1 # Comparing two early childhood home visiting models

2 Follow-up of a randomized trial at child age 7

3

4 M.Sc., Marie Lisanne Schepan,[1,2]* schepan@leibniz-bips.de

5 Prof. Malte Sandner,[3] malte.sandner@th-nuernberg.de

6 Prof. Gabriella Conti,[4] gabriella.conti@ucl.ac.uk

7 Prof. Sören Kliem,[5] soeren.kliem@eah-jena.de

8 PD Dr. Tilman Brand,[1] brand@leibniz-bips.de

9

10 [1] Department of Prevention and Evaluation, Leibniz Institute for Prevention Research and

11 Epidemiology – BIPS, Bremen, Germany

12 [2] Department of Health Sciences, University of Bremen, Bremen, Germany

13 [3] Department of Business Administration, Nuremberg Institute of Technology, Nuremberg &

14 Institute for Employment Research (IAB), Nürnberg, Germany

15 [4] Department of Economics and Social Research Institute, University College London, London,

16 United Kingdom

17 [5] Department of Social Work, Ernst-Abbe-Hochschule Jena, University of Applied Sciences,

18 Jena, Germany

19 *** Corresponding author:**
20 Marie Lisanne Schepan,
21 Leibniz Institute for Prevention Research and Epidemiology – BIPS,
22 Achterstr. 30, 28359 Bremen, Germany.
23 Phone: 004915234065863
24 Email: schepan@leibniz-bips.de

25 **Manuscript word count**: 2995/3000

26 **Date of revision:** 20.09.2024

27

28 **KEY POINTS**

29 **Question:** What are the long-term effects of two staffing models of a prenatal and infancy

30 home visiting program on child and maternal health outcomes at 7-year follow-up?

31 **Findings:** In this randomized trial of 525 participants, the intervention delivered by midwives

32 resulted in less abusive parenting and better maternal mental health outcomes than the

33 control group. Additionally, the intervention group involving both a social worker and a

34 midwife reported fewer child behavioral problems compared to their control group.

35 **Meaning**: Both staffing models produced positive intervention effects in Europe, with more

36 effects seen in the midwife-only model.

ABSTRACT

Importance: Home-based interventions targeting socially disadvantaged families may help to foster maternal and child health. Only a few studies have investigated how different staffing models affect early home visiting program outcomes.

Objective: To assess the effects of two staffing models of an early childhood intervention on mother and child outcomes.

Design: The baseline assessment of this randomized trial was conducted between 2006-2009. The follow-up assessment at offspring age 7 years was carried out by interviewers masked to treatment conditions from April 2015 to December 2017. Data analysis was performed from March 2023 to August 2023.

Setting: Multicenter study in Germany.

Participants: Pregnant women, with no previous live birth, low-income and at least one additional psychosocial risk factor were eligible. A total of 1,157 women were referred to the study by gynecologists, psychosocial counseling services or employment agencies, 755 were randomized to treatment conditions, and 525 completed the follow-up.

Interventions: Based on the Nurse-Family Partnership program, women assigned to the intervention group received visits by either a midwife (midwife-only model) or by a team consisting of a social worker and a midwife (tandem model) until child age 2. Women assigned to the control group had access to the standard health and social services.

Main Outcome(s) and Measure(s): Average treatment effects (ATEs) on the following primary outcomes were assessed using adjusted regression models with inverse probability weighting: developmental disorders, child behavioral problems, adverse, neglectful and abusive parenting, maternal mental health and life satisfaction.

60 **Results:** Mothers in the tandem model reported fewer internalizing child behavioral problems

61 compared to the control group (ATE=2.98; 95%CI: -5.49, -0.47; absolute reduction 13.3

62 percentage points). Beneficial intervention effects were found in the midwife-only group on

63 abusive parenting (ATE= -4.00; 95%CI: -6.82, -1.18), parenting stress (ATE= -0.13; 95%CI: -

64 0.20, -0.06), and maternal mental health burden (ATE= -3.63; 95%CI: -6.03, -1.22; absolute

65 reduction 6.6 percentage points in depressive symptoms), but not in the tandem group.

66 **Conclusions and Relevance:** Both staffing models produced positive intervention effects,

67 with more effects seen in the midwife-only model. These insights can guide future early

68 childhood intervention designs and improve health care for socially disadvantaged families.

69 **Trial Registration:**

70 German Clinical Trials Register (https://www.drks.de/drks_web/setLocale_EN.do),

71 Identifier DRKS00007554.

72

INTRODUCTION

Children exposed to early childhood adversities, such as lower socioeconomic conditions or maltreatment, are at increased risk of poor psychosocial and health outcomes (1-3). Home-based interventions that target socially disadvantaged families and children at an early age may create long-term benefits for maternal and child health and development (4-7). Despite growing evidence on early childhood interventions, careful program adaptation is crucial for an effective transfer across contexts (8, 9). Interventions adopted without adaptation are less effective than contextually adapted ones (10). Staff selection and training are key components when implementing preventive interventions (11) and are regarded as critical when delivering home visiting programs (12). So far, few studies have systematically investigated how staffing affects program outcomes in home visiting programs. Most research has examined the role of paraprofessional staff in delivering visits (4, 13, 14).

This study investigates the adaptation of the US *Nurse-Family Partnership Program* (NFP) to the German context. NFP was evaluated in the United States in three randomized controlled trials (RCTs) and has proven to be one of the most effective home visiting programs in recent decades (5, 15-17). Besides RCTs replicating the NFP in the Netherlands and the UK, showing some short-term benefits (18, 19), the program has been adapted as "Pro Kind" in Germany. One major step in adapting the program was that Pro Kind tested two different staffing models. In some sites, a midwife delivered the program (midwife-only model), while in others, a midwife and a social worker delivered it together (tandem model). The first model was closer to the original program, the second model reflected the division of labor between the professions in Germany (pre- and antenatal care by midwives, support for families in need after birth through social workers) and the respective funding schemes for family support. Another reason for adopting the tandem model was to combine the different competencies of both professions, enriching the support and reducing the need for intensive training. Currently, implementation differences between the two models in the Pro Kind Study have been analyzed. The tandem model showed a higher dropout rate, trends towards lower

100   ratings of the quality of helping relationship and lower satisfaction with the service during

101   pregnancy (20). This study aims to compare the intervention effects of the two staffing

102   models on mother and child outcomes at child age seven.

103   **METHODS**

104   This study is a follow-up of a multisite RCT around the child's seventh birthday. The trial was

105   carried out in 15 sites located in three German federal states (Bremen, Lower Saxony, and

106   Saxony) (21-23).

107   **Design and Participants**

108   Women were included in this study between 2006 and 2009 if they fulfilled the following

109   eligibility criteria: first-time mother (no live-birth before), second trimester of pregnancy,

110   eligible for unemployment benefits (<450€ per month), and at least one additional

111   psychosocial risk factor (e.g. poor education, psychological or physical health problems). The

112   participants were mainly recruited through gynecologists, psychosocial counseling services,

113   or employment agencies. All participants completed consent procedures and the ethics

114   committee of the German Society for Psychology (Registration No.: SK 122014) and of the

115   University Leipzig (406–14-15,122,014) approved the study.

116   The baseline randomization was conducted by the research team and stratified by site,

117   maternal age (18 years old), and maternal nationality (German versus non-German). Before

118   randomization, participants were assigned to one of the staffing models based on their place

119   of residence. For practical reasons, all sites except one implemented only one of the staffing

120   models. In the exceptional site, the control group was further stratified by randomly sampling

121   participants to reflect the proportions in the intervention groups. Four cases were excluded

122   from this analysis due to changes in the staffing model under the intervention.

123   Between April 2015 and December 2017 follow-up assessments were conducted by trained

124   interviewers masked to participants' intervention status (see Figure 1). The assessments

125   were based on face-to-face computer administered interviews with mothers and children,

126 including a developmental test for the children. Detailed methodology and results are

127 documented following the CONSORT checklist requirements in supplementary file 1.

Intervention and control conditions

129 The intervention aimed to improve pregnancy outcomes and child and maternal health by

130 strengthening maternal self-efficacy, attachment, and social support. It also aimed to support

131 maternal life course planning by encouraging active family planning, arranging continued

132 education, and financial autonomy. The Pro Kind intervention kept the core components of

133 the NFP intervention, including the target group criteria, the average number and duration of

134 visits, a structured approach (theory-based, visit-to-visit guidelines), a protocol of each home

135 visit and the background support through supervision. The intervention started between the

136 12th and 28th week of pregnancy and continued until the child's second birthday. The

137 frequency of visits varied between weekly, biweekly, and monthly arrangements for an

138 overall maximum of 52 home visits with an average duration of 90 minutes. In the tandem

139 model, most of the visits during pregnancy were delivered by the midwife, except for three

140 visits where both the midwife and the social worker were present. The social worker took

141 over delivering the visits approximately two months after birth. To further facilitate this

142 transition, two joint visits with both professions were planned after birth, and the visit

143 frequency (weekly) for the social worker during the 8th and the 12th week postpartum was

144 increased. In the midwife-only model, an increased visit frequency for this period was not

145 scheduled.

146 Families received an average of 32.4 visits (*SD* 18.1) in the midwife-only model and 33.0 (*SD*

147 19.4) in the tandem model. The average length of the visits was 82.6 minutes (*SD* 12.4) in

148 the midwife-only model and 79.6 (*SD* 14.3) in the tandem model. The control group had

149 access to the standard local health and social services (e.g., antenatal and perinatal care by

150 midwifes and gynecologists, psychosocial counselling).

Home Visitors' Characteristics and Training

152 In total, 62 home visitors delivered the intervention, including 37 midwives, 24 social workers

153 and one pediatric nurse. Their mean age was 40 years (*SD* 7.8) at intervention onset. All of

154 them were female and of German nationality. Each received approximately 16 days of in-

155 service training aligned with the NFP-curriculum, as well as training on early child

156 development. Apart from some specific training modules (e.g., training on client-centered

157 communication for midwives; training on feeding practices for social workers) the curriculum

158 was generally the same for both staffing models. Weekly clinical supervision sessions lasted

159 about 1 hour.

160 **Outcomes**

161 Due to the multi-faceted nature of the intervention, several primary outcomes were defined

162 (24).

163 Child development and life satisfaction.

164 Developmental disorders were measured by the Basic Diagnostics of Specific

165 Developmental Disorders in Elementary school Children (BUEGA (25)). The BUEGA is a test

166 battery that aims to assess specific developmental disorders in primary school children in the

167 areas of (non-) verbal intelligence, expressive language, reading, spelling, arithmetic, and

168 attention. Standardized T-scores (mean = 50, standard deviation (SD) = 10) were calculated

169 for the overall test results according the test manual (25).

170 The parent version of the Child Behavior Checklist (CBCL/ 6-18 R (26) (27)) was used to

171 assess the childrens behavioral problems. Raw scores for internalizing and externalizing

172 behavioral problems were calculated (Cronbach's $\alpha = 0.90$), and cut-offs based on age and

173 sex normed T-scores indicating clinically relevant behavioral or emotional problems.

174 Internalizing behaviors encompass mood disturbances such as anxiety, depression and

175 social withdrawal. Externalizing behaviors reflect conflict with other and violation of social

176 norms.

177 The children's life satisfaction was assessed using a 7-item inventory (28) covering the areas

178 of school, family, social contacts with peers, interests and leisure activities as well as

179 physical and mental health (5-point scale ; higher values indicated greater life satisfaction). It

180   was completed by children and mothers. Mean scores were calculated (α = 0.72 (parent

181   version) and 0.56 (child version)).

182   Maternal mental health and life satisfaction

183   Mother's life satisfaction was assessed by an 8-item questionnaire (29) covering satisfaction

184   with health, work, financial situation, leisure time, partnership, friends, and family life (5-point

185   scale, higher values indicated greater life satisfaction). A mean score was calculated (α =

186   0.78). Additionally, the short form of the Depression-Anxiety-Stress Scale (DASS-21 (30))

187   was used to measure mothers' negative emotional states of depression, anxiety and stress

188   (α = 0.93). A summary score was calculated across the three domains; higher values

189   indicated a higher mental health burden.

190   Adverse, abusive, and neglectful parenting

191   Mother's adverse parenting was assessed by an adapted version of the Parenting Scale (31,

192   32). This 30-item-scale measures dysfunctional disciplinary parenting behavior in response

193   to problematic child behavior, rated on a 4-point scale. A mean summary score was

194   calculated; higher values indicated more adverse parenting practices (α = 0.80).

195   Psychological aggression and physical abuse were assessed using both parent and child

196   versions of the Parent-Child Conflict Tactic Scale (33). This included 31 items covering non-

197   violent discipline, psychological aggression, and physical assaults on a 7-point scale (higher

198   values indicated more frequent abusive parenting; α = 0.78). A summary score excluding

199   non-violent discipline was calculated. The child version with 16 items and a binary response

200   option (yes/no) covered the same domains. Again, a summary score was calculated

201   excluding the non-violent discipline (α = 0.74).

202   We used the Multidimensional Neglectful Behavior Scale (34) to assess mothers' neglectful

203   parenting. This aims to measure child neglect across 4 core domains: cognitive, emotional,

204   physical and supervisory neglect, including exposure to violence, alcohol-related neglect,

205   abandonment, and children's appraisals of parenting. We used the self-report version for

206 parents consisting of 50 items (α = 0.78), and a children's version consisting of 31 items (α =

207 0.78) (35), and computed a summary score.

Sociodemographic variables and psychosocial adversities

209 At baseline, demographic information was collected, including mothers' age, marital status,

210 and nationality. Information on several psychosocial adversities was also captured, such as

211 underage, unwanted pregnancy, low social support (36), alcohol and drug use during

212 pregnancy, childhood experiences (living in custodial care, neglect, loss of a significant

213 other), history as a victim of interpersonal violence or violence during pregnancy, potential for

214 aggression (10-item rage and anger subscale (37)), diagnosed lifetime mental illness, severe

215 depression anxiety and stress symptoms (DASS-21), and socioeconomic disadvantages (low

216 education, income, and occupation (38)). A summary score of all psychosocial adversities

217 was calculated. At follow-up, information on the child's sex and child's and mother's ages

218 was collected.

Statistical Analyses

220 Descriptive statistics were used to characterize the study groups and compare participants

221 with drop-outs. Pairwise deletion was applied to handle missing data. For the main analysis,

222 Inverse Probability Weighting Regression Adjustment (IPWRA; (39, 40)) was employed to

223 estimate average treatment effects (ATE). The IPWRA procedure consisted of three steps: In

224 the first step, the inverse probability weighting (IPW) used a logit model including baseline

225 socio-demographic variables and psychosocial adversities to predict treatment status and

226 calculate inverse probability weights for each participant. This step balanced the treatment

227 groups based on the variables included in the model. IPW balancing was conducted in all

228 samples with valid observations for each respective outcome variable. In the second step,

229 the regression-adjustment (RA) models were fitted to estimate treatment-specific outcomes

230 for each participant, incorporating relevant predictors from the baseline variables. This step

231 was included because simulation studies have shown that adjusted analyses yield more

232 accurate results in RCTs than unadjusted analyses (41). Relevant outcome predictors were

233 identified using stepwise regression models with all baseline variables, applying backward

234 elimination (cut-off: α < 0.20). In the third step, ATEs were estimated by computing the

235 means of the treatment-specific predicted outcomes and contrasting them. For additional

236 analyses, outcome measures were categorized where clinical cut-offs existed (e.g., DASS,

237 CBCL), and logistic regressions were conducted to assess the clinical relevance of outcomes

238 where beneficial intervention effects were observed. All statistical analysis was performed

239 with Stata version 17 (Stata Corp, College Station, TX).

240 **RESULTS**

241 Of the 755 families initially enrolled, 525 were included in the analysis. Retention was similar

242 across all study groups (69.5%; Figure 1). Participants in the 7-year follow-up showed a

243 lower burden regarding psychosocial adversities compared to those lost to follow-up (eTable

244 1 and eTable 2 in supplementary file 2). On average, the mothers were 29.6 years of age

245 (*SD* 4.36; range 22.1 – 48.1), and children were 7.55 years of age (*SD* 0.75; range 5.44 –

246 10.19) at follow-up. For demographic characteristics and psychosocial adversities of the

247 sample see Table 1. The crude differences in the outcome measures are presented in Table

248 2.

249 Child development and life satisfaction

250 The results did not show beneficial intervention effects for developmental disorders or life

251 satisfaction of the children (Table 3). However, lower scores for internalizing behaviors were

252 found in the tandem visitor model (ATE= 2.98; 95%-CI: -5.49, -0.47). Additional analysis

253 showed an absolute reduction of 13.3 percentage points in clinically relevant internalizing

254 problems compared to the control group (18.4% vs. 31.7%; OR= 0.49; 95%-CI: 0.26, 0.92).

255 Maternal mental health and life satisfaction

256 Beneficial intervention effects were found for mothers' life satisfaction in the midwife-only

257 model (ATE= 0.31; 95%-CI: 0.13, 0.49). Additionally, lower scores on the DASS-21 scale

258 indicated a lower mental health burden for mothers in the midwife-only model (ATE= -3.63;

259 95%-CI: -6.03, -1.22). The additional analysis showed an absolute reduction of 6.6

260   percentage points in severe depressive symptoms in the midwife-only model compared to

261   the control group (7.7% vs. 14.3%; OR= 0.50; 95%-CI: 0.23, 1.09) and an absolute reduction

262   of 10.3 percentage points in severe stress symptoms in the midwife-only model compared to

263   the control group (13.3% vs. 23.6; OR= 0.50; 95%-CI: 0.27, 0.92).

264   Adverse, abusive and neglectful parenting

265   Lower scores for adverse parenting practices on the Parenting Scale (ATE= -0.1; 95%-CI: -

266   0.2, -0.1) and abusive parenting practices on the Conflict Tactics Scale (parent version)

267   (ATE= -4.00; 95%-CI: -6.82, -1.18) were found in the midwife-only model compared to the

268   control group. No beneficial effects were detected for abusive or neglectful parenting based

269   on child reports in either of the staffing models.

270   **DISCUSSION**

271   In this study, we compared the intervention effects of the two staffing models of the Pro Kind

272   program in Germany at child age 7. We found that early home visits delivered by the

273   midwife-only and by the tandem model had lasting intervention effects. More specifically, we

274   found one positive effect on maternal ratings of child internalizing behavioral problems in the

275   tandem model. Instead, we found exclusively positive effects on maternal mental health and

276   life satisfaction, and abusive and adverse parenting in the midwife-only model.

277   The midwife-only model, which adhered to the original NFP-staffing model more closely,

278   showed more and larger intervention effects. Previous NFP-program research in Denver,

279   USA explored different staffing models within an RCT, revealing smaller and less consistent

280   benefits with a paraprofessional-delivered program compared to the original nurse-delivered

281   version (42-44). Despite variations in staffing approaches, compared to the Pro Kind

282   adaptation, the original model consistently demonstrated larger effects. Recent in-depth

283   analysis from Germany further indicates that the midwife-only model was more successful

284   than the tandem model in preventing diagnoses of mental health disorders of children and

285   mothers (45).

286 How can the lack of intervention effects in the tandem model be explained? Indicators were

287 already identified when comparing the two Pro Kind staffing models on implementation level

288 (20). A higher dropout rate and trends towards lower ratings of the quality of the helping

289 relationship in the tandem model suggests that the shift between the midwife and the social

290 worker made it challenging to build and sustain a strong working alliance. In particular,

291 establishing a positive relationship between the client and the home visitor is crucial for this

292 intervention approach, predicted to enhance parent engagement and outcomes (46-48).

293 Moreover, midwives may be more trusted as home visitors in Germany due to negative

294 preconceptions about health and social service professionals or negative experiences with

295 the youth welfare office. Although both staffing models received the same training, the

296 practical experience and confidence in early childhood development might provide an

297 advantage for the midwife-only model. In contrast, although social workers bring expertise in

298 working with vulnerable families and additional training in child protection, the tandem model

299 did not demonstrate synergetic effects on outcomes of adverse, abusive and neglectful

300 parenting in mothers of the tandem model. However, a US home visiting program (Child

301 FIRST) involving social workers as home visitors showed positive effects on children and

302 parents (49).

303 **Practical Implications**

304 Despite the need for alternative staffing due to German financing structures and a shortage

305 of midwives, the tandem model requires careful adaptation to optimize the shift between the

306 two professions and strengthen the client-home visitor relationship. In order to draw further

307 conclusions on the effectiveness of both staffing models, research is needed to understand

308 the influence of home visitors' characteristics, such as experiences, personality traits (50,

309 51), and attachment status (52), on program effectiveness. Furthermore, the influence of the

310 community environment and specific supervisory practices should be investigated at the

311 implementation level.

312 **Strengths and Limitations**

313   This is one of the few studies that provide results on the long-term effectiveness of different

314   staffing models in early childhood home-based interventions in Europe. Our findings give

315   revealing insights to inform future adaptations and the design of these interventions and to

316   optimize health care for socially disadvantaged families. However, some limitations of this

317   study should be considered. Prior to the intervention and control group randomization,

318   mothers were allocated to the staffing models based on their place of residence, potentially

319   resulting in a selection bias. Furthermore, despite the use of well-established questionnaires,

320   response bias due to self-report assessments is possible. Additionally, a proportion of

321   participants was lost to follow-up, resulting in incomplete data for all times of measurement.

322   This means that some distorting effects cannot be absolutely excluded. Lastly, the interval

323   between the follow-up data collection and the analysis should be considered when

324   interpreting the results.

325   **Conclusions**

326   The findings from our study confirm that early childhood interventions can have a long-term

327   positive effect on mothers and children. Both staffing models produced positive intervention

328   effects five years after the end of the program. However, more and stronger intervention

329   effects were observed in the midwife-only model, which adhered more closely to the original

330   US-based program. This highlights the need for careful adaptation when transferring an

331   intervention to a different context.

332

333 **ABBREVIATIONS:**

334 ATE: average treatment effect (unstandardized linear regression coefficients)

335 BUEGA: Basic Diagnostics of Specific Developmental Disorders in Elementary school Children

336 CBCL: Child Behavior Checklist

337 CG: control group

338 CI: confidence interval

339 DASS: Depression-Anxiety-Stress Scale

340 ES: effect size

341 IG: intervention group

342 IPW: inverse probability weighting

343 IPWRA: inverse probability weighting regression adjustment

344 NFP: Nurse-Family Partnership

345 RA: regression adjustment

346 RCT: randomized controlled trial

347 SD: standard deviation

348

REFERENCES:

1. Shonkoff JP. Leveraging the biology of adversity to address the roots of disparities in health and development. Proceedings of the National Academy of Sciences. 2012;109(supplement_2):17302-7.
2. Goldfeld S, Price A, Smith C, Bruce T, Bryson H, Mensah F, et al. Nurse home visiting for families experiencing adversity: a randomized trial. Pediatrics. 2019;143(1).
3. Hughes K, Bellis MA, Hardcastle KA, Sethi D, Butchart A, Mikton C, et al. The effect of multiple adverse childhood experiences on health: a systematic review and meta-analysis. The Lancet Public Health. 2017;2(8):e356-e66.
4. Casillas KL, Fauchier A, Derkash BT, Garrido EF. Implementation of evidence-based home visiting programs aimed at reducing child maltreatment: A meta-analytic review. Child abuse & neglect. 2016;53:64-80.
5. Kitzman H, Olds DL, Knudtson MD, Cole R, Anson E, Smith JA, et al. Prenatal and infancy nurse home visiting and 18-year outcomes of a randomized trial. Pediatrics. 2019;144(6).
6. Molloy C, Beatson R, Harrop C, Perini N, Goldfeld S. Systematic review: Effects of sustained nurse home visiting programs for disadvantaged mothers and children. Journal of Advanced Nursing. 2021;77(1):147-61.
7. Sweet MA, Appelbaum MI. Is Home Visiting an Effective Strategy? A Meta-Analytic Review of Home Visiting Programs for Families With Young Children. Child Development. 2004;75(5):1435-56.
8. Moore G, Copeland L, Craig P. Adaptation of interventions for implementation and/or re-evaluation in new contexts: The ADAPTguidance (v1. 0). 2021.
9. Escoffery C, Lebow-Skelley E, Haardoerfer R, Boing E, Udelson H, Wood R, et al. A systematic review of adaptations of evidence-based public health interventions globally. Implementation Science. 2018;13(1):1-21.
10. Sundell K, Beelmann A, Hasson H, von Thiele Schwarz U. Novel programs, international adoptions, or contextual adaptations? Meta-analytical results from German and Swedish intervention research. Journal of Clinical Child & Adolescent Psychology. 2016;45(6):784-96.
11. Blase K, Fixsen D. Core Intervention Components: Identifying and Operationalizing What Makes Programs Work. ASPE Research Brief. US Department of Health and Human Services. 2013.
12. Azzi-Lessing L. Home visitation programs: Critical issues and future directions. Early Childhood Research Quarterly. 2011;26(4):387-98.
13. Gubbels J, van der Put CE, Stams G-JJ, Prinzie PJ, Assink M. Components associated with the effect of home visiting programs on child maltreatment: A meta-analytic review. Child Abuse & Neglect. 2021;114:104981.
14. Filene JH, Kaminski JW, Valle LA, Cachat P. Components associated with home visiting program outcomes: A meta-analysis. Pediatrics. 2013;132(Supplement_2):S100-S9.
15. Olds DL. The nurse–family partnership: An evidence-based preventive intervention. Infant Mental Health Journal. 2006;27(1):5-25.
16. Miller TR. Projected outcomes of nurse-family partnership home visitation during 1996–2013, USA. Prevention Science. 2015;16(6):765-77.
17. Olds DL, Kitzman H, Anson E, Smith JA, Knudtson MD, Miller T, et al. Prenatal and infancy nurse home visiting effects on mothers: 18-year follow-up of a randomized trial. Pediatrics. 2019;144(6).
18. Mejdoubi J, van den Heijkant SC, van Leerdam FJ, Heymans MW, Crijnen A, Hirasing RA. The effect of VoorZorg, the Dutch nurse-family partnership, on child maltreatment and development: a randomized controlled trial. PLoS One. 2015;10(4):e0120182.
19. Robling M, Bekkers M-J, Bell K, Butler CC, Cannings-John R, Channon S, et al. Effectiveness of a nurse-led intensive home-visitation programme for first-time teenage mothers (Building Blocks): a pragmatic randomised controlled trial. The Lancet. 2016;387(10014):146-55.

425 20. Brand T, Jungmann T. Implementation differences of two staffing models in the german
426 home visiting program "pro kind". Journal of Community Psychology. 2012;40(8):891-905.
427 21. Sierau S, Dähne V, Brand T, Kurtz V, von Klitzing K, Jungmann T. Effects of home
428 visitation on maternal competencies, family environment, and child development: a
429 randomized controlled trial. Prevention science. 2016;17(1):40-51.
430 22. Kliem S, Sandner M, Lohmann A, Sierau S, Dähne V, Klein AM, et al. Follow-up study
431 regarding the medium-term effectiveness of the home-visiting program "Pro Kind" at age 7
432 years: study protocol for a randomized controlled trial. Trials. 2018;19(1):1-20.
433 23. Sandner M, Cornelissen T, Jungmann T, Herrmann P. Evaluating the effects of a
434 targeted home visiting program on maternal and child health outcomes. Journal of health
435 economics. 2018;58:269-83.
436 24. Kliem S, Sandner M, Lohmann A, Sierau S, Dähne V, Klein AM, et al. Follow-up study
437 regarding the medium-term effectiveness of the home-visiting program "Pro Kind" at age 7
438 years: study protocol for a randomized controlled trial. Trials. 2018;19(1):323.
439 25. Esser G, Wyschkon A, Ballaschk K. BUEGA: Basisdiagnostik Umschriebener
440 Entwicklungsstörungen im Grundschulalter: Hogrefe Göttingen; 2008.
441 26. Achenbach TM. Manual for ASEBA school-age forms & profiles. University of Vermont,
442 Research Center for Children, Youth & Families. 2001.
443 27. Döpfner M, Plück J, Kinnen C. Arbeitsgruppe Deutsche Child Behavior Checklist.
444 CBCL Handbuch-Schulalter. Manual zum Elternfragebogen über das Verhalten von Kindern
445 und Jugendlichen. CBCL/6-18R), zum Lehrerfragebogen über das Verhalten von Kindern
446 und …; 2014.
447 28. Mattejat F, Remschmidt H. ILK: Inventar zur Erfassung der Lebensqualität bei Kindern
448 und Jugendlichen: Ratingbogen für Kinder, Jugendliche und Eltern: Verlag Hans Huber;
449 2006.
450 29. Fahrenberg J, Myrtek M, Schumacher J. Fragebogen zur Lebenszufriedenheit (FLZ):
451 Handanweisung, Fragebogen, Auswertungsbogen: Hogrefe-Verlag; 2000.
452 30. Lovibond PF, Lovibond SH. The structure of negative emotional states: Comparison of
453 the Depression Anxiety Stress Scales (DASS) with the Beck Depression and Anxiety
454 Inventories. Behaviour research and therapy. 1995;33(3):335-43.
455 31. Arnold DS, O'leary SG, Wolff LS, Acker MM. The Parenting Scale: a measure of
456 dysfunctional parenting in discipline situations. Psychological assessment. 1993;5(2):137.
457 32. Naumann S, Bertram H, Kuschel A, Heinrichs N, Hahlweg K, Döpfner M. Der
458 Erziehungsfragebogen (EFB). Diagnostica. 2010;56(3):144-57.
459 33. Straus MA, Hamby SL, Boney-McCoy S, Sugarman DB. The revised conflict tactics
460 scales (CTS2) development and preliminary psychometric data. Journal of family issues.
461 1996;17(3):283-316.
462 34. Straus MA, Kinard EM, Williams LM. The multidimensional neglectful behavior scale,
463 Form A: Adolescent and adult-recall version. Durham, NH: University of New Hampshire:
464 Family Research Laboratory Available in: http://pubpages unh edu/~ mas2. 1995.
465 35. Kantor GK, Holt MK, Mebert CJ, Straus MA, Drach KM, Ricci LR, et al. Development
466 and preliminary psychometric properties of the multidimensional neglectful behavior scale-
467 child report. Child Maltreatment. 2004;9(4):409-28.
468 36. Hosser D. Soziale Unterstützung im Strafvollzug. Hafterleben und protektive Faktoren
469 bei jungen Männern. Baden-Baden: Nomos Verl.-Ges.; 2001. 193 S. p.
470 37. Hampel R, Selg H. Fragebogen zur Erfassung von Aggressivitätsfaktoren: FAF.
471 Göttingen: Hogrefe; 1975.
472 38. Lampert T, Kroll L, Müters S, Stolzenberg H. Messung des sozioökonomischen Status
473 in der Studie zur Gesundheit Erwachsener in Deutschland (DEGS1).
474 Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz. 2013;56(5):631-6.
475 39. Sloczynski T, Uysal SD, Wooldridge JM. Doubly robust estimation of local average
476 treatment effects using inverse probability weighted regression adjustment. 2022;CESifo
477 Working Paper No. 10105.
478 40. Stata. teffects ipwra — Inverse-probability-weighted regression adjustment. 2024.

479   41.   Perneger T, Combescure C, Poncet A. Adjustment for baseline characteristics in
480   randomized trials using logistic regression: sample-based model versus true model. Trials.
481   2023;24(1):107.
482   42.   Olds DL, Robinson J, O'Brien R, Luckey DW, Pettitt LM, Henderson Jr CR, et al. Home
483   visiting by paraprofessionals and by nurses: a randomized, controlled trial. Pediatrics.
484   2002;110(3):486-96.
485   43.   Olds DL, Robinson J, Pettitt L, Luckey DW, Holmberg J, Ng RK, et al. Effects of home
486   visits by paraprofessionals and by nurses: age 4 follow-up results of a randomized trial.
487   Pediatrics. 2004;114(6):1560-8.
488   44.   Olds DL, Holmberg JR, Donelan-McCall N, Luckey DW, Knudtson MD, Robinson J.
489   Effects of home visits by paraprofessionals and by nurses on children: follow-up of a
490   randomized trial at ages 6 and 9 years. JAMA Pediatr. 2014;168(2):114-21.
491   45.   Conti G, Kliem S, Sandner M. Early Home Visiting Delivery Model and Maternal and
492   Child Mental Health at Primary School Age. AEA Papers and Proceedings. 2024;114:401–
493   06.
494   46.   Guralnick MJ. Developmental science and preventive interventions for children at
495   environmental risk. Infants and young children. 2013;26(4):270.
496   47.   Mahoney G, Perales F. Relationship-focused early intervention with children with
497   pervasive developmental disorders and other disabilities: A comparative study. Journal of
498   Developmental & Behavioral Pediatrics. 2005;26(2):77-85.
499   48.   Korfmacher J, Green B, Spellmann M, Thornburg KR. The helping relationship and
500   program participation in early childhood home visiting. Infant Mental Health Journal: Official
501   Publication of The World Association for Infant Mental Health. 2007;28(5):459-80.
502   49.   Lowell DI, Carter AS, Godoy L, Paulicin B, Briggs-Gowan MJ. A randomized controlled
503   trial of Child FIRST: A comprehensive home-based intervention translating research into
504   early childhood practice. Child development. 2011;82(1):193-208.
505   50.   Astuto J, Allen L. Home Visitation and Young Children: An Approach Worth Investing
506   In? Social Policy Report. Volume XXIII, Number IV. Society for Research in Child
507   Development. 2009.
508   51.   Harden BJ. Home Visitation with Psychologically Vulnerable Families: Developments in
509   the Profession and in the Professional. Zero to Three (J). 2010;30(6):44-51.
510   52.   Suess GJ, Mali A, Reiner I, Fremmer-Bombik E, Schieche M, Suess E. Attachment
511   representations of professionals− Influence on intervention and implications for clinical
512   training and supervision. Mental Health & Prevention. 2015;3(3):129-34.
513
514

515   **Figure 1.** Flowchart of Participants' Progress Over a 7-Year Follow-up Period, Subdivided
516   According to the Two Staffing Models

517 **Table 1.** Sociodemographic Characteristics and Psychosocial Adversities at Baseline and
518 Child Age and Sex at Seven-Year Follow-up

	Midwife-only model		Tandem model		Total
	Control group	Intervention group	Control group	Intervention group	
	(*n*=141)	(*n*=150)	(*n*=114)	(*n*=120)	
Demographic characteristics					
Mother's age at baseline, years, mean (SD)	21.9 (4.4)	21.4 (4.0)	21.5 (4.4)	22.0 (5.01)	21.7 (4.4)
No partnership at baseline (%)	30.5	28.7	25.4	34.2	29.7
Non-German nationality (%)	10.6	7.3	7.0	4.2	7.4
Child's age at interview, years, mean (SD)	7.5 (0.8)	7.6 (0.7)	7.5 (0.7)	7.6 (0.8)	7.6 (0.75)
Child sex, male (%)	48.9	51.0	43.4	46.7	47.8
Psychosocial adversities at baseline					
Underaged (< 18 years, %)	13.5	18.0	17.5	18.3	16.8
Low social support (%)	9.2	6.7	5.3	6.7	7.1
Unwanted pregnancy (%)	17.7	18.0	16.7	15.8	17.1
Alcohol abuse (%)	0.7	0.0	0.9	0.0	0.4
Drug abuse (%)	3.6	0.7	0.9	1.7	1.7
Experience of custodial care (%)	23.4	21.3	14.0	18.3	19.6
Loss of significant other during childhood (%)	56.7	51.3	55.3	43.3	51.8
Neglect or maltreatment during childhood (%)	39.7	32.0	33.3	40.0	36.2
Violence during pregnancy (%)	11.4	9.3	5.3	4.2	7.8
Lifetime violence (%)	58.2	54.0	54.4	51.7	54.7
Lifetime mental illness (%)	17.0	7.3	22.8	10.8	14.1
Potential for aggression (%)	19.9	12.7	20.2	13.3	16.4
Depressive symptoms (%)	12.8	12.7	8.8	9.2	11.1
Anxiety symptoms (%)	19.2	18.7	13.2	10.0	15.6
Stress symptoms (%)	31.2	30.0	27.2	26.7	29.0
Low education (%)	70.9	77.3	72.8	71.7	73.3
Low income (%)	79.4	80.0	81.6	78.3	79.8
Low occupation (%)	82.3	78.7	87.7	79.2	81.7
Sum of psychosocial adversities, mean (SD)	6.0 (2.5)	5.6 (2.6)	5.6 (2.1)	5.3 (1.9)	5.6 (2.3)

519

Table 2. Crude Comparison of Child Development, Maternal Mental Health and Parenting across Study Groups

	Midwife-only model					Tandem model				
	Control group		Intervention group		Group Difference (95%-CI)		Control group		Intervention group	Group Difference (95%-CI)
Child development and life satisfaction	n	Mean (SD)	N	Mean (SD)			n	Mean (SD)	n	Mean (SD)	
Developmental disorders	99	44.4 (12.4)	109	43.3 (10.8)	-1.1 (-4.3; 2.1)	91	45.5 (8.8)	91	42.8 (12.6)	-2.7 (-5.8; 0.5)
Internalizing problems	134	58.7 (8.8)	138	57.4(8.7)	-1.3 (-3.4; 0.8)	104	59.1 (9.8)	114	55.7 (9.3)	-3.4 (-5.9; -0.8)
Externalizing problems	136	61.0 (8.6)	143	59.3 (8.7)	-1.7 (-3.8; 0.3)	110	60.4- (8.9)	114	59.2 (8.6)	-1.2 (-3.5; 1.1)
Child's life satisfaction [a]	121	4.3 (0.5)	121	4.3 (0.5)	0.0 (-0.1; 0.1)	98	4.3 (0.5)	103	4.2 (0.5)	-0.1 (-0.2; 0.1)
Child's life satisfaction [b]	109	3.9 (0.6)	114	4.0 (0.6)	0.1 (-0.1; 0.2)	94	4.1 (0.6)	96	4.0 (0.7)	-0.1 (-0.3; 0.1)
Maternal mental health and life satisfaction										
Mental health (depression, anxiety, stress)	140	17.5 (11.3)	143	13.4 (10.2)	-4.0 (-6.5; -1.5)	113	16.4 (11.0)	116	15.0 (10.7)	-1.3 (-4.2; 1.5)
Mother's life satisfaction	131	3.3 (0.8)	135	3.6 (0.7)	0.3 (0.1; 0.5)	106	3.5 (0.7)	113	3.5 (0.7)	0.0 (-0.2; 0.2)
Adverse parenting, abusive and neglectful parenting										
Adverse Parenting	126	2.0 (0.3)	127	1.9 (0.3)	-0.1 (-0.2; 0.0)	99	2.0 (0.3)	110	2.1 (0.3)	0.0 (0.0; 0.1)
Abusive Parenting [a]	121	13.2 (9.5)	123	10.4 (8.7)	-2.8 (-5.1; -0.5)	97	11.4 (10.8)	106	10.7 (8.3)	-0.8 (-3.4; 1.9)
Abusive Parenting [b]	102	1.5 (1.9)	110	1.5 (2.1)	0.0 (-0.5; 0.5)	91	1.3 (1.6)	94	1.6 (2.0)	0.3 (-0.3; 0.8)
Neglectful Parenting [a]	119	26.8 (10.0)	122	24.4 (8.5)	-2.4 (-4.7; 0.0)	98	25.1 (8.6)	101	25.9 (8.9)	0.7 (-1.7; 3.2)
Neglectful Parenting [b]	110	4.3 (3.5)	113	4.5 (4.1)	0.3 (-0.8; 1.3)	93	4.2 (3.2)	96	4.9 (3.8)	0.7 (-0.3; 1.7)

[a] Parent version.
[b] Child version.

Table 3. Intervention Effects in the Midwife-Only and the Tandem Model

	Midwife-only model				Tandem visitor model			
	N	ATE	95%-CI	*p*	N	ATE	95%-CI	*p*
Child development and life satisfaction								
Developmental disorders	208	-.77	-3.79 2.25	0.62	182	-2.25	-5.23 .74	0.14
Internalizing problems	272	-1.05	-3.17 1.07	0.33	218	-2.98	-5.49 -.47	0.02
Externalizing problems	278	-1.85	-3.90 0.19	0.08	224	-0.72	-2.82 1.39	0.51
Child's life satisfaction [a]	242	0.03	-0.10 0.15	0.67	201	-0.53	-0.18 0.07	0.41
Child's life satisfaction [b]	223	0.09	-0.06 0.24	0.24	190	0.05	-0.22 0.13	0.61
Maternal mental health and life satisfaction								
Mental health (depression, anxiety, stress)	283	-3.63	-6.03 -1.22	0.003	229	-1.39	-4.24 1.46	0.34
Mother's life satisfaction	266	0.31	0.13 0.49	0.001	219	0.01	-0.17 0.19	0.89
Adverse parenting, abusive and neglectful parenting								
Adverse Parenting	253	-0.13	-0.20 -0.06	0.001	209	-0.04	-0.04 0.13	0.33
Abusive Parenting [a]	253	-4.00	-6.82 -1.18	0.005	209	0.12	-2.82 3.05	0.94
Abusive Parenting [b]	222	-0.21	-0.84 0.42	0.51	189	0.48	-0.13 1.08	0.12
Neglectful Parenting [a]	241	-1.89	-4.19 0.41	0.11	199	0.97	-1.26 3.21	0.40
Neglectful Parenting [b]	223	-0.12	-1.04 0.80	0.80	189	0.64	-0.29 1.56	0.18

Abbreviations: ATE, average treatment effect (unstandardized linear regression coefficients); CI, confidence interval coefficients adjustment and inverse probability weighting based on baseline variables in Table 1.
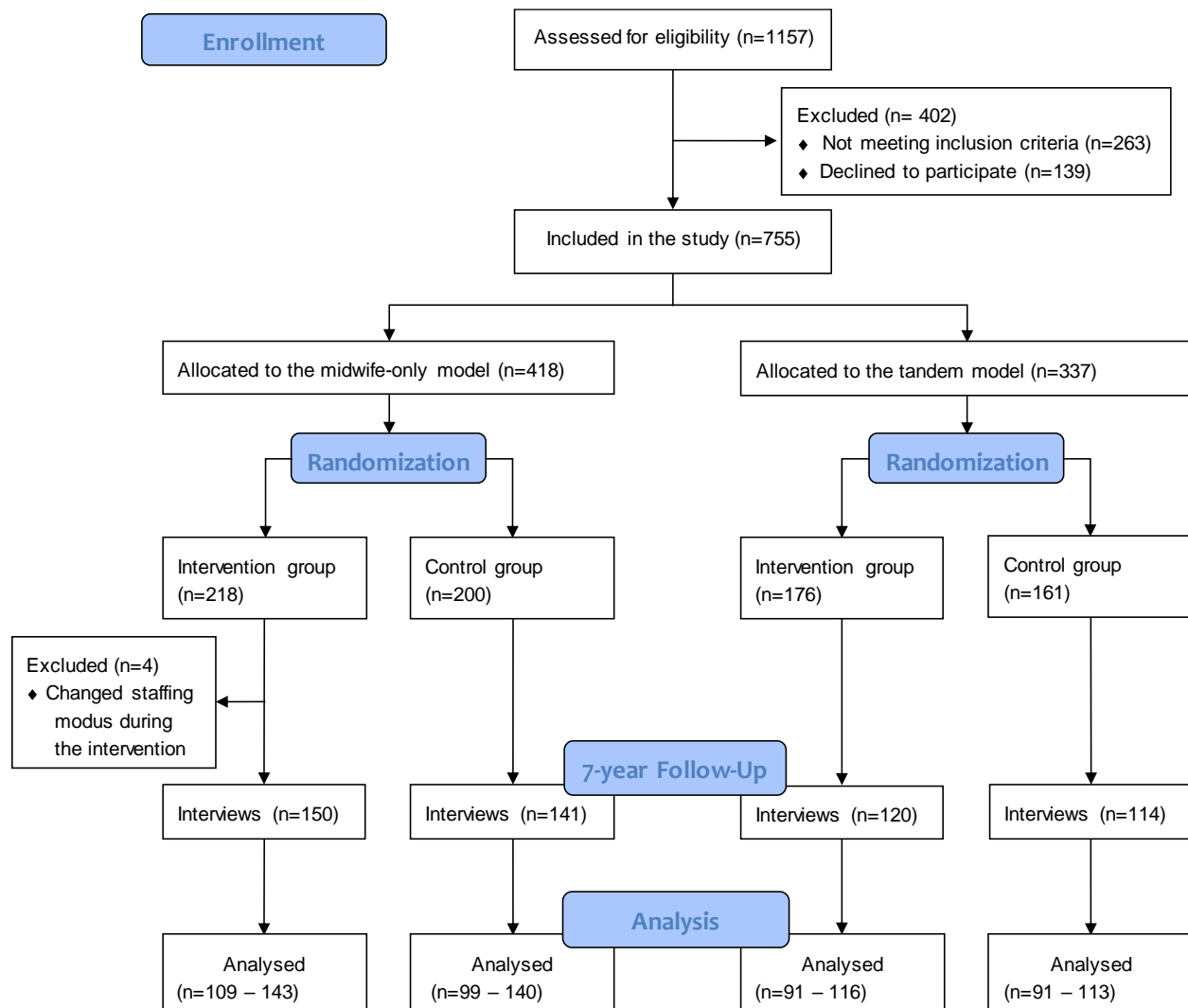[a] Parent version.
[b] Child version.

Figure 1. Flowchart of Participants' Progress Over a 7-Year Follow-up Period, Subdivided According to the Two Staffing Models