

One-year follow-up of The Incredible Years Parents and Babies Program: A pilot randomized controlled trial

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Abstract

Background: The foundation of a healthy life begins in pregnancy and early adversity can have detrimental long-term consequences for affected children.

Objective: This paper examines the effects of the Incredible Years Parents and Babies program (IYPB) at one-year follow-up when offered as a universal parenting intervention to parents with newborn infants.

Method: We conducted a pragmatic, two-arm, parallel pilot randomized controlled trial; 112 families with newborns were randomized to IYPB intervention (n = 76) or usual care (n = 36). The IYPB program is a group intervention with eight two-hour sessions. Follow-up outcomes collected a year after the intervention ended include parental stress, depression, well-being, reflective function, sense of competence, and child cognitive and socio-emotional development.

Results: There were no intervention effects on any of the primary or secondary parent-reported outcomes at one-year follow-up when the children were 18 months old. When examining the lowest-functioning mothers in moderator analyses, we found that mothers assigned to the IYPB group reported significantly lower scores for the interest and curiosity subscale of the parent reflective function scale than control mothers ($\beta = -1.07$ [-2.09, -0.06]).

Conclusion: We found no long-term effects of the IYPB when offered as a universal intervention for a relatively well-functioning group of parents with infants in a setting with a high standard of usual care. The intervention was developed for more vulnerable families in settings with a low level of universal care and the program may be effective for families in those circumstances.

Keywords: Parenting; parenting interventions; early intervention; early childhood; infant; Incredible Years

Introduction

The foundation of a healthy life begins in pregnancy and early adversity can have detrimental long-term consequences for affected children (1–4). This knowledge has led to increased investment in supporting early childhood development through interventions such as parenting programs (5).

Infants remain dependent upon their parents for many years after birth and are at risk of developmental harm if they suffer neglect or maltreatment during this time because brain plasticity is at its highest in the early years (6). In addition, infants are exposed to more potentially damaging experiences such as child neglect and violent abuse than older children (6–10). Compared to older children, infants are also more sensitive to

disruptions in parental care. Infants with mothers suffering from depression or severe stress can show biochemical, physiological, and behavioral dysregulations beginning shortly after birth, and may be at increased risk of mental and behavioral problems (11–13). These infants often show high levels of negative emotion and distress and have a higher risk of developing an insecure attachment to their caregivers (14, 15).

Early onset of behavioral or emotional problems increases the risk of later adverse outcomes such as violence, delinquency, teen pregnancies, substance abuse, mental health problems, school dropout, and long-term unemployment (1, 3, 16–23). The nature of early parent-child interactions is a central predictive factor of many developmental outcomes;

supporting parents in developing and applying positive parenting skills can stimulate healthy child development and prevent future problems (4, 5, 31–33, 23–30). The Incredible Years Parents and Babies (IYPB) program aims to support these child development goals.

The Incredible Years series (IY) offers prevention and treatment programs for parents, children, and teachers. The goal is to prevent and treat young children's behavior problems and promote their social, emotional, and academic competence. The IY parenting programs have shown effect sizes ranging from $d = 0.13$ for preventive studies to $d = 0.50$ for treatment studies on parent-reported child conduct problems in a meta-analysis (34) and an overall effects size of $d = 0.35$ for parent-reported conduct problems in a meta-analysis using individual participant data pooled from 14 European IY trials (32). The effectiveness of the IY intervention is retained when transported to other countries (35) and is consistent across socioeconomic and ethnic background (36–38). The IY Toddler BASIC program for children 1–3 years old has shown positive results (39–42), however, we know less about the effectiveness of IY programs for the youngest children (43). Also, as many of the IY trials are wait-list designs we also know less about the long-term effects of the programs than the short-term outcomes (44).

The Incredible Years Parents and Babies program (IYPB) was developed in 2010 for families with infants from birth to one year. A pre-post evaluation of IYPB in Wales found that parenting competence and mental health significantly improved over time for those who participated in the program (45). A second evaluation conducted in Wales with a control group, found a significant positive effect on observed mother sensitivity, while no differences were found between the two groups on child development, parenting confidence, or parental mental well-being (46). None of these studies, however, included randomization. A trial of both the IYPB and the IY toddler programs (the E-SEE trial) is currently running in the UK, but no results have been published yet (47). The present study is the first randomized controlled trial (RCT) of the IYPB. The trial was conducted in two Danish municipalities from 2013 to 2015. The trial protocol and results at post-intervention are presented in previous papers (48, 49). The sample included 112 families who were randomized to IYPB ($n = 76$) or usual care (UC) ($n = 36$). The mothers who participated in the study were relatively representative of the general population, but had slightly higher levels of education than the general population. There were no significant differences in demographic characteristics (including education) between the

IYPB group and the UC group at baseline. At post-intervention, when the children were approximately 5.5 months old, we found no differences between mothers who had received the IYPB intervention and those who received UC when examining parent-reported outcomes ($N = 104$). Moderator analyses, however, revealed that the 25% and 50% lowest functioning mothers who received the intervention reported higher parent stress, lower parenting confidence, and decreased mental health at post-intervention than the corresponding mothers in the control group; this result was statistically significant. In contrast, of the mothers in our sample who were the highest functioning at baseline, the mothers who received the IYPB intervention reported statistically significantly less parent stress than those in the control group (49).

In this paper, we examine the effects of the IYPB as a universal intervention on parent and child well-being and child development one year after the program ended and the children were 18 months old.

Methods

Study design

The trial is a pragmatic, two-armed, parallel pilot RCT. Institutional review board approval was obtained from SFI – the Danish National Center for Social Research. Parents provided informed consent before participation. The trial was carried out according to CONSORT guidelines (50, 51) and registered at ClinicalTrials.gov (reference number NCT01931917). Detailed information on recruitment, randomization, measures, and intervention and control conditions are provided in previous papers (48, 49).

Participants, randomization, and blinding

The eligible participants were mothers with infants 0–4 months old living in the Ikast-Brandø or Herning local authority area in Denmark. Where fathers were present, they were also invited to participate. Health visitors recruited families between August 2013 and August 2015. Parents were randomized to intervention or control groups by an independent research administrator. The allocation ratio was 2:1 (IYPB:UC). More families were randomized to treatment to ensure that enough families were available to start groups. We stratified participants by municipality and used a block size of three. In cases where consent to treatment was withdrawn but the participant agreed to remain in the research study, the participant was followed to completion. Given the nature of the trial, participants and group leaders could not be blinded to the condition. Interviewers, coders, and data analysts were blind to group allocation status.

IYPB intervention

The IYPB program is a group intervention aimed at promoting a nurturing parent-child relationship, and enhancing parent competencies (52). Groups were made up of 6–8 parents with infants and were led by two trained group leaders. The program consisted of eight two-hour sessions. To support the training and foster discussion in the group, during each session, group leaders showed video vignettes of real-life situations with parents and babies. Two group leaders were certified IYPB practitioners and two were in the process of gaining IYPB certification. The remaining practitioners were all experienced IY group leaders who were certified in the IY BASIC Parent Group and who attended three days of training sessions in IYPB. Group leaders attended supervision twice a year with an IYPB mentor.

Control

The families randomized to the control group received usual care (UC). Intervention families received IYPB in addition to UC. Usual care consisted of the offer of five to six free home visits from a health visitor and open consultation hours at a local well-child clinic. Although participation is voluntary almost all Danish families take advantage of these visits (53, 54). UC also consists of voluntary participation in a social group of six local mothers, and three free child-health visits at their general practitioner within the child's first year of life. Extra

appointments from health visitors are also offered free of charge to families who require extra care (e.g., extra home visits, family therapy, or a video-feedback intervention). The control families could not access the IYPB, but both the control and the intervention groups were free to participate in other infant activities offered by local organizations such as music and movement or baby massage. Most Danish children start full-time daycare when they are between 8 and 12 months old.

Measures

The timing of the administration of measures is shown in Table 1. Data were collected through home visits at baseline (T1) when the children were about 1.5 months old, at post-intervention (T2) after the intervention ended when children were about 5.5 months old, and at follow-up (T3). Follow-up data were collected in the home by an independent interviewer approximately one year after the intervention ended when the child was 18 months old. Baseline measures are described in more detail in the trial protocol (48) and outcomes at post-intervention are described in a separate paper (49). While both mothers and fathers could complete the questionnaire, only a few fathers did so (50 at T1, 14 at T2, 19 at T3), therefore, only data from mothers were used in these analyses. Families received a 200 DKK (~27 EUR) gift card at each data collection visit.

TABLE 1. Timing of outcomes

	T1 Baseline	T2 Post-test	T3 Follow-up
Parent measures			
Karitane Parenting Confidence Scale [KPCS]	✓	✓	
Sense of Coherence [SOC13]	✓		
Major Depression Inventory [MDI10]	✓	✓	✓
World Health Organization Well-Being Index [WHO5]	✓	✓	✓
Rosenberg Self-Esteem Scale [RSS]		✓	
Parental Stress Scale [PSS]		✓	✓
Being a Mother [BaM-13]			✓
Parental Reflective Functioning Questionnaire [PRFQ]			✓
Parenting Sense of Competence [PSOC]			✓
Background questions	✓	✓	✓
Single items on parent and child health, child temperament, parent life satisfaction, network, household budget	✓	✓	✓
Child measures			
Ages and Stages Questionnaire - Social-Emotional [ASQ:SE-2e]	✓	✓	✓
Cognitive Development Questionnaire [CDQ]			✓
Strengths and Difficulties Questionnaire ([SDQ]			✓
Parent-Child measures			
Mother and Baby Interaction Scale [MABISC]		✓	
Coding Interactive Behavior-video [CIB]		✓	

The primary outcome at follow-up is the 18-item Parenting Stress Scale (55, 56). The PSS measures parenting stress and satisfaction in parents of children 0-18 years old. The PSS consists of 18 items that are rated on a five-point scale (Strongly disagree, Disagree, Undecided, Agree, Strongly agree). For this paper, the PSS was scored according to the recommendations in the recent Danish psychometric evaluations (56, 57). The PSS consist of two subscales: Parental Stress (items 3, 4, 9, and 10-16) and Lack of Parental Satisfaction (items 1, 2, 5, 6, 7, 8, 17, and 18). When scoring the subscales LPS items were reversed, and item responses were dichotomized into 0 (strongly disagree and disagree) and 1 (undecided, agree, and strongly agree) and items 2 and 11 were left out. Cronbach's alpha for this sample was 0.73 for the PS subscale and 0.65 for the LPS subscale.

Secondary outcomes at follow-up include the following measures
The Major Depression Inventory (MDI10) (58) measures depressive symptoms and consists of 10 items that are scored on a six-point Likert scale (All the time, Most of the time, Slightly more than half the time, Slightly less than half the time, Some of the time, At no time). Cronbach's alpha for this sample was 0.87.

The World Health Organization (WHO)-5 Well-Being Index (59, 60) measures current mental wellbeing and consists of five items that are scored on a six-point Likert scale (All the time, Most of the time, Slightly more than half the time, Slightly less than half the time, Some of the time, At no time). Cronbach's alpha for this sample was 0.76.

The Being a Mother Scale (BaM-13) (61) measures a woman's satisfaction and experience with being a mother and consists of 13 items that are rated on a four-point scale (No, hardly ever, No, not very often, Yes, some of the time, Yes, most of the time). Cronbach's alpha for this sample was 0.77.

The Parental Reflective Functioning Questionnaire (PRFQ-1) (62) measures reflective functioning or mentalization in parents of young infants and children across three domains: pre-mentalizing modes (PM), certainty about mental states (CMS), and interest and curiosity in mental states (IC). The PRFQ-1 consists of 18 items that are scored on a seven-point Likert scale (7 Strongly Agree, 4 Neutral or Undecided, 1 Strongly Disagree). Cronbach's alpha for this sample was 0.42 for the PM subscale, 0.79 for the CMS subscale, and 0.66 for the IC subscale.

The Parenting Sense of Competence Scale (PSOC) (63) measures how parents perceive their own competences as a parent and consists of 16 items and two subscales: efficacy and satisfaction. The PSOC is scored on a sixpoint Likert scale (Strongly Agree, Somewhat Agree, Agree, Disagree, Somewhat

Disagree, Strongly Disagree). Cronbach's alpha for this sample was 0.84.

The Ages and Stages Questionnaire - Social-Emotional (ASQ-SE) (64, 65), measures social-emotional problems and competencies in children and consists of 19 to 33 items that are rated by parents on a three-point scale (Often or always, Sometimes, Rarely or never) and a box parents may check if the behavior is a concern for them. The Danish version is based on the experimental version of the second edition of the ASQ-SE but only differs minimally from the final second version. Cronbach's alpha for this sample was 0.62.

The Strengths and Difficulties Questionnaire (SDQ) (66, 67) for parents of 2-4 year-old children measures child behavior and psychopathology and consists of 25 items (five domains: hyperactivity/inattention, peer problems, conduct problems, emotional symptoms, and pro-social behaviors) that are rated by parents on a three-point scale (Not true, Somewhat true, Certainly true). Cronbach's alpha for this sample was 0.73.

The Cognitive Development Questionnaire (CDQ) (68) measures cognitive development of children from 8 to 24-months-old and consists of one section with 19 scripted games for parents to play with their infant, and a second section with 16 items asking about everyday behaviors. Items are rated by parents on a yes/no scale supplemented with information on e.g. how many blocks were used. The CDQ was sent by mail to the participants and collected by the interviewers when they visited the parents two weeks later to collect the remaining data. Because the CDQ was filled out on paper there are individual missing items and not all parents completed the questionnaire. Cronbach's alpha for this sample was 0.80.

Interaction was assessed with 15 items measuring parent and child interaction through activities such as singing, reading, and playing. These items were adapted from the evaluation of the Preparing for Life study and scored on a six-point scale (More than once a day, About once a day, A few times a week, A few times a month, Rarely, Not at all). Cronbach's alpha for this sample was 0.72.

Single items include parent and child health, parent life satisfaction, support, and network (all scored on an 11-point scale), and child temperament, height and weight.

Statistical analyses

The treatment effect is measured in a linear regression framework with a lagged dependent measure:

$$y_i = \gamma D_{i,treatment} + \mu y_i^{pre} + \theta X_i + \varepsilon_i$$

The model consists of an individual treatment dummy ($D_{i,treatment}$), the individual baseline measure of the dependent variable (y_i^{pre}) and a vector of individual covariates (X_i).

Categorical data are presented as numbers and percentages, and continuous data as means and standard deviations. The trial includes two sets of twins, both in the IYPB group. To account for the lack of independence between twins, we selected the first twin only for analyses of the parent outcomes, but kept both twins for child outcomes. We performed intention to treat analyses for primary and secondary outcomes with multiple regression analysis, including controls for site and baseline score.

Of the 112 mothers assessed at T1, 11 were lost due to attrition at T3. Attrition can lead to bias in the estimates, and to avoid this we chose to impute the missing observations. To deal with attrition, we first tested the assumption that data were missing completely at random (MCAR) by creating an indicator variable for observations missing at T3 and fitting it with a logit model. All baseline measures of the outcome variables and other covariates, along with the treatment dummy, were included as predictors. We found two significant predictors at the 5% level, indicating that the data is missing at random (MAR). Although the assumption of MAR data is not testable, imputation is still shown to produce less biased results than listwise deletion (69). Furthermore, should the data be MCAR instead of MAR, listwise deletion would lead to unbiased, albeit possibly inefficient, estimates. We generated 50 datasets with multiple imputations (70) using Stata's multiple imputation (mi) impute procedure on chained equations. We truncated the imputed datasets to fit within the original scales.

As the PSS is the primary outcome we recalculated the PSS scores at T2 according to the two-subscale scoring recommended by Pontoppidan et al. (56) to examine if this changed any of the results at T2. We also used the two-subscale version to calculate PSS scores at T3.

Scores for the CDQ were marked as missing if more than four items were missing (out of a total of 40). For participants with 1-3 missing values, the missing values were replaced by the mean score of the item calculated by the remaining scores. As there were more missing total scores for the CDQ than for the rest of the measures we did not perform any further imputation for this measure and all analyses on the CDQ are based on the not imputed data.

We estimated the model with ordinary least squares (OLS) regression. A two-tailed test $\alpha = 0.05$ was implemented for all analyses. We calculated effect sizes by dividing the adjusted mean difference

between the trial arms by the pooled standard deviation. We used robust standard errors to account for group effects. We applied paired sample t-tests for testing total group change over time. As described in the protocol (48), we examined heterogeneous effects by comparing IYPB to UC in the following subsamples: (1) mothers scoring within the lowest 25% of the distribution at baseline, (2) mothers scoring within the lowest 50% of the distribution at baseline, (3) mothers scoring within the highest 50% of the distribution at baseline, and (4) mothers scoring within the highest 25% of the distribution at baseline. In the moderator analysis, we included an interaction term between a dummy for being in the 25% or 50% lowest/highest scoring group and a dummy for intervention allocation. Analyses were performed with Stata version 14.

Results

Figure 1 presents the flow diagram of participants in the trial. Of the 125 families who had given their initial consent, 13 withdrew consent when the interviewer contacted them to schedule a home visit. Of the 112 randomized families, 76 were allocated to IYPB and 36 to UC. Eight families dropped out before T2 assessment, and a further three families dropped out between T2 and T3 assessment. The three families that dropped out between T2 and T3 all belonged to the UC group. We did not include further covariates in the analyses, as variables such as the mother's age, education, and parity did not affect the results.

We obtained data on parent participation from one of the two sites. On average, the participating mothers completed 6.3 sessions. Fathers participated less often than mothers (four sessions on average for the fathers who participated). The protocol describes Complier Average Causal Effects (CACE) analyses for two levels of participation: (1) mothers who participated in at least three of the eight sessions, and (2) mothers who participated in at least six of the eight sessions. However, as we could only obtain detailed participation data from one site, we could not perform these analyses.

Table 2 shows means and regression output comparing IYPB mothers and UC mothers at T3. The comparison of IYPB and UC mothers at long-term follow-up shows no significant difference in any of the outcomes.

We examine change over time for the full sample for the measures that were used at both T2 and T3 (PSS-PS, PSS-LPS, MDI, WHO5, and ASQ:SE-2e), to examine how the full sample developed after the intervention ended. There is a significant increase in the level of depressive symptoms (MDI $p = 0.04$), but no difference over time for parent stress (PSS-PS), parental satisfaction (PSS-LPS), mental health

(WHO5), and child socio-emotional development (ASQ:SE-2e). Child socio-emotional development was measured at all three time points, but whereas the same version of the ASQ:SE-2e was used at T1 and T2, a different version with different items was used at T3 when the child was 18 months old. Therefore, the total scores of the two versions are

not directly comparable. Because some of the measures were not strictly normally distributed we performed a sensitivity analysis by applying a non-parametric test (Wilcoxon signed-rank test) to the non-imputed data. Results are consistent with the t-test.

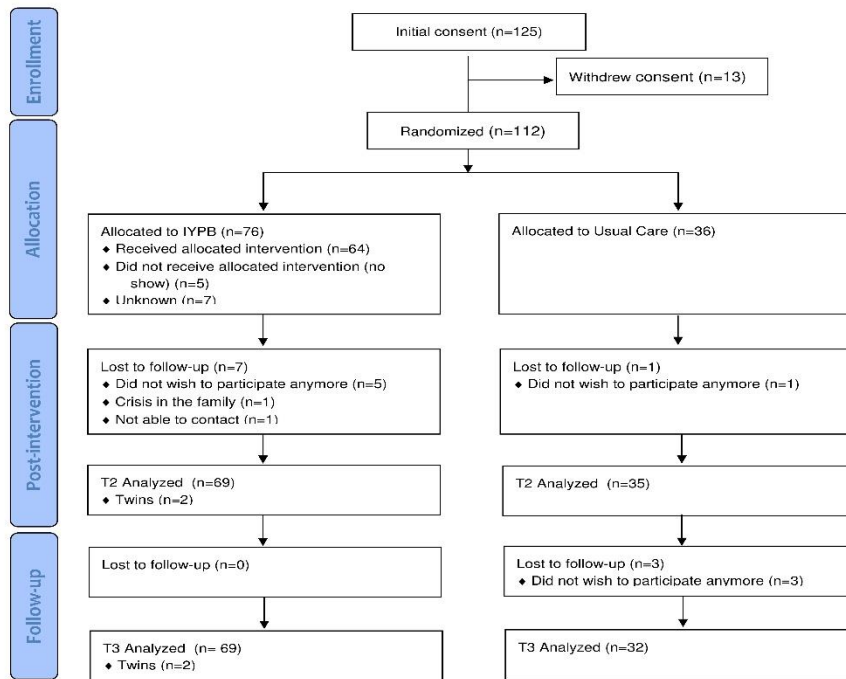


FIGURE 1. Trial flowchart

TABLE 2. Comparison of parent and child outcomes for families who received IYPB and usual care (UC) pre-intervention (T1), post-intervention (T2), and follow-up (T3) with regression coefficients, and 95% confidence intervals for multiple linear regressions on imputed data controlling for site and baseline score when possible

	IYPB			UC			B	95% CI
	T1 Mean	T2 Mean	T3 Mean	T1 Mean	T2 Mean	T3 Mean		
PSS- PS \bar{x}	-	3,21	3,10	-	3,01	3,40	-0.14	[-0,59,0,32]
PSS-LPS \bar{x}	-	0,06	0,07	-	0,06	0,09	-0.07	[-0,53,0,38]
BaM	-	-	6,69	-	-	6,49	0.08	[-0,35,0,51]
MDI \bar{x}	7.65	6.05	7.43	9.72	6.56	8.86	-0.03	[-0,43,0,36]
WHOS	64.16	69.95	69.49	59.44	69.68	68.19	0.00	[-0,42,0,43]
PSOC	-	-	57.31	-	-	57.15	0.00	[-0,51,0,51]
PRFQ-PM	-	-	9.91	-	-	8.88	0.32	[-0,08,0,72]
PRFQ-CMS	-	-	25.37	-	-	27.03	-0.18	[-0,65,0,29]
PRFQ-IC	-	-	36.86	-	-	36.45	0.17	[-0,28,0,63]
ASQ:SE-2e \bar{x}	47.17	25.73	29.13	50.25	25.16	28.28	0.05	[-0,46,0,53]
SDQ	-	-	7.86	-	-	7.69	0.04	[-0,43,0,50]
CDQ (n=27+54)	-	-	36.25	-	-	35.68	0.05	[-0,42,0,52]
Activities	-	-	2.89	-	-	2.97	-0.22	[-0,73,0,30]
Child height (cm)	56.99	70.39	83.83	57.09	70.42	82.78	0.23	[-0,28,0,74]
Child weight (kilo)	4.95	8.40	12.16	4.86	8.38	12.18	0.00	[-0,50,0,50]
<i>Single Items</i>								
Loneliness	7.07	7.15	7.39	7.06	7.27	7.59	-0.04	[-0,46,0,38]
Network	9.07	7.90	8.10	8.17	8.28	7.51	-0.08	[-0,43,0,28]
Confidants	9.61	9.74	9.39	9.06	9.51	9.58	-0.23	[-0,62,0,16]
Overall health self-report	8.70	8.86	8.40	8.42	8.52	7.94	0.17	[-0,26,0,60]
Life satisfaction	9.16	9.13	8.84	9.06	8.95	8.75	0.02	[-0,42,0,45]
Budget	7.85	7.29	7.00	7.42	6.56	6.70	0.03	[-0,34,0,39]
Child temperament	8.87	9.25	9.17	8.56	9.29	9.10	0.08	[-0,41,0,56]
Child overall health	9.59	9.45	8.97	9.11	9.42	9.07	-0.19	[-0,61,0,23]

Note. * $p < 0.05$; IYPB: Incredible Years Parents and Babies; UC: usual care; T1: Time 1 (baseline); T2: Time 2 (post-intervention); Time 3 (follow-up); β : standardized regression estimate; se: standard error of regression estimate; \bar{x} : low score is favorable; PSS-PS: Parenting Stress Scale- Parental Stress; PSS-LPS: Parental Stress Scale- Lack of Parental Satisfaction; BaM: Being a Mother; MDI: Major Depression Inventory; WHOS: Well-Being Index; PSOC: Parenting Sense of Competence; PRFQ-PM: Parental Reflective Functioning Questionnaire Pre Mentalizing ; PRFQ-CMS: Parental Reflective Functioning Questionnaire Certainty about Mental States; PRFQ-IC : Parental Reflective Functioning Questionnaire Interest and Curiosity; ASQ:SE-2e: Ages and Stages Questionnaire: Social-Emotional-2 experimental version; SDQ: Strengths and Difficulties Questionnaire; CDQ: Child Development Questionnaire

TABLE 3. Regression results of interaction analyses for mothers divided into groups based on pre-intervention (T1) scores of presented measures. Results compare mothers at follow-up who received the IYPB program to those who received usual care within the groups scoring in the lowest 25th and 50th percentiles and the highest 50th and 75th percentiles

	< 25% at T1		< 50% at T1		> 50% at T1		> 75% at T1	
	B	CI	β	CI	B	CI	β	CI
PSS-PS $\bar{x} \pm$	0,92	[-0,38,2,23]	0,43	[-0,47,1,33]	-0,43	[-1,33,0,47]	-0,63	[-1,64,0,37]
PSS-LPS $\bar{x} \pm$	0,46	[-0,27,1,18]	0,42	[-0,39,1,24]	-0,42	[-1,24,0,39]	0,18	[-0,44,0,80]
BaM $\bar{x} \pm$	0,25	[-1,00,1,49]	-0,08	[-0,94,0,79]	0,08	[-0,79,0,94]	-0,31	[-1,06,0,44]
MDI \bar{x}	-0,10	[-1,25,1,05]	0,01	[-0,85,0,87]	-0,01	[-0,87,0,85]	-0,02	[-1,09,1,06]
WHOS	-0,90	[-2,19,0,38]	-0,40	[-1,28,0,47]	0,40	[-0,47,1,28]	0,42	[-0,56,1,40]
PSOC	-0,10	[-1,09,0,88]	0,01	[-1,03,1,04]	-0,01	[-1,04,1,03]	-0,02	[-0,94,0,90]
PRFQ-PM $\bar{x} \pm$	0,63	[-0,15,1,40]	0,15	[-0,63,0,94]	-0,15	[-0,94,0,63]	-0,31	[-1,26,0,64]
PRFQ-CMS \pm	-0,18	[-1,54,1,19]	-0,63	[-1,57,0,31]	0,63	[-0,31,1,57]	0,49	[-0,61,1,60]
PRFQ-IC \pm	-1,07*	[-2,09,-0,06]	-0,56	[-1,50,0,37]	0,56	[-0,37,1,50]	0,95	[-0,03,1,94]
ASQ:SE-2e \bar{x}	0,55	[-0,70,1,79]	0,14	[-0,86,1,14]	-0,14	[-1,14,0,86]	-0,04	[-1,31,1,23]
SDQ $\bar{x} \diamond$	0,33	[-1,07,1,73]	0,08	[-0,88,1,04]	-0,08	[-1,04,0,88]	-0,26	[-1,29,0,78]

Note. * significant interaction effect at $p < 0.05$; T1: Time 1; β : standardized regression estimate for interaction term; se: standard error of regression estimate; \bar{x} : low score is favorable; \pm : KPCS score at baseline used for group; \diamond : ASQ:SE-2e score at baseline used for group; KPCS: Karitane Parenting Confidence Scale; PSS-PS: Parenting Stress Scale – Parental Stress, PSS-LPS: Parenting Stress Scale – Lack of Parental Satisfaction; BaM: Being a Mother; MDI: Major Depression Inventory; WHOS: Well-Being Index; PSOC: Parenting Sense of Competence; PRFQ-PM: Parental Reflective Functioning Questionnaire Pre Mentalizing ; PRFQ-CMS: Parental Reflective Functioning Questionnaire Certainty about Mental States; PRFQ-IC : Parental Reflective Functioning Questionnaire Interest and Curiosity; ASQ:SE-2e: Ages and Stages Questionnaire: Social-Emotional-2 experimental version; SDQ: Strengths and Difficulties Questionnaire

Differential effects

We divided the sample into quarters and halves to look for moderating effects. We only performed the moderator analyses on the rating scales (PSS, BaM, MDI, WHO5, PSOC, PRFQ-1, ASQ:SE-2e, and SDQ). We did not perform moderator analyses for the single items as they had very low variation and could not meaningfully be divided into groups. Table 3 shows regression outputs for follow-up outcomes for the following groups: mothers scoring within the lowest 25% and 50% at baseline, and mothers scoring within the highest 25% and 50% at baseline. For the interest and curiosity subscale of the parent reflective function scale (PRFQ-IC) intervention mothers who scored in the lowest 25% at baseline have significantly worse scores at follow-up compared to control mothers.

Sensitivity analyses

Sensitivity analyses included OLS regression without imputation, Difference-in-Difference (DiD) and

random effects modeling estimation on the imputed data using only T1 and T3 measures, as presented in Table 4. The results for the OLS model on non-imputed data lead to very similar estimates as those presented. For the DiD and the RE models, some of the estimates become larger than the presented model. This stems from the added time dimension in these models, which relaxes the assumption of the presented model of equal means at T1. The DiD and the RE models double the number of available observations, this does, however, not lead to increased precision except for the single item child overall health, which becomes significant on the 10%-level in the DiD model and on the 5%-level in the RE model. This is in line with what we expect since the groups are balanced at T1 and adding them to the estimation should therefore not add much more information than including the T1 measure in the cross-sectional estimation. Our results, therefore, seem to be robust to model specification.

TABLE 4. Sensitivity analyses comparing OLS regression without imputation, difference-in-difference estimation, and random effects modeling at follow-up for IYPB and usual care (UC) mothers

	OLS (n=99)		DiD (n=224)		RE (n=224)	
	B	CI	B	CI	β	CI
PSS PS α	-0.15	[-0.59,0.29]				
PSS LPS α	-0.02	[-0.45,0.41]				
WHO5	-0.04	[-0.43,0.35]	-0.17	[-0.78,0.43]	-0.17	[-0.69,0.35]
MDI α	-0.02	[-0.40,0.36]	0.16	[-0.45,0.77]	0.16	[-0.29,0.60]
PSOC	0.02	[-0.45,0.49]				
PRFQ-1-1	0.24	[-0.15,0.62]				
PRFQ-1-2	-0.28	[-0.72,0.15]				
PRFQ-1-3	0.12	[-0.31,0.54]				
BaM	0.09	[-0.32,0.50]				
ASQ:SE-2e α	0.07	[-0.35,0.50]	0.11	[-0.52,0.74]	0.11	[-0.47,0.68]
Activities	-0.17	[-0.58,0.23]				
Child height (cm)	0.26	[-0.17,0.69]	0.25	[-0.37,0.88]	0.25	[-0.35,0.86]
Child weight (kilo)	0.06	[-0.36,0.48]	-0.07	[-0.69,0.55]	-0.07	[-0.65,0.51]
SDQ	0.05	[-0.37,0.47]				
CDQ (n=27+54)	0.21	[-0.27,0.70]				
<i>Single items</i>						
Loneliness	-0.06	[-0.47,0.35]	-0.04	[-0.63,0.54]	-0.04	[-0.54,0.45]
Network	-0.06	[-0.38,0.26]	-0.25	[-0.88,0.37]	-0.25	[-0.62,0.11]
Confidants	-0.20	[-0.59,0.19]	-0.45	[-1.03,0.13]	-0.45	[-1.02,0.12]
Overall health self-report	0.15	[-0.22,0.51]	0.04	[-0.60,0.68]	0.04	[-0.43,0.51]
Life satisfaction	-0.01	[-0.41,0.40]	-0.05	[-0.66,0.55]	-0.05	[-0.60,0.49]
Budget	0.07	[-0.26,0.39]	-0.09	[-0.66,0.48]	-0.09	[-0.49,0.32]
Child temperament	-0.02	[-0.45,0.42]	-0.06	[-0.68,0.56]	-0.06	[-0.67,0.54]
Child overall health	-0.22	[-0.56,0.12]	-0.59	[-1.25,0.06]	-0.59*	[-1.14,-0.04]

Note. *significant at $p < 0.1$; LS: ordinary least squares; DiD: Difference-in-difference; RE: random effects; β: standardized regression estimate; se: standard error of regression estimate; α: low score is favorable; PSS: Parenting Stress Scale; WHO5: Well-Being Index; MDI: Major Depression Inventory; PSOC: Parenting Sense of Competence; PRFQ-PM: Parental Reflective Functioning Questionnaire Pre Mentalizing; PRFQ-CMS: Parental Reflective Functioning Questionnaire Certainty about Mental States; PRFQ-IC: Parental Reflective Functioning Questionnaire Interest and Curiosity; BaM: Being a Mother; ASQ:SE-2e: Ages and Stages Questionnaire: Social-Emotional-2 experimental version; SDQ: Strengths and Difficulties Questionnaire; CDQ: Child Development Questionnaire

Discussion

In this paper, we investigated the one-year follow-up effects of the IYPB program as a universal intervention for parents with infants aged 0-1 year. We did not find any statistically significant differences between the IYPB and the UC groups on any outcomes at long-term follow up one year after the intervention ended when the children were approximately 18 months old. This finding is consistent with the post-intervention results (49) in which we also found no significant differences for parent outcomes between the intervention and control groups, except for a single item. At post-intervention, mothers in the intervention group had smaller networks that helped them with practical matters than mothers in the control group. We do not find this result at the one-year follow-up, which supports the interpretation of the finding as a spurious effect. At one-year follow-up we also examined the mothers who scored in the lowest functioning 25th percentile at pre-intervention using moderator analyses; we found that the lowest functioning mothers in the IYPB group reported significantly lower scores on the interest and curiosity subscale of the parent reflective function scale than the lowest functioning mothers who participated in the UC condition. At post-intervention, the lowest functioning mothers who participated in the IYPB group reported statistically significantly higher parent stress, lower parenting confidence, and worse mental health than control mothers. In contrast, the IYPB mothers who were in the highest functioning 25th percentile reported significantly lower parent stress at post-intervention. These results were not maintained at one-year follow-up.

The lack of effectiveness of IYPB as a universal intervention in the present trial is in line with a recent systematic review of the effects of universal interventions for parents with infants (71), and other trials of universal parenting interventions (72–75). It also corresponds with the most recent research on the IY program where it has been stated that “children with more marked levels of conduct problems tend to benefit most from the intervention, suggesting it is more suitable for high-risk prevention or treatment, rather than universal prevention”(44). Both the short- and long-term results from our trial indicate that the IYPB intervention does not have effects on parent-reported outcomes either immediately following the intervention or one year after the end of the intervention when offered to a universal population in a country where the quality of usual care is high. It is important to note that the IYPB program was not developed as a universal intervention where there is already a high standard of care, but was intended to be used with disadvantaged families with observable difficulties in caring for their

infants. In addition, the program was developed in the U.S. where there is a much lower standard of usual care. Our moderator analyses found that the lowest functioning mothers in the IYPB group had worse outcomes for some measures. We do not know the reason for these findings, but the IYPB program may be more useful for families in the context the developer intended with more homogenous groups in environments with a low standard of usual care.

As discussed in the previous paper (49) the mothers in the study have a relatively high education level and standard of living, we therefore would expect most of them to do well caring for their infants without any intervention. Most measures used in the study are developed for at-risk or clinical samples and there is a risk of ceiling or floor effects when applying them to a universal group (76). This can make it difficult to assess improvement over time. Whereas we found that almost all rating scales significantly improved from T1 to T2 when examining all mothers in the trial as a whole, only one out of five changed significantly over time from T2 when the children were approximately 5.5 months old, to T3 when they were about 18 months old. Overall, parental stress, parental satisfaction, parental mental health and child socio-emotional development did not change significantly from T2 to T3. Parental depression levels, however, were significantly higher at T3 compared to T2. This result may be a spurious result but may also be found because the majority of mothers were back to full-time work and most children were attending full-time daycare at the time of the follow-up when the children are 18 months old. This can put more pressure on the family as a whole.

When interpreting the results of this trial, it is important to take into consideration that the control group received a high level of usual care, which is a relatively extensive intervention provided to families in the Danish health care system. Although we do not see a marked improvement from T2 to T3 as we did from T1 to T2, both parents and children have good scores on most outcomes, indicating that the universal intervention that is offered to Danish families is beneficial, or that this population of parents adjust well to their new roles over time. Because of the high level of care provided to our control group, we are not able to conclude whether offering a universal IYPB program would be superior to receiving low-level care or no intervention.

Because the children in the study were a year older at T3 than at T2 the measures we used at T3 were not the same as those administered at T2 to correspond with the developmental stage the child. The analysis of differential effects is therefore not directly

comparable from T2 to T3. At follow-up, we still find that most outcomes favor the IYPB group for the highest functioning half of the sample, whereas most outcomes favor the control group for the lowest functioning half. When conducting the moderator analyses, we find that for the interest and curiosity subscale of the parenting reflective functioning measure (PRFQ-1), IYPB mothers in the lowest-scoring quartile show lower interest and curiosity compared to control mothers. There is also a trend for intervention mothers in the highest-scoring quarter to show higher interest and curiosity than control mothers. This result, however, is not statistically significant [CI: -0,03;1,94] (Table 3). As we did 40 tests in all this may be a spurious effect.

Analyses at both post-intervention (T2) and follow-up (T3) indicate that the well-functioning mothers may benefit more from the IYPB intervention than the lowest functioning mothers when offered as a universal intervention. This may be due to the heterogeneity of the parents' functioning in the IYPB groups when it is offered as a universal intervention. Parents may compare their skills and life circumstances to others of higher or lower functioning and this may affect their assessments and feelings about themselves and their families. It may be that lower functioning families offered IYPB would show more improvement if they did not attend a universally offered group but received the program in a more homogenous setting with other families who have similar needs and backgrounds. This approach may also allow the IYPB group leaders to focus on areas that are more relevant to specific groups.

This is a pilot trial based on relatively small sample size and the results should, therefore, be interpreted with prudence. Furthermore, analysis of the quality of the parent-child relationship at post-intervention has not yet been published. These outcomes are rated by objective observers and could differ from the parent-reported outcomes that are presented in this and the previous paper on short-term outcomes (49).

Limitations of the study include the relatively small sample size and that usual care in Denmark is fairly comprehensive. It is important to note that the IYPB intervention was developed for use with homogenous groups of lower functioning families rather than a universal population. Future research should investigate the effects of the program with disadvantaged families who show observable difficulties in caring for their infants.

Clinical significance

When offered to a group of relatively well educated mothers who are already receiving a high level of usual care, we do not find any significant differences between the IYPB group and the intervention group.

The lowest functioning 25th percentile of mothers assigned to the IYPB group at pre-intervention reported significantly lower scores on the interest and curiosity subscale of the parent reflective function scale at one-year follow-up than control mothers, therefore further investigation into the cause of this result should be undertaken before being used with this population in universal groups. The IYPB intervention was developed for use with groups of lower functioning parents who do not have extensive access to other services, rather than a universal population with a high standard of care and it is important to be aware of this in clinical practice.

Trial registration

ClinicalTrials.gov NCT01931917 (registration date August 27, 2013)

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Conflict of interest

The authors declare no conflicts of interest.

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