to improve the language of the manuscript, as they are not native English speakers. After this step, the authors carefully checked and revised the entire text to ensure accuracy and clarity, and they take full responsibility for the final content of the publication.

Data Availability

The data sets generated and/or analysed during the current study are not publicly available because the participants did not consent to open accessibility of the data. Further information regarding data and stimulus material is available from the corresponding author on reasonable request.

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Figures

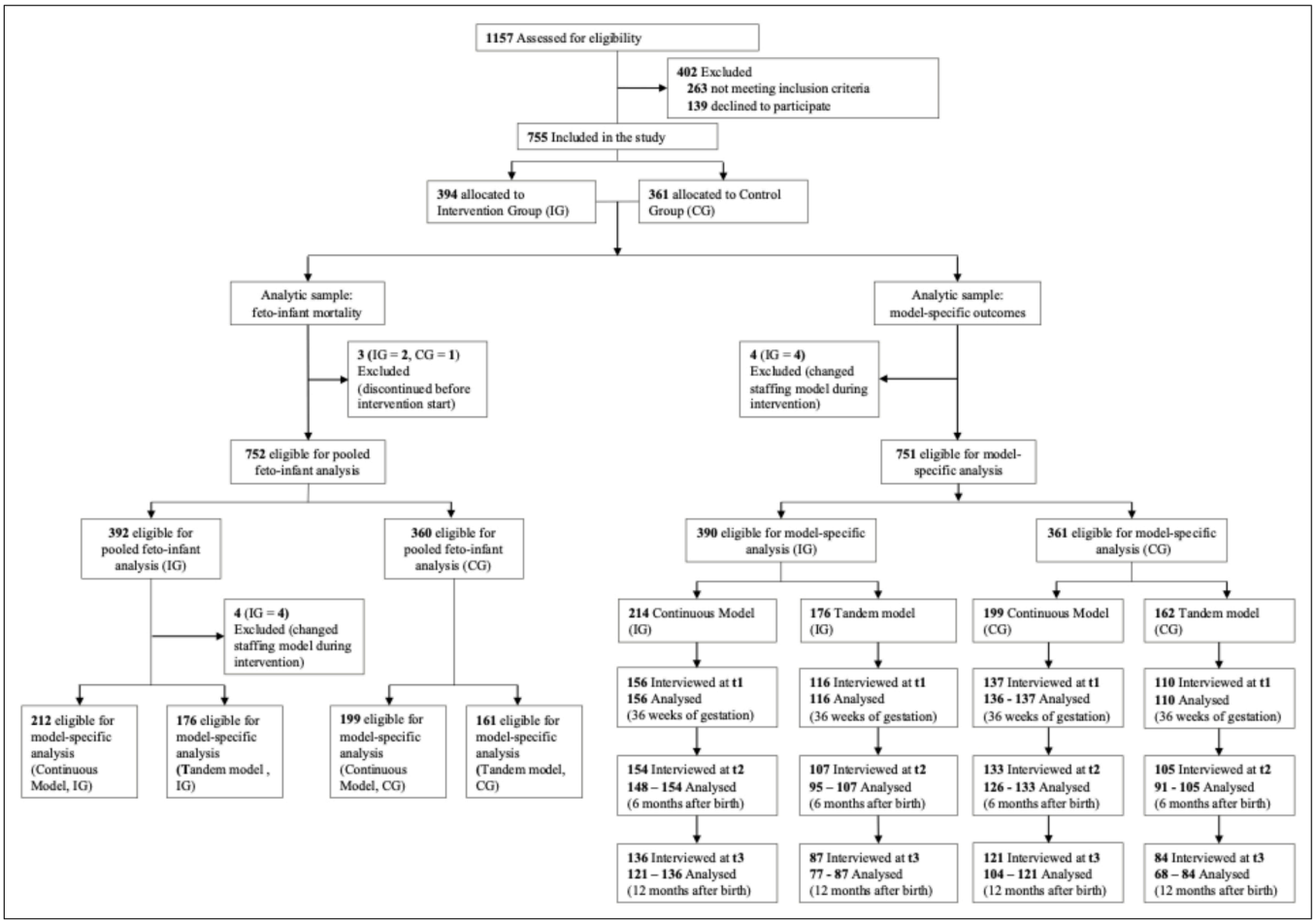


Figure 1

Participant flow through the ProKind trial

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