

Parent-child relationship outcomes of the Incredible Years Parents and Babies Program: A Pilot Randomized Controlled Trial

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Abstract

Background: A warm, sensitive, and responsive relationship to a caregiver is essential for healthy child development.

Objective: This paper examines the effects of the Incredible Years Parents and Babies (IYPB) program on the parent-child relationship at post-intervention 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 (76) or usual care (36). The IYPB program is a group intervention with eight two-hour sessions. In addition to parent-reported questionnaires, we collected a six-minute-long video at post-intervention from 97 families to assess the parent-child relationship, which was then coded with the Coding Interactive Behavior system.

Results: There were no significant intervention effects on either the total score or any of the seven subscales at post-intervention when the children were around 5.5 months old. For parental sensitivity, results were significant at the 10% level, favoring the IYPB group. When examining the lowest-functioning mothers in moderator analyses, we also found no significant differences between the two groups.

Conclusion: In line with parent-report outcomes, we did not find any statistically significant differences between the IYPB program and usual care on parent-child relationship 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. However, there was a positive trend for the total score, parental sensitivity and reciprocity with effect sizes in the range of .41-.51. It is possible that a larger sample would have resulted in significant differences for these outcomes.

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

Keywords: Parenting; parenting interventions; early intervention; early childhood; infant; Incredible Years; randomized controlled trial; universal intervention; prevention

Introduction

Early relationship experiences, especially warm, sensitive, and responsive interactions between parents and their infants, are crucial contributors to promoting a secure infant-parent attachment (1–4). The infant brain is extremely plastic in the first years of life and infants are therefore at risk of developmental harm if they suffer neglect or maltreatment during this time (5). Compared to older children, infants are more sensitive to disruptions in parental care.

Such disruptions can cause biochemical, physiological, and behavioral dysregulations in the infant and lead to high levels of negative emotion and distress, a higher risk of developing an insecure attachment to their caregivers, and a higher risk for later mental and behavioral problems (6–10). The

prevalence of problems such as emotion regulation, behavior and eating problems is 16-18% in 18-month-old Danish children (11), while in an international perspective around 40% of children do not have a secure attachment to their primary caregivers (12).

All healthy infants will seek to form an attachment bond toward their caregiver as forming such attachment is an evolutionary trait. However, the quality of the attachment bond depends on how sensitive the caregiver is and their ability to interpret the infant's signals and respond to them promptly and adequately (1,13–15). Parental sensitivity includes the parent's ability to notice the child's signals, to correctly interpret them, and to respond to them in a prompt and adequate manner (16). Parental sensitivity is considered an important protective

factor and is important for the infant to develop a secure attachment to the caregiver and for the infant to learn to regulate emotions and handle stress (2,17). Longitudinal studies show that positive, consistent and supportive parenting predicts enhanced cognitive development and low levels of child problem behavior and child abuse (18–25). Furthermore, to develop healthily, a child must have a secure attachment relationship to their caregivers, which is reflected in the fact that early parent-child interactions are central predictive factors of many developmental outcomes (26).

Supporting parents in developing and applying sensitive parenting skills can stimulate healthy child development and prevent future problems (20,25,27–37). To support the development of flexible, loving and secure attachment relationships between parents and infants, many parenting interventions have been designed and implemented. Studies find that both parental sensitivity and parent-child interactions can be improved through early intervention (27,38–44). This is found especially in interventions that focus clearly on maternal sensitive behavior and a modest number of sessions (45).

The parent-child relationship can be measured with various observational measures. Most measures include assessment of three dimensions: 1) parent, 2) child, and 3) the dyad. For the parent dimension, the most prevalent constructs include positive facets such as sensitivity, responsiveness, emotional availability, and scaffolding, and more negative facets such as intrusiveness, control and hostility (46). For the child dimension, the most prevalent constructs are engagement, responsiveness, involvement, and positive or negative affect (46). For the dyad dimension, the most prevalent constructs are synchrony, reciprocity, and mutuality (46). Observational measures of parent-child relationship correlate with parent-reported measures of relationship from a weak to moderate degree (46–48). Despite this correlation, only few intervention studies of interventions based on social learning theory have included both observational measures and parent-reported measures of the parent-child relationship.

The present study combines observational measures and parent-reported measures of the parent-child relationship to investigate the Incredible Years Parents and Babies (IYPB) intervention program. The IYPB program aims to prevent and treat young children's behavior problems and promote their social, emotional, and academic competence (49). The IYPB program is part of the Incredible Years series (IY) that offers prevention and treatment programs for parents, children, and teachers. In a meta-analysis of the IY parenting programs, the 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 (50), while a meta-analysis using individual participant data pooled from 14 European IY trials found an overall effects size of $d = 0.35$ for parent-reported conduct problems (28). The effectiveness of the IY intervention is retained when transported to other countries (51) and is consistent across socioeconomic and ethnic background (52–54). The IY Toddler BASIC program for children 1–3 years old has shown positive results (55–58), however, we know less about the effectiveness of IY programs for the youngest children (59). Furthermore, only a few studies have examined the effect of IY on the parent-child relationship – one study found positive effects on mother-child interaction quality for preschoolers with ODD (60), and two other studies found positive effects on the teacher-child relationship (61,62).

The IYPB program was developed in 2010 for families with infants from birth to one year. Compared to the IY programs aimed at older children and teachers, the IYPB program has a greater focus on promoting a positive attachment between parents and their infants to make the infants feel loved, safe and secure (63). A pre-post evaluation of the IYPB program in Wales found that parenting competence and mental health significantly improved over time for those who participated in the program (64). 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 (65). None of these studies, however, included randomization. A recent feasibility study in the UK that ran the IY infant and toddler programs in a proportionate universal model called Enhancing Social-Emotional Health and Wellbeing in the Early Years (E-SEE STEPS) found that a definitive trial is feasible (66,67).

The present study is the first randomized controlled trial (RCT) of the IYPB program. The trial was conducted in two Danish municipalities from 2013-15. The trial protocol and parent-reported results at post-intervention and one-year follow-up are presented in previous papers (68–70). The sample included 112 families who were randomized to the IYPB program (76) or usual care (UC - 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. For parent-reported outcomes, we found no significant differences between mothers who had

received the IYPB intervention and those who had received UC at both post-intervention, when the children were 5.5 months old, and at the one-year-follow-up, when the children were 18 months old (69,70). In this paper, we examine the effects of the IYPB program as a universal intervention on the quality of the parent-child relationship at post-intervention when the children were 5-6 months old. These results have not been presented in previous papers because the videos had not been coded at this time. The parent-child relationship is a secondary outcome.

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 (71,72) and registered at ClinicalTrials.gov (reference number NCT01931917). Detailed information on recruitment, randomization, measures, intervention and control conditions, and results from parent reported outcomes are provided in previous papers (68–70).

Participants, randomization, and blinding

The eligible participants were mothers with infants 0-4 months old living in the local authorities (municipalities) of Ikast-Brande or Herning in Denmark. All mothers were invited to participate as the intervention was offered as a universal intervention. Health visitors recruited families between August 2013 and August 2015. Mothers 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 IYPB 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.

The IYPB intervention

The IYPB program is a group intervention aimed at promoting a nurturing parent-child relationship, and enhancing parent competencies (49). In the present study, the IYPB groups consisted of six to eight parents with infants and were led by two trained group leaders. The program consisted of eight two-

hour sessions. To support the training and to foster discussion in the group, during each session, group leaders showed video vignettes of real-life situations with parents and babies. To get certified group leaders must complete two groups and receive feedback from a mentor/trainer based on two video recordings from group sessions and session checklists. Two group leaders were certified IYPB group leaders 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 had attended three days of training sessions in IYPB. Group leaders attended supervision twice a year with an IYPB mentor.

Control

Families in the control group received UC and intervention families participated in the IYPB program in addition to UC. Usual care consisted of five to six home visits from a health visitor and open consultation hours at a local well-child clinic. Most Danish families participate in these visits (73,74). Usual care also consisted of voluntary participation in a social group of six local mothers, and three child-health visits at their general practitioner within the child's first year of life. Extra appointments from health visitors are also offered 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 program, 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. The majority of mothers were on maternity leave when post-intervention data were collected, as 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 three time points: 1) baseline (T1) when the children were about 1.5 months old, 2) post-intervention (T2) after the intervention ended when children were about 5.5 months old, and 3) follow-up (T3) about one year after the intervention ended when the children were 18 months old. Baseline measures are described in more detail in the protocol for the trial (68), and parent-reported outcomes at post-intervention and follow-up are described in separate papers (69,70). While both mothers and fathers could complete the questionnaire, video data were only collected on mothers. Families received a DKK 200 (~EUR 27) 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 (52,53)	KPCS	√	√	
Sense of Coherence (54)	SOC13	√		
Major Depression Inventory (55)	MDI10	√	√	√
World Health Organisation Well-Being Index (56,57)	WHO5	√	√	√
Rosenberg Self-Esteem Scale (58)	RSS		√	
Parental Stress Scale (59)	PSS		√	√
Being a Mother (60)	BaM13			√
Parental Reflective Functioning Questionnaire (61)	PRFQ			√
Parenting Sense of Competence (62)	PSOC			√
<i>Background questions</i>		√	√	√
Single items on parent and child health, child temperament, parent life satisfaction, network, household budget		√	√	√
Child measures				
Ages and Stages Questionnaire - Social-Emotional (63,64)	ASQ:SE-2e	√	√	√
Cognitive Development Questionnaire (65)	CDQ			√
Strengths and Difficulties Questionnaire (66,67)	SDQ			√
Parent-Child measures				
Mother and Baby Interaction Scale (68)	MABISC		√	
Coding Interactive Behavior video (69)	CIB		√	

Mother-infant relationship

When the interviewer visited the family at T2, a 15-minute video was recorded. The mother was instructed to place her child on a mat on the floor and interact with the child as she normally would. The 15-minute video consisted of the following phases: six minutes of free play; four minutes during which the child is given a challenging toy; 30 seconds of separation; and three minutes of reunion. When reviewing the protocol (68), we decided to further refine the coding recommendations, as the coding systems originally suggested by the protocol proved to be less practically applicable in Denmark than the CIB system, which is comparable to the Emotional Availability Scales (EAS) system (75) or the Care Index system (76). Also the CIB system is preferred in other Danish studies.

The CIB system was developed by Ruth Feldman as a global rating of the quality of the parent-child relationship (77,78). The system is based on five-minute video-recorded 'free-play' interactions between parents and children. Certification to use the CIB system requires two days of training and a subsequent certification process. The CIB system contains 22 parent behavior codes, 16 child behavior codes, and five dyadic codes. The codes can be aggregated into the following composites: sensitivity, intrusiveness, limit setting, involvement, withdrawal, compliance, dyadic reciprocity, and dyadic negative

states. Each code is rated on a 5-point scale, with 1 indicating a minimal level of the specific behavior or attitude and 5 indicating a maximal level. The CIB system has been validated as an assessment measure in multiple studies of mother-child interactions in both normative and high-risk populations, and shows stability over time, predictive validity and adequate psychometric properties (40,79–82).

All infant-mother interactions were coded by the first author (MP) and the second author (TS), who were both blind to group allocation. Eighteen percent of the data was double coded for interrater reliability and showed an excellent interrater reliability of .94. For this analysis we coded 5 minutes of free-play from minute 1-6 of the recording, allowing parents and infants to become familiar with the situation. After coding the interaction, parent, child, and dyadic codes were summarized into the eight CIB composites and a total score. For this sample, internal consistency of the composites measured by Cronbach's alpha ranged from unacceptable to excellent: total score: $\alpha=.92$; sensitivity: $\alpha=.92$; intrusiveness: $\alpha=.53$; involvement: $\alpha=.71$; withdrawal: $\alpha=.26$; reciprocity: $\alpha=.84$; and negative states: $\alpha=.41$. The two subscales withdrawal and negative states only consist of two items, which can explain their low alpha values.

We collected demographic characteristics such as parent age, education, occupation, primary language

spoken in the home, number of children, household budget, substance abuse, birth weight, gestational age, child health, and whether parents cohabit or the mother lives alone. Parent-reported outcomes were collected at post-intervention and 1-year-follow-up and included: the 18-item Parenting Stress Scale measuring parenting stress and satisfaction (83,84), the 15-item Karitane Parenting Confidence Scale (KPCS) (85,86) the 10-item Major Depression Inventory (MDI10) (87), the 5-item World Health Organization (WHO)-5 Well-Being Index (88,89), the 10-item Rosenberg Self-esteem Scale (90) the 13-item Being a Mother Scale (BaM-13) (91), the 18-item Parental Reflective Functioning Questionnaire (PRFQ-1) (92), the 16-item Parenting Sense of Competence Scale (PSOC) (93), the 19-to-33-item Ages and Stages Questionnaire - Social-Emotional (ASQ-SE) (94,95), the 25-item Strengths and Difficulties Questionnaire (SDQ) (96,97), the Cognitive Development Questionnaire (CDQ) (98), and single items on parent health, parent life satisfaction, support, network, child health, child temperament, child height, and child weight. The analyses of the parent-reported outcomes at post-intervention and follow-up are reported in previous papers (69,70).

Statistical analyses

The treatment effect is measured in a linear regression framework with a proxy measure for the lagged dependent variable:

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

The model consists of an individual treatment dummy ($D_{i,treatment}$), the individual proxy measure for the baseline value 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. Since the analysis examines infant-mother interaction outcomes, we keep both twins in the sample. We used multiple regression analysis to perform intention-to-treat analyses for the outcomes, including controls for site and baseline score.

The infant-mother relationship outcomes from the CIB system are observed only at T2. Hence, we are unable to include a lagged dependent variable to control for baseline values. Instead, as in previous analyses (69,70), we use the baseline KPCS score as a proxy variable for CIB baseline measures, as the KPCS was the primary outcome.

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.

As described in the protocol (68), we examined heterogeneous effects by comparing the IYPB program to UC in the following subsamples: (1) mothers scoring within the lowest 50% of the KPCS distribution at baseline, and (2) mothers scoring within the highest 50% of the KPCS distribution at baseline. In the moderator analysis, we included an interaction term between a dummy for being in the group within the lowest 50% of the KPCS distribution at baseline, a dummy for intervention allocation, and a dummy for being in the group within the highest 50% of the KPCS distribution at baseline. Thus, the coefficient estimate on the interaction measures the differential effect between the two subsamples. Analyses were performed with Stata version 16.

Of the 112 mothers assessed at T1, eight were lost due to attrition at T2. Six mothers did not wish to be recorded and one video could not be coded because the mother was talking in a language that we could not understand. The total sample of videos at T2 is therefore 97. Attrition can lead to bias in the estimates, and therefore we have performed attrition analyses to examine the likelihood of data that are missing completely at random (MCAR). We performed a series of regressions of an attrition indicator on baseline measures of covariates and the treatment indicator. We found no difference in the likelihood of attrition between the treatment and control groups. The regressions on covariates found only two (out of 36) significant predictors of attrition at the 5% level, suggesting that data are missing at random.

We test for baseline differences between the treatment and control group using a regression of the covariate of interest, measured at baseline, on the treatment indicator. We use robust standard errors. These results revealed only minor differences between treatment and control families. In general, the results show insignificant differences between the treatment and control groups at baseline. The only statistically significant differences at a 5% level are found for depression (MDI), parental reports of a help network, and parent-assessed child health. We include these variables as controls in our main analysis.

Results

Figure 1 presents the flow diagram of participants in the trial with regard to video data. 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 the IYPB program and 36 to UC. The total number of videos analyzed is 97. Table 2 shows means and regression output for mother-infant relationship total score and subscales comparing IYPB mothers and UC mothers at T2. The comparison of IYPB mothers and UC mothers shows no significant difference between the groups for mother-infant relationship total score and subscale scores.

Because some of the measures were highly skewed in their distribution and thus make the assumption of normally distributed residuals questionable, we performed a sensitivity analysis by applying a non-parametric test (Wilcoxon rank-sum test) to the data. Results are consistent with the regression results

for mother-infant relationship total score and subscale scores. Because some of the measures were highly skewed in their distribution and thus make the assumption of significant difference in mother-infant relationship total or subscale scores between IYPB and UC mothers within the lowest- and highest-scoring mothers at baseline.

Sensitivity analyses

Sensitivity analyses included OLS regression without adjustment for baseline imbalances, OLS regression without a proxy for baseline values of CIB outcomes, OLS regression with an alternative proxy variable, and OLS regression without robust standard error. In addition, we report the standardized beta coefficients for comparison. Results are shown in Table 4. The regression estimates are relatively

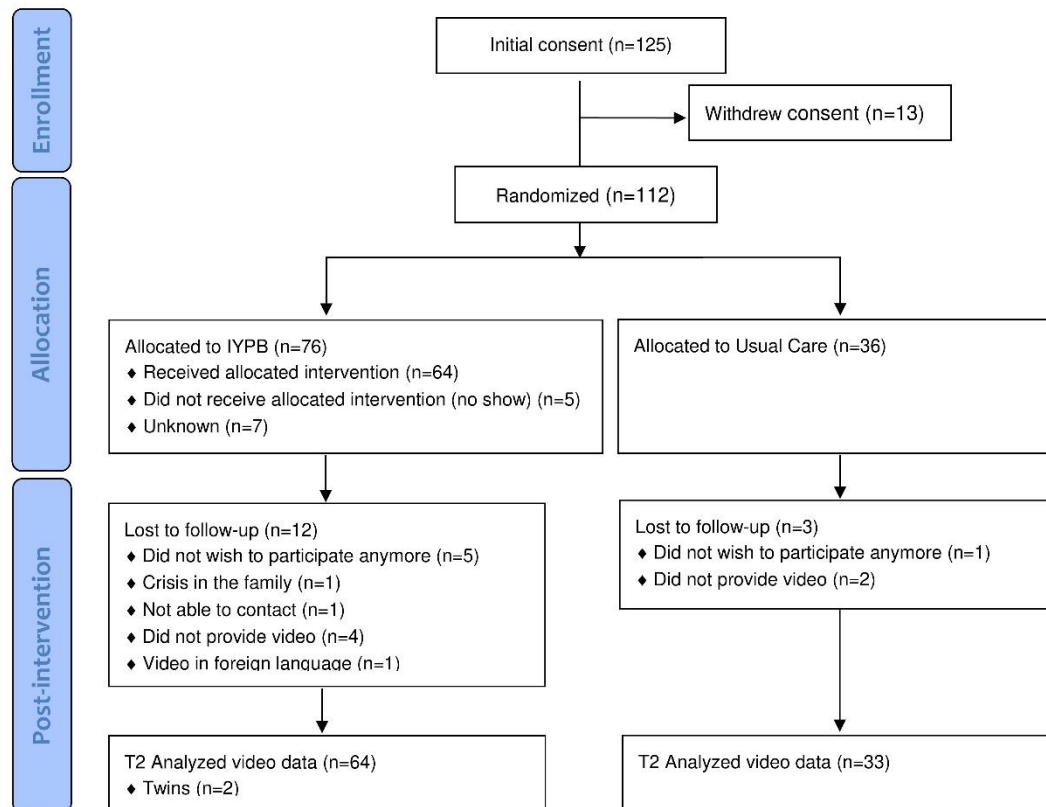


FIGURE 1. Trial flowchart

Differential effects

We divided the sample into halves to look for moderating effects. Table 3 shows regression outputs for CIB subscales for the following groups: mothers scoring within the lowest 50% at baseline (KPCS), and mothers scoring within the highest 50% at baseline (KPCS). The comparison shows no Table 2 shows means and regression output for mother-infant relationship total score and subscales comparing IYPB mothers and UC mothers at T2. The comparison of IYPB mothers and UC mothers shows no significant difference between the groups

similar across the analyses but, as expected, the confidence intervals change somewhat when applying the OLS regression without robust standard errors. Without the robust standard errors, the difference between intervention and control becomes statistically significant for parental sensitivity. The sensitivity analyses indicate that our results seem to be robust to model specification.

TABLE 2. Comparison of parent-child relationship outcomes for families who received IYPB program and families who received usual care (UC) at post-intervention (T2) with regression coefficients, 95% confidence intervals, and Cohen's d for multiple linear regressions controlling for site and baseline score

CIB Scales	IYPB		UC		β	<i>p</i>	95 % CI	<i>d</i> (adj.)	<i>d</i> (raw)
	Mean	SD	Mean	SD					
Parent Sensitivity	4.34	0.54	4.08	0.75	0.32	0.08	[-0.04-0.68]	0.52	0.43
Parent Intrusiveness [‡]	1.37	0.34	1.35	0.34	0.07	0.35	[-0.08-0.22]	0.21	0.06
Parent Limit-Setting	4.90	0.31	4.79	0.52	0.11	0.31	[-0.11-0.33]	0.28	0.28
Child Social Involvement	3.77	0.48	3.64	0.53	0.09	0.45	[-0.15-0.33]	0.18	0.27
Child Withdrawal [‡]	1.27	0.37	1.27	0.34	-0.02	0.79	[-0.19-0.14]	-0.06	0.00
Dyadic Reciprocity	4.41	0.61	4.17	0.71	0.27	0.11	[-0.06-0.59]	0.41	0.38
Dyadic Negative States [‡]	1.29	0.48	1.40	0.54	-0.14	0.29	[-0.41-0.12]	-0.29	-0.22
CIB Total	4.35	0.38	4.19	0.47	0.17	0.13	[-0.05-0.39]	0.41	0.39
<i>N</i>	64		33						

* $p < 0.05$, [‡]: low score is favorable

IYPB: Incredible Years Parents and Babies; UC: usual care; T2: Time 2 (post-intervention); CIB: Coding Interactive Behavior; SD: standard deviation; β : regression estimate; CI: 95% confidence interval of the regression estimate; *d* (adj.): the adjusted Cohen's d effect size; *d* (raw.): the raw Cohen's d effect size;

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

CIB Scales	KPCS < 50 % at T1			KPCS > 50 % at T1		
	β	<i>p</i>	95 % CI	β	<i>p</i>	95 % CI
Parent Sensitivity	0.12	0.65	[-0.39-0.63]	0.45	0.17	[-0.19-1.08]
Parent Intrusiveness [‡]	0.15	0.13	[-0.05-0.34]	-0.21	0.20	[-0.54-0.11]
Parent Limit-Setting	0.11	0.48	[-0.20-0.43]	0.01	0.97	[-0.39-0.40]
Child Social Involvement	-0.04	0.82	[-0.38-0.30]	0.28	0.24	[-0.19-0.75]
Child Withdrawal [‡]	0.07	0.55	[-0.17-0.32]	-0.21	0.20	[-0.53-0.11]
Dyadic Reciprocity	0.03	0.91	[-0.45-0.51]	0.53	0.10	[-0.11-1.16]
Dyadic Negative States [‡]	-0.02	0.90	[-0.41-0.36]	-0.29	0.24	[-0.77-0.19]
CIB Total	0.02	0.92	[-0.31-0.34]	0.35	0.09	[-0.06-0.75]
<i>N</i>	97			97		

* $p < 0.05$, [‡]: low score is favorable

T1: Time 1; β : regression estimate for interaction term; [‡]: low score is favorable; KPCS: Karitane Parenting Confidence Scale; CIB: Coding Interactive Behavior

Discussion

In this paper, to investigate the appropriateness of the IYPB program as a universal intervention for parents with infants aged 0-1 year, we examine the effects of the IYPB program on the mother-infant relationship at post-intervention when the infants are 5-6 months old. We did not find any statistically significant differences in the mother-infant relationship total or subscale scores for the IYPB group and the UC group. This finding is consistent with the analyses of the parent-reported outcomes at post-intervention (69) and one-year-follow-up (70) in which we also found no significant differences between the intervention and control groups.

However, whereas the effect sizes for the parent-reported outcomes were close to zero, several of the

mother-infant scores showed medium-sized effect sizes and *p* levels approaching significance. This is the case for the CIB total score ($d=0.41$, $p=0.13$); sensitivity ($d=0.52$, $p=0.08$); and reciprocity ($d=0.41$, $p=0.11$) – all favoring the IYPB group. It is therefore possible that these results would have become significant with a larger sample. Usually it can take some time for skills learned in sessions to become internalized. Finding medium-sized (non-significant) differences immediately after an eight-session program therefore indicates a substantial improvement. A systematic review of 88 studies based on sensitivity and attachment interventions found that the effect size for parental sensitivity was $d=0.33$ for randomized interventions (45), which is a much smaller effect size than we found in the present

TABLE 4. Sensitivity analyses comparing OLS regression without adjustment for baseline imbalance, without proxy for baseline CIB outcome, and with RSS as proxy for baseline CIB outcome.

CIB Scales	Without adjustment for baseline imbalance		Without proxy for baseline CIB outcome		With RSS as proxy for baseline CIB outcome		Without robust standard errors		Standardized regression estimates	
	β	95 % CI	β	95 % CI	β	95 % CI	β	95 % CI	β	95 % CI
Parent Sensitivity	0.26	[-0.05-0.56]	0.31	[-0.05-0.66]	0.32	[-0.03-0.67]	0.32*	[0.04-0.60]	0.24	[-0.03-0.52]
Parent Intrusiveness [‡]	0.02	[-0.13-0.17]	0.05	[-0.10-0.20]	0.04	[-0.10-0.19]	0.07	[-0.09-0.23]	0.10	[-0.11-0.31]
Parent Limit-Setting	0.12	[-0.08-0.31]	0.12	[-0.09-0.33]	0.13	[-0.08-0.34]	0.11	[-0.07-0.30]	0.13	[-0.13-0.40]
Child Social Involvement	0.11	[-0.11-0.32]	0.07	[-0.16-0.31]	0.09	[-0.14-0.32]	0.09	[-0.14-0.32]	0.09	[-0.14-0.31]
Child Withdrawal [‡]	0.02	[-0.14-0.18]	-0.00	[-0.17-0.16]	-0.00	[-0.17-0.16]	-0.02	[-0.19-0.15]	-0.03	[-0.25-0.19]
Dyadic Reciprocity	0.23	[-0.07-0.53]	0.25	[-0.07-0.57]	0.27	[-0.05-0.59]	0.27	[-0.03-0.56]	0.19	[-0.04-0.43]
Dyadic Negative States [‡]	-0.09	[-0.33-0.14]	-0.13	[-0.39-0.13]	-0.14	[-0.40-0.13]	-0.14	[-0.38-0.09]	-0.14	[-0.39-0.12]
CIB Total	0.15	[-0.05-0.34]	0.16	[-0.06-0.38]	0.17	[-0.04-0.39]	0.17	[-0.02-0.36]	0.20	[-0.06-0.45]
<i>N</i>	97		97		97		97		97	

* $p < 0.05$, [‡]: low score is favorable

β : regression estimate for interaction term, CI: 95% confidence interval of the regression estimate.

study, where the effect size for parental sensitivity was $d=.52$ (but insignificant, and slightly lower if based on the raw mean differences).

As a part of the sensitivity analyses, we ran the analyses without applying robust standard errors. For this analysis, parental sensitivity was significantly higher for the IYPB group compared to the UC group. This analysis also indicates that the IYPB program may have a positive effect on parental sensitivity. Based on a power calculation for normally distributed outcomes and using a two-sided alpha of 0.05, and a power of 80%, the sample sizes needed to detect effect sizes of .41 and .52 are 210 (140 intervention and 70 UC) and 130 (87 intervention and 43 UC), respectively. The three scales where we find medium effect sizes have the highest Cronbach's alpha (total score: $\alpha=.92$; sensitivity: $\alpha=.92$; reciprocity: $\alpha=.84$), indicating a high internal consistency of both the total score and the two composites.

Other studies of the IY baby and toddler programs find inconsistent results. In the non-randomized IYPB study from Wales with 80 participants, no differences were found for parent-reported outcomes (child development, parenting confidence, and parental mental well-being), but a significant positive effect was found on observed mother sensitivity, corresponding to a medium effect size of .58 (65). In this study, sensitivity was measured by the observational measure Parent Infant Play

Observation code (PIPOc), which was developed specifically for the IYPB program (99). However, in the larger E-SEE trial including 205 participants, no effect of IY infant and toddler was found for parent-reported outcomes and sensitivity, measured by the observational tool Care Index.

Parent-child relationship is not often measured as an outcome in trials of interventions such as the IY interventions that are based on social learning theory, as the primary focus of these interventions is usually behavior problems that are most often measured by parent-reported measures. An RCT from the UK examining the effects of an IY intervention on 4- to 6-year-olds behavior problems did, however, find that there was a positive impact on sensitive response of parent to the child, as rated by researchers blind to treatment status (100). Parent-child relationship is usually measured by independent observation methods such as the CIB system. Contrary to parent-reported outcomes, the direct observation provides an immediate and objective measure of the parent-child relationship, which can provide crucial information about individual parent and child behaviors, and about interactions between them. An observational measure can therefore capture behavioral and relational qualities of the interaction that are difficult to describe or quantify and observational measure are more objective than self-reporting measures (46,101). With the observational measure, the concept one wishes to assess is defined consistently and reliably by the researcher, rather

than by the parent who can be influenced by systematic biases related to, for example, mood, stress level or social desirability (46,102). Some studies find that observational measures can be particularly sensitive to changes and that they are better predictors of long-term outcomes than parent-reported measures (102). Whereas parents may provide excellent information about some areas of interest, this is not necessarily the case when parents are asked to assess their own parenting behaviors. Correlations between parent-reported and observational measures range between non-significant to low-to-moderate, and may be weaker for positive parenting items compared to negative parenting items (47,48). Also, studies find greater discrepancy between parent-reported and observational measures among parents that experience higher distress and among families from lower SES backgrounds (48).

Although we do not find any significant differences between the two groups in the moderator analyses, several of the estimates for the highest-functioning half of the sample are relatively high and close to significance compared to the lowest-functioning half, where the estimates are close to zero. This indicates that at both post-intervention and follow-up the highest-functioning half of the mothers seem to benefit more from the intervention than the lowest-functioning half, which corresponds with our previous analyses. It is possible that this positive effect for the highest-functioning mothers was found because of heterogeneity between the parent's functioning in our universal setup. For a group-based intervention, the equivalence of the therapeutic relationship is cohesion (103). In contrast to individual therapy cohesion within groups include relationships on different levels including participant-to-participant, participant-to-group, and participant-to-group leader. For the participant, cohesion includes their sense of belonging, acceptance, commitment, and allegiance to the group (103). An important therapeutic factor of group interventions is universality – that participants recognize that other participants share similar feelings, thoughts, and problems (103–105). If parents in a group have widely varying experiences of becoming a parent, these differences may reduce the level of cohesion within the group. For instance, a study found, that the lowest-functioning members of a group experienced negative effects if the other members of the group functioned at a much higher level (106). When parents of different function are mixed in a group, they may compare their skills and life circumstances, which may affect their feelings about themselves and their skills. Lower-functioning families may show more improvement if they attended a more homogenous IYPB group with

other families with similar needs and backgrounds. This would also enable the IYPB group leaders to focus on areas that are more relevant to specific groups.

When interpreting the results of this trial, it is important to take into consideration that the control group received the Danish health care system's usual care, which in itself is a relatively extensive intervention. 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. It is also possible that the relatively high level of education in Denmark makes it harder to benefit from the IYPB intervention as well-resourced families generally show higher levels of parental sensitivity (107). The E-SEE STEPS feasibility study which was conducted in the UK where the level of universal care is lower than in Denmark, did, however, also not find indications of an effect of IY on child social-emotional development or parent mental health (67). Due to budget constraints, the parent-child relationship was only measured at post-intervention and not at the one-year follow-up. Therefore, we cannot say whether these results are still present at the follow-up.

This is a pilot trial based on a relatively small sample size and the results should therefore be interpreted with prudence, especially since usual care is fairly comprehensive in Denmark. A recent Danish factor analysis of the CIB system including 93 parents of 5-year-old children did not show a good model fit with the original composites (81). We have not examined the factor structure in our sample, but Cronbach's Alpha values indicate a high internal consistency for both the total score and the two composites where we find medium effect sizes. 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. As interventions aimed at parents of infants are important, future research should investigate the effects of the program for disadvantaged families who show observable difficulties in caring for their infants.

Clinical significance

Although we do not find any significant differences between the IYPB group and the UC group, the analysis of the observational data suggests that there may be a positive moderate effect on maternal sensitivity, reciprocity, and the CIB total score. Our results also indicate, that the highest-functioning half of the mothers seem to benefit more from the intervention than the lowest-functioning half. Further investigation should be undertaken before using the IYPB intervention 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 therefore important to be aware of this in clinical practice.

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