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PhD Thesis

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The Effects of Universally Offered Parenting Interventions for Parents with Infants

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Preface

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List of papers

The thesis is based on the following five papers:

Paper 1 Pontoppidan, M., Klest, S.K., Patras, J., Rayce, S.B. The effects of universally offered parenting interventions for parents with infants: A systematic review and meta-analysis
Submitted to BMJ Open

Paper 2 Pontoppidan, M., Niss, N.K., Pejtersen, J.H., Julian, M., Væver, M.S. Parent report measures of infant social-emotional development: A systematic review
Submitted to Pediatrics

Paper 3 Pontoppidan, M., Andrade, S.B., Kristensen, I.H., Mortensen, E.L. Internal and external validity of the Danish version of the Karitane Parenting Confidence Scale (KPCS)

Paper 4 Pontoppidan, M. 2015: The effectiveness of the Incredible Years™ Parents and Babies Program as a universal prevention intervention for parents of infants in Denmark: Study protocol for a pilot randomized controlled trial. *Trials*, 16(1), 386

Paper 5 Pontoppidan, M., Klest, S.K., Sandoy, T.M. Short-term effects of the Incredible Years Parents and Babies Program as a universal prevention intervention for parents of infants in Denmark: A pilot randomized controlled trial

Contents

Summary

The importance of early experiences in children's long-term development is well established. Infancy is characterized by rapid growth and development, and early experiences shape the developing brain. Brain plasticity is high, and adverse experiences and stressors can have immediate and lifelong impacts on the infant's health and well-being. Substantial evidence has linked adverse experiences in childhood to conditions later in life, such as depression, mental health problems, substance abuse, teen pregnancy, violence, school dropout, delinquency, and long-term unemployment. Risk factors have a cumulative effect – the more adversity a child encounters, the greater the odds of developmental delays and negative outcomes later in life.

Becoming a parent can be challenging and stressful for both mothers and fathers. To develop self-regulation and adaptive capacities, infants need a responsive environment of nurturing, consistent, and protective interaction with adults. Supporting parents in providing sensitive and responsive care can improve function in the family, promote healthy child development, and prevent future problems. The availability of appropriate parenting interventions to families with infants is crucial, as early childhood interventions have been found to be effective. The aim of this project was to evaluate assessment measures of infant social-emotional development and parent confidence, and to examine the effects of universal interventions offered to parents with infants from birth to 12 months old.

Paper 1 examined the effects on child development and parent-child relationship of universal parenting interventions offered to parents with infants aged 0–12 months. The study was a systematic review and meta-analyses with the following inclusion criteria: 1) randomized controlled trials of structured, psychosocial interventions offered to a universal population of parents with infants aged 0–12 months in Western OECD countries; 2) interventions with a minimum of three sessions, at least half of which are delivered postnatally; and 3) reported program outcomes for child development or parent-child relationship. Fourteen papers representing seven studies were included. There were no statistically significant effects of the intervention for the majority of the primary outcomes across the studies. Meta-analysis revealed one significant positive effect and three insignificant effects for child development and parent-child relationship outcomes. We conclude that the findings of the review are mixed and that no clear conclusions can be drawn about

the effects of universally offered parenting interventions on child development and parent-child relationship for this age group.

Paper 2 evaluated parent-report measures of social-emotional development in young children. The study was a systematic review including parent-report measures of infant social-emotional development with data on validity and reliability. In all, 18 measures of infant social-emotional development were included. Ten of the measures were developed specifically for measuring social-emotional development, while eight were broader measures with subscales measuring social-emotional development. Although all 10 measures of infant social-emotional development show acceptable reliability, we conclude that the most comprehensive and psychometrically sound measures are the Ages and Stages Questionnaires: Social-Emotional – 2 (ASQ:SE-2), Brief Infant-Toddler Social and Emotional Assessment (BITSEA), Infant-Toddler Social and Emotional Assessment (ITSEA), and Child Behavior Checklist 1½–5 (CBCL).

Paper 3 evaluated the internal and external validity of the Karitane Parenting Confidence Scale (KPCS), and examined how scores change over time according to the risk status of the mother. The sample consisted of a community sample of 695 first-time mothers who were part of an intervention study in the Central Denmark Region. The sample was divided into at-risk and not-at-risk groups based on gestational age, mother age, education, and level of depression. We found acceptable internal consistency in the KPCS, but many items had high means and low variation, resulting in a ceiling effect. We found that at-risk mothers had significantly lower confidence at both two and six months compared to not-at-risk mothers, but that at-risk mothers improved significantly more than not-at-risk mothers over time.

Papers 4 and 5 examined the effects of the Incredible Years Parents and Babies (IYPB) program offered to a universal population, on parent confidence, parent well-being, child development, and parent-child relationship. The study was a pragmatic, two-arm, parallel external pilot randomized controlled trial (RCT) involving 112 families with newborns in two local authorities in Denmark. Families were randomized to the Incredible Years Parents and Babies program or usual care with a 2:1 allocation ratio. The primary outcome was parenting confidence, measured after 20 weeks by the Karitane Parenting Confidence Scale (KPCS) and Parental Stress Scale (PSS). Secondary outcomes include measures of parent mental health, reflective functioning, parent-child relationship, and child development. We conclude that it is possible to recruit families to an

effectiveness trial aimed at evaluating a universal intervention, and that the majority of parents in the intervention group participated in the intervention, although their satisfaction with the program was not high. Examining the effects of IYPB, we found that apart from one outcome – parent report of own network, in which the intervention mothers reported a significantly lower network post-intervention than the control mothers – there were no differences between IYPB and the UC group immediately after the intervention ended. When dividing the sample into the lowest and highest performing half at baseline, we found indications of negative effects on parent stress and mental health. Based on feedback from parents and group leaders, the IYPB program may need adjustment to fit the expectations and needs of a universal group of parents.

In conclusion, although some studies do identify positive effects, we do not find much support for universal interventions for parents with infants from birth to 12 months. We suggest applying a selected approach for areas with families with well-known challenges, more use of screening measures, and more effort to ensure that interventions are not only offered to, but also received by the families with the greatest needs.

Danish Summary

Betydningen af de første år af et barns liv i forhold til deres videre udvikling er veletableret. Det første leveår er karakteriseret af rivende vækst og udvikling, og barnets hjerne bliver formet af forholdene under opvæksten. Hjernen er plastisk og formbar i de første år, og uhensigtsmæssige forhold kan få både øjeblikkelige og livslange konsekvenser for barnets helbred og trivsel. Solid forskning har dokumenteret, at ugunstige forhold i de tidlige år kan medføre problemer senere i livet som fx depression, mentale helbredsproblemer, misbrug, uønskede graviditeter, vold, skolefrafald, kriminalitet og langtidsledighed. Risikofaktorerne er kumulative, det vil sige, at jo flere ugunstige forhold et barn oplever, jo større er risikoen for forsinket udvikling og negative følgevirkninger senere i livet.

At blive forælder kan være udfordrende og belastende for både mødre og fædre. For at et barn kan udvikle selv-regulering og adaptive funktioner har det brug for et miljø præget af omsorgsfuld, støttende og forudsigelig omgang med voksne. Støtter man forældre i at være følsomme og lydhøre, kan man forbedre trivslen i familien, forbedre barnets udvikling og forebygge senere problemer. Forskning viser, at passende forældreindsatser kan være effektive. Derfor er det vigtigt, at sådanne indsatser er tilgængelige for forældre. Formålet med dette projekt er dels at evaluere måling af små børns socio-emotionelle udvikling og tryghed i forældrerollen, dels at undersøge effekten af en universelt forebyggende indsats til forældre med børn fra 0 til 1 år. Afhandlingen består af fem artikler.

I den første artikel undersøges effekten af universelle indsatser (indsatser tilbudt til hele befolkningen uanset risikofaktorer og risikoadfærd) tilbudt til forældre til børn fra 0 til 1 år i forhold til barnets udvikling og forældre-barn relationen. Studiet er en systematisk forskningsoversigt og metaanalyse med følgende inklusionskriterier: 1) Randomiseret, kontrolleret studie af en struktureret, psykosocial indsats tilbudt universelt til forældre med børn i alderen 0 til 12 måneder i et vestligt OECD land. 2) Interventioner bestående af mindst tre sessioner, hvoraf mindst halvdelen skal foregå, efter at barnet er født. 3) Der skal være mål for enten barnets udvikling eller for forældre-barn relation. Fjorten artikler omfattende syv studier blev inkluderet. For hovedparten af effektmålene var der ingen statistisk signifikant effekt af indsatsen. Metaanalysen viste én signifikant positiv effekt, men ingen effekt for de resterende tre effektmål i forhold til barnets udvikling og forældre-barn relation. Vi konkluderer, at resultaterne er blandede, og at vi ikke kan

drage nogen sikre konklusioner om effekten af universelt tilbudte forældreindsatser i forhold til børns udvikling og forældre-barn relation for børn i denne alder.

I den anden artikel evalueres forældrerapporterede instrumenter til at måle små børns socio-emotionelle udvikling. Studiet er en systematisk forskningsoversigt, der inkluderer forældrerapporterede spørgeskemaer af små børns udvikling, hvor der er information om validitet og reliabilitet. I alt 18 spørgeskemaer blev inkluderet. Heraf var 10 specifikt udviklet til at måle socio-emotionel udvikling, og 8 var bredere instrumenter med en underskala, der måler socio-emotionel udvikling. Alle 10 spørgeskemaer, der måler små børns socio-emotionelle udvikling, har acceptabel reliabilitet, men vi konkluderer, at de mest omfattende og psykometrisk solide spørgeskemaer er Ages and Stages Questionnaires: Social-Emotional – 2 (ASQ:SE-2), Brief Infant-Toddler Social and Emotional Assessment (BITSEA), Infant-Toddler Social and Emotional Assessment (ITSEA) og Child Behavior Checklist 1½ – 5 (CBCL).

I den tredje artikel evaluerer vi intern og ekstern validitet af skalaen Tryghed i forældrerollen (the Karitane Parenting Confidence Scale – KPCS) og undersøger, hvordan scorer ændrer sig over tid afhængig af moderens risikostatus. Studiet består af 695 førstegangsmødre, der indgik i et interventionsstudie i Region Midtjylland, og som udfyldte et spøgeskema, da børnene var 2 og 6 måneder. Mødrene blev delt op i en risiko- og ikke-risikogruppe baseret på, om barnet var for tidligt født, moderens alder og uddannelsesniveau samt niveau af depressionssymptomer. Vi fandt, at intern konsistens for KPCS var acceptabel, men at mange items havde meget lav variation, hvilket var forbundet med en loftseffekt. Vi fandt desuden, at risikomødre havde signifikant lavere tryghed i forældrerollen end ikke-risikomødrene, både når barnet var 2 og 6 måneder gammelt, samt at risikomødrene forbedrede sig signifikant mere end ikke-risikomødrene over tid.

I den fjerde og femte artikel undersøges effekten af De Utrolige År baby programmet (DUÅ baby) (Incredible Years Parents and Babies – IYPB) tilbudt universelt til forældre og målt i forhold til tryghed i forældrerollen, forældretrivsel, barnets udvikling og forældre-barn relationen. Studiet er et pragmatisk, to-armet, randomiseret kontrolleret pilotforsøg omfattende 112 familier med nyfødte i to danske kommuner. Familierne blev randomiseret til DUÅ baby eller standard tilbud i et 2:1 forhold. Det primære effektmål var tryghed i forældrerollen efter 20 uger målt med KPCS og Parental Stress Scale (PSS). Sekundære effektmål omfattede forældres mentale helbred, forældre-barn relation og barnets udvikling. Vi konkluderede, at det var muligt at rekruttere forældre til et

pragmatisk randomiseret studie af en universel intervention, og at hovedparten af forældrene i interventionsgruppen deltog i programmet, selvom deres tilfredshed med programmet ikke var så stor. I forhold til effekter af DUÅ baby fandt vi, at bortset fra et enkelt spørgsmål (mødres vurdering af eget netværk), hvor mødrene i interventionsgruppen rapporterede signifikant mindre netværk end kontrolgruppen, fandt vi ikke nogen forskelle imellem DUÅ baby gruppen og kontrolgruppen, umiddelbart efter at indsatsen var slut. Når vi delte mødrene op i den bedst og dårligst scorende halvdel ved første måling, fandt vi indikationer på negativ effekt på forældrestress og mentalt helbred for de dårligst fungerende mødre. Baseret på feedback fra forældre og gruppeledere foreslår vi, at DUÅ baby programmet tilpasses, så det bedre matcher forventningerne og behovene fra en universel gruppe af forældre.

Overordnet konkluderer vi, at selvom nogle studier finder positive effekter, så er der ikke megen evidens for effekten af universelle interventioner til forældre med børn fra 0 til 12 måneder. Vi foreslår at undersøge en mere målrettet tilgang, hvor indsats tilbydes i områder, hvor man ved, at familier har udfordringer, at man i højere grad anvender validerede screeningsinstrumenter, samt at allokere flere ressourcer til at sikre, at familier med de største udfordringer får adgang til effektive indsatser.

Introduction

"A vital and productive society with a prosperous and sustainable future is built on a foundation of healthy child development" (Shonkoff et al., 2012, p. 242).

Professionals serving the needs of families and government policy-makers are faced with children with developmental challenges on one side and budget constraints on the other. They must decide how best to spend the limited funds available. It is in everyone's interest (policy-makers, professionals, taxpayers, and families) that the money is spent on interventions that are as cost-effective and helpful to families as possible. Interventions are usually provided on the basis of the belief that any kind of help will improve the situation of families in need, no matter what kind of intervention is provided (Macintyre & Petticrew, 2000; Oakley, 1998). Often, there has also been an understanding that because families face complex problems, then a long and costly intervention will be more helpful than a short one. We now know that not all interventions have positive effects; some have iatrogenic effects, meaning that the recipients of the intervention are worse off than if they had not received it. Prominent examples of interventions showing iatrogenic effects are documented in the Scared Straight study (Petrosino, Turpin-Petrosino, Hollis-Peel, & Lavenberg, 2013) and the Cambridge-Somerville study (McCord, 1978). We also know that some interventions work better than others (e.g. Furlong et al., 2013; Little, Berry, et al., 2012), and that brief, focused interventions can be as effective or more effective than long-term interventions (Bakermans-Kranenburg, van IJzendoorn, & Juffer, 2003; Fonagy, 1998; Shaw, Dishion, Supplee, Gardner, & Arnds, 2006). It is therefore important to evaluate the effects of the interventions offered to families.

The focus on early intervention for children and families was intensified by recent advances in the neurobiological, behavioral, and social sciences (Shonkoff & Phillips, 2000), which brought about a paradigm shift in which "nature dancing with nurture over time" (Shonkoff et al., 2012, p. 234) has replaced the "nature versus nurture" debate. This has led to the development of a new ecobiodevelopmental framework for early childhood programs and policies (Sameroff, 2010; Shonkoff et al., 2012). The early intervention field is also influenced by the work of economist and Nobel Prize-winner James Heckman. Using the Perry Preschool, the Abecedarian, and the Nurse Family Partnership program trials (Heckman, 2008), Heckman showed that high-quality intervention in early childhood for families in need has great potential to positively change later

health, economic, and social outcomes. In addition to family outcomes, he also demonstrated that investing in early childhood development can have great economic benefits for society (Conti & Heckman, 2014; Darling-Hammond et al., 2008; Doyle, Harmon, Heckman, & Tremblay, 2009; Elango, Heckman, & Garc, 2015; Heckman & Masterov, 2007a, 2007b; Heckman, n.d.; Knudsen, Heckman, Cameron, & Shonkoff, 2006a).

There is now general agreement within the research field that early life experiences are important and that early relationships are central to infant[1] development (Allen, 2011a, 2011b; Anda et al., 2006; Center on the Developing Child at Harvard University, 2010; Heim, Shugart, Craighead, & Nemeroff, 2010; IOM (Insitute of Medicine) and NRC (National Research Council), 2012). The next question is how best to support families to enhance children's development.

Objectives

In this project, I evaluate assessment measures of infant social-emotional development and parent confidence, and examine the effects of an early universal intervention offered to parents with infants from birth to 12 months old. The thesis consists of five papers, each with its own research question:

Paper 1: What are the effects of universal parenting interventions for families with infants, in terms of child development and parent-child relationship?

Paper 2: Which parent-report measures are available for measuring social-emotional development in young children?

Paper 3: What is the internal and external validity of the Karitane Parenting Confidence Scale (KPCS), and how do scores change over time according to the mother's risk status?

[1] Infancy is here defined from birth to 12 months old – except in Paper 2, where it covers birth to 24 months.

Papers 4 and 5: What are the effects on parent confidence, parent well-being, child development, and parent-child relationship of the Incredible Years Parents and Babies (IYPB) program offered to a universal population?

The overall aim of the project is to provide high-quality research of relevance to researchers, policy-makers, and professionals working with families on the assessment of infant social-emotional development and on the effects of universal interventions for parents with infants.

Background

The foundations of health

Adverse experiences occurring in infancy can have lifelong consequences for the child's physical and mental well-being (Anda et al., 2006; Center on the Developing Child at Harvard University, 2010; Davidson & McEwen, 2012; Heim et al., 2010; Kolb & Gibb, 2011; Shonkoff, 2011; Shonkoff et al., 2012). The foundations of health can be divided into three domains (Center on the Developing Child at Harvard University, 2010, p. 4): 1) a stable and responsive environment of relationships; 2) safe and supportive physical, chemical, and built environments; and 3) sound and appropriate nutrition. All three domains influence the infant's present and future life. The first domain is the focus of this project. Central to this domain is that, in order to enhance learning, self-regulation, and adaptive capacities to promote well-regulated stress response systems, infants need consistent, nurturing, and protective interactions with adults (Center on the Developing Child at Harvard University, 2010; Shonkoff et al., 2012).

Early onset of emotional or behavioral problems increases the risk of numerous adverse outcomes that persist into adolescence and adulthood, such as delinquency, violence, substance abuse, mental health problems, teen pregnancies, school dropout, and long-term unemployment (Barlow & Parsons, 2003; Center on the Developing Child at Harvard University, 2010; Conti & Heckman, 2014; Dishion et al., 2008; Heckman, 2008; IOM (Insitute of Medicine) and NRC (National Research Council), 2012; Piquero, Farrington, Welsh, Tremblay, & Jennings, 2008; Skovgaard et al., 2007, 2008; Zeanah Jr & Zeanah, 2009). The relationship is cumulative, meaning that greater numbers of stressful life events in early life can result in a greater likelihood of negative outcomes later in life (Anda et al., 2006; Anderson et al., 2003; Center on the Developing Child at Harvard University, 2010; IOM (Insitute of Medicine) and NRC (National Research Council), 2012).

The infant brain

Three weeks after conception, the embryo possesses a primitive brain. After 100 days, the brain looks distinctly human (Kolb & Whishaw, 2015). The brain is shaped by the interaction between genes and the environment. Although the brain continues to develop throughout life, plasticity is highest from the prenatal period to the first two to three years of life (Kolb, 2009). During this period, around 700 new neural connections are formed every second, with a great deal of the

developmental influences stemming from the infants' interactions with adults (Center on the Developing Child at Harvard University, 2009; Davidson & McEwen, 2012). Sensitive periods are windows of opportunity in which the neural circuits are most responsive to development. During the first years of life, these sensitive periods involve low-level circuits such as vision, hearing, language, and responses to social cues (National Scientific Council on the Developing Child, 2007). For these areas to develop properly, infants need basic sensory, social, and emotional experiences (Davidson & McEwen, 2012; Kolb & Gibb, 2011; National Scientific Council on the Developing Child, 2007; Shonkoff, 2011). Because plasticity is high in the early years, the fetal and infant brain is also very susceptible to stressors (Davidson & McEwen, 2012; Kolb & Gibb, 2011; Shonkoff, 2011).

Infant development

Infants are born in an immature state and remain dependent upon their parents for many years. To maintain their safety, they need to learn to identify, remember, and prefer their parents (Kolb & Gibb, 2011). Basically, infants need a responsive environment of nurturing, consistent, and protective interaction with adults. Infants experience their world as an environment of relationships, and form virtually all aspects of their development through this experience (National Scientific Council on the Developing Child, 2004b). In the first year of life, the social relationship of an infant is characterized by the following phases: 1) the first month, where the infant is attracted by voice, eyes and odor, and their relationship to others is mediated through touch and holding; 2) at two months, the infant responds socially through, for example, vocalization and smiling, and is able to sustain eye-contact, and use face-to-face interactions; 3) at four to five months, the infant starts reaching and grabbing, can focus on a topic, and play with objects and body games; 4) at nine to ten months, the infant communicates directly with others, and their interactions include joint, reciprocal play (Murray, 2014). Infants seek out contact with other humans, and parents respond to the developmental shifts that occur during the first year of life by altering their behavior accordingly (Murray, 2014).

Parenting

Having a child is a significant life transition that causes neurobiological and neurophysiological changes in parents' brains (Mayes, Rutherford, Suchman, & Close, 2012). In late pregnancy and the first postpartum months, hormones contribute to an increased focus on feelings and thoughts about the infant in the mother. When touching and having affectionate contact with infants, the levels of

the hormone oxytocin increase in both fathers and mothers (Murray, 2014). The transition to parenthood can be both a gratifying and an enlightening experience, but it is also the most taxing experience for young adults (Coleman & Karraker, 1998). Most parents describe the first year of having a child as stressful and overwhelming, but manageable (Cowan & Cowan, 1995; Nyström & Öhrling, 2004). In some studies, mothers report feelings of being satisfied and confident, but also strained and fatigued if they are primarily responsible for the infant (Nyström & Öhrling, 2004). Fathers report feeling confident as a father and a partner, but also feel strained and find it challenging to become emotionally close to the child at the same time as being the family's protector and provider (Nyström & Öhrling, 2004).

Common challenges experienced by mothers in the first months center around how to calm and comfort the infant, understanding the infant's needs, issues around feeding (Kronborg, Vaeth, & Kristensen, 2012), how to handle infant crying (which peaks around seven weeks after birth) (St James-Roberts, 2006), and issues around settling to sleep. Sleep problems are very common in the first months, and more severe sleeping disturbances affect about a quarter of all infants (Armstrong, Quinn, & Dadds, 1994; Kuhn & Weidinger, 2000; Murray, 2014). The majority of parents succeed in developing sufficient parenting skills to facilitate healthy child development, but a minority experience difficulties such as lack of persistence, inadequate parenting skills, a feeling of being burdened by the child, and finding little joy or reward in the parenting role (Coleman & Karraker, 1998).

Learning to self-regulate is a fundamental but challenging task for infants, which encompasses regulating and controlling behavior, and managing states and feelings (Murray, 2014). Most infants develop skills that enable them to regulate and self-soothe within the first year of life, but some infants persist with regulatory problems such as difficulties with feeding, sleeping, consoling and hyperarousal, which can be challenging for parents (Dale, O'Hara, Keen, & Porges, 2011). Research has suggested three parent patterns that can interfere with normal patterns of responsiveness: 1) the withdrawn pattern, where parents fail to respond to and notice the infant's cues, and stay withdrawn and self-absorbed; 2) the intrusive pattern, where parents who, for example, are depressed or in very adverse conditions, feel rejected by the infant turning away to regulate their state and intensively stimulate the infant or force them to re-engage; and 3) the anxious, over-protective pattern, where parents show high levels of worry and anxiety with regard to the infant, may be preoccupied with their own worries, and perceive the infant as very vulnerable

(Murray, 2014). All three patterns can make it difficult for the infant to develop appropriate self-regulation skills.

A healthy relationship between the primary caregiver and the infant is crucial for the latter's development and well-being (Fonagy, Gergely, & Jurist, 2004; IOM (Insitute of Medicine) and NRC (National Research Council), 2012; Levy, 2000; National Scientific Council on the Developing Child, 2004b; Schore & Schore, 2008; Thompson, 2008). The early relationship between a parent and infant plays a key role in the development of the infant brain (IOM (Insitute of Medicine) and NRC (National Research Council), 2012; Kolb & Gibb, 2011; Schore & Schore, 2008). The Incredible Years framework defines the following skills as necessary for parents: how to play with children; coaching of social, emotional, persistence, and academic skills; effective praise and use of incentives; predictable routines and rules; effective limit-setting; strategies to manage misbehavior; and teaching children how to self-regulate and problem-solve (Webster-Stratton & Reid, 2010b). Within the Circle of Security framework, a child needs the parent to: watch over me, delight in me, help me, enjoy with me, protect me, comfort me, delight in me, and organize my feelings. A central tenet is that parents should "Always be bigger, stronger, wiser and kind. Whenever possible, follow your child's need. Whenever necessary, take charge" (B. Powell, Cooper, Hoffman, & Marvin, 2009, pp. 451–452).

Parent-infant relationship

Research on the parent-infant relationship (i.e. attachment) was pioneered by John Bowlby (Bowlby, 1958), who claimed that forming attachment bonds is an evolutionary trait and that all healthy infants will form an attachment if there is a caregiver to interact with (Weinfield, Sroufe, Egeland, & Carlson, 2008). Bowlby's work was furthered by Mary Ainsworth, who developed the Strange Situation Procedure as a way of assessing the quality of the attachment between parents and their children. She defined the notion of maternal sensitivity as "the ability to accurately perceive and interpret the infant's attachment signals, and to respond to them promptly and adequately" (Ainsworth, 1979; Belsky & Fearon, 2008; van IJzendoorn, Juffer, & Duyvesteyn, 1995, p. 226). The core features of sensitive parenting include: awareness, responsiveness, cooperation, and acceptance (Murray, 2014). According to researchers in this field, the most important task during the first year of life for the infant and the primary caregiver is to develop a secure attachment (Levy, 2000; Schore & Schore, 2008).

The attachment bond between infant and parent is created in an ongoing reciprocal relationship, in which infants instinctively reach out to parents for safety and security, and in return parents nurture and protect their baby (Levy, 2000). The quality of the early attachment relationship influences the child's development of internal working models, and their ability to regulate behavior and adapt to changes. These skills make up the foundations of resilience and are critical to the development of the infant (Fonagy et al., 2004; National Scientific Council on the Developing Child, 2015; Thompson, 2008). In other words, for an infant, developing a secure attachment to a caregiver is an especially important starting point for their future life trajectory. Individual studies and systematic reviews suggest that parenting interventions can help ease the transition into parenthood, promote a healthy relationship between parent and infant, and enhance the development and well-being of both parent and infant (Barlow et al., 2011; Center on the Developing Child at Harvard University, 2010; Conti & Heckman, 2014; Cowan & Cowan, 1995; Darling-Hammond et al., 2008; Doyle et al., 2009; Furlong et al., 2013; Heckman & Masterov, 2007b; Knudsen, Heckman, Cameron, & Shonkoff, 2006b; Olds, Sadler, & Kitzman, 2007; Piquero et al., 2008; van IJzendoorn et al., 1995).

Intervention approaches

When offering parenting interventions to families, providers need to decide which intervention approach to use. Following the framework proposed by Gordon, parenting interventions can be either indicated, selective, or universal (Fonagy, 1998; Gordon, 1983).

Indicated approach

Indicated interventions are offered to families where the child is perceived to have a disorder or where there is a high risk of the child developing future psychopathology (Fonagy, 1998; Gordon, 1983; Offord, Kraemer, Kazdin, Jensen, & Harrington, 1998; Offord, 2000). Some advantages of the indicated approach are that the intervention is offered to the group with the highest needs, the intervention is more likely to be appropriate for the select group, and the potential for high levels of provider and subject motivation. The disadvantages are that screening procedures for identifying the indicated group are costly, compliance is low, families are subjected to labeling and stigmatization, and it is often difficult to accurately identify the high-risk group (Gordon, 1983; Hutchings, Griffith, Bywater, Williams, & Baker-Henningham, 2013; Offord et al., 1998; Offord, 2000; Rose, 2001). It can be difficult to correctly identify indicated groups because many high-risk families are able to cope well, while low-risk families can experience difficulties without ever being detected (Fonagy, 1998; Rose, 2001; Spoth, Kavanagh, & Dishion, 2002). Child behavior problems tend to

be normally distributed across the population, and many families experiencing problems would be overlooked by a targeted approach based solely on demographic risk factors (J. Patterson, Mockford, Barlow, Pyper, & Stewart-Brown, 2002).

Selective approach

Selective interventions are typically offered to families who belong to a distinguishable subgroup or live in environments that are known to be characterized by risk factors, such low-income neighborhoods with high crime rates (Fonagy, 1998; Gordon, 1983). The primary advantage of the selective approach is that the intervention is offered to a group that will potentially benefit from it, and it is relatively easy to select eligible participants. The disadvantage of the selective approach is that the families who agree to participate in the intervention may not be those in the greatest need (Hutchings et al., 2013).

Universal approach

Finally, universal interventions are offered to all families in a population, regardless of existing risk factors or identified problems, and therefore have the widest reach (Fonagy, 1998; Gordon, 1983; Offord et al., 1998; Offord, 2000). There are several advantages to universal interventions. For example, they can be offered to all families in a non-stigmatizing way, the quality of the intervention tends to be high due to middle-class participation, they can be a valuable tool for identifying families who need extra support, and may be an effective method of reducing the overall levels of child maltreatment and developmental problems within the general population (Barlow & Stewart-Brown, 2003; Barnes, 2003; Fonagy, 1998; Offord et al., 1998; Offord, 2000; Prinz & Sanders, 2007; Rose, 2001; Sanders, Cann, & Markie-Dadds, 2003). Applying universal interventions also has disadvantages: they are expensive, they might not appeal to the public and policy-makers, they may not be appropriate to either the low- or high-risk population, the individual benefits tend to be small, and it is difficult to demonstrate overall effects (Offord, 2000; Rose, 2001). Further, social inequality may be increased if low-risk families benefit the most from the interventions (Offord, 2000; Rose, 2001).

Ideally, interventions should only be offered to families who need them. However, although this sounds quite simple, correctly identifying who needs help is difficult. This phenomenon is described as Rose's prevention paradox: "A preventive measure which brings much benefit to the population offers little to each participating individual" (Rose, 2001, p. 432). Because the high-risk group is small, only a minority of cases will come from the high-risk population; the majority of

cases will come from the low- or moderate-risk population, which is a much larger group (Rose, 2001). An effective prevention strategy needs to incorporate all three intervention approaches (Offord, 2000; Rose, 2001). If we only offer intervention to the high-risk group, there will be large numbers of families with needs who do not get any intervention.

As the indicated approach is the one most commonly applied within family interventions, some researchers argue that the universal population-level approach is the most appropriate level of intervention, and that there is a need for this kind of intervention in order to provide the best framework for preventing child developmental problems (Barlow & Stewart-Brown, 2003; Fonagy, 1998; J. Patterson et al., 2002; Sanders et al., 2003).

The Incredible Years parenting programs

The Incredible Years (IY) Training Series was developed by Carolyn Webster-Stratton in 1980 and offers a range of programs for parents, teachers and children aged from birth to 12 years. The IY programs are used in more than 24 countries worldwide. Theoretically, the programs draw on social learning theory – in particular, the notions of modeling and self-efficacy described by Bandura (Bandura, 1971, 1977), and Patterson's coercion hypothesis of negative and positive reinforcement (G. R. Patterson, Dishion, & Bank, 1984).

The IY parenting programs aim to strengthen parenting competences and promote children's social, emotional and academic competences. The parenting programs are delivered in a group format and parents participate in 8–20 weekly group sessions of 2–3 hours, with two trained group leaders. Group sessions have a specific focus on nurturing relationships, reducing harsh discipline, strengthening parent-child interactions, and fostering parents' ability to promote children's social, emotional, and language development (Webster-Stratton & Reid, 2010a).

Incredible Years Parents and Babies

The IYPB program is one of the most recent additions to the IY training series. Its main aim is the promotion of positive attachment between infants and parents, in order to make the infants feel safe, loved, and secure. Through collaborative learning, parents are taught optimal strategies for enhancing the infants' social, emotional, and language development. The strategies used are predictable routines, setting clear limits, and distractions and redirections (White & Webster-Stratton, 2014). IYPB also focuses on strengthening infant safety and reducing harsh discipline.

Group leaders receive two days' training and use comprehensive manuals with suggested questions for group discussion, relevant vignettes, handouts for activities in the home, and session key points (White & Webster-Stratton, 2014). Ideally, parents are provided with a book specifically developed for IYPB participants (Webster-Stratton, 2011). IYPB is usually offered as a group intervention, but it can also be offered, partially or entirely, as a home-based version (White & Webster-Stratton, 2014).

The topics covered in the sessions are (White & Webster-Stratton, 2014, p. 33):

- Getting to know your baby (0–3 months)
- Babies as intelligent learners (3–6 months)
- Providing physical, tactile and visual stimulation
- Parents learning to read babies' minds
- Gaining support
- Babies' emerging sense of self (6–12 months)

To ensure fidelity of the IYPB intervention, group leaders are trained by accredited trainers and mentors, undergo a certification process, and receive ongoing supervision. Furthermore, checklists are completed after each session.

Effectiveness studies of the IY parenting programs

IY parenting interventions have been evaluated in several meta-analyses and RCTs, and have been found to be effective in relation to both parent and child outcomes (Axberg, Hansson, & Broberg, 2007; Baker-Henningham, Scott, Jones, & Walker, 2012; Bywater et al., 2009; Dishion et al., 2008; Furlong et al., 2013; Gardner, Burton, & Klimes, 2006; Gridley, Hutchings, & Baker-Henningham, 2015; Griffith, 2011; Hurlburt, Nguyen, Reid, Webster-Stratton, & Zhang, 2013; Hutchings et al., 2012, 2007; Little, Social, & Kingdom, 2012; Marcynyszyn, Maher, & Corwin, 2011; Menting, Orobio de Castro, & Matthys, 2013; Pidano & Allen, 2014; Presnall, Webster-Stratton, & Constantino, 2014; Scott, Briskman, & O'Connor, 2014; T. Trillingsgaard, Trillingsgaard, & Webster-Stratton, 2014). A recent meta-analysis of IY parenting programs for children from three to nine years old shows a mean effect size across informants of d=0.27 for child disruptive behavior (Menting et al., 2013). Parent report outcomes showed larger effect sizes for indicated approaches (treatment studies d=0.50) than selective approaches (indicated studies d=0.20, selective studies

d=0.13) (Menting et al., 2013). No studies were offered for a universal approach. Effects were larger for children with severe problems.

Another recent meta-analysis of mainly IY studies of children from three to 12 years old shows reduced levels of child conduct problems both from parent reports (standardized mean differences (SMD) = -0.44) and independent reports (SMD= -0.53), and reduced levels of negative or harsh parenting (SMD= -0.77) (Furlong et al., 2013). The intervention was also found to be cost-effective. The IY programs show consistent positive results on both child and parent outcomes for children three years old and older. The positive results are found in studies from many different countries, regardless of whether the developer was a part of the study or not (Menting et al., 2013; Pidano & Allen, 2014).

There is, however, less knowledge of the effects of the IY toddler and baby programs for children under three (Pidano & Allen, 2014). One trial of the IY Parent-Toddler program with parents and teachers in day care centers for low-income families found higher parent self-efficacy, more positive behaviors, less coercive discipline, but no effects on child behavior problems (Gross et al., 2003). Another more recent trial of toddlers at risk of or demonstrating behavior problems in rural and urban pediatric clinics found improvements in both parenting practices and child disruptive behaviors for the intervention group (Perrin, Sheldrick, McMenamy, Henson, & Carter, 2014). Furthermore, a third recent trial of parents of toddlers recruited through early intervention centers across Wales found positive effects on two outcomes (passive and encouraging language interaction), but no effects on the remaining three outcomes (quantity and variety of parental speech, parent-led or critical language) when examining the effects on parental language (Gridley et al., 2015).

IYPB for parents with infants from birth to one year old has been initially evaluated in two small samples in Wales, and a pilot RCT of IYPB and IY Toddler (the E-SEE trial) began recruiting in the UK in 2015 (Bywater & Teare, 2015). Ewans et al. (Ewans, Davies, Williams, & Hutchings, 2015) reported pre- and post-measures from 12 IYPB groups offered to families in disadvantaged Flying Start areas in Wales. The study found that parenting competence (*d*=0.61) and mental health (*d*=0.25) significantly improved over time. The study did not have a control group.

Jones et al. (C. H. Jones, Hutchings, Erjavec, & Hughes, 2012), in their evaluation of participants' reflections, found that most parents and group leaders were positive about the IYPB program. Parents appreciated the group format and felt that they had learned how to encourage infant development, manage coping strategies, and develop effective routines. The study also performed a cost evaluation. In a second paper, Jones et al. (C. H. Jones, Erjavec, Viktor, & Hutchings, n.d.) evaluated the effects of the IYPB group compared to a non-randomized waiting list group. The study included 54 intervention families and 26 comparison families living in a disadvantaged area of Wales. They found a positive effect on mother sensitivity for intervention mothers, but no effects on any other outcomes, including parenting confidence, mental well-being, and child development (C. H. Jones et al., n.d.).

Effect studies

Traditionally, intervention studies are subject to the evidence hierarchy shown in Figure 1. Randomized controlled trials (RCT) and systematic reviews, at the top, are the gold standard, because these methods are able to deal with selection bias, which is difficult to avoid in studies that utilize other designs (Shadish, Cook, & Campbell, 2002). To evaluate the effects of universal parenting interventions, we conducted both a systematic review and an RCT.

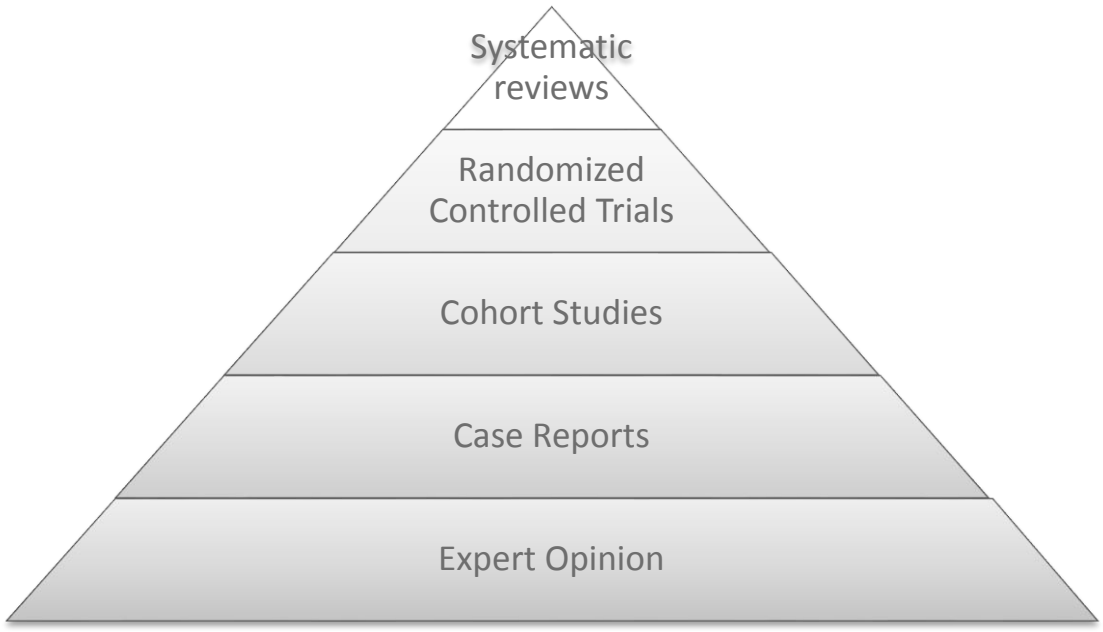

Figure 1 Evidence hierarchy

Systematic review of universal parenting interventions

The systematic review was carried out in collaboration with the SFI Campbell Center (especially Signe Boe Rayce and Rikke Eline Wendt) and conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (Liberati et al., 2009).

Originally, the plan was to produce a review that broadly synthesized the evidence on parenting interventions for parents with infants. We did not expect many RCTs within this field. However, while performing the pilot search, we became aware that there were many trials, with a large degree of heterogeneity between them. It would not be possible to include everything in one review. We still wanted to retain the possibility of evaluating different interventions, and therefore applied a broad search strategy. Studies that fulfilled the overall inclusion criteria were divided into the following population categories:

1. Mothers with depression
2. Young mothers (<20 years)
3. Preterm and low birth weight infants
4. Mothers not included in categories 1–3

The trials in category 4 were further subdivided into the following categories, based on recruitment strategy:

1. Universal recruitment
2. Selected or indicated recruitment

Many trials evaluate the effects of parenting interventions on parenting outcomes, anticipating that parenting outcomes mediate the ultimate effect – an improvement of the parent-child relationship or the development of the child. In order to narrow the focus of the reviews to the most important outcomes, we include only trials that assessed at least one measure of parent-child relationship or child development.

We include only RCTs in order to ensure high methodological quality and minimize the risk of potential confounding factors. While this rather strict inclusion criterion can be seen as a strength, only including RCTs might also be a limitation, as it may have made it more difficult to find comparable studies with respect to intervention approaches. There may be non-randomized studies

evaluating the effects of parenting interventions that could be relevant to this area of research, but the results from such studies would be subject to their own set of qualifying factors.

The review of universal parenting interventions is included as Paper 1 in this thesis. Systematic reviews of a) parenting interventions for mothers with depression, and b) selective and indicative parenting interventions for parents with infants are currently being prepared for submission in collaboration with Signe Boe Rayce, Sihu Klest, and Joshua Patras.

Paper 1 The effects of universally offered parenting interventions for parents with infants: A systematic review and meta-analysis

The objective of paper 1 was to review and conduct a meta-analysis of universally offered interventions for parents with infants aged 0–12 months. The review included randomized controlled trials of interventions that report outcomes for child development or parent-child relationship.

The literature search yielded 16,292 articles. We identified seven studies (14 papers) evaluating the effects of interventions for parents with infants on child development and parent-child relationship outcomes. The studies included a total of 2,870 participants, with individual studies ranging from 19 to 1,593 participants. The risk of bias was reasonable for all studies and revealed no major differences, although many studies reported insufficient information on which to judge some of the domains.

Participant characteristics

Three studies recruited only primiparous parents (Doherty, Erickson, & LaRossa, 2006; Feinberg & Kan, 2008; Vlismas, Malloch, & Burnham, 2012), while four recruited both primi- and multiparous parents (Aronen, 1993; Dickie & Gerber, 1980; Hiscock et al., 2008; Minkovitz et al., 2003). Two studies began in the second or third trimester (Doherty et al., 2006; Feinberg & Kan, 2008), three between birth and six months old (Aronen, 1993; Minkovitz et al., 2003; Vlismas et al., 2012), one when the infants were eight months old (Hiscock et al., 2008), and one when the infants were between four and 12 months old (Dickie & Gerber, 1980).

Table 1 Participant and intervention characteristics

Study	Country	Infant age	N	Intervention	Sessions	Format	Follow up at child age
Feinberg & Kan 2008 , Feinberg et al. 2009, 2010, Solmeyer et al. 2014	USA	22.9 weeks' gestation	152	Family Foundations (FF). Aimed at mothers and fathers.	8	Group	6.5 and 13.7 months
Hiscock et al. 2008 Bayer et al. 2010	Australia	Child age 8 months	733	Toddlers without tears. Aimed at mothers and fathers.	3	Group	8, 24, and 36 months
Doherty et al. 2006	USA	Second trimester	165	Parenting Together. Aimed at mothers and fathers.	8	Home visit and group	6, and 12 months
Vlismas et al. 2013	Australia	Child mean age 3.3 months	48	Face-to-face (F2F). Aimed at mother and child.	5	Group	3–7 months
Aronen 1993, Aronen & Kurkela 1996 , 1998, Aronen & Arajärvi 2000	Finland	Child age 6 months	160	Psychodynamic counselling. Aimed at mothers and fathers.	10 times a year for 5 years	Home visits	10–11, 14–15 and 20–21 years
Dickie & Gerber 1980	USA	Child mean age 8.05 months	19	Parent training. Aimed at mothers, fathers and infants.	16 hours over 8 weeks	Group	6–14 months
Minkowitz et al. 2007	USA	Child age 0–4 weeks	1,593	Healthy Steps for Young Children. Aimed at mothers and fathers.	Minimum 6 visits during 3 years	Home visits, individual sessions and groups	61–66 months

Interventions

In all studies included in this review, families randomized to the intervention group were offered a parenting intervention. Four of the interventions in the studies were group-based (Dickie & Gerber, 1980; Feinberg & Kan, 2008; Hiscock et al., 2008; Vlismas et al., 2012), one consisted of individual home visits (Aronen, 1993), and two interventions included both individual home visits and group sessions (Doherty et al., 2006; Minkovitz et al., 2003). Five interventions were relatively short (3–8 sessions) and lasted until the infants were between three and 15 months old (Dickie & Gerber, 1980; Doherty et al., 2006; Feinberg & Kan, 2008; Hiscock et al., 2008; Vlismas et al., 2012), whereas two interventions were relatively long (18–50 sessions) and lasted until the children were three to five years old (Aronen, 1993; Minkovitz et al., 2003). One study did not report on the background of the trainers (Dickie & Gerber, 1980); the others were carried out by professionals.

Control groups

In three studies (Hiscock et al., 2008; Minkovitz et al., 2003; Vlismas et al., 2012), the control groups did not receive any intervention, or were offered "services as usual"; minor interventions were offered in two studies (Aronen, 1993; Feinberg & Kan, 2008); one study used a waiting list control group (Dickie & Gerber, 1980); and one study did not describe the control condition (Doherty et al., 2006).

Outcomes

Five studies reported immediate post-intervention outcomes (Dickie & Gerber, 1980; Doherty et al., 2006; Feinberg & Kan, 2008; Hiscock et al., 2008; Vlismas et al., 2012), three studies reported short-term (up to six months post-intervention) follow-up outcome data (Doherty et al., 2006; Feinberg, Kan, & Goslin, 2009; Hiscock et al., 2008), and four studies reported long-term (more than six months post-intervention) follow-up outcome data (Aronen & Arajärvi, 2000; Aronen & Kurkela, 1996; Aronen, 1993; Bayer, Hiscock, Ukoumunne, Scalzo, & Wake, 2010; Feinberg, Jones, Kan, & Goslin, 2010; Solmeyer, Feinberg, Coffman, & Jones, 2014).

Four studies reported measures of child social-emotional development (Aronen, 1993; Feinberg & Kan, 2008; Hiscock et al., 2008; Minkovitz et al., 2003), including the Infant Behavior Questionnaire (IBQ), Head Start Competence Scale, Rutter Scale A, Parents' Evaluation of Developmental Status (PEDS), the Social Skills Rating System (SSRS), and several versions of the Achenbach System of Empirically Based Assessment (ASEBA): Child Behavior Checklist (CBCL), Youth Self Report (YSR), and Young Adult Self Report (YASR). Measures of parent-child relationship based on video-recorded observations are reported in three studies (Dickie & Gerber, 1980; Feinberg & Kan, 2008; Vlismas et al., 2012), and include the Parent Behavior Rating Scale and two scales developed specifically for the evaluation of the intervention. One study included a parent-report measure of parent-child relationship (Doherty et al., 2006): the Maternal Postnatal Attachment Scale.

Results and conclusion

Meta-analysis could only be conducted on four outcomes due to heterogeneity in the outcome measures and the timing of follow-up assessments. The results were inconclusive. For one of the four outcomes (father positivity), we found a statistically positive effect (0.30 [0.06; 0.54]), but we did not find any statistically significant effects on the remaining three outcomes (externalizing (0.10 [-0.01; 0.26]), internalizing (0.10 [-0.05; 0.25]), and father negativity (0.50 [-1.21; 1.75]).

The results for the individual studies were mixed. More than half of the outcomes did not show any significant differences between the intervention and control families. Three studies found one or more significant positive effects on child development or parent-child relationship for the intervention families, but one study also found a significant negative effect on parent-child

relationship. Four studies did not find any significant effects on either child development or parent-child relationship outcomes.

The studies varied according to intervention, methods, control conditions, outcome measures, and timing of follow-up assessments. This could contribute to the mixed findings. However, there was no apparent structure in the studies that could explain the different results. We conclude that there are mixed results of universal parenting interventions for families with infants aged 0–12 months. Based on the current studies, no clear conclusions can be drawn about the effects on child development and parent-child relationship.

Randomized controlled trial with a universal intervention

Background

The idea behind this project was born on September 9th 2010, when I attended a conference on the Incredible Years with Dr Carolyn Webster-Stratton. At the conference, she presented the latest addition to the program series – IYPB. At the following break I asked Dr Webster-Stratton if anyone was conducting impact studies of the program. She replied, "No, not yet. But it would be great to have." After the conference, I contacted the Danish IY mentors, local authorities, and the National Board of Social Services to find out if a trial would be feasible. Recruiting local authorities is challenging, as they are not used to the logic of a RCT and often find the idea of randomizing families unethical, even repulsive. Fortunately, some local authorities were interested in collaborating, and in 2012 I obtained funding for the project. Four-and-a-half years after the initial idea, we can now publish the first results from the trial. I was the project's principal investigator, and consulted with the head of department, supervisors, colleagues and my international research network during the process.

Trial design

Trial population

Initially, this project was designed to measure the effects of a targeted intervention aimed at disadvantaged parents. However, when collaborating with local authorities driven by policy-makers, things can often change in the time it takes to prepare and run an RCT. In this case, the IYPB program was offered to disadvantaged parents in the participating areas, and the sample size calculation was therefore based on this target group. Once everything was set up and we were ready to start recruiting parents, I had a meeting with the health visitors, instructing them in the practicalities of the trial. At this meeting, it emerged that a political decision had been taken to run the intervention as a universal offer to all first-time mothers, and that no groups for disadvantaged parents would be offered within the next two years. There was nothing we could do about this, as the decision had already been published in local newspapers. Shortly afterward, the other participating local authority also adopted this strategy – however, it decided to recruit all mothers, not just first-time mothers.

Sample size

The consequence of this change in population was that the expected effect size of the intervention was significantly reduced from a Cohen's *d* of about 0.5 to about 0.2. Whereas about 128 families are needed in a trial to detect an effect size of around 0.5, 800 are needed to detect an effect size of 0.2 with equal allocation, a two-sided alpha at 0.05 and power of 0.80. The policy-makers, of course, were not aware of this when they decided to change the target population.

Randomization ratio

Another issue was that the local authorities wished to offer the intervention to as many families as possible and needed enough parents in the intervention group to be able to start groups. From their perspective, a 1:1 allocation would have "thrown away" half of the families who might have been eligible to receive the intervention. A 2:1 randomization was therefore incorporated so that the intervention would be offered to the majority of families. Again, this slightly affected the power of the study. Based on the original effect size of 0.5, 144 families would be needed with a 2:1 randomization, while 900 would be needed for an effect size of 0.2.

Trial status

For a long time, a lot of effort was directed toward recruiting more local authorities in order to obtain a larger sample size. After some time, we realized that recruiting 900 families within the time limit of the PhD, and on a budget based on 128 families, would be impossible. After corresponding with the funding agency, the status of the trial was changed to a pilot study. One consequence of this change is that the effect results of the trial cannot be considered conclusive, due to the small size of the sample. Another consequence is that a closer focus on feasibility was adopted.

Recruitment

The two participating local authorities, Ikast-Brande (population 40,620) and Herning (population 47,765), border each other in central Jutland, about three hours' drive from Copenhagen. Consequently, we could not be present at both sites during the recruitment process. Each site had a senior level manager responsible for recruitment. During the project, I attended meetings with senior managers and health visitors who were in direct contact with the families. Leaflets with information about the trial were handed out to managers, recruiters and participants (parent leaflet in Appendix). As both health visitors and senior managers were new to RCT research projects, we created a short YouTube video about the trial, accessed via a direct link or a Quick Response (QR) code, for use by both recruiters and families. Apart from a couple of other trials at SFI that were

initiated around the same time as the IYPB trial, we are not aware of other trials that incorporated a YouTube video in the recruitment process. The YouTube video was accessed 88 times and is available at www.sfi.dk/godtrivsel.

Outcome assessment

Outcome measures are a crucial part of effect studies, as it is not possible to establish effect parameters without measures of, e.g. child development, parenting confidence, or marital satisfaction. The process of selecting outcome measures for a trial is therefore critical, but often underestimated. When selecting outcome measures for the IYPB trial, I quickly became aware that few measures of child development for children below the age of three existed, and even fewer had been translated into Danish. To access relevant measures for the trial, I first had to translate them. I took a period of three months' leave from the project, during which I was commissioned to evaluate measures of well-being of 0–3-year-olds for the Danish National Board of Social Services (Pontoppidan & Niss, 2014). Paper 2 was not originally a part of the project, but was added because of its relevance.

Measuring child development

The development of 0–3-year-old children is probably one of the hardest areas to measure. The main reason for this is that the first years of a child's life consist of rapid and dramatic changes across all domains of development. This means that there is vast variation in young children's development (Center on the Developing Child at Harvard University, 2010; Cohen, Ngozi, Clothier, & Poppe, 2005; Kolb, 2009) and that no two children develop in the same way (Carter, Briggs-Gowan, & Ornstein Davis, 2004; Center on the Developing Child at Harvard University, 2010). Further, cultural and family-value differences affect parents' perception of acceptable and unacceptable behavior in young children (Carter et al., 2004; Squires, Bricker, & Twombly, 2002).

Research has shown that infants and young children can suffer from psychopathological conditions (Briggs-Gowan, Carter, Bosson-Heenan, Guyer, & Horwitz, 2006; Carter et al., 2004; National Scientific Council on the Developing Child, 2012; Skovgaard et al., 2007; Wakschlag & Danis, 2009), and that this may cause serious lifelong problems (Center on the Developing Child at Harvard University, 2010; Dishion et al., 2008; Heckman, n.d., 2008; Rutter, Kim-Cohen, & Maughan, 2006; Zeanah Jr & Zeanah, 2009).

Psychopathology in young children is often found within the social-emotional domains (Briggs-Gowan et al., 2006) and these problems tend to be persistent over time (Briggs-Gowan et al., 2006; Wakschlag & Danis, 2009). Child social-emotional development is here defined as "a child's developing capacity to: (1) experience, manage and express the full range of positive and negative emotions; (2) develop close, satisfying relationships with other children and adults; and (3) actively explore their environment and learn" (American Academy of Pediatrics, n.d.; Cohen et al., 2005).

Social-emotional skills are the foundation for competences later in life, such as the ability to function in school and to build lasting relationships with friends and family. These skills are therefore central to an infant's development (Carter et al., 2004; Center on the Developing Child at Harvard University, 2010; Cohen et al., 2005; Curby, Brown, Bassett, & Denham, 2015; Denham, 2006; Feinberg et al., 2010; National Scientific Council on the Developing Child, 2004a; Whitcomb & Merrell, 2012; Zins, Bloodworth, Weissberg, & Walberg, 2007; Zuckerman, Lieberman, & Fox, 2002). If we embrace the concept of early intervention, then practitioners working with infants and young children in first-line services such as physicians' offices and health centers, as well as in second-line services such as child welfare centers and child psychiatric centers, must be able to reliably assess social-emotional skills in order to identify infants (and families) with developmental problems and impaired socio-emotional development, who may have special needs in terms of support and intervention (Carter et al., 2004; Carter, 2002; Curby et al., 2015; Denham, 2006; Macias & Saylor, 2004).

Parental concern is a good indicator of social-emotional developmental problems, but it is not in itself sufficient. Some parents are very worried about children with normal development, while a considerable number of young children have scores that ought to raise concerns, but the parents are not worried about the child's development (American Academy of Pediatrics. Council on Children With Disabilities, 2006; Briggs-Gowan et al., 2006; Briggs-Gowan & Carter, 2008). Parents may observe some behaviors (e.g. blunted emotions or overly friendly behavior) without recognizing them as problematic (Berger, Hopkins, Bae, Hella, & Strickland, 2010). To supplement parental concern, parent-report screening measures are often used in early child-care settings. The use of screening measures has been shown to significantly increase the detection rate for children with developmental delays (Hix-Small, Marks, Squires, & Nickel, 2007). The need for early screening is further highlighted by the fact that only about a third of children in need of services have been identified by the time they begin school (Earls & Hay, 2006). In line with this, the American

Academy of Pediatrics (AAP) recommends developmental screening at 9, 18, and 24 to 30 months (American Academy of Pediatrics. Council on Children With Disabilities, 2006).

The majority of pediatric clinicians agree that early detection of children with developmental problems is a priority, and many embrace parent-report measures in order to screen for delays (Tanner, Stein, Olson, Frintner, & Radecki, 2009). However, they also point out the challenges involved in selecting appropriate measures that can help direct resources toward the families in most need. For a measure to work in a practical setting in which many children need to be assessed, critical criteria must be fulfilled. The measure must be acceptable to the child, the family and the professionals; the measure must be easy to understand, administer, score, and interpret; the cost (e.g. equipment, staff time) must be relatively low; and the measure must have good psychometric properties, especially sensitivity and specificity (Macias & Saylor, 2004).

The quality of infant-assessment measures has greatly improved over the last decade (Carter, Godoy, Marakovitz, & Briggs-Gowan, 2012; Whitcomb & Merrell, 2012). Although they are still not 100% accurate (and probably never will be), they are still important in a clinical context (Berger et al., 2010). As a result of increasing awareness that infants can suffer from a range of psychiatric problems, clinicians need to be able to effectively screen infants and toddlers for social-emotional development problems, in order to direct early intervention to the right families. Furthermore, parent-report measures of infant social-emotional development are relevant because the development of social-emotional skills for an infant primarily occurs within the context of the infant-parent relationship (Berger et al., 2010). Therefore, there is a need for good-quality standardized parent-report measures of infant social-emotional development.

Paper 2: Parent-report measures of infant social-emotional development: A systematic review

The aim of Paper 2 was to conduct a systematic review, based on a systematic and comprehensive literature search of parent-report measures of socio-emotional development in infants aged 0–24 months, that can be used in first- and second-line child services.

Results and conclusion

The literature search yielded a total of 3,310 articles, of which 313 met the inclusion criteria. Full-text screening of the 313 articles resulted in a list of 242 unique measures of child development that

were screened for eligibility. A total of 18 measures met the inclusion criteria. The 18 included measures were divided into two groups:

1: Measures developed specifically for measuring social-emotional development (SED measures):

1. Ages and Stages Questionnaires: Social-Emotional – 2 (ASQ:SE-2) (Squires et al., 2002; Squires, Bricker, Twombly, et al., 2015)
2. Baby Pediatric Symptom Checklist (BPSC) (Sheldrick et al., 2013) and Preschool Pediatric Symptom Checklist (PPSC) (Sheldrick et al., 2012)
3. Brief Infant-Toddler Social and Emotional Assessment months (BITSEA) (Briggs-Gowan et al., 2013; Briggs-Gowan, Carter, Irwin, Wachtel, & Cicchetti, 2004; Karabekiroglu, Briggs-Gowan, Carter, Rodopman-Arman, & Akbas, 2010)
4. Child Behavior Checklist 1½–5 (CBCL) (Rescorla, 2005)
5. Devereux Early Childhood Assessment for Infants and Toddlers (DECA-I/T) (LeBuffe, Ross, Fleming, & Naglieri, 2013; G. Powell, Mackrain, & Lebuffe, 2007)
6. Early Childhood Screening Assessment (ECSA) (Gleason, Zeanah, & Dickstein, 2010)
7. Greenspan Social-Emotional Growth Chart (SEGC) (Bayley, 2006)
8. Infant-Toddler Social and Emotional Assessment (ITSEA) (Briggs-Gowan & Carter, 1998; Carter, Briggs-Gowan, Jones, & Little, 2003)
9. Merrill-Palmer-Revised Scales of Development (M-P-R) – Social-Emotional (Roid & Sampers, 2004)
10. Social-Emotional Assessment/Evaluation Measure (SEAM™) (Squires et al., 2013, 2014)

2: Measures that, while developed for measuring a broader construct, include at least one subscale measuring SED (SED subscale measures):

1. Adaptive Behavior Assessment System, 3rd Ed. (ABAS-3) (Harrison & Oakland, 2015)
2. Child Development Inventories (CDI) (Ireton, 1992)
3. Child Development Review (CDR-PQ) (Ireton, 1996)
4. Child Development Review – Infant Development Inventory (IDI) (Ireton, 1996)
5. Developmental Profile 3 (DP-3) (Alpern, 2007)
6. Communication and Symbolic Behavior Scales Developmental Profile – Infant-Toddler Checklist (CSBS-DP) (Eadie et al., 2010; Gaze, 2002)

7. Parents' Evaluation of Developmental Status (PEDS) (Brothers, Glascoe, & Robertshaw, 2008)
8. PedsQL Infant Scales – Pediatric Quality of Life Inventory (Varni et al., 2011)

Originally, the plan was to rate the measures based on psychometric data. However, a thorough evaluation was not possible, as there was less data on psychometric properties of the measures than expected. Furthermore, most of the psychometric data on the measures was sourced from manuals, not peer-reviewed journals – in other words, it had not been though any peer-review process. This does not necessarily diminish the quality of the data and the psychometric analyses, but makes it much harder to judge.

Based on the findings, we conclude that a range of measures is available for assessing the social-emotional development of infants aged 0–24 months. The focus on measuring the social-emotional development of young children is relatively recent, as the majority of the measures have been developed or thoroughly revised within the last decade. The measures vary in many dimensions, such as number of items, wording of items, number of subscales, cost, and psychometric data available. Consequently, measures should be available for catering to different needs in primary care settings. Most analyses applied classical test theory and factor analyses, whereas modern test theory (e.g. Item Response Theory) was applied much less often. We point out that, in order to ensure the quality of the measures, it is critical that more analyses of psychometric properties are published in peer-reviewed journals. Finally, we conclude that although all ten SED measures show acceptable reliability data, the most comprehensive and psychometrically sound measures are the ASQ:SE-2, ITSEA, BITSEA, and CBCL.

Trial outcome measure conceptualization

As previously mentioned, selecting measures is a critical and often underestimated aspect of running a trial – particularly in a case like this, where only a few measures were available in Danish at the beginning of the project.

Assessment mode

Interviewers collected data for the trial by visiting the parents at home. Using interviewers is expensive compared to collecting data online or using paper questionnaires, but leads to higher

response rates. Here, it was critical to minimize the levels of missing data as much as possible, and home visits were chosen as the best way to collect data.

Mothers completed the web-based questionnaire on a laptop brought by the interviewer. Fathers could, if they wished, complete the questionnaire simultaneously on a private computer. The interviewer completed the first demographic items (e.g. the child's name and date of birth, number and age of siblings, relationship to the child, education and work information), as education and work information in particular can be difficult to categorize correctly. The parents completed the rest of the questionnaire without interaction with the interviewer, unless they needed help. This ensured a degree of privacy for the parents, as some items related to sensitive subjects. The questionnaire was designed to take less than an hour to complete. The prioritized measures were those that had been used in other trials, that were relatively short, and that were easy to read and understand.

Translations

Because only a limited number of assessment measures were available in Danish when we initiated the trial, I had to translate a number of measures. All translations followed the World Health Organization's "Process of translation and adaptation of instruments." This method comprises the following steps: forward translation, expert panel, back-translation, pre-testing and cognitive interviewing, and final version.

IYPB aims

The main aims of the IYPB intervention are to promote a warm and nurturing parent-child relationship, and to enhance parent competences with a view to promoting babies' physical, emotional and language development (Webster-Stratton & Reid, 2010b).

Following conceptualization of the main aims of the IYPB program, we identified the following areas to be assessed in the trial:

1. Parenting self-efficacy
2. Child social-emotional development
3. Child cognitive development
4. Child health
5. Parent-child relationship
6. Parent mental health

Parental efficacy

Bandura developed self-efficacy theory in the 1970s, as a part of social cognitive theory (Bandura, 1977). Bandura defined self-efficacy as "people's beliefs about their capabilities to exercise control over their own level of functioning and over events that affect their lives" (Bandura, 1993, p. 118). Self-efficacy beliefs "influence how people feel, think, motivate themselves, and behave" (Bandura, 1993, p. 118) through four processes: cognitive, motivational, affective, and selection processes (Bandura, 1993). Bandura based his self-efficacy theory on the assumption that all psychological procedures "serve as means of creating and strengthening expectations of personal efficacy" (Bandura, 1977, p. 193). Self-efficacy is therefore a critical outcome for measuring the effects of a psychological intervention.

Parental efficacy (also called perceived parental efficacy or perceived parental self-efficacy) was developed on the foundation of Bandura's self-efficacy theory. In their concept analysis, de Montigny and Lacharite define perceived parental efficacy as "beliefs or judgements a parent holds of their capabilities to organize and execute a set of tasks related to parenting a child" (de Montigny & Lacharite, 2005, p. 390). They identified four different aspects that contributed to perceived parental efficacy, namely "positive enactive mastery experiences, vicarious experiences, verbal persuasion and an appropriate physiological and affective state"(de Montigny & Lacharite, 2005, p. 387). Jones and Prinz define parental self-efficacy as "the expectation caregivers hold about their ability to parent successfully" (T. L. Jones & Prinz, 2005, p. 342).

Especially after the birth of a first child, it is crucial that parents develop parental efficacy (de Montigny & Lacharite, 2005). Low levels of parental efficacy can be detrimental for the child's development, whereas high levels can act as a buffer in disadvantaged families (Coleman & Karraker, 1998; T. L. Jones & Prinz, 2005). Parental efficacy is central to parenting and can be changed through intervention (T. L. Jones & Prinz, 2005). Measures of parental efficacy are therefore essential when evaluating an intervention. We incorporated a number of measures in order to capture different dimensions of parental efficacy during the three assessments. By including areas such as parent confidence, stress, self-esteem, and satisfaction, we employ a broad understanding of the term parental efficacy.

Parent confidence

Parent confidence is measured by the Karitane Parenting Confidence Scale (KPCS) (Črnčec, Barnett, & Matthey, 2008a, 2008b). The KPCS is a 15-item measure rated on a four-point scale, and can be used with parents of infants aged 0–12 months. It is measured at T1 and T2, but not at T3, since the children are too old at this assessment. The KPCS at T2 (together with the PSS) is the primary outcome of the trial. Specifically for use in this project, the KPCS was translated in collaboration with Ingeborg Kristensen, and a validation study of this measure is reported in paper 3. The KPCS was also used in the two Welsh evaluations of IYPB (Ewans et al., 2015; C. H. Jones et al., n.d.).

Parent stress

Parent stress is measured by the Parental Stress Scale (PSS) (Berry & Jones, 1995), which can be used with parents of children up to 18 years old. It consists of 18 items, rated on a five-point scale. Cronbach's alpha is 0.83 (Berry & Jones, 1995). A Danish version of the PSS was translated in collaboration with Tine Nielsen prior to this project. The PSS is administered at T2 and T3, but not at T1, since many of the items are not ideal for parents of newborns. The PSS (together with the KPCS) is the primary outcome at T2 and T3. Choosing the PSS might be seen as a controversial choice, as the most commonly used measure of parent stress is without doubt the Parenting Stress Index (PSI) (Loyd & Abidin, 1985). The PSS was chosen for the following reasons: 1) it requires less reading skills; 2) it is shorter; 3) it has a high correlation (0.75) with the PSI; and 4) it is freely available.

Parent self-esteem

Parent self-esteem is measured by the Rosenberg Self-Esteem Scale (RSS) (Rosenberg, 1965), a measure of global self-worth in adults. The RSS consists of 10 items, rated on a four-point Likert scale. Cronbach's alpha is 0.81 (Schmitt & Allik, 2005).The RSS is administered at T1 and T2.

Parent satisfaction

Parent satisfaction is measured by the Being a Mother Scale (BaM-13) (Matthey, 2011). BaM-13 measures a woman's satisfaction and experience with motherhood. It is developed within the same framework as the KPCS, but can be used for parents with older children. BaM-13 consists of 13 items, rated on a four-point scale. Cronbach's alpha is 0.80 (Matthey, 2011). BaM-13 is administered at T3. It was translated specifically for this project in collaboration with Lene Hammer-Helmich.

Parent reflective functioning

Parent reflective functioning is measured by the Parental Reflective Functioning Questionnaire (PRFQ-1) (Luyten, Mayes, Nijssens, & Fonagy, n.d.). PRFQ-1 assesses three domains of reflective functioning or mentalization in parents of young infants and children: pre-mentalizing modes, certainty about mental states, and interest in and curiosity regarding mental states. PRFQ-1 consists of 39 items, scored on a seven-point Likert scale. Cronbach's alpha is 0.70 for pre-mentalizing, 0.82 for certainty, and 0.74 for interest and curiosity subscales (Luyten et al., n.d.). The 18 items that feed into the three subscales were used. PRFQ-1 was translated by Mette Skovgaard Væver and Johanne Smith-Nielsen. It is only administered at T3, as it was not available in Danish at the beginning of the trial.

Parent competence

Parent competence is measured by the Parenting Sense of Competence Scale (PSOC) (Johnston & Mash, 2010; Ohan, Leung, & Johnston, 2000). It measures how parents perceive their own competences as a parent, and consists of 16 items and two subscales: efficacy and satisfaction. The PSOC is rated on a six-point Likert scale. Cronbach's alpha is 0.75-0.79 (A. Trillingsgaard & Damm, 2012). Although the most recent Danish translation of the PSOC is relatively difficult to understand (especially item 1), we use the original form. The Danish version of PSOC was developed by A-M Lange and K.K. Frantzen, and is administered at T3.

Parent coherence

Parent coherence is measured by the 13-item version of the Sense of Coherence Scale (SOC13) (Antonovsky, 1993; Eriksson & Lindström, 2005; Feldt et al., 2007). SOC13 measures how people manage stress and stay well (Antonovsky, 1993). It consists of 13 items, scored on a five-point Likert scale. Cronbach's alpha is 0.70–0.92 for the 13-item version (Feldt et al., 2007). A Danish version developed by Tine Nielsen is administered at T1. As sense of coherence is not believed to change much over time, we use it at baseline only.

Child social-emotional development

As mentioned previously, social-emotional development includes the child's experience, management and expression of emotions, the ability to develop relationships, and to explore and learn. The following measures are used to assess child social-emotional development:

The Ages & Stages Questionnaires: Social-Emotional, Second Edition (ASQ:SE-2) (Squires, Bricker, & Twombly, 2015; Squires et al., 2002) measures social-emotional problems and competences in children aged one to 72 months. The specific domains assessed are self-regulation, compliance, social-communication, adaptive functioning, autonomy, affect, and interaction with people. The ASQ:SE-2 consists of 16 to 36 items rated by parents on a three-point scale, as well as a box parents may check if the particular behavior is a concern for them. As the second version was not published until 2015, we have used an experimental version for the second edition (Experimental version for 2e) that differs slightly from the final second version. Cronbach's alpha for the second version is 0.84 (Squires, Bricker, Twombly, et al., 2015). Although the second version has a version for one-month-old infants, this was not accessible in 2012. We used the six-month version, mindful of the fact that the infants were younger than was ideal – however, we wanted to establish a baseline measure for the ASQ:SE-2. The six-, 12- and 18-month experimental ASQ:SE-2 versions were translated specifically for this project in collaboration with Ingeborg Kristensen and Tea Trillingsgaard, and were administered at T1, T2, and T3. Updated translations according to the final ASQ:SE-2 are currently in process.

The Strengths and Difficulties Questionnaire (SDQ) (Goodman, 2001; Janssens & Deboutte, 2009; Niclasen et al., 2012; Obel et al., 2004) measures child behavior and psychopathology in children from two to 17 years old. The SDQ consists of 25 items, rated on a three-point scale. Cronbach's alpha for the total difficulties scale ranges is 0.75-0.88 (Niclasen et al., 2012). The 2014 revision of the Danish 2–4 version was administered at T3. After consulting with Carsten Obel, the SDQ was included even though the children are 18 months old, not 24 months (the recommended lower age limit). Because the target group for the intervention is a universal group of mothers, we believe that it is likely that their children will be able to obtain reasonable scores even though they are younger than recommended.

Child cognitive development

The IYPB program focuses on the importance of high brain plasticity, stimulation of the brain through mindful parenting, and urging parents to read and sing to the infant. Improvement of child cognitive development is a long-term goal of the program, and as such it was only measured at the follow-up assessment.

The Cognitive Development Questionnaire (CDQ) (Baker, Schafer, Alcock, & Bartlett, 2013) was used to measure child cognitive development. CDQ is a parent-report questionnaire designed to measure child cognitive development in 8–24-month-old children. The CDQ consists of two sections: section one has 19 scripted games for parents to play with their infant, while section two consists of 16 items asking about everyday behaviors. Items are rated by parents on a yes/no scale, supplemented with information regarding, e.g. how many blocks were used. Cronbach's alpha is 0.92 for the games section, and 0.84 for the questionnaire (Baker et al., 2013). The CDQ is constructed so that parents have approximately a week to carry out the tasks with the child. It was printed and sent via post to the parents about two weeks before the T3 interview, at which the interviewer collected the questionnaire. As yet, no data is available, but the interviewer reports that the families assessed at T3 reported no problems with completing the CDQ.

Child health

Single items assessing child health, temperament, height, and weight are administered at T1, T2, and T3. Child health and temperament are scored on an 11-point scale.

Parent-child relationship

Parent-child relationship is often assessed by observation (live or video), but can also be assessed by self-report questionnaires. Promoting the parent-child relationship is an essential part of the IYPB program, and therefore the trial includes both video assessment and a self-report measure.

Mother-child relationship: self-report

The Mother and Baby Interaction Scale (MABISC) (Hackney, Braithwaite, & Radcliff, 1996; Høivik, Burkeland, Linaker, & Berg-Nielsen, 2013) is a self-report measure of the mother-infant relationship. The MABISC consists of ten items, scored on a five-point Likert scale. Cronbach's alpha is 0.69 (Høivik et al., 2013). The MABISC is administered at T2. It was translated specifically for project, in collaboration with Nete Krogsgaard Niss.

Mother-child relationship: video

A 15-minute video aimed at assessing the mother-child relationship was administered at T2. 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 consists 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. I have not been trained to code these videos within the timeframe of this

project. The videos will be coded using the Coding Interactive Behavior (CIB) system (Feldman, 1998) and the results will be reported in a separate paper.

Parent-child interaction

Single items measuring parent-child interaction, e.g. singing songs, dancing, and telling stories, are administered at T2 and T3. Three single items are administered at T2. One item (*My child enjoys reading time*) is scored on an 11-point scale. The other two items (*How many days a week do you read a book for your child?* and *How many days a week do you sing with your child?*) are scored according to the number of days in a week on which the activity was performed.

At T3, parent-child interaction is measured by 14 items that are adapted from the evaluation of the Irish Preparing for Life program (PFL evaluation team, 2011) and scored on a six-point scale. The items assess how often the parent has engaged the child in activities such as peek-a-boo, singing, dancing, reading, playing outside, family visits, shopping, and organized activities.

Parent mental health

Mental health problems in parents, such as depression and anxiety, can have lifelong consequences for the infant's health (Center on the Developing Child at Harvard University, 2010). Postnatal depression is a relatively common disorder in mothers, with a prevalence of around 13% (Leahy-Warren & McCarthy, 2007; Maimburg & Væth, 2015; O'Hara & Swain, 1996), and can lead to a dysfunctional relationship between mother and infant (Milgrom, Ericksen, McCarthy, & Gemmill, 2006). It is therefore crucial to include measures of parent mental health.

Depression

The Major Depression Inventory (MDI10) (Olsen, Jensen, Noerholm, Martiny, & Bech, 2003) measures depressive symptoms present within the last 14 days in adults. The MDI10 consists of 10 items, scored on a six-point Likert scale. Cronbach's alpha is 0.90 (Olsen et al., 2003). The MDI10 is administered at T1, T2, and T3. The most common measure used to assess postnatal depression in mothers is the Edinburgh Postnatal Depression Scale (EPDS) (Cox & Holden, 2003). We opted for the MDI10 over the EPDS due to the former's close relationship to a clinical diagnosis of depression, and because depression is measured at three different time points. A measure of postnatal depression would be relevant for T1 and T2 but not for T3, when the child is 18 months old.

General well-being

The World Health Organization Well-Being Index (WHO-5) (Bech, 2004, 2011) measures current mental well-being in adults. The WHO-5 consists of five items, scored on a six-point Likert scale. Cronbach's alpha is 0.84 (Bech, 2004). The items are easy to read and positively framed. The WHO-5 is administered at T1, T2, and T3.

Single items on parent health, parent life satisfaction, support, and network are administered at T1, T2, and T3. Items are scored on an 11-point scale.

Background questions

A different number of background questions and socio-demographics are collected at T1, T2, and T3, including on parent age, education, occupation, ethnicity, number of children, household status, housing situation, household economy, substance abuse, child birth weight, child gestation at birth, and child health.

If further funding is obtained, data can be collected at later time points (such as 36 and 48 months) in order to identify long-term effects and dropout rates. It is also possible to follow participants via registers for key long-term outcomes such as school performance, education, income, hospitalization, diagnoses, prescription drug use, marriage status, and childbirths. Register data can be collected for all participants and compared to the full population if needed.

Table 2 lists of the timing of the assessment measures.

Table 2 Timing of assessment measures

Measure		T1 Baseline	T2 Post-test	T3 Follow-up
Parent measures				
Karitane Parenting Confidence Scale	KPCS	✓	✓	
Parental Stress Scale	PSS		✓	✓
Parenting Sense of Competence	PSOC			✓
Sense of Coherence	SOC13	✓		
Major Depression Inventory	MDI10	✓	✓	✓
World Health Organization Well-Being Index	WHO5	✓	✓	✓
Rosenberg Self-Esteem Scale	RSS	✓	✓	
Parental Reflective Functioning Questionnaire	PRFQ			✓
Socio-demographics: education, occupation, ethnicity, number of children, economy		✓	✓	✓
Single items on parent health, parent life satisfaction, support and network		✓	✓	✓
Parent-child measures				
Mother and Baby Interaction Scale	MABISC		✓	
Being a Mother	BaM-13			✓
Video			✓	
Single items on interactions with child			✓	✓
Child measures				
Ages and Stages Questionnaire: Social-Emotional, 2e	ASQ:SE-2e	✓	✓	✓
Strengths and Difficulties Questionnaire	SDQ			✓
Cognitive Development Questionnaire	CDQ			✓
Single items on child health and child temperament		✓	✓	✓

Paper 3: Internal and external validity of the Danish version of the Karitane Parenting Confidence Scale (KPCS)

One of the primary outcomes of the trial – the Karitane Parenting Confidence Scale (KPCS) – was translated during the process, and data for a validation study was collected. The objective of Paper 3 was to examine the internal and external validity of the Karitane Parenting Confidence Scale (KPCS) in a Danish community sample of first-time mothers, in order to investigate how scores change over time according to the mother's risk status.

The KPCS (Črnčec et al., 2008a, 2008b) measures parenting confidence for parents of infants aged 0–12 months. The KPCS consists of 15 items, rated on a four-point scale (*No, hardly ever; No, not very often; Yes, some of the time; Yes, most of the time*). Two items also include a *not applicable* response, e.g. if the parent has no partner. Cronbach's alpha is 0.83 and the four-week test-retest

reliability is 0.81. Each item is scored 0, 1, 2, or 3, and scores are summed to produce a total score. Item 12 is reverse-scored. Scores range from 0 to 45, with high scores being favorable. Clinical cut-off scores are: severe clinical range ≤31; moderate clinical range 31–35[2]; mild clinical range 36–39; and non-clinical range ≥40. An improvement of six points or more indicates a reliable change (Črnčec et al., 2008b).

Translation process

The KPCS was translated in collaboration with Ingeborg Kristensen (IK). Based on two independent translations by Maiken Pontoppidan (MP) and IK, a first draft was agreed upon and presented to an expert panel consisting of two experienced researchers with in-depth knowledge of assessment instruments and infant development. We consulted a professional translator because the words "confident" and "confidence", which are central to measuring parenting confidence, are difficult to translate meaningfully into Danish. The phrase "I am confident…" is present in five of the 15 questions, but it was not possible to find a Danish phrase that could replace "I am confident" in a meaningful way in all five questions. Hence, four different phrases are used in the Danish version.

Based on the input from the expert panel, MP and IK agreed on a second version, which was piloted on a small group of parents of infants. Small changes were made to the second version based on the feedback. The proposed title was changed, as one father commented that the title was aimed more at mothers than fathers. The final title in Danish is "Tryghed i forældrerollen" (Confidence in the Parenting Role).

The third version was piloted on a group of eight socially disadvantaged parents. No changes were made to the wording, as the only feedback received was that there might be a little overlap between some of the questions. Version three was back-translated by a native-speaking English researcher fluent in Danish. Small changes to version three were made based on the back-translation, leading to the final version. The English and Danish versions of the KPCS are presented in the Appendix.

[2] The value 31 is included in both severe and moderate clinical range. We defined severe clinical range as <31

Sample

The sample was collected through an intervention study including data from first-time mothers who answered questionnaires two and six months after birth. The study was conducted in a community setting with six municipalities in the Central Denmark Region. Between September 2013 and December 2014 all first-time mothers (1549) were invited to participate in this study. In all, 909 (68%) answered the baseline questionnaire and 856 (64%) answered the follow-up questionnaire. Only mothers with no missing items on the KPCS at both 2 and 6 month assessment were included in the present analyses, reducing the sample to 695 (76%) mothers. Of the 695 a total of 50 mothers received intervention. They were characterized as being vulnerable mothers based on a moderate preterm birth (gestational age ≥32<37), moderate symptoms of depression (Edinburgh Postnatal Depression Score (EPDS) ≥8<13), or low parenting confidence (KPCS < 40).

Sample 2 was divided into two subsamples: a not-at-risk and an at-risk sample, based on demographic baseline scores. Mothers were included in the at-risk sample if they fulfilled at least one of the following criteria: 1) young mother: age < 20; 2) low education: grade 9 or 10; 3) symptoms of depression: Edinburgh Postnatal Depression Score (EPDS) > 7; or 4) preterm birth: gestational age < 37 weeks. A total of 207 mothers (30%) fulfilled at least one of the inclusion criteria and were categorized as being at-risk.

Results and conclusion

Internal consistency was acceptable, with alphas ranging from 0.72 to 0.79. Item-rest correlations were low for five items and acceptable for the rest. The total KPCS mean score was 41.08 (SD 3.37, skew -1.34, kurtosis 2.37, range 25–45) at two months and 42.03 (SD 2.69, skew -1.52, kurtosis 3.42, range 27–45) at six months. We found that many items have means above 2.80 on a scale from 0–3, causing a ceiling effect on the total score. There was a correlation of 0.62 between total score at two and six months. For concurrent validity, we found correlations ranging from -0.64 to -0.65 between the KPCS and the Parental Stress Scale (PSS), and -0.60 to -0.61 for the KPCS and the Edinburgh Postnatal Depression Scale (EPDS).

There was a significant difference between not-at-risk and at-risk mothers at both two and six months. Both groups improved significantly over time, but at-risk mothers improved significantly more than not-at-risk mothers. We found a prevalence of moderate to severe levels of confidence in 3–6% of the mothers, and mild clinical levels in 11–20%.

Further analyses of the Karitane Parenting Confidence Scale (KPCS)

During the project, we collected KPCS data from another sample that is not included in Paper 3. This second sample primarily differs from the sample in Paper 3 in that it includes both first-time mothers and mothers with more children, and consists of mothers with infants of all ages between birth and 12 months.

Sample 2

Sample 2 is a community sample collected both through a website and by home visits: 1) An ad was placed on the website of a health-visitor organization frequently visited by parents of small children in Denmark (Sundhedsplejersken.dk). The site has around 60,000 hits every month and is widely used by Danish mothers; 2) As part of their routine home visits, health visitors employed by the local authority presented families with an information sheet on the study, which invited parents to complete a web survey. Health visitors visit 97–99% of all families five to six times within the first year of the infant's life (Foreningen for ledere af sundhedsordninger for børn og unge i Danmark, 2013; Sundhedsstyrelsen, 2011). In total, 160 health visitors from 16 different local authorities handed out the information sheet to families with infants aged 0–12 months. The 16 local authorities were mostly smaller ones, but are reasonably representative of the 98 municipalities in Denmark. All parents completed the exact same questionnaire, regardless of how they were recruited to the study. Sample 1 was collected between May and October 2013. At the end of the questionnaire, parents could enter their email address to participate in a prize draw (five gift vouchers for a baby equipment retailer, each worth around €40) and also to indicate willingness to complete a second questionnaire approximately four weeks later, for test-retest analysis. In all, 238 parents (76%) submitted their email address, and 88 parents (29% of the total sample) submitted responses to the second questionnaire.

Sample 2 consists of 315 mothers of infants from birth to one year old who completed all of the KPCS items. Both mothers and fathers were invited to complete the questionnaire, but as only 18 fathers responded, their responses were discarded. About half of the mothers were recruited through the website, the other half through home visits. Aside from age – the mothers recruited through the homepage were significantly older than those recruited through home visits (mean age 34.03 compared to 31.54) – there were no significant differences between the two groups. Sample 2 is relatively representative of mothers with infants from birth to 12 months in Denmark.

Measures

Parents filled out the Parental Stress Scale (PSS) (Berry & Jones, 1995) as in sample 1, but also the 13-item version of the Sense of Coherence (SOC) (Feldt et al., 2007).

SOC13 – Sense of Coherence (Eriksson & Lindström, 2005; Feldt et al., 2007)

SOC measures a person's sense of coherence or capacity to respond to stressful situations. Here, the 13-item scale with a five-point response format is used. High scores are favorable. Cronbach's alpha is 0.70–0.92 and test-retest 0.69–0.72 (Feldt et al., 2007). SOC is widely used and is considered a reliable, valid and cross-culturally applicable instrument (Eriksson & Lindström, 2005). Tine Nielsen developed the Danish version.

Results

Table 3 presents descriptive statistics for mothers and infants.

Table 3 Descriptive statistics

		Mean	**SD**
CHILD	Infant age (months)	5.84	3.66
MOTHER	Mother age (years)	31.68	4.67
		N	**%**
Smoking	Smoker	30	10
	Non-smoker	268	85
	No information	17	5
Alcohol consumption	>1 a week	13	4
	1 a week – 1 a month	77	24
	Never or <1 a month	208	66
	No information	17	5
Education	Short education (grade 9 or 10)		
	Long education (>grade 10)		
	No information		
Home ownership	Own home	216	69
	Rent home	71	23
	No information	28	9
CHILD			
Gender	Boy	145	46
	Girl	167	53
	No information	3	1

Gestational age	<37 weeks	18	6
	37–42 weeks	272	86
	>42 weeks	7	2
	No information	18	6
Birthweight	<2,500 grams	15	5
	2,500–4,200 grams	260	83
	>4,200 grams	22	7
	No information	18	6

Cronbach's alpha was 0.78 and item-rest values ranged from 0.23 to 0.52. For this sample, only items 1, 14, and 15 had low levels of item-rest correlations. The correlation coefficient between KPCS and PSS was -0.59, which is marginally lower than for sample 1. For KPCS and SOC13, the correlation coefficient was -0.24. The four-week test-retest correlation was 0.78, which is marginally lower than in the original sample (Črnčec et al., 2008a).

Table 4 Item-rest correlation, Cronbach's alpha and summary statistics for 9- and 15-item versions

	Item-rest correlation		15 item		9 item	
Item	15 item	9 item	Mean	SD	Mean	SD
1. Feeding baby	0.24	-	2.97	0.18	-	-
2. Settle baby	0.38	-	2.90	0.30	-	-
3. Establish good sleep routine	0.40	0.39	2.60	0.59	2.60	0.59
4. Know what to do when baby cries	0.50	0.47	2.77	0.43	2.77	0.43
5. Understand baby's signals	0.39	0.43	2.56	0.53	2.56	0.53
6. Soothe baby when distressed	0.46	0.43	2.86	0.35	2.86	0.35
7. Playing with baby	0.40	0.42	2.74	0.49	2.74	0.49
8. Handling cold or minor illness	0.35	0.35	2.60	0.60	2.60	0.60
9. Feel sure about support from partner	0.33	-	2.79	0.46	-	
10. Baby is doing well	0.45	0.38	2.93	0.26	2.93	0.26
11. Make decisions about care of baby	0.43	-	2.94	0.24	-	-
12. Being a mother/father is very stressful	0.31	0.28	1.89	0.81	1.89	0.81
13. Feel doing a good job as mother/father	0.52	0.49	2.82	0.39	2.82	0.39
14. Other people believe doing a good job	0.23	-	2.92	0.28	-	-
15. Feel sure about support from others	0.25	-	2.68	0.57	-	-
Total alpha	***0.78***	***0.74***	***40.97***	***3.24***	***23.78***	***2.53***

Total KPCS mean score was 40.97 (SD 3.24, skew -1.22, kurtosis 1.76, range 27–45), which is lower than for sample 1 at six months, but almost identical to the two-month data (although kurtosis is smaller in sample 2). Prevalence within sample 2 was that 6% showed moderate or severe clinical levels of confidence, 19% showed mild clinical levels, and 75% were within the non-clinical level. The proportion of mothers with clinical levels is higher than for sample 1 at six months, but identical to the levels at two months.

To examine how the KPCS total score varied over time in this sample, in which all mothers are only examined once, we divided the sample into three groups according to infant age: 1–4 months (n=148), 5–8 months (n=62), and 9–12 months (n=105). As families receive scheduled visits from the health visitor both in the first month of life and when infants are around eight months old, there are more mothers in these age groups. We expected that scores would increase over time, as we found in sample 1, which would be consistent with the research finding that the first months as a parent are particularly challenging (Armstrong et al., 1994; Coleman & Karraker, 1998; Cowan & Cowan, 1995; Kuhn & Weidinger, 2000; Matthey, 2011; Murray, 2014; Nyström & Öhrling, 2004; St James-Roberts & Halil, 1991). Surprisingly, we found no difference in the KPCS total score between mothers with infants aged 0–4 months (40.95, SD 3.47), 5–8 months (40.69, SD 2.86), and 9–12 months (41.17, SD 3.13). A linear regression with the KPCS total score as the dependent variable and infant age in months as the independent variable was also not significant ($\beta = -0.004$, $p=0.94$).

As the sample includes both first-time mothers (n=150, equal to 48%) and mothers with more children (n=165, equal to 52%), this may influence the results. Table 5 shows the means and standard deviations according to parity. For both primi- and multiparous mothers, KPCS means are the same for all ages (primiparous: $\beta = 0.03$, $p=0.68$; multiparous: $\beta = -0.04$, $p=0.52$). Distribution of the KPCS scores and regression line for primi- and multiparous mothers according to infant age are presented in Figure 2.

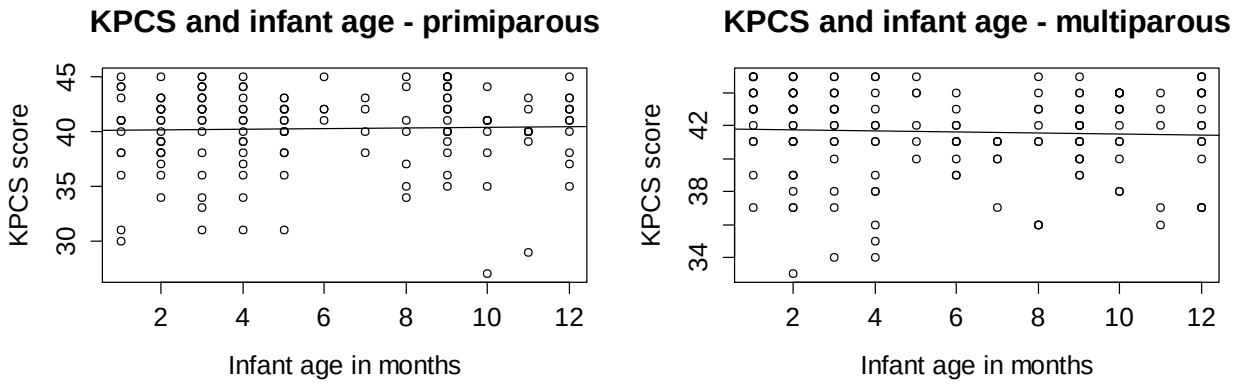

Figure 2 Distribution of KPCS scores according to infant age for primi- and multiparous mothers with regression line

Contrary to the findings from sample 1, for sample 2 there is no difference in total KPCS score according to infant age. Aside from the fact that sample 2 includes multiparous mothers, the main difference between the two samples is that in sample 1 everyone is the same age and is measured twice, whereas in sample 1 age varies from birth to 12 months and everyone is measured only once. It is possible that the change over time in sample 1 is a Hawthorne effect, i.e. it is observed because the participants are part of an intervention study and are assessed twice with the same measure. However, we also find no difference over time for the 88 mothers who were assessed twice in this study for test-retest reliability (mean = 40.98, SD = 3.49 at first assessment; mean = 40.94, SD = 3.35 at the second assessment, four weeks later).

Table 5 KPCS means and standard deviation according to infant age and parity

	0–4 months		*5–8 months*		*9–12 months*		*All*	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Primiparous	40.07	3.76	40.27	3.23	40.46	3.68	40.24	3.61
Multiparous	41.73	3.00	41.09	2.45	41.82	2.39	41.64	2.70

For the whole sample, and for 0–4 months and 9–12 months, the KPCS score is significantly higher for multiparous mothers compared to primiparous mothers. This finding is as expected, because multiparous mothers have more parenting experience (Matthey, 2011; Murray, 2014).

To sum up further analyses of the KPCS, we find that the psychometric properties are consistent with the findings from sample 1, and that multiparous mothers are significantly more confident than primiparous mothers. Contrary to the findings from Paper 3, for this sample with primi- and

multiparous mothers with infants from birth to 12 months, we find no change in confidence over time.

Paper 4 The effectiveness of the Incredible Years™ Parents and Babies Program as a universal prevention intervention for parents of infants in Denmark: Study protocol for a pilot randomized controlled trial

Paper 4 is the study protocol for the IYPB trial. It describes how the trial will be conducted and how the data will be analyzed. The paper describes the main aims of the trial, which are the same as those presented in Paper 5. Paper 4 does not include additional aims, apart from a detailed description of the different parts of the trial.

The paper concludes that the trial is the first RCT of IYPB, and one of the first rigorous evaluations of truly preventive interventions carried out in a universal community setting. IYPB is a relatively short group-based intervention that can be offered to all parents in a non-stigmatizing way. The trial will provide information regarding the feasibility of running a universal intervention in a community setting, including information on parent recruitment and participation in a trial using health visitors employed by the local authority, as well as information on experiences with implementing a universal prevention intervention. The trial will also provide initial information on the effects of IYPB as a universal intervention.

The paper has been accessed 1,058 times since its publication in August 2015 in the journal *Trials*.

Paper 5 Short-term effects of the Incredible Years Parents and Babies Program as a universal prevention intervention for parents of infants in Denmark: A pilot randomized controlled trial

The objectives of paper 5 were to estimate the effects of the IYPB program offered as a universal intervention in Denmark on parent and infant well-being, development and relationships, and to establish parameters for a future definitive trial. Its secondary aims were to provide information on the usability of parent and infant measures; to test recruitment procedures and determine rates of recruitment and consent; to investigate the implementation of and parents' acceptance of IYPB in a universal setting; and to provide information on the cost of offering IYPB as a universal preventive program.

Study design

The study was a pragmatic, two-arm, parallel external pilot randomized controlled trial (RCT) involving 112 families with newborns in two local authorities in Denmark. Families were randomized to IYPB (76) or UC (36) with a 2:1 allocation ratio. Interviewers assessed families at home visits at baseline (T1), after the intervention ended (T2), and when the child was 18 months old (T3 – data collection is ongoing). There were no differences in demographic variables at baseline. Intention-to-treat principles were applied, and data for the eight families that were assessed at T1 but dropped out prior to T2 assessment were imputed by multiple imputation.

Outcomes

The primary outcomes were parenting confidence measured after 20 weeks by the KPCS and parent stress by the PSS. Secondary outcomes include measures of parent mental health (WHO5, MDI), self-esteem (RSS), competence (PSOC), reflective functioning (PRFQ-1), parent-child relationship (BaM-13, MABISC), child development (ASQ:SE-2e, SDQ, CDQ), and single items measuring life satisfaction, support, network, loneliness, economy, and parent-child activities.

Participants

The sample consisted of 112 mothers mean age 29.25 (SD 0.46) with a mean of 1.38 (SD 0.07) children. Infants (55% boys) were 1.5 months old (SD 0.08) with a mean birthweight of 3,503 grams (SD 214). The majority of mothers worked before giving birth (74%), whereas 12% were studying and 14% were unemployed. A total of 10% of the mothers had a low education (grade 9), whereas 39% had a medium education (high school, vocational and secondary) and 51% had a high education (college, bachelor and PhD). Most mothers did not smoke (87%), drank alcohol once a month or never (74%) or between once a week and once a month (25%), and only one mother reported having a history of drug abuse (1%).

Results

When the sample is evaluated as a whole, all rating scale outcome measures except self-esteem (RSS) significantly improve between T1 and T2. The majority of single items do not change over time (confidants, loneliness, child health, parent health, overall life satisfaction). Two single items (mother report of family economy, network) decline significantly from T1 to T2, whereas mother report of child temperament improves significantly.

Table 6 Comparison of parent and child outcomes in IYPB and UC

	IYPB		UC				
	T1	T2	T1	T2			
	Mean	Mean	Mean	Mean	β	CI	*d*
KPCS	41.30	42.60	40.67	42.45	-0.08	[-0.81,0.65]	-0.02
PSS ¤	-	30.76	-	30.05	0.79	[-1.85,3.42]	0.05
MDI ¤	7.65	6.05	9.72	6.56	0.36	[-1.36,2.09]	0.03
WHO5	64.16	69.95	59.44	69.68	-1.48	[-6.55,3.60]	-0.04
RSS	25.35	25.93	23.86	25.19	-0.17	[-1.63,1.29]	-0.02
MABISC ¤	-	11.20	-	11.48	-0.23	[-1.39,0.94]	-0.03
ASQ:SE-2e ¤	47.17	25.73	50.25	25.16	1.33	[-4.98,7.64]	0.04
Child Height	56.99	70.39	57.09	70.42	0.01	[-1.31,1.34]	0.00
Child weight (kilo)	4.95	8.40	4.86	8.38	-0.01	[-.31,0.30]	-0.00
Single Items							
Loneliness	7.07	7.15	7.06	7.27	-0.15	[-1.04,0.75]	-0.03
Network	9.07	7.90	8.17	8.28	-1.07	**[-1.85,-0.28]**	-0.18
Confidants	9.61	9.74	9.06	9.51	0.19	[-0.20,0.57]	0.09
Overall health self-report	8.70	8.86	8.42	8.52	0.23	[-0.23,0.69]	0.09
Life satisfaction	9.16	9.13	9.06	8.95	0.15	[-0.20,0.50]	0.07
Economy	7.85	7.29	7.42	6.56	0.33	[-0.29,0.95]	0.07
Child temperament	8.87	9.25	8.56	9.29	-0.12	[-0.58,0.35]	-0.05
Child overall health	9.59	9.45	9.11	9.42	-0.04	[-0.46,0.38]	-0.02
Child enjoy to read	-	6.53	-	6.21	0.34	[-0.59,1.27]	0.07
Days reading	-	3.54	-	2.78	0.80	[-0.15,1.75]	0.15
Days singing	-	6.42	-	6.07	0.35	[-0.32,1.02]	0.11

IYPB: Incredible Years Parents and Babies; UC: Usual Care; T1: Time 1; T2: Time 2; β: regression estimate; CI: 95% confidence interval of regression estimate, **bold** is significant p<0.05; *d*: Cohen's d; ¤: low score is favorable

Table 6 shows means and regression output comparing IYPB mothers and UC mothers. At T2, we find that mother reports of access to a network that can help with practical issues is significantly lower for those in the IYPB group compared to UC (β=-1.07 [-1.85,-0.28], *d*=-0.18). For all other outcomes, there is no significant difference between the two groups.

Table 7 shows regression outputs for the following four groups: mothers scoring within the highest 25% and 50% at baseline and mothers scoring within the lowest 50% and 25% at baseline. No significant effects were found for the highest 25% and 50%. With the exception of KPCS and PSS for the 25% highest scoring and MDI for mothers in both groups, all outcomes favor the

intervention group. However, when examining the lowest performing 50% and 25%, we find that all outcomes favor the control group. For the lowest 50%, parent stress (PSS *d*=0.33) is significantly higher for IYPB mothers, and for the lowest 25% mental health (WHO5 *d*=-0.49) is significantly worse for IYPB mothers.

Table 7 Regression results for mothers divided into groups based on baseline (T1) score

	<25 at T1		**<50 at T1**		**>50 at T1**		**>75 at T1**	
	β	95% CI	β	95% CI	β	95% CI	β	95% CI
KPCS	-1.91	[-4.71,0.90]	-0.17	[-1.74,1.40]	0.22	[-0.55,0.98]	-0.39	[-2.02,1.24]
PSS ¤ ±	7.84	[-1.14,16.83]	4.68	**[0.76,8.61]**	-0.80	[-3.99,2.40]	1.18	[-5.15,7.52]
MDI ¤	1.70	[-3.22,6.62]	0.04	[-3.74,3.82]	0.10	[-1.86,2.05]	1.02	[-5.05,7.09]
WHO	-16.55	**[-31.59,-1.51]**	-4.13	[-12.69,4.44]	0.75	[-5.81,7.31]	3.69	[-7.06,14.43]
RSS	-0.43	[-4.25,3.38]	-0.59	[-3.06,1.89]	0.75	[-0.97,2.47]	0.99	[-1.52,3.49]
MABISC ¤ ±	1.99	[-0.83,4.81]	0.53	[-1.53,2.58]	-0.18	[-1.64,1.29]	-1.27	[-4.25,1.72]
ASQ:SE2e ¤	2.16	[-14.38,18.70]	6.77	[-2.13,15.66]	-2.67	[-11.61,6.26]	-2.12	[-12.73,8.50]

T1: Time 1; β: regression estimate; CI: 95% confidence interval of regression estimate, **bold** is significant p<0.05; ¤: low score is favorable; ±: KPCS score at baseline used for group.

Ikast Brande Council reported that the cost per family of IYPB was approximately DKK 7,000 (~EUR740) for groups consisting of eight families.

Conclusion

We conclude that it is feasible to recruit families to an effectiveness trial for the purpose of evaluating a universal parenting intervention. The majority of the parents in the intervention group participated in the intervention, although satisfaction with the program was not very high. For IYPB, we found that intervention mothers reported a significantly lower network post-intervention than control mothers. As this is one outcome out of 20 tested, this may be a spurious effect. We found no differences between the IYPB and the UC group on any other outcomes post-intervention. When dividing the sample into the highest and lowest performing halves at baseline, we found indications of intervention mothers reporting higher levels of parent stress and worse mental health than control mothers. Based on group leader and parent feedback, the IYPB program might need adjustment to fit the needs and expectations of a universal parent group.

Discussion

Main results

In this project, I evaluate assessment measures of infant social-emotional development and parent confidence and examine the effects of universal interventions offered to parents with infants aged 0–12 months. The specific objectives were to:

- evaluate parent-report measures of social-emotional development in young children
- evaluate the internal and external validity of the Karitane Parenting Confidence Scale (KPCS) and how scores change over time according to the mother's risk status
- examine the effects of universal parenting interventions for families with infants in the areas of child development and parent-child relationship
- examine the effects on parent confidence, parent well-being, child development, and parent-child relationship of the Incredible Years Parents and Babies (IYPB) program in a universal population.

We identified ten measures of infant social-emotional development and conclude that the most comprehensive and psychometrically sound are the Ages and Stages Questionnaires: Social-Emotional – 2 (ASQ:SE-2), Infant-Toddler Social and Emotional Assessment (ITSEA), Brief Infant-Toddler Social and Emotional Assessment (BITSEA), and Child Behavior Checklist 1½–5 (CBCL).

We conclude that internal consistency of the KPCS was acceptable, but that many items have high means and low variation, resulting in a ceiling effect. We found that at-risk mothers had significantly lower confidence at both two and six months compared to not-at-risk mothers, but that over time, at-risk mothers improved significantly more than not-at-risk mothers.

For the systematic review, we conclude that the results are mixed and inconclusive for child development or parent-child relationship outcomes. Meta-analysis revealed one significant positive effect on father positivity, but no difference on the remaining three outcomes (externalizing, internalizing, and father negativity). For the individual study outcomes, more than half did not show any significant differences between the intervention and control families. Out of seven studies, three

found one or more significant positive effects on child development or parent-child relationship, one also found a significant negative effect on parent-child relationship, and four did not find any significant effects.

For the RCT of IYPB as a universal intervention, we conclude that there was no difference between the IYPB and the UC group immediately post-intervention. Furthermore, there were indications of negative effects among the mothers with the lowest scores at baseline.

Effectiveness of universal parenting interventions

The results of the systematic review of universal parenting interventions and the RCT of IYPB are mixed, but provide little support for universal interventions within this age group. Although there are studies that show positive effects on child development and parent-child relationship outcomes, the majority of the results indicate no differences between intervention and control. Some of the different factors that I will discuss in this section may contribute to this result.

Although the overall picture of our results indicates no effect of the universal interventions, we did find some studies with positive results in the systematic review (Paper 1). The interventions with positive results were Family Foundations (Feinberg et al., 2010, 2009; Feinberg & Kan, 2008), Parenting Together (Doherty et al., 2006), and psychodynamic counseling (Aronen & Arajärvi, 2000; Aronen & Kurkela, 1996). All three interventions showed effects on some outcomes, but far from all. Unfortunately, we did not find any systematic differences between the interventions with no effects and the ones with positive effects on, e.g. method, control conditions, outcome measures, or the timing of measures. As such, we are not able to make any conclusions on that basis. However, these results do highlight that it may be possible to achieve positive effects through a universal intervention approach.

Socio-economic status

It is often the case that families participating in research have higher social economic status (e.g. a higher level of education) than the general population. Generally, these families have fewer problems with parenting and are expected to do well without intervention. As their baseline problem scores tend to be low and general life satisfaction is high, it may not be surprising that these families do not derive extra benefit from intervention. As was pointed out in the background chapter, some of the disadvantages of universal interventions are that overall effects are difficult to

demonstrate and that individual benefits tend to be small (Offord, 2000; Rose, 2001). When programs reach the stage of being offered as universal interventions, their elements tend to be already widely disseminated and applied by the general population, which makes it hard to evaluate the impact of any intervention (Offord, 2000). Furthermore, when offering the same intervention to families with different social economic status, there is a risk that because the intervention must be relevant to all participants, it ends up fitting no-one and does not adequately address the challenges that face either high- or low-risk families (Offord et al., 1998).

The psychodynamic counseling study by Aronen and colleagues was the only study that took social economic status at baseline into account and stratified randomization within low- and high-risk groups. As reported in Paper 1, the study found significant positive effects of the intervention on mental health and behavior outcomes at 10 and 15 years' follow-up. When taking the initial risk status into account, they also find significant interaction between initial risk status and psychiatric symptoms – the children in the high-risk group improved significantly more than the low-risk group even though their scores were still worse than the low-risk group at the time of follow-up (Aronen & Arajärvi, 2000; Aronen & Kurkela, 1996).

Ceiling or floor effects

Many measures of child development and functioning are developed to identify and diagnose pathology after symptoms arise. These symptoms are very rare in the general population, and therefore such measures are not ideally suited to the general population (Adler-Tapia, 2012). Ceiling or floor effects are also common in measures of parenting confidence (Črnčec, Barnett, & Matthey, 2010), quality of life (Fayers & Machin, 2016), depression (Evans, Heron, Francomb, Oke, & Golding, 2001), and mental health (Bech, Olsen, Kjoller, & Rasmussen, 2003). In the IYPB trial, we find ceiling effects on the measures of parent confidence (KPCS Figure 3) and self-esteem (RSS), and a floor effect on depression (MDI-10 Figure 4).

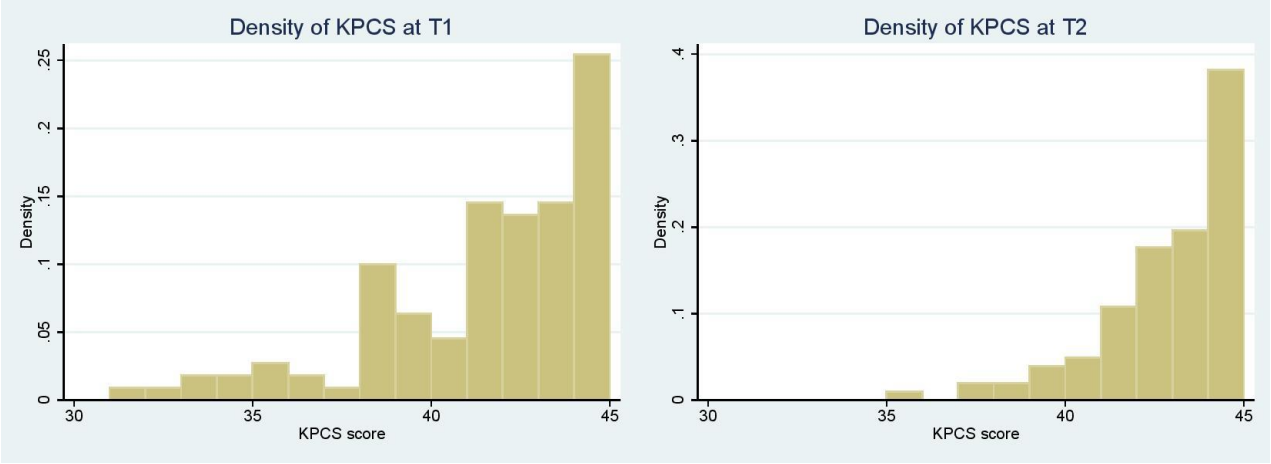

Figure 3 Histogram of KPCS scores at T1 and T2

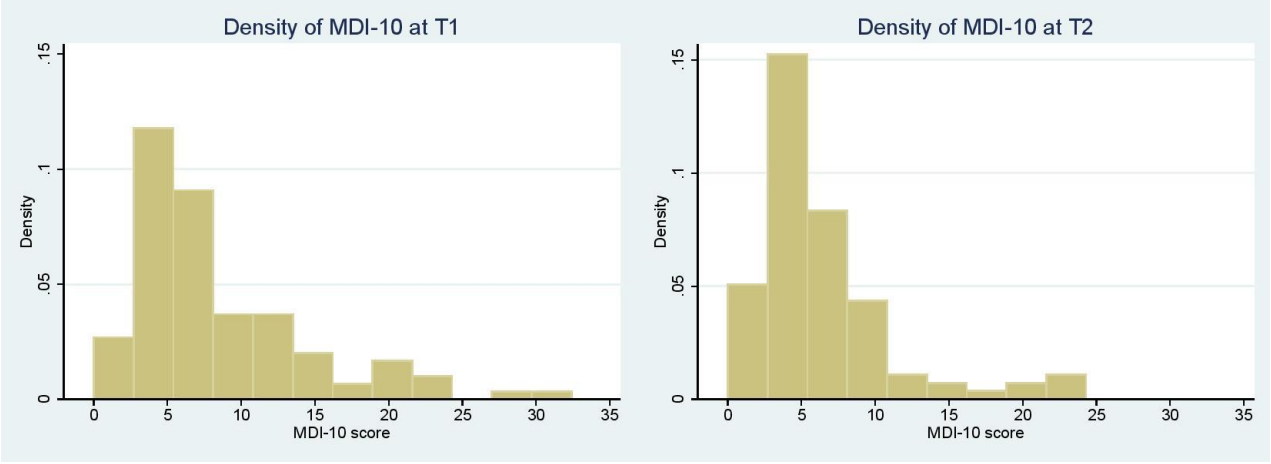

Figure 4 Histogram of MDI-10 scores at T1 and T2

Measures with ceiling or floor effects, i.e. where a high proportion of respondents choose either the maximum or minimum score, are problematic because these scales have poor discrimination and lower levels of responsiveness and sensitivity (Fayers & Machin, 2016; Hoffmeister & Mensink, 2004). Using measures with ceiling or floor effects is particularly problematic with regard to intervention studies, because it is almost impossible to identify improvement over time. If there is no difference between the intervention and control group post-intervention, this may be because the intervention has no effect or because the measure is not able to capture improvement (Črnčec et al., 2010; Streiner & Norman, 2008). It is very likely that some of the measures used as outcome measures in studies of universal interventions have ceiling or floor effects, which may contribute to why we do not see any effects from universal interventions. For instance, this is the case for the Strengths and Difficulties Questionnaire (SDQ) (Niclasen et al., 2012), and for the CBCL used in several of the studies in Paper 1 (Nix, 2001; Whitcomb & Merrell, 2012).

Differential effects

Contrary to our hypothesis, we find signs of negative effects of IYPB at post-intervention for the lowest-functioning mothers at baseline. Although the overall result is that there is no difference between the two groups post-intervention, it is notable that when we split the sample into the highest and lowest scoring halves at baseline, all outcomes favor the control group for the lowest scoring half (one outcome – parental stress – is significant), whereas the opposite is the case for the highest scoring half, except for confidence and parent stress for the 25% highest scoring group and depression for mothers in both groups. For the mothers who score in the lowest quarter, all outcomes favor the control group, and two outcomes (general well-being and parental stress) are significantly worse for IYPB mothers compared to UC.

I suggest that this indication of a negative effect is primarily due to the group format, where all kinds of families are mixed in the groups when the intervention is applied to a universal population. Usually, group interventions draw strength from being a safe space in which the participants feel that others share their difficulties and concerns. The cohesion within the group makes everyone feel accepted and validated, and gives them a sense of belonging (Joyce, Piper, & Ogrodniczuk, 2007; Yalom & Leszcz, 2005). If groups comprise parents with very different experiences and perceptions of parenting, this could reduce the level of cohesion within the group and thereby influence the outcomes. Research has found that when a group's members are very different from each other, this can cause negative effects for the lowest functioning group (Carrell S. & West, 2013). If a group of parents consists of a minority who find parenting challenging and a majority who feel competent and confident, this may compromise the feeling of acceptance, belonging, and cohesion in the group. This could therefore make the minority feel even less competent and more insecure, and even contribute to increasing inequality. The fact that universal interventions may increase inequality and make "nice kids even nicer" (Offord, 2000, p. 835) is a disadvantage that has been pointed out by several researchers (Offord et al., 1998; Rose, 2001). A study of parenting interventions within a disadvantaged area also found that it was children from the relatively less disadvantaged families that benefitted from the intervention, whereas the children from the most deprived families experienced adverse effects (Belsky & Melhuish, 2007).

Although this trial finds signs of negative effects on the mothers with the lowest scores at baseline, this is not the same as saying that we would generally expect negative effects from IYPB for disadvantaged mothers. A trial that only recruited disadvantaged mothers should have better group

coherence, because those in the group would have more similar experiences of motherhood. This should therefore enhance acceptance, validation, and a sense of belonging to the group.

Methodological considerations

When conducting systematic reviews and RCTs, there are many decisions that have to be made at an early stage that have consequences for the later analyses and conclusions that can be drawn from the studies. Here I will point out some of the limitations of the studies.

Systematic review of universal parenting interventions

The pilot search revealed many more studies than anticipated, with very different populations, interventions, and outcomes. To be able to synthesize the results in a meaningful way, we had to add more inclusion criteria to the final search than first planned. Many of these inclusion criteria are relatively arbitrary – for example, the age limit of 12 months could just as well be 11 or 13 months. As we wanted to focus on interventions that are aimed at improving parenting in the first year of the infant's life, we found that the 12-month limit was appropriate.

Much consideration was also given to defining which interventions to include. Although we defined that interventions had to be structured, psychosocial parenting interventions that employed double coding, the final decision of whether a specific intervention should be included or not is always subjective when examining a broader range of interventions, rather than a specific intervention such as the Incredible Years, Circle of Security, or group-based programs.

A further restriction of the systematic review was that we only included RCTs, and not studies including other kinds of comparison groups. The reason for this was that although non-RCTS can be of high quality, the RCT is still the most rigorous design when addressing effectiveness. Risk of bias is therefore (in theory) lower when only including RCTs, as long as the quality of the RCT is high. As we already had to deal with heterogeneity with regard to, e.g. outcome assessment, intervention method, and length, we decided to reduce heterogeneity with regard to study design by only including RCTs.

Based on our inclusion and exclusion criteria, we have ended up with a relatively focused group of studies examining the effects of structured, psychosocial parenting interventions offered to parents with infants aged 0–12 months. A limitation of this is that we could only conduct meta-analysis for

four outcomes due to heterogeneity in the outcome measures and the timing of follow-up assessments.

RCT of IYPB as a universal intervention for parents with infants

The main methodological limitation with the RCT is that because the study population changed from a disadvantaged group to a universal group, it ended up being a small pilot sample that was not sufficiently powered for either the main results of the whole group or the subgroup analyses. The power of the study refers to the probability of detecting an effect (if there is one). A low-powered study entails a larger risk of a type II error, i.e. not finding an effect that is there, because the sample is too small (Pocock, 2009). Although the analyses followed the principles stated in the protocol (Pontoppidan, 2015), the results of the trial should therefore be treated with caution (Loscalzo, 2009). Another problem with small pilot samples is that baseline variables are often imbalanced (Lancaster, Dodd, & Williamson, 2004). This was, however, not the case in our trial. Furthermore, sensitivity analysis revealed the same results as the main analysis. Especially for the 25% and 50% lowest performing groups at baseline, all outcomes point in the same direction favoring the control group. It is unlikely that increasing the number of participants would change this.

Another limitation with the IYPB trial is that although the outcomes used in the trial are validated measures that are used in international research, they are primarily based on parent reports. The one measure that is based on observation has not yet been analyzed. Using data from multiple informants is preferable (Whitcomb & Merrell, 2012), but we were unable to obtain data from more than a minority of fathers, and therefore have to rely on data from mothers only.

Implications for research

This project's RCT of IYPB is, despite being a pilot study, the first rigorous effectiveness study of the IYPB. The feasibility results of the trial show that it is possible to recruit families to a research project evaluating a universal intervention, and that the majority of parents in the intervention group participated in the intervention even though their satisfaction with the program was not very high. The data suggests that the intervention had no short-term effect when offered universally. As the comparison group received a relatively intensive universal intervention that is implemented as usual care in Denmark, we do not know whether the improvement over time for most outcomes that we

saw for all mothers in the trial was because both IYPB and the usual care improve the mothers' parenting and well-being, or if this improvement would also be present for a universal group of mothers who received no intervention at all. To further evaluate whether the universal IYPB intervention is effective, it should be applied in a context in which the usual care offered is very limited. Based on feedback from parents and group leaders in our trial, it would also be sensible to tailor the program better for a universal population. As IYPB was originally designed for disadvantaged families, it would also be relevant to conduct a proper RCT in order to evaluate the effectiveness of the program for disadvantaged families. Such a study is currently being piloted in the UK (Bywater & Teare, 2015).

Implications for future policy and practice

Although the overall results of this project are not in favor of universal interventions for parents with infants aged 0–12 months, this does not necessarily mean that universal interventions should be abandoned. It does, however, point out that significant effort must be put into considerations of how to best support families with infants in order to secure the well-being of all children and families.

Many families with developmental challenges will be overlooked if interventions are only offered within an indicated framework, which means there is still a need for a combination of indicated, selected and targeted approaches to offering parenting interventions (Offord, 2000). As the universal interventions are expensive and have difficulties in terms of achieving effects, it may be cost-effective to use a selective approach to offer a higher number of interventions, i.e. directed at everyone in a selected area where there are known to be challenges. The selective approach has some of the advantages of universal interventions, such as being non-stigmatizing for the individual, but it also has the strength of the intervention being provided to the families with the highest needs (Barnes, 2003). Within this framework, there is also a higher chance that group members will not be too different from each other. Furthermore, a more widespread use of screening measures to determine need and eligibility would also help target interventions at the families with the highest needs (Hutchings et al., 2013).

I suggest that, when offering interventions to families, the most important consideration is that the intervention is tailored to be relevant and appropriate to their needs and challenges. Becoming a parent is challenging, and new parents are bombarded with information on how to look after their

children. Interventions therefore need to be sensitive and relevant to the parents. Another important issue is that a considerable amount of effort must be directed toward ensuring that the families with the greatest needs receive the intervention. Getting families with the highest needs to participate is difficult, but one way to achieve it could be via volunteer or paid community ambassadors who have knowledge of specific challenges, concerns, and obstacles in the high-risk families in the recruitment and assessment process. This approach is being successfully implemented in, e.g. the MomBa, MomBa Live Long, and the New Haven Mental Health Outreach for MotherS (MOMS) Partnership trials conducted at the Yale Child Study Center.

In connection with obtaining population effects of parenting interventions, Prinz and Sanders point out that it is key that programs are transdiagnostic and can be used with families with different problems, that interventions should not be longer than necessary, and that easy access for everyone is crucial (Prinz & Sanders, 2007). They further point out that high-quality training and supervision of providers, involvement of different service providers, and support from management is also central (Prinz & Sanders, 2007). All of these issues must be taken into account when adapting parenting interventions in practice.

Conclusion

This project studied assessment measures of infant social-emotional development and parent confidence, and examined the effects of universal interventions for parents with infants.

To prevent problems later in life, it is crucial to identify infants with socio-emotional developmental problems at an early stage. To that end, several measures have been developed within the last decade. We identified 10 measures of infant social-emotional development, all of which show acceptable reliability, but the most comprehensive and psychometrically sound are the Ages and Stages Questionnaires: Social-Emotional – 2 (ASQ:SE-2), Brief Infant-Toddler Social and Emotional Assessment (BITSEA), Infant-Toddler Social and Emotional Assessment (ITSEA), and Child Behavior Checklist 1½–5 (CBCL).

The validation of the KPCS found acceptable internal consistency, but also that many items have high means and low variation, resulting in a ceiling effect. We found that at-risk mothers had significantly lower confidence at both two and six months compared to not-at-risk mothers, but that at-risk mothers improved significantly more than not-at-risk mothers over time.

In the systematic review of universal interventions, we conclude that results are mixed and inconclusive for child development or parent-child relationship outcomes. Meta-analysis revealed one significant positive effect on father positivity, but there were no effects on the remaining three outcomes. Although three out of seven studies found positive effects (with one negative), the majority of outcomes did not show any effects of the intervention.

For the RCT of IYPB as a universal intervention, we find that it is possible to recruit families to a research project evaluating a universal intervention, and that the majority of parents in the intervention group participated in the intervention even though their satisfaction with the program was not very high. Examining the effects of IYPB, we found that besides one outcome (parent report of own network), in which the intervention mothers reported a significantly lower network post-intervention than control mothers, there were no differences between IYPB and the UC group immediately post-intervention. When dividing the sample into the lowest and highest performing halves at baseline, we found indications of negative effects on both parent stress and mental health.

Based on parent and group leader feedback, the IYPB program may need to be adjusted to fit the expectations and needs of a universal group of parents.

In conclusion, although some studies do find positive effects, we find little support for universal interventions for parents with infants from birth to 12 months. We suggest applying a selected approach for areas with families with well-known challenges, more use of screening measures, and more effort put into ensuring that interventions are not only offered to, but also received by families with the greatest needs.

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Appendix

TRYGHED I FORÆLDREROLLEN – til forældre med børn 0-12 mdr.

Dit navn:

Din alder:

Du er barnets (sæt cirkel omkring): mor / far

Hvilke sprog tales i hjemmet:

Barnets navn:

Barnets alder (i måneder):

Hvor mange børn har du i alt:

Dato:

Dette spørgeskema handler om at være forælder til et lille barn, og nogle af de følelser man kan have som forælder. Skemaet har 15 spørgsmål. Marker det svar, der bedst beskriver, hvordan du generelt har det.

1. **Jeg føler mig tryg ved at give mit barn mad (også amning eller flaske)**
   - □ Nej, næsten aldrig
   - □ Nej, ikke særlig ofte
   - □ Ja, noget af tiden
   - □ Ja, det meste af tiden
   - □ *Ikke relevant (min partner giver barnet mad)*

2. **Jeg kan berolige mit barn**
   - □ Nej, næsten aldrig
   - □ Nej, ikke særlig ofte
   - □ Ja, noget af tiden
   - □ Ja, det meste af tiden

3. **Jeg føler mig sikker på, at jeg kan hjælpe mit barn til at få gode søvnvaner**
   - □ Nej, næsten aldrig
   - □ Nej, ikke særlig ofte
   - □ Ja, noget af tiden
   - □ Ja, det meste af tiden

4. **Jeg ved, hvad jeg skal gøre, når mit barn græder**
   - □ Nej, næsten aldrig
   - □ Nej, ikke særlig ofte
   - □ Ja, noget af tiden
   - □ Ja, det meste af tiden

5. **Jeg forstår, hvad mit barn prøver at fortælle mig**
   - □ Nej, næsten aldrig
   - □ Nej, ikke særlig ofte
   - □ Ja, noget af tiden
   - □ Ja, det meste af tiden

6. **Jeg kan trøste mit barn, når han/hun er ked af det**
   - □ Nej, næsten aldrig
   - □ Nej, ikke særlig ofte
   - □ Ja, noget af tiden
   - □ Ja, det meste af tiden

7. **Jeg føler mig sikker på mig selv, når jeg leger med mit barn**
   - □ Nej, næsten aldrig
   - □ Nej, ikke særlig ofte
   - □ Ja, noget af tiden
   - □ Ja, det meste af tiden

8. **Hvis mit barn har en almindelig forkølelse eller let feber, ved jeg, hvad jeg skal gøre**
   - □ Nej, næsten aldrig
   - □ Nej, ikke særlig ofte
   - □ Ja, noget af tiden
   - □ Ja, det meste af tiden

9. **Jeg er sikker på, at min partner vil være der for mig, når jeg har brug for støtte**
   - □ Nej, næsten aldrig
   - □ Nej, ikke særlig ofte
   - □ Ja, noget af tiden
   - □ Ja, det meste af tiden
   - □ *Ikke relevant (Jeg har ikke en partner).*

10. **Jeg er sikker på, at mit barn trives**
    - □ Nej, næsten aldrig
    - □ Nej, ikke særlig ofte
    - □ Ja, noget af tiden
    - □ Ja, det meste af tiden

11. **Jeg kan tage beslutninger om mit barns pleje**
    - □ Nej, næsten aldrig
    - □ Nej, ikke særlig ofte
    - □ Ja, noget af tiden
    - □ Ja, det meste af tiden

12. **At være mor/far er meget stressende for mig**
    - □ Nej, næsten aldrig
    - □ Nej, ikke særlig ofte
    - □ Ja, noget af tiden
    - □ Ja, det meste af tiden

13. **Jeg synes, at jeg gør det godt som mor/far**
    - □ Nej, næsten aldrig
    - □ Nej, ikke særlig ofte
    - □ Ja, noget af tiden
    - □ Ja, det meste af tiden

14. **Andre mennesker synes, at jeg gør det godt som mor/far**
    - □ Nej, næsten aldrig
    - □ Nej, ikke særlig ofte
    - □ Ja, noget af tiden
    - □ Ja, det meste af tiden

15. **Jeg er sikker på, at andre vil være der for mig, når jeg har brug for støtte**
    - □ Nej, næsten aldrig
    - □ Nej, ikke særlig ofte
    - □ Ja, noget af tiden
    - □ Ja, det meste af tiden

KARITANE PARENTING CONFIDENCE SCALE

FOR PARENTS OF INFANTS

Reference as: Črnčec, R., Barnett, B., & Matthey, S. (in press: 2008). Development of an instrument to assess perceived self-efficacy in the parents of infant. *Research in Nursing and Health.*

Your name: _____ Baby's name: _____

Your age: _____ Baby's age (months): _____

You are baby's (circle): mother / father Number of children including baby: _____

Cultural background:_____ Today's date: _____

This scale has 15 items. Please underline the answer that comes closest to how you generally feel.

Here is an example already completed:

eg. I am confident about holding my baby

No, hardly ever
No, not very often
Yes, some of the time
Yes, most of the time

Office use only.

Page 1 ____

Page 2 ____+

Total ____

This would mean "*I feel confident about holding my baby some of the time*".

Please complete the other questions in the same way.

---

1. I am confident about feeding my baby

Not applicable (my partner feeds the baby)
No, hardly ever
No, not very often
Yes, some of the time
Yes, most of the time

2. I can settle my baby

No, hardly ever
No, not very often
Yes, some of the time
Yes, most of the time

3. I am confident about helping my baby to establish a good sleep routine

No, hardly ever
No, not very often
Yes, some of the time
Yes, most of the time

4. I know what to do when my baby cries

No, hardly ever
No, not very often
Yes, some of the time
Yes, most of the time

Continued over the page ⇨

5. I understand what my baby is trying to tell me

No, hardly ever
No, not very often
Yes, some of the time
Yes, most of the time

6. I can soothe my baby when he / she is distressed

No, hardly ever
No, not very often
Yes, some of the time
Yes, most of the time

7. I am confident about playing with my baby

No, hardly ever
No, not very often
Yes, some of the time
Yes, most of the time

8. If my baby has a common cold or slight fever, I am confident about handling this

No, hardly ever
No, not very often
Yes, some of the time
Yes, most of the time

9. I feel sure that my partner will be there for me when I need support

Not applicable (I don't have a partner)
No, hardly ever
No, not very often
Yes, some of the time
Yes, most of the time

Office use only:
All items scored 0,1,2,3. N/A=2.

10. I am confident that my baby is doing well

No, hardly ever
No, not very often
Yes, some of the time
Yes, most of the time

11. I can make decisions about the care of my baby

No, hardly ever
No, not very often
Yes, some of the time
Yes, most of the time

12. Being a mother / father is very stressful for me

Yes, most of the time
Yes, some of the time
No, not very often
No, hardly ever

13. I feel I am doing a good job as mother / father

No, hardly ever
No, not very often
Yes, some of the time
Yes, most of the time

14. Other people think I am doing a good job as a mother / father

No, hardly ever
No, not very often
Yes, some of the time
Yes, most of the time

15. I feel sure that people will be there for me when I need support

No, hardly ever
No, not very often
Yes, some of the time
Yes, most of the time

Thank you for completing this questionnaire

ET GAVEKORT SOM TAK

Jeres deltagelse er en stor hjælp for forskningsprojektet og vigtig for at udvikle bedre forældreindsatser. Vi sætter pris på, at I vil bruge tid på at besvare spørgeskemaerne. Som tak for hjælpen får familien et gavekort på 200 kr. til hvert besøg.

Hvis I har lyst, sender vi også gerne løbende et brev eller en email med nyheder om forskningsprojektet. I må også meget gerne få de endelige resultater, når de er klar.

DERFOR BØR I SIGE JA TIL AT DELTAGE

Ved at dele jeres oplevelser er I med til at forbedre kommunens tilbud til familier med nyfødte. Vi håber derfor meget, at I vil være med.

GARANTI FOR FORTROLIGHED

Alle de oplysninger, som I giver til os, bliver behandlet fortroligt. Kommunen får ikke adgang til oplysningerne, og alt bliver anonymiseret i forskningsprojektet.

MED VENLIG HILSEN

Projektleder Maiken Pontoppidan
email mpo@sfi.dk
telefon 33 69 77 20
Afdelingsleder Mette Deding
email mcd@sfi.dk
telefon 33 48 09 99

SFI DET NATIONALE FORSKNINGSCENTER FOR VELFÆRD
HERLUF TROLLES GADE 11 • DK-1052 KØBENHAVN K
TEL +45 3348 0800 • MAIL SFI@SFI.DK • WWW.SFI.DK

SFI er Danmarks nationale forskningscenter for velfærd. Vi arbejder blandt andet med børns og familiers vilkår, og hvordan de kan blive bedre.

Forskningsprojekt om GOD TRIVSEL I FAMILIEN

INFORMATION TIL FORÆLDRE

Tillykke med den lille ny i familien! Vi vil gerne invitere jer og jeres barn til at deltage i et forskningsprojekt for nybagte forældre, som undersøger, hvordan man bedst kan støtte op om god trivsel i familien.

Jeres oplevelser kan være med til at forbedre vores viden om, hvad der virker bedst.

Denne folder beskriver forskningsprojektet, og I må meget gerne kontakte os for at høre mere eller stille spørgsmål, før I beslutter jer for, om I vil deltage i projektet. Vores kontaktoplysninger står på bagsiden.

Scan koden

Se en kort video om projektet.
www.sfi.dk/godtrivsel

SFI DET NATIONALE FORSKNINGSCENTER FOR VELFÆRD

HVAD GÅR PROJEKTET UD PÅ?

En baby i familien bringer mange nye oplevelser med sig. Som nybagte forældre er der meget nyt at tage hånd om i hverdagen, og der er både glæder og udfordringer i forbindelse med familieforøgelsen. Mange kommuner tilbyder indsatser for at støtte op om god trivsel i familien. Forskningsprojektet skal undersøge, om nogle typer tilbud virker bedre end andre. Deltagere i projektet modtager derfor forskellige indsatser målrettet nybagte forældre, som vi kan sammenligne.

HVEM FORETAGER UNDERSØGELSEN?

Undersøgelsen gennemføres af forskere fra SFI – Det Nationale Forskningscenter for Velfærd – i samarbejde med en række kommuner. Projektet er finansieret af TrygFonden.

HVAD SKER DER, HVIS I SIGER JA TIL AT DELTAGE?

1) Kommunen sender moderens kontaktoplysninger til SFI.
2) Inden for en uges tid bliver mor kontaktet af en interviewer fra SFI, der vil aftale en tid til det første af tre interviews hjemme hos jer. Mor og eventuelt far vil blive bedt om, at udfylde et spørgeskema, med spørgsmål om fx trivsel og udvikling. Ved det første interview skal mor underskrive den vedlagte samtykkeerklæring. Besøget varer knap 1 time.
3) Efter første interview vil kommunen fortælle jer, hvilket tilbud I skal følge, og hvornår det starter.
4) Omkring fire måneder efter tilbuddets start bliver det andet interview gen-nemført hjemme hos jer. Besøget varer 1 time. Hvis I synes, det er i orden, vil der blive lavet en lille videooptagelse af mor og barn sammen.
5) Det sidste interview finder sted, når barnet er omkring 18 mdr. Det varer ca. 1 time. Et par uger inden besøget får du nogle opgaver du skal løse sammen med barnet.

Det er vigtigt, at vi kan følge jeres og barnets udvikling. Derfor håber vi meget, at I vil afsætte tid til alle tre besøg.

DET ER FRIVILLIGT AT DELTAGE

I kan på ethvert tidspunkt og uden begrundelse trække jeres samtykke om deltagelse tilbage og forlade forskningsprojektet, uden at dette påvirker nuværende eller fremtidige tilbud fra kommunen.

TILDELING AF TILBUD

Jeres kommune har to typer indsatser, de kan tilbyde jeres familie. Hvis I deltager i forskningsprojektet, vil valget mellem tilbuddene ske ved lodtrækning, så det bliver tilfældigt, hvem der modtager hvilken indsats. Dette er vigtigt, for at man kan vurdere indsatsernes virkning. Den ene indsats består af fem hjemmebesøg af sundhedsplejerske, Mødregruppe, Åbent Hus og eventuelt ekstra besøg ved behov. Den anden indsats består af fem hjemmebesøg af sundhedsplejerske, DUÅ forældregruppe med otte mødegange, Åbent Hus og eventuelt ekstra besøg ved behov.

Begge indsatser udføres af kompetente medarbejdere, så hvis I vælger at deltage i projektet vil I under alle omstændigheder få en indsats, der er tilpasset nye forældre.

Hvis I ønsker at deltage, sender kommunen mors kontaktoplysninger til SFI

I løbet af to uger
Første interview

Tilbuddet begynder

Efter 3-4 måneder
Andet interview

Når barnet er ca. 18 måneder
Tredje interview

SAMTYKKEERKLÆRING

DET NATIONALE FORSKNINGSCENTER FOR VELFÆRD

Kære forældre,

SFI – det Nationale Forskningscenter for Velfærd er i gang med et forskningsprojekt, hvor vi sammenligner forskellige måder at arbejde med trivsel på i familier med små børn. Forskningsprojektet er beskrevet i informationsfolderen "Forskningsprojekt om god trivsel i familien", som I har fået udleveret.

I vil få besøg af en interviewer tre gange i løbet af projektet:

Besøg	1	2	3
Tidspunkt	Inden for 14 dage	Efter ca. 4 mdr.	Når barnet er ca. 18 mdr.
Varighed	45-60 min	1 time	1 time
Spørgeskema	x	x	x
Videooptagelse (hvis I vil)		x	
Barnet løser opgaver			x

Det er helt frivilligt at deltage, og I kan til enhver tid kan trække tilsagn om deltagelse tilbage, uden at det påvirker nuværende eller fremtidige tilbud fra kommunen. For at kunne deltage, skal I have modtaget både mundtlig og skriftlig information om forskningsprojektet og underskrevet denne samtykkeerklæring.

Projektansvarlig er ph.d. studerende Maiken Pontoppidan (mpo@sfi.dk, telefon 3369 7720). I er velkomne til at kontakte mig, hvis I har spørgsmål. Forskningsprojektet er bevilget af TrygFonden og gennemføres af forskere på SFI i samarbejde med en række kommuner og TrygFondens Børneforskningscenter. Projektet er godkendt af Datatilsynet.

Alle oplysninger behandles fortroligt og ingen enkeltpersoner vil kunne genkendes i formidlingen af projektet.

Jeg bekræfter hermed,

- At jeg ønsker at deltage i ovennævnte undersøgelse
- At jeg er blevet grundigt informeret om projektet - både mundtligt og skriftligt
- At jeg har modtaget folderen "Forskningsprojekt om god trivsel i familien"

Dato	Mors Navn	CPR-nummer
Dato	Fars Navn	CPR-nummer

Jeg ønsker løbende information om forskningsprojektet – ca. to gange årligt

o Ja – mobil nr: Email adresse:

o Nej

Papers 1–5

Paper 1

The effects of universally offered parenting interventions for parents with infants: A systematic review and meta-analysis

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Keywords: Child development, infant development, parenting intervention, universal intervention, systematic review.

Abbreviations: RCT: Randomized Controlled Trial; RR: Risk Ratio; OR: Odds Ratio.

ABSTRACT

Objectives: From a developmental perspective, infancy is a critical stage of life. Early childhood interventions aim to support caretakers, but the effects of universal interventions for parents with infants are unknown. The objective was to determine the effects of universal parenting interventions offered to parents with infants 0-12 months on child development and parent-child relationship.

Design: A systematic review and meta-analyses**.** Using Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) we extracted publications from ten databases in January 2015 and supplemented by grey and hand search. Risk of bias was assessed, effect sizes were calculated, and meta-analysis was conducted.

Participants: Inclusion criteria were: 1) Randomized controlled trials of structured, psychosocial interventions offered to a universal population of parents with infants 0-12 months old in western OECD countries, 2) Interventions with a minimum of three sessions and at least half of the sessions delivered postnatally, and 3) Program outcomes reported for child development or parent-child relationship.

Results: Fourteen papers representing seven studies were included. There were no statistically significant effects of the intervention for the majority of the primary outcomes across the studies. Meta-analysis revealed one significant positive effect and three insignificant effects for child development and parent-child relationship outcomes.

Conclusions: The findings of this review are mixed. No clear conclusions can be drawn about the effects of universally offered parenting interventions on child development and parent-child relationship for this age group.

Strengths and limitations of this study:

- Comprehensive search strategy and screening procedure
- Include both child development and parent-child relationship outcomes
- Meta-analyses on only a few outcomes due to heterogeneity

INTRODUCTION

The importance of early experiences in children's long-term development is well established. The first year of life is a period of rapid development critical to infants' health, emotional wellbeing, and developmental trajectories.[1,2] The first signs of mental health problems are often exhibited during infancy; however, the symptoms may be overlooked by parents and health care providers because they can be less intrusive when a child is young.[3–8] Early onset of emotional or behavioral problems increases the risk of numerous adverse outcomes that persist into adolescence and adulthood, such as delinquency, violence, substance abuse, mental health problems, teen pregnancies, school dropout, and long-term unemployment.[1,2,4,9–15]

Parents are crucial for the healthy development of infants because they are primarily responsible for the environment in which the child develops. Pregnancy and birth, particularly of a first child, is a period of major lifestyle changes that can be stressful for both mothers and fathers.[16–18] The highest rates of child neglect and violent abuse occur when children are under five years of age,[19,20] with the most serious cases of injury and death caused by parental violence against children occurring when infants are under one year of age.[21]

Early childhood interventions aim to make the first year of parenthood easier by supporting caretakers. These interventions typically focus on improving adjustment and function in the family by teaching parents to use specific skills or strategies that foster healthy child development.[22] Parenting interventions can be delivered within an indicated, selective, or universal framework.[23,24] Indicated interventions are offered to families with known risk factors or professional evaluations that suggest

the parents or the child may be experiencing problems.[23,24] Selective interventions are typically offered to families who come from environments that are known to have risk factors, such as neighborhoods with low socio-economic status or high crime rates.[23,24] Finally, universal interventions are offered to all families in a population regardless of existing risk factors or identified problems, and they therefore have the widest reach.[23,24]

Individual studies and reviews suggest that high-quality parenting interventions delivered to families within the indicated and selective populations can mitigate problems at a relatively low cost.[2,10,11,25–31] The effectiveness of individual universal interventions has been evaluated, but no reviews currently exist of universal interventions aimed at supporting parents with infants aged 0-12 months. It is important to determine the effectiveness of universal interventions because they offer several potential advantages over indicated and selective approaches: (1) Universal interventions are offered to all families, and they can reach those in need in a non-stigmatizing setting, which may increase the number of families with problems who accept support; (2) these interventions may be an effective method of identifying families who require extra support or further treatment before problems reach elevated levels. Parents who are neglectful or emotionally or physically abusive to their children do not necessarily meet any of the criteria that would indicate they may be at risk of harming their children and they may therefore never come to the attention of those who could offer support; (3) finally, universal interventions may be an effective method of reducing the overall levels of child maltreatment and developmental problems within the general population because they have the potential to reach all families. Targeted interventions do not generally reach enough families to see population-level effects (e.g., reduction in emergency

room visits due to child abuse or population level reduction in child mental health problems).[23,32–34]

The aim of this review was to systematically review and conduct a meta-analysis of universally offered interventions for parents with infants aged 0-12 months. Randomized controlled trials of interventions reporting outcomes for child development or parent-child relationship are included in the review

METHOD

Search strategy

This review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). We did not register a protocol. The database searches were performed in June 2013 and updated in January 2015. We searched ten international bibliographic databases: Campbell Library, Cochrane Library, CRD (Centre for Reviews and Dissemination), ERIC, PsycINFO, PubMed, Science Citation Index Expanded, Social Care Online, Social Science Citation Index, and SocIndex. Operational definitions were determined for each database separately. The main search was made up of conjunctions of the following terms: infant*, neonat*, parent*, mother*, father*, child*, relation*, attach*, behavi*, psychotherap*, therap*, intervention*, train*, interaction, parenting, learning, and education. The searches included Medical Subject Headings (MeSH), Boolean operators, and filters. We furthermore searched for grey literature; hand searched four journals, and snowballed for relevant references.

Eligibility criteria and study selection

All publications were screened based on abstract and title. Publications which could not be excluded were screened based on the full text version. Inclusion and exclusion criteria are presented in Table 1.

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Population	
Universal population of parents of infants 0-12 months old in western OECD countries	Studies offered to a selected or indicated group of parents; including studies only including young mothers (<20 years), divorced parents, parents with mental health problems such as abuse and depression and children born pre-term, at low birth weight or with congenital diseases.
Intervention	
Structured psychosocial parenting intervention consisting of at least three sessions and initiated either antenatal or during the child's first year of life with at least half of the sessions delivered postnatally.	Interventions not focusing specifically on parenting (e.g. baby massage, reading sessions with child, or breastfeeding interventions), and unstructured interventions (e.g. home visits if they are not offered in a structured format).
Control group	
No restrictions were imposed. All services or comparison interventions received or provided to the control group were allowed.	
Outcome	
Child development and/parent child relationship outcomes	Studies reporting only physical development such as height and weight. Papers with insufficient quantitative outcome data to generate standardized mean differences (Cohen's d), risk ratios (RR) and confidence intervals (CI).
Design	
Randomized controlled trials (RCT) or quasi-RCTs.	Other systematic reviews
Publication type	
Studies presented in peer-reviewed journals, dissertations, books or scientific reports.	Abstracts or conference papers. Studies published in languages others than English, German or the Scandinavian languages (Danish, Swedish and Norwegian).

Each publication was screened by two research assistants under close supervision by MP and SBR. Uncertainties regarding inclusion were discussed with MP and SBR. Screening was performed in Eppi-Reviewer 4.

Data extraction and risk of bias assessment

We developed a data extraction tool for the descriptive coding and extracted information on 1) study design, 2) sample characteristics, 3) setting, 4) intervention details, 5) outcome measures, and 6) child age post intervention and at follow-up. The extracted information was checked by SBR. Primary outcomes were child socio-

emotional development and parent-child relationship. Secondary outcomes were other child development markers, such as cognitive development. When reported, both total scores and subscale scores were extracted. Outcomes were extracted and reported for both mothers and fathers when provided, and were combined to one single measure of child development outcome if feasible.

Numeric coding of outcome data was conducted independently by MP and SBO. Disagreements were resolved by consulting a third reviewer. Risk of bias was assessed separately for each relevant outcome for all studies based on a risk of bias model developed by Professor Barnaby Reeves and the Cochrane Nonrandomized Studies Method Group (Reeves, Deeks, Higgins, & Wells, unpublished data, 2011). This extended model is organized and follows the same steps as the existing risk of bias model presented in the Cochrane Handbook, Chapter 8.[35] The assessment was conducted by SBR. Any doubts were discussed with another member of the review team.

Analyses

We calculated effect sizes for all relevant outcomes with sufficient data provided in the article. Effect sizes were reported using standardized mean differences (Cohen's *d*) with 95% confidence intervals for continuous outcomes. For dichotomous outcomes risk ratios (RR) with 95% confidence intervals were used as the effect size metric. Data used to calculate Cohen's *d* included post-intervention and follow-up means, standard deviations, and sample size. Furthermore, *t*-values, *F*-tests, χ^2, *p*-values, β-coefficients, and adjusted mean differences were used. Data used to calculate RRs were number of events and sample sizes or odds ratios (OR). When using ORs, the RR was approximated based on OR and $risk_0$ using the method

presented in Zhang and Yu (1998).[36] When insufficient numeric outcome information was included in the paper to calculate effect sizes, we contacted the corresponding author for more information. All studies but one were randomized at the individual level. When calculating effect sizes and confidence intervals for the outcomes of the cluster-randomized study, we used methods described in Hedges (2007)[37] to correct for the tendency towards overly narrow confidence intervals. For all outcomes we used data from adjusted analyses to calculate effect sizes where available.

Meta-analysis was performed when intervention outcome and timing of assessments were comparable. Random effects inverse variance weighted mean effect sizes were applied and 95 % confidence intervals were reported. Studies with larger sample sizes were therefore given more weight, all else being equal. Due to the small number of studies and an assumption of between-study heterogeneity, we used a random effects model. Variation in standardized mean difference attributable to heterogeneity was assessed with the I^2-statistic. Results were summarized for child development and parent-child relationship outcomes, respectively.

RESULTS

The literature search yielded 16,292 articles after removal of duplicates. A flow diagram of study inclusion is provided in Figure 1. Seven studies (14 papers) met the inclusion criteria. A total of 2,870 (1,449 intervention, 1,421 control) participants were included in the seven studies. Besides one cluster randomized study,[38,39] all studies were randomized at the individual level. The seven trials examined the effects of different parenting interventions. Four studies were American,[40–46] two were Australian,[38,39,47] and one study was Finnish.[48–51] One paper was

excluded due to insufficient numeric outcome to calculate effect sizes and confidence intervals.[52]

Figure 1 about here

Participant characteristics

Participant characteristics are presented in Table 2. Three studies recruited only primiparous parents, whereas four recruited both primi-and multiparous parents. Two studies began in pregnancy, the remaining five started when infants where between 0 and 12 months old.

Table 2 Participant characteristics

Study	Country	Parent mean age at start	Age of children at start	Primiparous %	Intervention (n)	Control (n)
Feinberg & Kan. 2008[40] Feinberg et al. 2009,[41] 2010[42] Solmeyer et al. 2014[43]	USA	Mother: 28.33; father: 29.76	22.9 weeks gestation	100	79	73
Hiscock et al. 2008[38] Bayer et al. 2010[39]	Australia	Mother: 33.1	Child age 8 months	54	329	404
Doherty et al. 2006[44]	USA	Mother: 30; father: 31	Second trimester	100	95	70
Vlismas et al. 2013[47]	Australia	Mother: 32.62	Child mean age 3,3 months	100	24	24
Aronen 1993[48] Aronen & Kurkela 1996,[49] 1998[50] Aronen & Arajärvi 2000[51]	Finland	Not reported	Child age 6 months	Not reported	80	80
Dickie & Gerber 1980[45]	USA	Not reported	Child mean age 8.05 months	82	10	9
Minkowitz et al. 2007[46]	USA	Mother: age <20:14%, 20-29:51%, ≥30:36%	Child age 0-4 weeks	46	832	761

Interventions and controls

Four of the interventions were group based, one was individual home visits, and two interventions included both individual home visits and group sessions. The majority of interventions were relatively short (3-8 sessions), but two were relatively long (18-50 sessions) and lasted until the children were 3 to 5 years old. The control groups did not receive any intervention or were offered "services as usual", minor interventions, or waitlist. See Table 3 for details of the interventions.

Table 3 Intervention characteristics

Study	No. of sessions	Intervention	Delivery mode	Format	Intensity and duration	Control intervention	Outcome measures	Follow up at child age
Feinberg & Kan 2008 Feinberg et al. 2009, 2010 Solmeyer et al. 2014	8	Family Foundations (FF). Aimed at mothers and fathers.	Two group leaders with 3 days training offered at childbirth education departments at local hospitals.	Group	Four sessions in pregnancy, four sessions after child is born until about 6.5 months old.	The control group received a brief brochure in the mail about selecting quality childcare	Child development Parent -child relationship	6.5, and 13.7 months
Hiscock et al. 2008 Bayer et al. 2010	3	Toddlers without tears. Aimed at mothers and fathers.	Nurse and parenting expert/child psychologist. Offered at the local Maternal and Child Health centre /MCH).	Group	Three sessions from infant is 8 months to 15 months old	Treatment as usual	Child development	8, 24, and 36 months
Doherty et al. 2006	8	Parenting Together. Aimed at mothers and fathers.	Licensed parent educator. Group sessions in clinic	Home visit and group	One home visit and 3 group sessions in pregnancy, four group sessions from the child is 2-5 months old	Not described	Parent-child relationship	6, and 12 months
Vlismas et al. 2013	5	Face-to-face (F2F). Aimed at mother and child.	Psychologist led (the PI). Place not reported	Group	One weekly session during 5 weeks until the child is 3-7 months old	No treatment	Parent-child relationship	3-7 months
Aronen 1993 Aronen & Kurkela 1996, 1998 Aronen et al. 2000	10 times a year for 5 years	Psychodynamic counselling. Aimed at mothers and fathers.	Psychiatric nurse	Home visits	Ten sessions a year from birth to the child is 5 years old	3-6 home visits from birth to the child was 6 months old	Child development	10-11, 14-15 and 20-21 years
Dickie & Gerber 1980	16 hours over 8 weeks	Parent training. Aimed at mothers, fathers and infants.	Not reported	Group	16 hours over 8 weeks from child age 4-12 months to child age 6-14 months old.	No treatment - waiting list	Parent-child relationship	6-14 months

Minkowitz et al. 2007	Minimum 6 visits during 3 years	Healthy Steps for Young Children. Aimed at mothers and fathers.	Trained Healthy steps specialists. Offered in homes and at clinics.	Home visits, individual sessions and groups	Well-child visits, minimum 6 home visits, telephone line, developmental assessments, written materials, parent groups, and linkage to community ressources from birth to age 3 years old.	Treatment as usual	Child development	61-66 months.

Outcomes:

Most studies reported immediate post-intervention outcomes, but half of the studies also reported short term (up to six months post-intervention) and long-term (more than six months post-intervention) follow-up outcome data. Four studies reported measures of child social-emotional development and three studies reported measures of parent-child relationship. Due to heterogeneity in the outcome measures and the timing of follow-up assessments, we could only conduct meta-analysis for four outcomes.

Risk of Bias:

Risk of bias assessment is shown in the online table 1. Assessments on the specific risk of bias domains were divided into child development and parent-child relationship outcomes, respectively. Overall, risk of bias was reasonable for all studies and revealed no major differences. Risk of bias was assessed as low to medium in those domains where a clear judgement could be made. However, many of the studies delivered insufficient information in relation to at least two risks of bias domains, thus hindering a clear judgment for all risk of bias domains.

Child development:

Table 4 shows the individual results of the four studies reporting child development outcomes. Results from subscales are shown in the online table 2.

Table 4 Child development outcomes as reported across studies included in the systematic review

Study	Measure	Outcome	Assessment	Child age	Time	Intervention		Control		Cohen's d	Other statistics
						n	Mean(SD)	n	Mean(SD)		
Feinberg & Kan 2008	IBQ-R	Duration of orienting	Q	6.5 months	PI	79		73		**0.34 (0.02; 0.66)**	F=4.33
	IBQ-R	Infant soothability	Q	6.5 months	PI	79		73		Mother: -0.03 (-0.34;0.29) **Father: 0.33 (0.01; 0.65)**	Mother: β=-0.021; SD of DV: 0.84¤ Father: B=0.312; SD of DV: 0.96¤
	Child sleep habits	Child sleep habits	Q	6.5 months	PI	79		73		0.27 (-0.05; 0.58)	F=2.67
Feinberg et al. 2009	Homemade	Child behavior - Self-soothing	V	13.7 months	SF	73		68		Mother: **0.42 (0.09; 0.76)**	β =0.30 SD=0.73
	Homemade	Child behaviour - Sustained attention	V	13.7 months	SF	73		68		Mother:0.06 (-0.27; 0.39)	β=0.05 SD=0.78
Feinberg et al. 2010	CBCL	Total	Q	36 months	LF	70	45.23(8.67)	65	46.17(8.54)	0.11 (-0.23; 0.45)	
	Head Start Competence Scale	Social competence	Q	36 months	LF	69		65		**0.43 (0.09; 0.77)**	β=0.20; SD of DV= 0.48¤
	Head Start Competence Scale	Emotional competence	Q	36 months	LF	69		65		0.25 (-0.09;0.59)	β=0.13; SD of DV=0.53¤
Solmeyer et al. 2014	Homemade	Child adjustment problems	V	36 months	LF	65	0.005 (0.82)	63	-0.01 (0.65)	-0.02 (-0.37; 0.33)	
Hiscock et al. 2008	CBCL	Externalising	Q	18 months	PI	295		373		-0.02 (-0.20; 0.15)	Adjusted mean dif: 0.16,SD of DV: 6.84¤
	CBCL	Internalising	Q	18 months	PI	295		373		-0.12 (-0.27; 0.04)	Adjusted mean dif: 0.49, SD of DV: 4.26¤
	CBCL	Externalising	Q	24 months	SF	292		362		0.11 (-0.07; 0.29)	Adjusted mean dif: -0.79, SD of DV: 7.31¤
	CBCL	Internalising	Q	24 months	SF	292		362		-0.03 (-0.19; 0.12)	Adjusted mean dif: 0.19, SD of DV: 6.04¤
Bayer et al. 2010	CBCL	Externalising	Q	36 months	LF	259		330		0.11 (-0.08; 0.30)	Adjusted mean dif: -0.8 SD of DV: 7.36¤
	CBCL	Internalising	Q	36 months	LF	259		330		0.11 (-0.05; 0.28)	Adjusted mean dif: -0.6 SD of DV: 5.44¤

Aronen 1993	Rutter Scale A	Mental State	Q	10-11 years	LF	70		66		RR=0.13 (0.02; 1.07)	
Aronen & Kurkela 1996	CBCL	Total	Q	14-15 years	LF	75	13.92(10.45)	63	19.35(15.5)	**0.42 (0.08; 0.76)**	df= 1. t=2.49, p=0.014
	CBCL or YSR	Total	Q	14-15 years	LF	75		63		**RR=0.11 (0.01; 0.82)**	Event/No event: Intervention:1/74 Control:8/55
	YSR	Total	Q	14-15 years	LF	74	25.2(15.4)	62	32.5(19.1)	**0.42 (0.08; 0.76)**	
Aronen & Arajävi 2000	YASR	Total	Q	20-21 years	LF	73		63		**0.37 (0.03; 0.71)**	β= 7.001, SD of DV=19.35¤
	YASR	Total	Q	20-21 years	LF	73		63		**RR= 0.31 (0.11; 0.94)**	Event/No event: Intervention:4/69 Control:11/52
	BDI	Total	Q	20-21 years	LF	73	3.00 (3.77)	63	4.68(5.22)	**0.37 (0.03; 0.71)**	t=2.154, p=0.033
Minkowitz et al. 2007	CBCL 1½-5	Emotionally reactive, anxious/depressed, sleep problems, or attention problems subscales	Q	61-66 months	LF	676		632		RR=1.21 (0.95; 1.52)	OR 1.26 (0.94-1.69)
	PEDS		Q	61-66 months	LF					RR 0.94 (0.76; 1.16)	Event/No event: Intervention:138/538 Control:137/495
	SSRS	Total	Q	61-66 months	LF	676	55.9(9.8)	632	55.2(10.0)	0.07 (-0.04; 0.18)	

Bold: significant at a 5% level
¤: Calculated based on information in the study
PI: Post Intervention
SF: Short term Follow up (≤6 months post intervention)
LF: Long term Follow up (>6 months post intervention)
Q: Questionnaire
V: Video
DV: Dependent variable
IBQ-R: Infant Behavior Questionnaire-Revised
CBCL: Child Behavior Checklist
YSR: Youth Self Report
YASR: Young Adult Self Report
PEDS: Parents' Evaluation of Development Status
SSRS: Social Skills Rating Scale

Feinberg and colleagues[40–43] examined the effect of Family Foundations among 152 couples expecting their first child and living in rural areas, towns, and small cities in the USA. Families were recruited through local childbirth education programs at two local hospitals. The intervention was aimed at enhancing co-parenting quality and consisted of eight sessions; four during the second and third trimesters, and four in the first 6.5 months postpartum. The control group received a brief brochure in the mail about selecting quality childcare. The study reported outcomes post intervention, at short-term and long-term follow-up and found significant positive results on one or more outcomes.

Hiscock and colleagues[38,39] examined the effect of Toddlers without Tears in a cluster RCT including 733 mothers recruited through maternal and child health nurses in Victoria, Australia. The intervention was aimed at reducing behavioral problems and consisted of three sessions from the child was eight to 15 months old. The control group received services as usual and may have included general information for parents. The study reported outcomes post intervention, at short-term and long term follow-up. No significant effects were found on any outcomes.

Aronen and colleagues[48–51] examined the effect of psychodynamic counselling among 160 families in Helsinki, Finland in 1975-1976. The families were randomly selected from the total birth cohort. All families received three to six home visits in the first six months of the child's life. When the infants were six months old they were divided into high- or low-risk groups according to data records and assessment results and then randomized within the groups to receive either the intervention or to serve as a control family. The intervention was aimed at preventing mental disturbances by improving family interactions and childrearing practices and

consisted of up to ten home-visits per year over five years. The control group did not receive any intervention. The study reported outcomes at three long-term follow-up time points. The study reported outcomes post intervention, at short-term and long-term follow-up and found significant positive results on one or more outcomes.

Minkowitz and colleagues[46] examined Healthy Steps for Young Children in 1,593 families with newborns at six different sites (hospital-based clinics and pediatric practices) across the USA from 1996 to1998. The full sample included 5,565 families, but only the randomized subsample was included in this review. The intervention was aimed at enhancing relationship between parents and their children and improving delivery of developmental and behavioral support services. The intervention consisted of well-child visits, a minimum of six home visits, a telephone hotline to discuss the baby's development, developmental assessments, written materials on infant development and health issues, parent support groups, and referral to community resources from the birth of the child to age three years. The control group received the usual pediatric services. The study reported three outcomes at long-term follow-up. No significant effects were found on any outcomes.

Parent-child relationship

Table 5 shows the individual results of the four studies reporting parent-child relationship outcomes.

Table 5 Parent-child relationship outcomes as reported across studies included in the systematic review

Study	Measure	Outcome	Assessment	Child age	Time	Intervention		Control		Cohen's d	Other statistics
						n	Mean(SD)	n	Mean(SD)		
Feinberg et al. 2009	Homemade	Parenting - Positivity	V	13.7 months	SF	70		68		Mother: **0.36 (0.02; 0.69)** Father: **0.37 (0.03; 0.70)**	Mother: β=0.30, SD af DV: 0.86 Father: β=0.32; SD af DV: 0.89
	Homemade	Parenting - Negativity	V	13.7 months	SF	70		68		Mother: **0.58 (0.24; 0.93)** Father: **1.38 (1.00; 1.75)**	Mother: β=-0.19, SD af DV: 0.34 Father: β=- 0.34, SD af DV: 0.31.
Doherty et al. 2006	Parent Behavior Rating Scale	Total father-child interaction	V	6 months	PI	70	29.78(7.30)	62-64	27.55 (6.22)	0.33(-0.02; 0.67)	
	Parent Behavior Rating Scale	Warmth and emotional support	V	6 months	PI	70	4.76 (1.59)	62-64	4.28 (1.43)	0.32 (-0.03; 0.66)	
	Parent Behavior Rating Scale	Intrusiveness	V	6 months	PI	70	4.89(1.43)	62-64	4.31 (1.71)	**0.37 (0.03; 0.71)**	
	Parent Behavior Rating Scale	Engagement with child	V	6 months	PI	70	5.49(1.40)	62-64	5.37 (1.29)	0.09 (-0.25; 0.43)	
	Parent Behavior Rating Scale	Positive affect	V	6 months	PI	70	4.69(1.62)	62-64	4.33 (1.39)	0.24 (-0.10; 0.58)	
	Parent Behavior Rating Scale	Negative affect	V	6 months	PI	70	6.32(1.60)	62-64	6.62 (0.76)	-0.24 (-.58; 0.11)	
	Parent Behavior Rating Scale	Dyadic synchrony	V	6 months	PI	70	3.64(1.90)	62-64	2.86 (1.40)	**0.46 (0.12; 0.81)**	
	Parent Behavior Rating Scale	Total father-child interaction	V	12 months	SF	70	29.72(6.65)	62-64	28.63 (6.29)	0.17 (-0.17; 0.51)	
	Parent Behavior Rating Scale	Warmth and emotional support	V	12 months	SF	70	4.71(1.59)	62-64	4.41 (1.46)	0.20 (-0.15; 0.54)	
	Parent Behavior Rating Scale	Intrusiveness	V	12 months	SF	70	4.81(1.52)	62-64	4.72 (1.45)	0.06 (-0.28; 0.40)	
	Parent Behavior Rating Scale	Engagement with child	V	12 months	SF	70	5.41(1.39)	62-64	5.18 (1.42)	0.16 (-0.18; 0.50)	
	Parent Behavior Rating Scale	Positive affect	V	12 months	SF	70	4.85(1.57)	62-64	4.52 (1.41)	0.22 (-0.12; 0.56)	

	Parent Behavior Rating Scale	Negative affect	V	12 months	SF	70	6.28(1.70)	62-64	6.77 (0.66)	**-0.37 (-0.7; -0.03)**	
	Parent Behavior Rating Scale	Dyadic synchrony	V	12 months	SF	70	3.66(1.76)	62-64	3.08 (1.33)	**0.37 (0.03; 0.71)**	
Vlismas et al. 2013	Maternal Postnatal Attachment Scale	Quality of Attachment	Q	3-7 months	PI	24	39.1 (2.31)	24	39.0 (2.52)	0.04 (-0.52; 0.61)	
	Maternal Postnatal Attachment Scale	Absence of Hostility	Q	3-7 months	PI	24	19.2(3.58)	24	19.0 (2.72)	0.07(-0.50; 0.63)	
	Maternal Postnatal Attachment Scale	Pleasure of Interaction	Q	3-7 months	PI	24	20.9(2.93)	24	20.6 (3.78)	0.09 (-0.48; 0.65)	
	Maternal Postnatal Attachment Scale	Total attachment	Q	3-7 months	PI	24	79.2(7.79)	24	78.6 (7.39)	0.08 (-0.49; 0.65)	
Dickie & Gerber 1980	Homemade	Frequency of infant-initiated interaction	V	6-14 months	PI	8	3.5	6	2.0	0.94(-0.18; 2.05)	Father: F 3.41

Bold: significant at a 5% level
PI: Post Intervention
SF: Short term Follow up (≤6 months post intervention)
Q: Questionnaire
V: Video

Feinberg and colleagues[41] study of Family Foundations (previously described) reported two parent-child relationship outcomes at short term follow-up and found significant positive results on one or more outcomes.

Doherty and colleagues[44] examined Parenting Together among 165 families expecting their first child. Families were recruited through local obstetric clinics in the USA. The intervention was aimed at enhancing the quality of father-child interaction and consisted of eight sessions; the first session was a home visit during pregnancy, the next three sessions were group meetings during the second and third trimester, and the last four sessions occurred two to five months postnatally. There was no description of the control group. The study reported outcomes post intervention and at short term follow-up and found significant positive results on one or more outcomes, but also one significant negative effect.

Vlismas and colleagues[47] examined Face to Face (F2F) among 48 primiparous mothers. Families were recruited from three Maternal and Child Health Clinics in Brisbane, Australia. The overall aim of the study was to examine the effects of Music and Movement (M&M) in a two by two factorial model, comparing M&M to M&M combined with F2F, F2F alone, and a no intervention control condition. Because the M2M intervention does not meet the definition of a parenting intervention, we only used the results of the F2F group. The F2F intervention consisted of five group sessions when the infants were 2 to 4 months old; the control group did not receive an intervention. The F2F group sessions aimed to give parents instructions for play activities and to provide an opportunity to discuss parenting issues. The study reported outcomes post intervention. No significant effects were found on any outcomes.

Dickie and colleagues[45] examined parent training in 19 families in the USA. Families were recruited through a newspaper report. The intervention was aimed at increasing parental competence to assess, predict, and respond to their infant and consisted of 16 hours of training over eight weeks when the children were 4 to 12 months old. The families randomized to the control condition were put on a waiting list to receive the intervention following study assessments. It was only feasible to use a single outcome from this study because we lacked data to calculate standardized mean differences or could not calculate appropriate confidence intervals for the other reported outcomes. Only statistically significant outcomes were reported in the study. The outcome was reported post intervention. No significant effect was found.

Meta-analyses

We were able to conduct a meta-analysis of two child development outcomes at long-term follow-up (approximately 21-30 months post intervention, child age was about 36 months) and two parent-child relationship outcomes at short-term follow-up (approximately 6 months post intervention; child age around 12 months). For child development outcomes two studies (including 724 participants) were included in the meta-analysis.[39,42] There was no significant effect of the intervention for either Internalizing or Externalizing. For parent-child relationship outcomes two studies (276 participants) were included in the meta-analysis.[41,44] A significant effect was found for Father Positivity (0.30 [0.06; 0.54]). We found no significant effect of Father Negativity. See Table 6 for the results of the meta-analysis.

Table 4 Meta-analysis of child development and parent-child relationship outcomes

Study	Effect size	95% CI		% Weight	Heterogenity measure ($I^{2)}$:
Child development outcomes					
Externalizing					
Feinberg et al. 2010	0.05	-0.29	0.39	23.26	
Bayer et al 2010	0.11	-0.08	0.30	76.74	
Overall effect	0.10	-0.01	0.26	100.00	0.00
Internalizing					
Feinberg et al. 2010	0.05	-0.29	0.39	19.07	
Bayer et al. 2010	0.11	-0.05	0.27	80.93	
Overall effect	0.10	-0.05	0.25	100.00	0.00
Parent-child relationship outcomes					
Father Negativity					
Doherty et al. 2006	-0.37	-0.71	-0.03	50.08	
Feinberg et al. 2009	1.38	1.01	1.75	49.92	
Overall effect	0.50	-1.21	1.75	100.00	97.84
Father Positivity					
Doherty et al. 2006	0.22	-0.12	0.56	49.33	
Feinberg et al. 2009	0.37	0.03	0.71	50.67	
Overall effect	**0.30**	0.06	0.54	100.00	0.00

Bold: significant at a 5% level

DISCUSSION

We identified fourteen papers representing seven RCTs that examined the effects of universal parenting interventions for families with infants 0 to 12 months old. Meta-analysis was only conducted for four outcomes due to heterogeneity in the outcome measures and the timing of follow-up assessments. For three outcomes (Externalizing, Internalizing, and Father Negativity) there were no significant overall differences between the intervention and control groups. For Father Positivity, a significant positive effect of parenting interventions was found. Each meta-analysis only comprised two studies and the results of the meta-analysis are inconclusive. No consistent results were found across the seven studies. Four studies reported child development outcomes (of which one study also reported parent-child relationship outcomes). Of these, two reported one or more significant positive effects on child development,[40,48] while the other two did not.[52,53] Four studies reported parent-child relationship outcomes. Two of these studies found one or more significant positive effect,[40,44] however, one of the studies also found a significant negative effect.[44] Two studies found no significant effects of the parenting interventions.[45,47] Small to medium effect sizes were reported for the majority of the studies with statistically significant results (Cohen's *d* 0.33-0.60). Overall, more than half of the child development and parent-child relationship outcomes reported in the papers showed no significant effect of receiving the intervention.

The studies were varied in the interventions, methods, control conditions, outcome measures, and timing of follow-up assessments. These varied approaches may have contributed to the overall finding that the evidence for use of universal interventions is currently unclear. These differences may have led to unclear conclusions for several reasons. There may be differences between interventions initiated in

pregnancy compared to interventions initiated after a child is born. Two studies were initiated during pregnancy with four sessions offered prenatally and four session offered after the birth of the infant.[40–44] These two studies found conflicting results at short term follow-up: one study found a statistically significant result of Parent Negativity in favor of the intervention group,[40] whereas the other found a statistically significant effect of Negative Affect in favor of the control condition.[44] For Father Positivity, one study[41] found a positive significant effect while the other[44] did not. There were no consistent differences in effects between studies that included antenatal sessions and exclusively postnatal interventions.

There may be different effects according to duration and timing of the interventions. Three of the five relatively short interventions did not show any significant effects for either outcome evaluated.[38,45,47] The remaining two found significant positive effects on child development[44] and significant (both positive and negative) effects on parent-child relationship.[40] The two longer interventions, which ran for three and five years, respectively, also showed conflicting results; one found no significant effects[52] and the other found significant positive results of the intervention on child development in two of the three follow up assessments.[50,51] Given the results, there was no clear indication whether the duration of the intervention affected the outcomes.

Differential effects may have resulted from the timing of the assessments. Three studies reported child development outcomes between 2-2½ years post intervention,[39,42,43,46] and one study reported outcomes at 5, 10, and 15 years post intervention.[48,49,51] Significant positive results of the interventions were found at post intervention, short-term follow-up, and long-term follow-up; however,

for the majority of outcomes there was no effect at all time points. Three studies reported parent-child relationship outcomes at post intervention[44,45,47] and two studies reported outcomes at short term follow-up. [41,44] Significant positive results were found at both time points; however, the majority of outcomes showed no effects. One statistically significant negative effect for those receiving an intervention was found at short-term follow-up. Results were also mixed for assessment timing and there were no consistent trends for the effects.

Methodological issues such as sample size and implementation of the intervention could also have influenced these results. Generally, larger studies have more power to detect significant effects compared to small studies. The seven studies included in this review differed with regard to sample size; the smallest included 19 participants, the largest 1,593. The two smallest studies included 19 and 48 participants[45,47] and found no significant intervention effects on parent-child relationship (no child development outcomes were reported). The three medium sized studies included 152 to 165 participants[40,44,48] and they all found one or more significant outcome on child development and parent-child relationship; whereas the two large studies that included 733 and 1,593 participants[52,53] found no significant effects on child development (no parent-child relationship outcomes were reported). The sample size did not indicate a consistent trend in these studies.

Implementation quality may have at least partly explained the mixed findings in this review. Implementation quality has become a focus of intervention studies in recent years because of how it may impact treatment outcomes. Four studies[38,40,44,52] in the present review reported at least some information about implementation, such as how many sessions the parents attended and treatment quality of the intervention.

More details about training, certification, and supervision of interventionists would also provide valuable information about treatment quality. Without a more comprehensive overview of the implementation process it is difficult to assess whether the findings could have been affected by implementation quality. Inclusion of basic implementation information, such as the level of practitioner fidelity to the intervention and the parent completion rate of the intervention would have provided a clearer picture of how well the interventions were delivered across the different studies.

This review was developed employing a broad search and scope and included parenting interventions with diverse approaches and lengths. The broad scope facilitated the identification of as many relevant parenting intervention studies as possible. A limitation of the study was the large variation in outcomes measures used and different timing of assessments across studies. Due to this heterogeneity, we could only conduct meta-analysis for four outcomes.

CONCLUSION

This review identified seven studies evaluating the effects of interventions for parents with infants on child development and parent-child relationship outcomes. The results were mixed and inconclusive for the primary aim of this review. For more than half of the outcomes there were no differences between the intervention and control families. Three studies found one or more significant positive effect of participating in the intervention for child development or improving parent-child relationship; however, one of these studies also found a significant negative effect on parent-child relationship for the intervention group, and four studies did not find any significant effects. A meta-analysis of two child development outcomes

(Externalizing and Internalizing) and two parent-child relationship outcomes (Father Positivity and Father Negativity) found a statistically positive effect on Father Positivity but did not show any statistically significant effects between the control and intervention groups on the remaining three outcomes. This review indicates that there are mixed results of universal parenting interventions for families with infants 0 to 12 months, and no clear conclusions can currently be drawn regarding intervention effects on child development and parent-child relationship.

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CONTRIBUTERS
Maiken Pontoppidan conceptualized and designed the study, co-led the review process, contributed to screening, data extraction, and data synthesis, drafted the first manuscript, critically revised the manuscript, and approved the final manuscript as submitted.

Signe Boe Rayce co-led the review process, contributed to study design, screening, data extraction, and data synthesis, performed risk of bias judgement and meta-analysis, drafted the first manuscript, critically revised the manuscript, and approved the final manuscript as submitted.

Sihu K Klest and Joshua Patras contributed to study design, data synthesis, critically revised the manuscript, and approved the final manuscript as submitted.

COMPETING INTERESTS: Maiken Pontoppidan is principal investigator for an RCT of the Incredible Years Parents and Babies program as a universal intervention for parents with infants. The study is not yet published and therefore not included in this review.
Sihu Klest is currently the principal investigator for an RCT evaluating the effectiveness of the Incredible Years Baby Program that is offered as a universal intervention in Norwegian health stations. She will also serve as a co-author on Maiken Pontoppidan's evaluation. The remaining authors have stated that that they have no conflicting interests.

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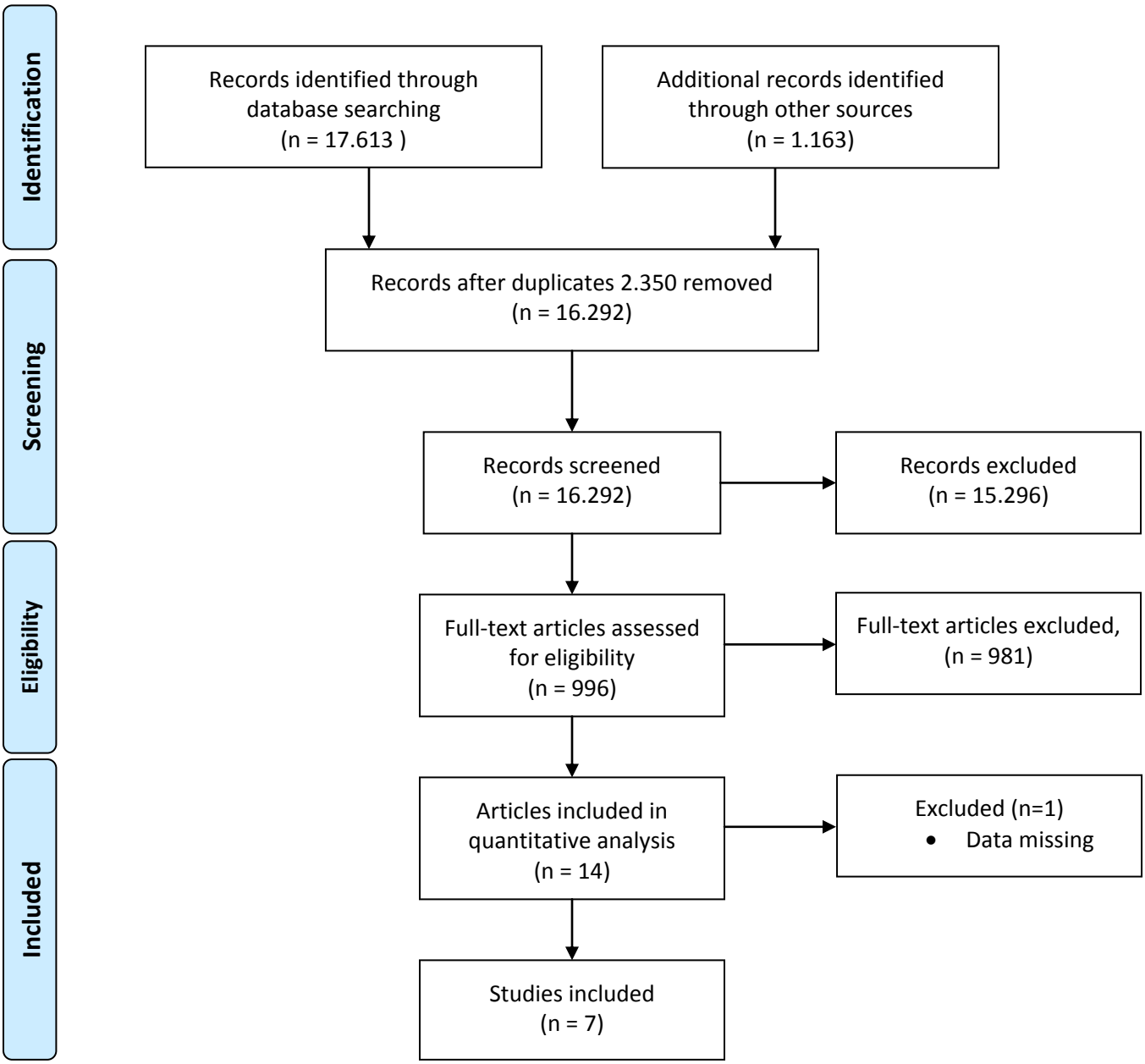
List of figures and tables

Figure 1 Flow diagram for study selection process



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Paper 2

Parent report measures of infant social-emotional development: A systematic review

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Abbreviations: SED: Social-emotional development; CBCL: Child Behavior Checklist ASQ-3: Ages and Stages Questionnaire; PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses; ROC: Receiver Operating Characteristic; IRT: Item Response Theory; DIF: Differential Item Functioning; ASQ:SE-2: Ages and Stages Questionnaires: Social-Emotional – 2; BPSC: Baby Pediatric Symptom Checklist; PPSC: Preschool Pediatric Symptom Checklist; BITSEA: Brief Infant-Toddler Social and Emotional Assessment months; CBCL 1½-5: Child Behavior Checklist 1½ - 5; DECA-I/T : Devereux Early Childhood Assessment For Infants And Toddlers; ECSA: Early Childhood Screening Assessment; SEGC: Greenspan Social-Emotional Growth Chart; ITSEA: Infant-Toddler Social and Emotional Assessment; M-P-R: Merrill-Palmer-Revised Scales of Development - Social-Emotional; SEAM: Social-Emotional Assessment/Evaluation Measure; ABAS-II: Adaptive Behavior Assessment System, 2nd Ed.; CDI: Child Development Inventories; CDR-PQ: Child Development Review; IDI: Child Development Review - Infant Development Inventory; DP3: Developmental Profile 3; CSBS-DP: Communication and Symbolic Behavior Scales Developmental Profile - Infant-Toddler Checklist; PEDS: Parents' Evaluation of Developmental Status; PedsQL Infant Scales: Pediatric Quality of Life Inventory; ASD: Autism Spectrum Disorder; DIPA: Diagnostic Infant Preschool Structured Interview

Contributers' Statements:

Mrs. Pontoppidan conceptualized and designed the study, led the review process, made substantial contribution to article and measure review, data extraction, drafted the original manuscript, critically reviewed and revised the manuscript, and approved the final manuscript as submitted.

Mrs. Niss and Dr. Pejtersen contributed to study design, article and measure review, data extraction, critically reviewed and revised the manuscript, and approved the final manuscript as submitted.

Dr. Julian contributed to study design, critically reviewed and revised the manuscript, and approved the final manuscript as submitted.

Dr. Væver contributed to study design, measure review, critically reviewed and revised the manuscript, and approved the final manuscript as submitted.

Abstract

Context
Identifying young children with socio-emotional developmental problems at an early stage, to prevent serious problems later in life, is crucial. Therefore, we need high quality measures.

Objective
The objective of this review was to systematically identify parent report measures of infant (0-24 months) social-emotional development for use in primary care settings.

Data sources
Medline, PsychInfo, Embase and SocIndex were searched for articles published from 2008 through September 2015.

Study Selection
Parent-report measures of infant social-emotional development with data on validity and reliability were located and screened.

Data Extraction
Data on the characteristics of the measures, including psychometric data, were collected.

Results
From 3310 screened articles, 242 measures were located and examined, and 18 measures of infant social-emotional development were included. Ten of the measures were developed specifically for measuring social-emotional development and eight were broader measures with subscales measuring social-emotional development. The measures varied with respect to e.g. the time of publication, number of items, age span, cost and amount of psychometric data available.

Limitations
Only measures for which we could obtain a free copy for review are included.

Conclusions
Several measures of infant social-emotional development have been developed within the last decade. The majority of psychometric data are available through manuals, not peer-reviewed journals. Although all measures show acceptable reliability, the most comprehensive and psychometrically sound measures are the Ages and Stages Questionnaires: Social-Emotional – 2, Infant-Toddler Social and Emotional Assessment, Brief Infant-Toddler Social and Emotional Assessment and Child Behavior Checklist 1½ – 5.

Introduction

Substantial evidence has shown that infants (defined as children ages 0-24 months old in this article) and young children can suffer from psychopathological conditions,[1–5] and that unfavorable conditions early in life may cause serious lifelong problems.[6–13] An estimated 5 to 26% of 0 to 5-year-old children suffer from serious emotional or behavioral problems,[14] and only about one-third of children in need of services have been identified by the start of school, highlighting the need for developmental screening at a younger age.[15]

Psychopathology in young children is often found within the social-emotional domains[3] and tends to persist over time.[3,4] As social-emotional skills form the foundation for later functioning in school and building lasting relationships with friends and family, the need to assess such skills in infants and young children is now widely accepted.[1,7,16–26] Social-emotional development (SED) is defined here as "a child's developing capacity to: (1) experience, manage and express the full range of positive and negative emotions; (2) develop close, satisfying relationships with other children and adults; and (3) actively explore their environment and learn."[16,27]

As SED primarily occurs within the context of the infant-parent relationship, parent-report measures are relevant when assessing infant SED.[28] Several parent-report instruments to measure young children's SED are being used in practice today, such as the Child Behavior Checklist (CBCL) and the Ages and Stages Questionnaire (ASQ-3).[29] The overall quality of parent-report rating scales has improved notably over time.[17,30] The use of parent-report measures significantly increases the detection of development delays in young children in early child care settings,[31] and routine screening is recommended by the American Academy of Pediatrics at ages 9, 18 and 24 to 30 months; however, this has been difficult to implement.[12,32,33] One reason is that, as pediatric

clinicians point out, selecting appropriate measures is challenging.[33] The availability of high-quality measures is crucial, but measures must also be practical for routine use in community contexts.[34]

Although research on the assessment of young children exists,[1,17,29,30,32,35–38] we found no up-to-date systematic review of available parent-report measures of infant SED. The aim of this article was to conduct a systematic review based on a comprehensive literature search of parent-report measures of SED in infants aged 0 to 24 months that can be used in first and second line child services.

Methods

Search strategy

This review was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). We did not register a protocol for this study. An information specialist searched the databases in October 2013 and updated the searches in September 2015. We searched Medline, PsychINFO, Embase and SocIndex. The search terms comprised of conjunctions of the following terms: child*, baby, babies, infant*, toddler*, infants, develop*, assessment, inventory, questionnaire*, screen, screening, scale*, instrument*, validation and validity. The search was narrowed by the following strategies: MeSH descriptors or subject headings, proximity operators, limitations of searches to title and abstracts and articles published from 2008. This limitation only applied to the article search; there was no age limit for the measures. The year 2008 was the starting point as several reports on assessment measures were published in 2008.[35,37,39] In addition to the database searches, we also searched Google, Google Scholar and publishers' homepages. After measures that met all the inclusion criteria were identified, an information specialist completed an

additional search with the title of each measure to locate articles with psychometric properties of the measures. All screening was performed in EPPI-Reviewer 4.

Study selection

Each publication was screened based on abstract and title. Articles were included if an instrument for measuring development in children less than 3 years old was mentioned in the title or abstract. The included articles were retrieved in full text and examined. Finally, a list of measures to be screened for eligibility was compiled. Screening was performed by the first or second author, Maiken Pontoppidan or Nete Kroghsgaard Niss (hereafter referred to as MP or NN). Any uncertainties were discussed with a third reviewer.

A measure was included if it met all of the following inclusion criteria: (1) it was a parent-report rating scale; (2) it was aimed at measuring infant SED; (3) it had at least one item within each of the following domains: (a) experience, manage, and express the full range of positive and negative emotions, (b) develop close, satisfying relationships with other children and adults and (c) actively explore their environment and learn; (4) it could be used with infants in the age group of 0 to 24 months old; (5) it had data on validity and reliability; (6) it was available in English; (7) it was developed in a western country; (8) it was commercially or otherwise available for use; and (9) it could be obtained as a free copy for review.

Data extraction

Data extraction was performed by MP and NN using a structured data extraction sheet. The following data were extracted for each measure based on available manuals, technical reports, journal articles and reports: number of domains, age range, year of publication, administration time,

number of items, response categories, proportion of strength-based or problem-based items, size of norm sample, cost and psychometric properties. This involved Test-retest, Cronbach's alpha, inter-rater reliability, sensitivity/specificity, receiver operating characteristic (ROC) curves, validity, factor analysis, Item Response Theory modeling (IRT) and differential item functioning (DIF).

Results

The literature search yielded a total of 3310 articles, of which 313 articles met the inclusion criteria. We were able to retrieve 263 (84%) articles in full text; for the majority of the remaining articles, we were able to extract the names of the measures in the abstract. A flow diagram of study inclusion is provided in Figure 1.

Figure 1 about here

The screening of the 313 articles yielded 242 unique measures of child development. The measures were screened for eligibility by MP and NN, who consulted with a third reviewer. A total of 18 measures met the inclusion criteria. These were divided into two groups: 1) measures developed specifically for measuring SED (hereafter called “SED measures”), and 2) measures that, while developed for measuring a broader construct, included at least one subscale measuring SED (hereafter called “SED subscale measures”). The measures appear in alphabetical order in Tables 1 and 2. As the measures in the first group were the primary focus of the article, they are presented in more detail than those in the second group. Moreover, as psychometric data are mostly provided for the whole scale and not for subscales, collecting psychometric properties of the SED subscales of the measures in the second group was not possible.

The 10 SED measures include: 1) Ages and Stages Questionnaires: Social-Emotional – 2 (ASQ:SE-2),[40,41] 2) Baby Pediatric Symptom Checklist (BPSC)[42] and Preschool Pediatric Symptom Checklist (PPSC),[43] 3) Brief Infant-Toddler Social and Emotional Assessment months (BITSEA),[44–46] 4) Child Behavior Checklist 1½ – 5 (CBCL),[47] 5) Devereux Early Childhood Assessment for Infants and Toddlers (DECA-I/T),[48,49] 6) Early Childhood Screening Assessment (ECSA),[50] 7) Greenspan Social-Emotional Growth Chart (SEGC),[51] 8) Infant-Toddler Social and Emotional Assessment (ITSEA),[52,53] 9) Merrill-Palmer-Revised Scales of Development (M-P-R) – Social-Emotional[54] and 10) Social-Emotional Assessment/Evaluation Measure (SEAM™).[55,56]

The eight SED subscale measures include: 1) Adaptive Behavior Assessment System, 3rd Ed. (ABAS-3),[57] 2) Child Development Inventories (CDI),[58] 3) Child Development Review (CDR-PQ),[59] 4) Child Development Review – Infant Development Inventory (IDI),[59] 5) Developmental Profile 3 (DP-3),[60] 6) Communication and Symbolic Behavior Scales Developmental Profile – Infant-Toddler Checklist (CSBS-DP),[61,62] 7) Parents' Evaluation of Developmental Status (PEDS)[63] and 8) PedsQL Infant Scales – pediatric quality of life inventory.[64]

Table 1 about here

When examining the 10 SED measures in Table 1, we see that the measures vary on dimensions such as the number of items, domains included, and the wording of items, even though they were all developed specifically for assessing SED. We highlighted some of the differences between the measures, differences that may have consequences for the choice of measure, depending on the primary aim of its use.

Publication time

As most of the measures have been published or revised within the last 10 to 15 years, the development of measures designed primarily for SED is relatively new. Seven of the 10 measures were either published or revised within the last five years. The CBCL (published in 1982) is the oldest measure, and SEAM (published in 2014) is the newest.

Length

While the majority of the SED measures are relatively short (12-42 items) and can be completed in less than 10 minutes, two are significantly longer: the CBCL (99 items) and ITSEA (166 items). The shorter measures might be preferable for early screening, because they minimize the burden on both staff and families.[29,34,65] If concern about a young child's development is raised after the use of a brief measure, the use of a more comprehensive parent-report measure or a measure based on professional observation or interview is generally recommended.[66]

Usability

For use in primary care settings, a measure that covers a wide age range is advantageous because it reduces the need for different systems. Most of the SED measures cover a rather wide age range, from birth to 6 years. Some measures consist of different versions for different ages, such as the ASQ:SE2 (nine versions) and SEAM (three versions). Other measures consist of one version covering the full age range but with different items according to age, such as the M-P-R Social-Emotional and SEGC. The ITSEA and BITSEA cover the shortest age range, 12 months through 35 months. For the CBCL and ECSA, children must be 18 months or older.

Strength/problem-focused

The SED measures also differ in the wording of the items. Some are specifically developed within a resilience or strength-based framework (DECA-I/T, SEGC, M-P-R Social-Emotional and SEAM). Others focus on deficits, difficulties or problems (BPSC/PPSC, CBCL and ECSA). The remaining three measures have a mix of strengths and problem-focused items: ASQ:SE-2 with a majority of strength-based items, and ITSEA and BITSEA with a majority of problem-based items. Examples of strength-based items are "can separate from you in familiar environment with minimal distress" and "enjoys interacting with others," whereas examples of problem-based items are "has trouble adjusting to changes" and "hits others."

Seven of the SED measures concern domains such as self-regulation, irritability, externalizing, dysregulation, initiative and child expresses a range of emotions. The ECSA, SEGC and M-P-R include no domains. The difference between measures with a strength focus and measures with a problem focus is also present in the classification of the domains. The measures with strength-based items have domains focusing on positive aspects such as initiative, attachment and empathy (e.g., SEAM and DECA-I/T), whereas the measures with problem-based items have domains focusing on problematic behavior such as inflexibility, aggressive behavior and attention problems (e.g., CBCL and ECSA). The three measures that have a mix of strength-based items and problem-based items either have strength-based domains (ASQ:SE-2) or problem-based domains and a competence score (ITSEA and BITSEA).

The two long measures, CBCL and ITSEA, include several items measuring more pathological development, such as "too much playing with own sex parts" and "playing with own poop." While these measures might not be ideal for first-stage screening, they are more relevant for the second-stage screening of young children for which substantial worry exits about their SED.

Norm samples

Although all SED measures have norms, a difference existed in the size of the norming samples spanning 279 (ECSA) to 16,424 children (ASQ:SE-2).

Psychometrics

While we were able to locate psychometric data on all 10 measures, the amount of data differed. For eight measures, we found peer reviewed articles including psychometric data, but we did not find any for the SEGC and M-P-R. The measure with the most articles was the CBCL, the oldest measure. We also found articles on the ITSEA, BITSEA, DECA I/T and ASQ:SE-2. We found one article on the BPSC/PPSC, SEAM and ECSA, whereas we could not find any articles on the SEGC or M-P-R. Data from these articles may be on earlier versions of the measure (e.g., the CBCL 2-3, DECA and ASQ:SE).

Most of the psychometric information was available either through assessment guides[35–38] or the technical report part of the manual. Only a minor part was available through peer reviewed journal articles. Generally, the reported psychometric data are based on classical test theory (such as test-retest, Cronbach's alpha, inter-rater reliability) and factor analyses, with limited data based on modern test theories such as IRT.

Test-retest coefficients are reported by all but one measure (SEGC) and range from 0.68-0.99. Cronbach's alpha coefficients range from 0.52 to 0.95, the majority ranging from 0.80 to 0.95. Generally, a reliability coefficient of at least 0.70 is recommended, but for measures of personality and other issues that are harder to measure than IQ, for example, coefficients between 0.6 and 0.8

are common.[67] All measures have acceptable reliability coefficients, only a few of the reported reliability coefficients are below 0.6.

Six measures have inter-rater reliability data. Both father-mother, parent-teacher and teacher-teacher inter-rater reliability data are reported, ranging from 0.28 to 0.95. The samples used to calculate inter-rater reliability are generally small. Parent-teacher inter-rater reliability does not necessarily have to be high, as children can have problems in one context (e.g., the school) but not in another (e.g., the home). Both teacher-teacher and father-mother inter-rater reliability should be within the ranges of the other reliability coefficients, although there can be examples where a mother and a father have very differing perceptions of the levels of problems exhibited by their child. The ITSEA, BITSEA, CBCL and DECA-I/T all have coefficients that are acceptable, but in the low end, whereas the ASQ:SE-2 coefficient is excellent. SEAM coefficients range from 0.32-0.95, which is from unacceptable to excellent.

All but two measures (M-P-R and SEAM) have data on prediction. Sensitivity/specificity data are reported for eight measures and three also report ROC curves. Sensitivity/specificity data and ROC curves express how well a measure correctly classifies a child as having problems that merit treatment or not and are therefore critical for clinical use.[68,69] To calculate prediction data, the measure that is being evaluated is compared to the test that is considered to be the gold standard within the specific area.[69] Because there is no gold standard within the area of infant SED, there is no agreement on the test to compare the measures with to get prediction data. The measures that have prediction data base the calculations on, for example, parent report of diagnosis, Autism Spectrum Disorder (ASD) measures or diagnosis, samples with infants with SED problems, Diagnostic Infant Preschool Structured Interview (DIPA), DECA-I/T, ITSEA and CBCL.

Factor analysis data are reported for all measures except (SEGC and SEAM). IRT) data are reported for three measures (ASQ:SE-2, M-P-R and SEAM). Contrary to classical test theory, IRT models emphasize formal statistical models to the probabilities of item responses.[70] IRT methods focus especially on making assessment measures efficient and precise. DIF is reported for two measures (ASQ:SE-2 and BPSP/PPSP). DIF analyses are performed to check for any differences in the way an item functions across groups such as gender, age or education for a given level of the scale score, and they are an important element of evaluating bias in a measure.[71]

Cost

Comparing the costs of the measures is difficult, as the time necessary for training the professionals differs as do the monetary and time costs of using a Web-based scoring system compared to pen-and-pencil scoring. Here we report the price for a starter kit, which includes a number of forms and a manual. Two of the measures are free (BPSC/PPSC and ECSA). The remaining eight have starter kits priced from $49.95 (SEAM) to $925 for the full M-P-R, which covers other developmental areas than SED.

Table 2 about here

The eight SED subscale measures in Table 2 are generally older than the SED measures; most were developed in the 1980s or 1990s. Three have been revised within the last 10 years, and ABAS-3 was just released in 2015. Five of the SED subscale measures are relatively short (e.g., PEDS and CDR-PQ), but three are larger scales with 180 to300 items (DP-3, ABAS-3 and CDI). Whereas all the SED measures have three to five response categories, only half of the SED subscale measures

have yes/no response categories. CDR-PQ and IDI stand out because they use charts instead of questions; ABAS-3 stands out because it focuses on adaptive behavior; PEDS-QL stands out because it also measures physical symptoms; DP3 and CDI stand out because of their in-depth measuring.

Discussion

This systematic review identified 10 measures of infant SED and another eight measures with subscales measuring infant SED, which are available for use in primary care settings. As pointed out previously, choosing which measure to use is difficult. In this article, we provide information that can aid in the process of choosing an SED measure.

All of the SED measures are developed or have been thoroughly revised within the last decade, reflecting the recent focus on the SED of young children. The differences in the SED measures highlight that infant SED is not a separate and distinct area, but it overlaps with other areas of child development, such as executive functioning (which, while viewed as a cognitive ability, includes areas such as self-regulation — a central part of social-emotional behavior).[72]

Infant SED is challenging to measure, mainly because the first years in a child's life contain rapid and dramatic changes across all developmental domains. Distinguishing between deviant and typical development is difficult, as most social-emotional behaviors are not either present or not present because they are a part of normal development (e.g., smiling at others and having tantrums).[4] Therefore, measuring SED becomes more of a question of evaluating whether or not the problem behaviors limit the functioning of the child (e.g., with reduced or heightened intensity, duration and/or frequency).[1]

The quality of parent-report measures is debated, and observational measures are often considered to be more accurate as they are filled out by professionals independently of parents. For infants, however, the use of observational measures is difficult because infants are very susceptible to contextual changes and are more influenced by the testing situation itself than older children (e.g., item refusal).[17,28,30] Although parent-report measures are not flawless, their main advantage is that they draw on the extensive knowledge parents have about their infant across context and time.[30,73,74]

Altogether, the available published data on reliability and validity appeared to be reasonably good, but as mentioned in the results section, most of the psychometric information came from technical reports in manuals that have not been subject to peer review. It is crucial that the psychometric properties of the measures used in primary care settings are excellent, since they are used for making decisions about young children and their parents' future course of treatment. Most SED measures (except M-P-R and SEAM) report predictive data that are crucial for a screening measure that is to be used in clinical practice. As there is yet to be a gold standard to compare the measures to, it is hard to evaluate how well the different measures correctly predict which infants need treatment.

All SED measures show acceptable reliability data. Based on the data available for this article, the most comprehensive and psychometrically sound measures were the relatively short measures ASQ:SE-2 and BITSEA, and the longer measures ITSEA and CBCL. Of the four, ASQ:SE-2 is the only measure that can be used with the whole age range of 0 to 24 months. The ITSEA and BITSEA can be used with children ages 12 to 35 months, and the CBCL can be used with children from 18 months. The BPSC/PPSC, DECA-I/T, ECSA and SEAM have been rigorously developed,

but psychometric data are still few, which is probably mainly because all these measures are still relatively new (published between 2010-15). The SEGC and M-P-R both have limited sound psychometric data available.

Partly because of copyright constraints, publishing psychometric data on measures that are commercially published is difficult. Therefore, most of the information on the measures distributed through publishers is available in manuals, not in peer-reviewed journal articles. Getting more psychometric data on measures of infant SED published in peer reviewed journals is necessary.

Apart from looking at costs, psychometric quality and the ease of use in choosing a measure, considering the theoretical background of both the measure and the setting (families and clinicians) is also important. Some child and family settings are based on theoretical perspectives rooted in resilience or positive psychology theory, and their practitioners often find it essential to measure child strengths and competencies to understand the development of the child.[1,17,30,75] In such settings, using a strength-based measure (e.g., DECA I/T and SEAM) may be important. Studies have shown that competence scores predict psychiatric disorders and that young children with lower social-emotional competence scores than their peers are at risk for later social-emotional problems.[76] Moreover, both teachers and parents tend to find some of the problem-focused questions irrelevant or even offensive, especially in the measures for older children.[17,65] Strength-based measures may be a better fit for screening in primary care or early education settings, whereas problem-focused measures may be a better fit for clinical settings.

During the screening process of this study, we found that the available measures for school-aged children appeared to greatly outweigh those available for children below the age of 2 and even

fewer below the age of 1. Also, some measures for young children were simply downward-age extensions of measures developed for older children and therefore may not be sufficiently sensitive to the developmental problems in young children.[17] With the more recent acknowledgement that mental health problems can be present in very young children, the need for high-quality measures of young children's SED and routine use in primary care settings becomes essential. Given the complexity of measuring young children's development, such as the rapid development and lack of language, however, the use of measures with infants also merits great caution. Although more work is still needed, the recent development within the field of infant SED measures shown in this paper leaves reason for optimism.

Strengths and limitations

A strength of this study is that it was built on a thorough and systematic literature search and screening procedure for identifying available measures for assessing infant SED. A limitation of the study is that we could only include the measures for which we could obtain a free copy for review. In most cases, however, we were able to obtain copies; we were only unable to obtain access for a few measures.

Conclusion

Measuring infant SED in primary care settings is critical. Within the last decade, new measures have been developed and older measures have been revised, yielding a range of available measures for assessing the SED of 0 to 24-month-old infants. Ten measures are specifically developed for measuring SED, and eight have subscales measuring SED. As these measures vary in many ways, they are likely to be available for catering to different needs in primary care settings. The majority of psychometric data are available through manuals, not peer reviewed journals, and are based on

classical test theory and factor analysis whereas only a few utilize DIF analyses and IRT. Although all SED measures show acceptable reliability data, the most comprehensive and psychometrically sound measures seem to be the ASQ: SE-2, BITSEA, CBCL and ITSEA.

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Table 2 Characteristics of SED measures

Measure	ASQ:SE-2	BPSC/PPSC	ITSEA	BITSEA	CBCL	DECA-I/T	ECSA	SEGC	M-P-R	SEAM
Comments		Part of The Survey of Wellbeing of Young Children (SWYC)		Short version of ITSEA	Part of the ASEBA		4 items screen for depression in parent. A new shorter verion is being developed		A part of the Merrill-Palmer-Revised (M-P-R)	
Domains	Self-regulation, compliance, communication, adaptive behaviors, autonomy, affect, and interaction with people	BPSC: Irritability, Inflexibility and Difficulty with Routines PPSC: Externalizing, Internalizing, Attention Problems, and Parenting Challenges.	Externalizing, Internalizing, Dysregulation, (problem domains) and Competence. Item clusters: Maladaptive, Atypical, and Social Relatedness	Internalizing, Externalizing, and Dysregulation, autism spectrum disorders, other psychopathologies, social-emotional competencies	Internalizing, Externalizing, Total Problems, Emotionally Reactive, Anxious/Depressed, Somatic Complaints, Withdrawn, Sleep Problems, Attention Problems, Aggressive Behavior, Depressive Problems, Anxiety Problems, Autism Spectrum Problems, Attention Deficit/Hyperactivity Problems, Oppositional Defiant Problems.	1-18 months: Initiative and Attachment. 18-36 months: Initiative, Attachment and Self-regulation	None	None	None	Child participates in healthy interactions, Child expresses a range of emotions, Child regulates social-emotional responses, Child begins to show empathy for others, Child attends to and engages with others, Child explores hands and feet and surroundings (infants)/demonstrates independence (toddlers), Child displays a positive self-image, Child regulates activity level, Child cooperates with daily routines and requests, Child shows a range of adaptive skills
Ages	1–72 months	1-65 months	12-35 months	12-35 months	18-60 months	1-36 months	18-60 months	0-42 months	1-78months	2-64 months
Versions	9	2	1	1	1	2	1	1	1	3
Published	ASQ:SE 2002, ASQ:SE-2 2015	2012	2006, revised 2011	2006, revised 2011	1982, revised 2000	2007, revised 2011	2010	2004	2004	2014
Administration time	Less than 10 min.	Less than 5 min.	20-30 min.	5-7 min.	15 min.	Less than 10 min.	6-7 min.	Less than 10 min	Less than 5 min.	Less than 10 min.

Items for 0-24 months	16-33	12 (BPSC), 18 (PPSC)	166	42	99	33-36	40	35	12	35
Response categories	3 (Frequency)	3 (Frequency)	3 (Agree/Frequency)	3 (Agree/Frequency)	3 (Agree)	5 (Frequency)	3 (Frequency)	5 (Frequency)	4 (Frequency)	4 (Agree)
Strengths- or problem-based	Primarily strengths-based 65%	Problem-based 100%	Primarily problem-based 72%	Primarily problem-based 74%	Problem-based 100%	Strengths-based 100%	Problem-based 100%	Strengths-based 100%	Strengths-based 100%	Strengths-based 100%
Norm sample	16,424	405 (BPSC), 817 (PPSC)	600	600	700 US sample, 3446 multicultural sample.	2,183 (987 infants and 1196 toddlers)	279	456	1,400	2,201
Test-retest	0.89 (1-3 weeks)	PPSC: 0.75.	0.69-0.90 (mean of 44 days)	Problem scale: 0.87, Competence scale: 0.85 (10-45 days)	0.85 (0.68-0.92) 8 days.	0.85-0.97	0.81 (10 days).		0.89 (3 weeks)	0.97-0.99
Cronbach's alpha	Overall: 0.84 (0.71- 0.87)	BPSC: 0.64-0.83, PPSC: 86-0.92,	Externalizing 0.66-0.79; Internalizing 0.85 (0.52-0.73), Dysregulation 0.86 (0.62-0.83), Competence 0.56-0.79.	Problem scale: 0.80, Competence scale: 0.69	Domains: 0.66 - 0.92, total score: 0.95	0.9-0.95;	0.91.	Ovarall 0.90 (0.83-0.94)	Overall 0.93 (0.90-0.94)	0.9-0.91
Inter-rater reliability	0.91		Parent: 0.43-0.79	Parent: 0.61-0.68, Parent-teacher problem scale 0.28, competence scale 0.59	Parent: 0.61; Teacher: 0.65; parent-teacher: 0.40.	0.68-0.74				Teacher: 0.32-0.95
Validity	Agreement with similar measures 0.81-0.95.	Agreement with BPSC domains. ASQ:SE 0.02-0.51. PSI 0.10-0.42. PHQ-2: 0.02-0.15.	Agreement with BITSEA 0.57-0.77. CBCL: 0.41-0.60. ASQ:SE: 0.34-0.69. Bayley III: 0.32-0.48. ABAS II: -0.13-0.52	Agreement with ASQ:SE: 0.55. CBCL 0.51-0.79. ABAS-II: 0.39-0.56. Bayley-III: 0.25-0.51	Agreement with Toddler Behavior Screening Inventory and ITSEA 0.48-0.70.	Agreement between DECA and DECA-T 0.83-0.91.	Agreement with CBCL: 0.81. BITSEA 0.60.	Agreement with Bayley III: 0.18-0.25; WPPSI-III: 0.27-0.53; Preschool Language Scales-4: 0.20-0.23; PDMS-2: 0.06-0.33	Agreement with Bayley Mental Scale 0.79, Bayley Motor 0.54. Leiter-R 0.48-0.76).	Agreement with DECA I/T: 0.75; ITSEA: -0.42-0.65; ASQ: -0.56

Sensitivity/specificity	Sensitivity 0.81, Specificity 0.84 Percent agreement 0.83, Under-identified 0.04, Over-identified 0.13, Positive predictive value 0.59	PPSC: Sensitivity 0.75-0.92 and specificity 0.77 compared to parent report of diagnosis. Sensitivity 0.50-0.83 and specificity 0.82 compared to ASQ:SE.	ITSEA significantly differentiates autistic toddlers from those with a developmental delay and those developing typically.	Autism: sensitivity 0.72-0.93, Specificily: 0.76-0.85. Significantly predicted CBCL/1.5-5 and ITSEA scores one year later.	Correctly classified 84 % of a sample of children with emotional/behavioral problems. Sensitivity 0.85-0.89 and specificity 0.90-0.92 for ASD compared to typical development.	Infant: Sensitivity 0.27-0.47, specificity 0.87. Toddler: Sensitivity 0.41-0.57, specificity 0.80-0.87. Positive predictive value 0.75- 0.77.	Sensitivity: 0.86, Specificity: 0.83 compared to diagnoses by Diagnostic Infant Preschool Structured Interview (DIPA)	Sensitivity 0.87, specificity 0.90		
ROC	X			x	x		x			
Factor analysis	x	x	x	x	x	x	x		x	
IRT	X								x	x
DIF	X	x								
Cost of starter kit	$275	Free	$286-348 for ITSEA and BITSEA combined	$286-348 for ITSEA and BITSEA combined	$160-375	$199.95	Free	$115	$925 for the full M-P-R	$49.95
Source	Manual, jounal articles	Journal articles	Journal articles	Journal articles	Manual, Journal articles	Manual	Journal article	Manual	Manual	Manual

ASQ:SE-2: Ages and Stages Questionnaires: Social-Emotional – 2; BPSC: Baby Pediatric Symptom Checklist; PPSC: Preschool Pediatric Symptom Checklist; ; ITSEA: Infant-Toddler Social and Emotional Assessment; BITSEA: Brief Infant-Toddler Social and Emotional Assessment months; CBCL 1½-5: Child Behavior Checklist 1½ - 5; DECA-I/T : Devereux Early Childhood Assessment For Infants And Toddlers; ECSA: Early Childhood Screening Assessment; SEGC: Greenspan Social-Emotional Growth Chart; M-P-R: Merrill-Palmer-Revised Scales of Development - Social-Emotional; SEAM: Social-Emotional Assessment/Evaluation Measure

ROC: Receiver Operating Characteristic; IRT: Item Response Theory;

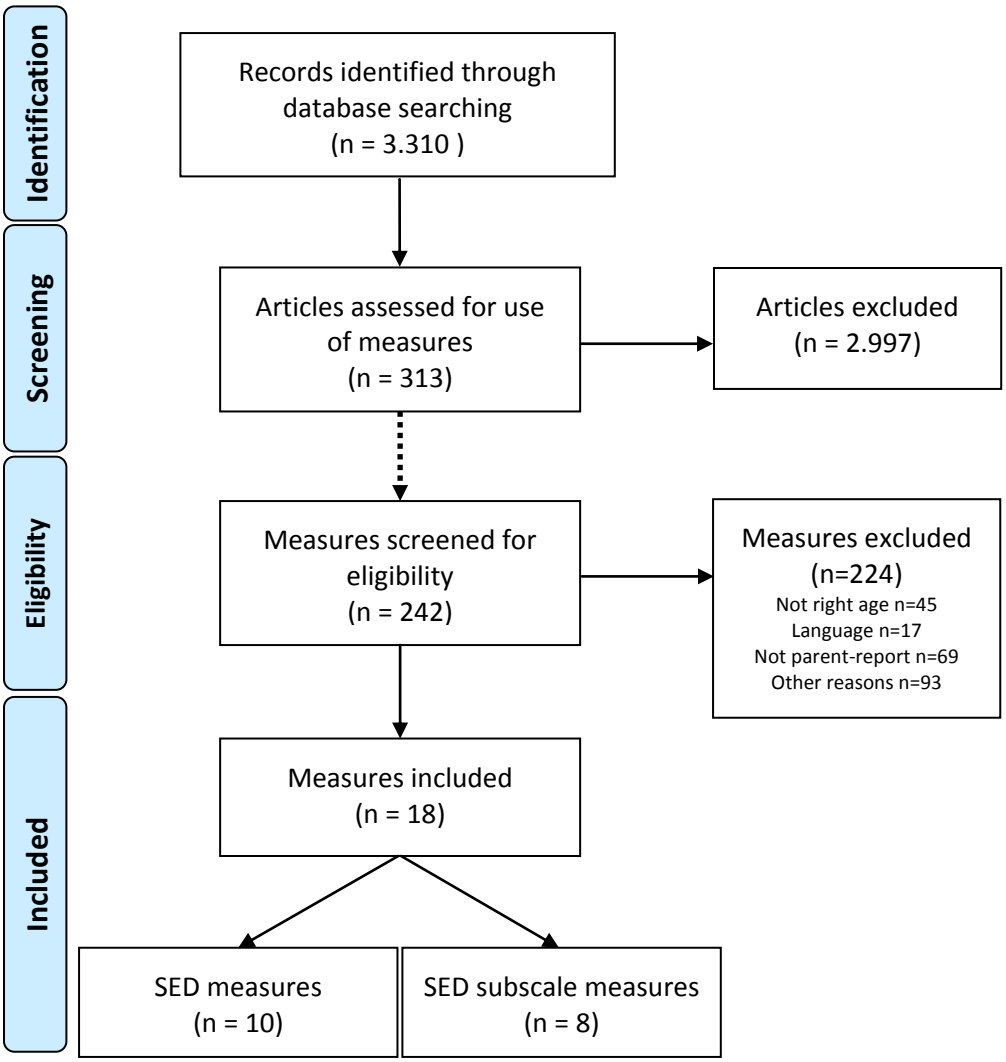
DIF: Differential Item Functioning;; ABAS-II: Adaptive Behavior Assessment System, 2nd Ed.; CDI: Child Development Inventories; CDR-PQ: Child Development Review; IDI: Child Development Review -

Table 2 Characteristics of SED subscale measures

Measure	ABAS-3	CDI	CDR-PQ	IDI	DP-3	CSBS DP	PEDS	PEDS-QL
Comments		Part of Child Development Review (CDR)	Part of Child Development Review (CDR)	Part of Child Development Review (CDR)	Single scales can be used as each scale was separately normed.			
Subscales	Conceptual; Social Practical	Social Development, Self Help, Gross Motor, Fine Motor, Language, Letters and Numbers, Possible Problems	Social, Self-Help, Gross Motor, Fine Motor, and Language	Social, Self-Help, Gross Motor, Fine Motor, and Language	General Development, Physical, Adaptive Behavior, Social-Emotional, Cognitive, Communication	Social, Speech and Symbolic composites	Global/Cognitive, Expressive Language and Articulation; Receptive Language; Fine-Motor; Gross-Motor; Behavior; Social-emotional; Self-Help; School; and Other.	Physical Functioning, Physical Symptoms, Emotional Functioning, Social Functioning, Cognitive Functioning
Ages	0-89 years	18 month-5 years	18 months-5 years	0-18 months	0-12 years	6-24 months	0-9 years	1-24 months
Published	ABAS-II 2003, ABAS-3 2015	1992	1990, revised 2005	1994, revised 2005	DP-II 1980, DP-3 2007, revised 2011	2002	1997	1998
Administration time	20 min.	20 min.	5 min.	5 min.	20-40 min	Less than 10 min.	Less than 5 min.	Less than 10 min.
Total Items	241	300	6 open ended items + 25 + Child development chart	2 open ended items + Infant Development Chart	180	24	10	36/45
Items in SED subscale	48	40	Tick child skills in chart	Tick child skills in chart	8	4	2	16-17
Response categories	4 (Frequency)	2 (Yes/No)	2 (Yes/No)	2 (Yes/No)	2 (Yes/No)	3 (Frequency)	3 (Yes/No/A little) + comments	5 (Frequency)

ABAS-3: Adaptive Behavior Assessment System, 3rd Ed.; CDI: Child Development Inventories; CDR-PQ: Child Development Review; IDI: Child Development Review - Infant Development Inventory; DP3: Developmental Profile 3; CSBS-DP: Communication and Symbolic Behavior Scales Developmental Profile - Infant-Toddler Checklist; PEDS: Parents' Evaluation of Developmental Status; PedsQL Infant Scales: Pediatric Quality of Life Inventory

Figure 1 Flow diagram for study selection process



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.

Paper 3

Internal and External Validity of the Danish Version of the Karitane Parenting Confidence Scale (KPCS)

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ABSTRACT

Parenting confidence is believed to be a key factor in predicting a range of outcomes for both parents and children, such as parental depression, parental stress, and child health development. This study examines the psychometric properties of the Karitane Parenting Confidence Scale (KPCS) in a community sample of first-time mothers. The total sample consisted of 695 mothers (488 not-at-risk and 207 at-risk). The results indicate acceptable internal consistency, but also an overall ceiling effect, and many items are characterized by low discrimination. There was a significant difference between at-risk and not-at-risk mothers' confidence when their infants were aged two and six months, and at-risk mothers improved significantly more than not-at-risk mothers.

INTRODUCTION:

Infants are dependent on their parents' ability to actively support their development, especially in the first few months of their life. Parenting confidence, or how parents perceive themselves in the parent role, is believed to be a key factor in predicting a range of parental and child outcomes such as parental depression, parental stress, and child development (Coleman & Karraker 1998; Črnčec Barnett, & Matthey 2008a; de Montigny & Lacharite 2005; T.L. Jones & Prinz 2005).

Interventions aimed at improving parenting competences, and thereby parenting confidence (such as Incredible Years (Webster-Stratton & Reid 2010), Family Nurse Partnerships (Olds, Sadler, & Kitzman 2007), and Circle of Security (Powell, Cooper, Hoffman, & Marvin 2009)), are widely used in developed countries. To determine whether parents are in the target group for an intervention, and whether the intervention will improve their competences, it is essential for both clinicians and researchers to assess parenting confidence (Črnčec, Barnett, & Matthey 2008b).

Recent studies on parenting confidence are closely linked to Bandura's seminal late 1970s work on parental self-efficacy (Bandura 1977). The concept of *perceived parental efficacy* is based on Bandura's work, and is defined as "beliefs or judgments a parent holds of their capabilities to organize and execute a set of tasks related to parenting a child" (de Montigny & Lacharite 2005, p. 390). A concept analysis of perceived parental efficacy identified a degree of confusion about the concept, and that the literature used a range of different terms such as *perceived parenting self-efficacy*, *self-efficacy*, *self-confidence*, and *sense of competence* (de Montigny & Lacharite 2005). In line with Črnčec and colleagues, we use the term *parenting confidence* throughout this article.

According to Črnčec and colleagues, there are three different approaches to measuring parenting confidence (Črnčec, Barnett, & Matthey 2010): 1) scales employing task-specific items tailored to specific child ages; 2) scales employing general items not linked to specific parenting tasks; and 3) scales employing a global approach in which parenting confidence is seen as a part of a more stable personality trait that influences a range of tasks. As no task-specific assessment instrument was available in Danish for measuring parenting confidence in parents of infants, the decision was taken to translate and validate such an instrument for use in both research and clinical practice, namely the Karitane Parenting Confidence Questionnaire (KPCS) (Črnčec et al., 2008b).

The Karitane Parenting Confidence Scale (KPCS)

The KPCS was developed in 2008 by Rudi Črnčec, Bryanne Barnett, and Stephen Matthey for the Australian organization Karitane (Črnčec et al. 2008b). The scale is based on attachment theory and builds on a strengths-based relationship, in which the focus is on acknowledging the parents' strengths and knowledge of their child. The KPCS is grounded in Bandura's self-efficacy theory and is constructed as a task-specific scale for measuring perceived parenting self-efficacy (PPSE) (Bandura 1993; Črnčec et al. 2010). It is designed to be simple to administer, complete and score, and thereby easy to use for both researchers and practitioners working within a clinical setting with parents of infants up to 12 months old (Črnčec et al. 2008b). The KPCS consists of 15 items, scored 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 is 0.81 and test-retest reliability is 0.88, with a 28-day retest interval. The possible score range is 0–45, with high scores being favorable. Suggested clinical cut-off scores based on the Australian data are: Severe clinical range ≤31, Moderate clinical range 31–35 (the value 31 is included in both the severe and moderate clinical ranges. We defined severe clinical

range as <31), mild clinical range 36–39, and non-clinical range ≥40, with an improvement of six points or more indicating a reliable change (Črnčec et al. 2008b).

The validation sample consisted of 187 mothers aged 18 years or more with an infant aged below 12 months. The sample comprised a community control group (n = 47); an early intervention group (n = 42) with self-referred women who participated in a parenting class; a moderate difficulties group (n = 55) with mothers referred to an outpatient program; and a major difficulties group (n = 53) with mothers attending a residential parenting program (Črnčec et al. 2008b). The mean age of the mothers was 32.0 years, mean infant age was 24.7 weeks, and mothers had a mean of 1.5 children. In all, 8% of the mothers had not completed a University or vocational course.

To our knowledge, apart from this initial study, based on a relatively small sample of mothers by the developers (Črnčec et al. 2008a, 2008b), no psychometric evaluation of the KPCS has been conducted, although the measure is used in Norway, Wales (Ewans, Davies, Williams, & Hutchings 2015; C.H. Jones, Hutchings, Erjavec & Hughes, 2012), Australia (B.A. Jones et al. 2013), and Denmark. The aim of this study was to evaluate the internal and external validity of the Danish version of the KPCS in a community sample of first-time mothers, and to examine how scores change over time in both an at-risk and a not-at-risk group.

METHOD

Translation Procedure

The KPCS was translated according to the World Health Organization's (WHO) "Process of translation and adaptation of instruments". The stages in this process consist of forward translation, expert panel, back-translation, pre-testing, cognitive interviewing, and a final version. MP and IK

independently translated the original scale and discussed the first draft with an expert panel consisting of two experienced researchers with in-depth knowledge of assessment instruments and infant development. There is no direct Danish translation for "I am confident…", and therefore we use four different phrases in the five items that include this phrase.

MP and IK agreed on a second version, which was piloted on a small group of parents of infants. A third version with minor changes was piloted on a group of eight socially disadvantaged parents. As no changes were suggested by the cognitive interviewing, the third version was back-translated by a native-speaking English researcher fluent in Danish. Small changes to version three were made based on the back-translation, leading to the final version of the instrument.

Sample

The sample was collected through an intervention study including data from first-time mothers who answered questionnaires two and six months after birth. The study was conducted in a community setting comprising six local authorities in the Central Denmark Region. Between September 2013 and December 2014, all first-time mothers (1,549) in these areas were invited to participate in the study. In all, 909 (68%) answered the baseline questionnaire and 856 (64%) answered the follow-up questionnaire. Only mothers with no missing items on the KPCS at both the two- and six-month assessment were included in the present analyses, reducing the sample to 695 (76%). Of this number, a total of 50 mothers received intervention. They were characterized as vulnerable mothers based on a moderate preterm birth (gestational age ≥32<37), moderate symptoms of depression (Edinburgh Postnatal Depression Score (EPDS) ≥8<13), or low parenting confidence (KPCS < 40).

The current study sample was divided into two subsamples: a not-at-risk and an at-risk sample, based on well-known demographic risk factors at baseline. Mothers were included in the at-risk sample if they fulfilled at least one of the following criteria: 1) young mother: age < 20; 2) low education: grade 9 or 10; 3) symptoms of depression: EPDS ≥ 8; and 4) preterm birth: gestational age < 37 weeks. The youngest mother in the sample was 20, so criterion 1 was not relevant. A total of 207 (30%) mothers fulfilled at least one of the inclusion criteria and were categorized as at-risk. Of the 50 intervention mothers, 26 were in the at-risk group and 24 were in the not-at-risk group. Since the number of intervention mothers in the two groups was almost identical, we did not include intervention as a covariate in the main analyses.

Measures

To establish concurrent validity of the KPCS, mothers also completed the Parental Stress Scale (PSS) and the Edinburgh Postnatal Depression Scale (EPDS). The EPDS was used in the original study.

PSS – Parental Stress Scale (Berry & Jones 1995). The PSS measures parental stress and consists of 18 items rated on a five-point Likert scale. A total score is calculated, with a high score indicating higher levels of parental stress. Cronbach's alpha is 0.83 and the test-retest correlation is 0.81 (Berry & Jones 1995). The Danish version was translated by the first author and Tine Nielsen.

EPDS – Edinburgh Postnatal Depression Scale (Cox, Holden, & Sagovsky 1987; Cox & Holden 2003). The EPDS measures maternal depression and consists of 10 items rated on a four-point scale. A total score is calculated, with a high score indicating higher levels of maternal depression.

Cronbach's alpha is 0.87 (Cox et al. 1987). The Danish version of the EPDS is currently being validated.

The following socio-demographic variables were also included in the questionnaire: parental age, infant gender, birth weight, gestational age, parental education, and smoking status.

Statistical Analyses

Descriptive statistics (means and standard deviations) were calculated for all variables. Internal consistency was analyzed using Cronbach's alpha, and test-retest reliability by Pearson correlation coefficients. Coefficients of 0.70 or higher are considered acceptable (Fayers & Machin 2016). The differences between scores were evaluated with the Mann-Whitney U test for independent groups and the Wilcoxon signed-rank test for dependent groups. For demographic data, t-tests were applied to test for differences for continuous variables, while Chi-square tests were applied for categorical variables. Concurrent validity was evaluated by assessing Pearson correlations between the KPCS score and the PSS and EPDS scores. It was hypothesized that concurrent validity would be reflected in large negative correlations between KPCS and PSS total scores, and medium to large positive correlations between KPCS and EPDS total scores. STATA 14 and R 3.2.2 were used for data analyses.

RESULTS

Table 1 presents the demographic characteristics of the sample. The mothers in the at-risk sample are significantly younger and smoke significantly more than not-at-risk mothers. As low education was a criterion for becoming an at-risk mother, there is also a difference between the two groups in terms of education level.

Table 1 Demographic characteristics of not-at-risk and at-risk mothers

	All (n=695)		*Not-at-risk (n=488)*		*At-risk (n=207)*	
	Mean	SD	Mean	SD	Mean	SD
Mother age***[a]	30.14	4.00	30.54	3.87	29.09	4.15
Gestational age in weeks	39.71	1.74	40.05	1.16	38.94	2.47
EPDS	4.59	3.36	3.46	2.00	7.14	4.29
PSS	32.38	7.78	31.20	6.70	35.16	9.33
Background variables	N	%	N	%	N	%
Smoker**[b]	28	4	12	2	16	8
Non-smoker**[b]	658	95	471	97	187	90
No information	9	1	5	1	4	2
Boy	340	49	228	47	112	54
Girl	350	50	255	52	95	46
No information	5	1	5	1	1	0
Short education (grade 9 or 10)	85	12	0	0	85	41
Long education (>grade 10)	608	87	486	100	122	59
No information	2	0	2	0	0	0

**** $p < 0.000$; ** $p < 0.01$; * $p < 0.05$; a=independent t-test comparing at-risk and not-at-risk mothers; b=Chi-square test comparing at-risk and not-at-risk mothers*

Internal Validity

Table 2 shows the distribution of responses for the sample when the infant is two and six months old. The table clearly shows that item scores are skewed. For about half of the items, the response option 0 was not used, while option 1 was not used for one item at two months and six items at six months.

Table 2 Response distribution at two and six months n=695

	2 months all					6 months all				
Response	*0*	*1*	*2*	*3*	*Mean*	*0*	*1*	*2*	*3*	*Mean*
1. I am confident about feeding my baby	2	1	13	679	2.97	0	3	20	672	2.96
2. I can settle my baby	0	1	44	650	2.93	0	0	17	678	2.98
3. I am confident about helping my baby to establish a good sleep routine	1	44	244	406	2.52	2	34	214	445	2.59
4. I know what to do when my baby cries	0	5	125	565	2.81	2	0	57	636	2.91
5. I understand what my baby is trying to tell me	0	6	242	447	2.63	1	7	170	517	2.73
6. I can soothe my baby when he/she is distressed	1	1	80	613	2.88	0	0	27	668	2.96
7. I am confident about playing with my baby	0	10	138	547	2.77	0	7	104	584	2.83
8. If my baby has a common cold or slight fever, I am confident about handling this	11	64	307	313	2.33	1	12	190	492	2.69
9. I feel sure that my partner will be there for me when I need support	1	7	76	611	2.87	1	10	89	595	2.84
10. I am confident that my baby is doing well	0	8	70	617	2.88	1	0	34	660	2.95
11. I can make decisions about the care of my baby	0	2	44	649	2.93	0	0	18	677	2.97
12. Being a mother/father is very stressful for me	14	247	223	211	1.91	13	218	265	199	1.94
13. I feel I am doing a good job as mother/father	1	7	119	568	2.80	0	2	91	602	2.86
14. Other people think I am doing a good job as a mother/father	0	0	29	666	2.96	0	0	29	666	2.96
15. I feel sure that people will be there for me when I need support	0	3	65	627	2.90	0	4	85	606	2.87

Responses: 0: No, hardly ever; 1: No, not very often; 2:Yes, some of the time; 3:Yes, most of *the time*

Table 3 shows internal consistency for the KPCS at two and six months according to risk status. Cronbach's alpha was acceptable, with only slight differences between assessments, ranging from 0.72 to 0.79. Item-rest correlations ranged from 0.17 to 0.57. Items 1, 9, 11, 14, and 15 had low item-rest correlations, whereas this statistic was acceptable for the remaining items.

Table 3 Item-rest correlations and total Cronbach's alpha for 15- and nine-item versions at two and six months according to risk status

	2 MONTHS		6 MONTHS	
	Item-rest correlation		*Item-rest correlation*	
Item	15 items	9 items	15 items	9 items
1. Feeding baby	0.21	-	0.17	-
2. Settling baby	0.39	-	0.39	-
3. Establishing good sleep routine	0.49	0.49	0.41	0.39
4. Knowing what to do when baby cries	0.57	0.56	0.38	0.38
5. Understanding baby's signals	0.51	0.53	0.47	0.46
6. Soothing baby when distressed	0.48	0.46	0.37	0.32
7. Playing with baby	0.37	0.35	0.38	0.38
8. Handling cold or minor illness	0.37	0.36	0.34	0.35
9. Confidence in support from partner	0.18	-	0.19	-
10. Baby is doing well	0.49	0.47	0.34	0.32
11. Making decisions about care of baby	0.36	-	0.24	-
12. Being a mother/father is very stressful	0.47	0.46	0.37	0.37

13. Feel doing a good job as mother/father	0.57	0.56	0.49	0.47
14. Other people believe doing a good job	0.29	-	0.31	-
15. Feel sure about support from others	0.23	-	0.33	-
Alpha	**0.79**	**0.79**	**0.76**	**0.72**

We examined the 15 items of the KPCS to see if there were items that only provided minimal information and therefore could be left out in order to achieve a more internally consistent scale. All items were ranged according to the following characteristics at two and six months in both at-risk and not-at-risk groups: high mean, small standard deviation, ability to differentiate between either time or risk status. Based on these characteristics and the item-rest scores, we identified six items that provided only minimal information (items 1, 2, 9, 11, 14, and 15). We thus evaluated a nine-item version of the KPCS consisting of the following items from the 15-item version: 3, 4, 5, 6, 7, 8, 10, 12, and 13. Table 3 presents the item-rest correlations and Cronbach's alpha for the nine- and 15-item versions. Although Cronbach's alpha automatically increases with more items, the alphas for the nine-item version are identical to the 15-item version at two months, and lower at six months.

External Validity

The mean KPCS score for the full sample was 41.08 (SD 3.37, skewness -1.34, kurtosis 2.37, range 25–45) at two months and 42.03 (SD 2.69, skew -1.52, kurtosis 3.42, range 27–45) at six months. The correlation between the KPCS total scores at two and six months was 0.62 for the whole sample. The score at six months was significantly higher than the score at two months. For the nine-item version, mothers improved significantly from 23.52 at two months to 24.45 at six months.

For both groups, there was a ceiling effect on the total KPCS score, especially at six months. Skewness and kurtosis were acceptable for the at-risk group (skewness -0.67, kurtosis 0.10 at two months and -1.28 and 2.09, respectively, at six months) but more problematic for the not-at-risk

group (skewness -1.73, kurtosis 5.29 at two months and -1.51 and 3.65 respectively at six months). Many items had mean values well above 2.80 and standard deviations around 0.3, both for the not-at-risk and at-risk samples. The mean of this sample is consistent with the mean of the control group (approximately 42) as reported in the original study (Črnčec et al. 2008a), indicating that a ceiling effect was also present in their study.

Table 4 KPCS means, standard deviations, and differences between and within groups for nine- and 15-item versions at two and six months

	2 months		6 months		Δ	
	Mean	SD	Mean	SD	Mean	SD
15-item version						
All	41.08	3.37	42.03	2.69	0.95***	2.72
Not-at-risk	41.75	2.86	42.41	2.37	0.67***	2.26
At-risk	39.51	3.92	41.12	3.15	1.60***	3.49
Group Δ	1.7***		0.99***		-0.93**	
9-item version						
All	23.52	2.87	24.45	2.23	0.93***	2.37
Not-at-risk	24.03	2.49	24.74	1.97	0.72***	2.00
At-risk group	22.33	3.22	23.75	2.63	1.42***	3.02
Group Δ	1.70***		0.99***		-0.70**	

*** $p < 0.000$; ** $p < 0.01$; * $p < 0.05$

Δ: Difference between means at two and six months. Positive value indicates higher score at six months. Group Δ: Difference between at-risk and not at risk group. Positive value indicates higher score in not-at-risk group.

Change over time

The mean of not-at-risk mothers was 41.75 at two months, and increased significantly to 42.41 at six months. According to the Australian clinical guidelines, the not-at-risk mothers are within the non-clinical range at both time points, which was as expected. For the nine-item version, not-at-risk mothers increased significantly, from 24.03 at two months to 24.75 at six months. The mean of the at-risk mothers was 39.51 at two months, and increased significantly to 41.12 at six months. At two months, the mean of the at-risk group was equal to the mean of the moderate difficulties group in the original study (approximately 39), but higher than the clinical groups (approximately 36). As the at-risk group in this study is not a clinical group, this is expected. The at-risk group mean is just

below the cut-off and therefore in the mild clinical range at two months, but in the non-clinical range at six months. For the nine-item version, at-risk mothers increased significantly from 22.33 at two months to 23.75 at six months.

Differences Between At-risk and Not-at-risk Groups

When comparing the means of the at-risk and the not-at-risk groups at both time points, there was a significant difference between total score at both two and six months. At two months, the difference between the two groups was 2.24 points. At six months, the difference was reduced to 1.29 points. Although the not-at-risk group was significantly more confident than the at-risk group at six months, the at-risk mothers improved significantly more over time. We also find that the intervention mothers improved significantly more than mothers who did not receive intervention.

Table 4 shows summary statistics and the differences over time and within the groups for the nine- and 15-item versions at two and six months according to risk status. The range for the nine-item version is 0–27. The correlations between the nine- and 15-item versions are 0.98 at two months and 0.96 at six months. The mean for the not-at risk group significantly increased from 24.03 at two months to 24.74 at six months, and from 22.33 at two months to 23.75 at six months for the at-risk group. As with the 15-item version, the difference between the not-at-risk and at-risk group was significant at both two and six months. Furthermore, improvement over time was also significantly larger for the at-risk group than the not-at-risk group. Skewness and kurtosis were marginally better for the nine-item version than the 15-item version. Because the means of the six dropped items were close to the maximum score (three), both the within and between differences are almost the same as for the 15-item version, even though the range of the nine-item version's total scores is 18 points less than the 15-item version.

Concurrent Validity

Concurrent validity was established by examining the correlations between the KPCS total score and the total scores of parental stress (PSS) and depression (EPDS) at both time points. The correlation between KPCS and PSS was -0.65 at two months and -0.64 at six months. For KPCS and EPDS, the correlations were -0.60 at two months and -0.61 at six months.

Prevalence

Table 5 shows the prevalence of clinical levels of mothers' parenting confidence, based on the Australian clinical cutoffs. The majority of mothers (74–86%) show non-clinical levels of parent confidence. Moderate to severe levels are found in 3–6% of mothers, whereas mild clinical levels are found in 11–20%, depending on infant age at KPCS administration. The clinical levels must be interpreted with caution, as they may not be applicable to a Danish population.

Table 5 Clinical levels of KPCS scores according to infant age at time of assessment

	2 months		*6 months*	
	N	%	N	%
Non-clinical range	511	74	596	86
Mild clinical range	139	20	78	11
Moderate clinical range	35	5	16	2
Severe clinical range	10	1	5	1
Total	695	100	695	100

DISCUSSION

In this study, we examined the psychometric properties of the Karitane Parenting Confidence Scale, including estimates of reliability and external validity.

Internal consistency was acceptable, but many items showed small variance, and both item scores and the total score showed ceiling effects. Concurrent validity was expressed as a medium to high

negative relationship, with both parental stress (PSS) and depression (EPDS) as hypothesized for both the nine- and 15-item versions. Correlations with both PSS and EPDS were as hypothesized. In the original study, correlations between the KPCS and Parenting Stress Index short form (PSI-sf) were -0.63, while correlations between KPCS and EPDS were -0.56, which for EPDS is marginally lower than our results.

Ceiling Effect

The 15-item version of the KPCS showed high mean scores and relatively high skewness and kurtosis in the study samples. Skewed distributions are not unusual for this type of measure (Črnčec et al. 2010) – they are also found with, for example, measures of depression (Evans, Heron, Francomb, Oke, & Golding 2001) and other mental symptoms (Bech, Olsen, Kjoller, & Rasmussen, 2003). As these measures are constructed to capture a concept that is present in a minority, they are almost inherently skewed when applied to a community sample. It remains an open question whether the observed skewness reflects the actual distribution of parenting confidence or rather item content and selection.

The KPCS's four response options (*No, hardly ever; No, not very often; Yes, some of the time; Yes, most of the time*) may also contribute to the ceiling effect. During the pilot phase, some parents pointed out that they missed being able to choose the options *Yes, always* or *No, never*. The omission of these options probably reduced the variation in responses. As parents expressed that the existing response options were not adequate, it may be relevant to either revise the response options or add more.

The items in the KPCS may not fully capture all essential aspects of parent worries in relation to infant care, which may partly explain the ceiling effect. If this is the case, constructing new items or rewording existing ones could improve the scale properties and make the ceiling effect less pronounced. For instance, we know that issues in relation to feeding – e.g. how to recognize hunger cues, how often and how much the infant should eat – are sources of worry for mothers of infants (Kronborg, Vaeth, & Kristensen 2012; Murray 2014). However, variance in feeding-related worries is not captured by item 1 ("I am confident about feeding my baby"), as the mean score of the item is 2.95–2.98. As such, item 1 should either be rephrased or supplemented by new items related to infant feeding.

Despite the observed skewness of the KPCS scores, it was still possible to distinguish between a not-at-risk and at-risk group in the study sample. For intervention studies, a ceiling effect is problematic, as a very high score at baseline makes it difficult to improve over time (Črnčec et al. 2010). However, the KPCS has been used as an outcome in several other studies of parenting interventions for infants, with significant improvement in total scores over time (Ewans et al. 2015; C.H. Jones, Erjavec, Viktor, & Hutchings n.d.; Pontoppidan 2015). Although the nine-item version includes the items with most variation and acceptable item-rest values, it still has a marked ceiling effect, which makes analyses of changes over time problematic.

Changes Over Time

The results show that mothers generally felt less confident at two months than at six months. This is consistent with other research showing that the first months as a parent can be stressful and challenging, especially for first-time parents (Coleman & Karraker 1998; Cowan & Cowan 1995; Matthey 2011; Nyström & Öhrling 2004). Studies report that many mothers report difficulty

soothing and comforting the infant in the first months after childbirth (Kronborg et al. 2012), that infant crying peaks about seven weeks after birth (St James-Roberts 2006), and that around a quarter of all infants are affected by sleep disturbances (Armstrong, Quinn, & Dadds 1994; Kuhn & Weidinger 2000). One important factor is that standard care in Demark represents a relatively comprehensive intervention – nearly all families are entitled to five to six free visits from a health visitor and three free child-health visits to a general practitioner within the first year after birth (Foreningen for ledere af sundhedsordninger for børn og unge i Danmark 2013; Sundhedsstyrelsen 2011). These visits are universally offered to all families – both at-risk and not-at-risk. More visits can be offered if the health visitor deems it necessary. The improvement in KPCS score over time for both the at-risk and the not-at-risk groups may be due to the relatively intensive usual care that all mothers receive. It is an open question whether the KPCS score improves over time in countries where usual care is less intensive.

Discriminative Validity

We found that the KPCS is able to discriminate between at-risk and not-at-risk groups based on well-known risk factors. At-risk mothers felt less confident than not-at-risk mothers at both time points. This is also consistent with other research, which found that mothers with more risk factors – e.g. low socio-economic status or a history of abuse or depression – generally had lower self-efficacy than other mothers (Črnčec et al. 2010; Kohlhoff & Barnett 2013). We did, however, find that at-risk mothers improved significantly more over time than not-at-risk mothers, and that the difference between the two groups was reduced by more than 50% over time. Thus, the at-risk group is catching up with the not-at-risk mothers, even though the difference between the two groups is still significant at six months. However, the group difference in change over time could also be caused by the ceiling effect – it is difficult for the not-at-risk mothers to improve as they are

already close to the maximum score. Interestingly, of the 50 intervention mothers, only 26 were in the at-risk group. The 24 intervention mothers in the not-at-risk group all had clinical levels of KPCS scores, but none of the risk factors that were used to define the at-risk group. This shows that if only risk factors are used to identify mothers for intervention, a considerable group of mothers with low parenting confidence according to the KPCS will not be selected for intervention.

The current study presents some limitations. First, we did not include a clinical group of mothers, and therefore we do not know how mothers with lower levels of parent confidence would score and change over time. Second, the sample only included mothers, as the intervention study was aimed at mothers, and no data on fathers was collected. The original study of the KPCS also only included mothers, which means we do not know how this instrument works with fathers. A few fathers were included in our pilot phase, but aside from commenting on the first suggestion for the Danish title of the measure, they did not express any concerns about the KPCS. Third, the intervention study only included first-time mothers. As mothers with more than one child have more experience of being a parent, we would expect them to have higher levels of parent confidence than first-time mothers (Matthey 2011).

In conclusion, the internal consistency of the KPCS is acceptable, but there is an overall ceiling effect and many items are characterized by low discrimination. However, the KPCS discriminates between mothers according to risk status at both two and six months. All mothers improved their confidence over time, and at-risk mothers improved significantly more than not-at-risk mothers. We evaluated a reduced nine-item version of the KPCS but did not find it superior to the original 15-item version.

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CONFLICT OF INTEREST

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Paper 4

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TRIALS

STUDY PROTOCOL Open Access

The effectiveness of the Incredible Years™ Parents and Babies Program as a universal prevention intervention for parents of infants in Denmark: study protocol for a pilot randomized controlled trial

Maiken Pontoppidan[1,2]

Abstract

Background: Infancy is an important period in a child's life, with rapid growth and development. Early experiences shape the developing brain, and adverse experiences can have both an immediate and lifelong impact on health and wellbeing. Parenting interventions offered to parents of newborns can support parents in providing sensitive and responsive care, and reinforce healthy development for their infants. This study aims to evaluate the impact of the Incredible Years™ Parents and Babies Program in a universal setting for parents with infants.

Methods/Design: This is a pragmatic, two-arm, parallel, pilot, randomized controlled trial (RCT) where 128 families with newborn infants up to four-months-old are recruited in two municipalities in Denmark. Families are randomized to the Incredible Years Parents and Babies Program or usual care with a 2:1 allocation ratio. The primary outcome is parenting confidence measured after 20 weeks by the Karitane Parenting Confidence Scale and Parental Stress Scale. Secondary outcomes include measures of parent health, reflective functioning, relationship with the infant, and infant development. Interviewers and data analysts are blind to allocation status.

Discussion: This is the first RCT of the Incredible Years Parents and Babies Program, and one of the first rigorous evaluations of a universally offered preventive intervention for parents with infants. The trial will provide important information on the effectiveness of a relatively brief, universally offered parenting intervention for parents of infants, and will also provide information on infant measures, parent recruitment and participation, and implementation of the program, which could inform future trials.

Trial registration: This trial was registered with Clinicaltrials.gov (identifier: NCT01931917) on 27 August 2013.

Keywords: Parenting, Parenting interventions, Early intervention, Early childhood, Infants, Incredible Years™, Randomized controlled trial, Universal intervention, Prevention

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Background

Substantial evidence has documented the importance of a child's experiences in the first years of life, linking adverse experiences in childhood to later conditions in life, such as depression, health problems, drug abuse, teen pregnancy, and delinquency [1–4]. The relationship is cumulative, as greater numbers of stressful life events in early life results in a greater risk of negative outcomes later in life [2, 5]. The quality of the attachment relationship between the infant and their parents is pivotal in the early years and greatly influences the child's social, emotional, and cognitive development [6]. A secure attachment to the caregiver predicts a healthy development, whereas an insecure attachment is related to later behavior problems and poor peer relations [7]. It is therefore crucial that appropriate parenting interventions are available to families with infants, especially since interventions in early childhood have been shown not only to be effective [8–13], but also to be more effective than interventions later in life, because it is easier to intervene before problems become entrenched [1, 14].

Parent interventions can be either targeted or universal. In a targeted intervention, families are singled out and offered the intervention because they are thought to be at risk and/or in need of help [15]. Universal interventions on the other hand, are directed at all residents in a specific geographic area and no one is singled out for intervention [15]. Universal interventions have both advantages and disadvantages. The main advantages are: that there is no labelling or stigmatization involved, that the quality of the interventions tend to be high because the middle class is involved, and that at-risk families can be identified and offered more help if needed [15, 16]. The main disadvantages are: that universal programs are expensive, the individual benefits tend to be small, and it can be difficult to find overall effects. Further, it might enlarge social inequality if well-functioning families benefit the most from the interventions [15, 16]. A targeted approach is often applied, but relies on correct identification of families in need of support, which is challenging, as screening instruments never are perfectly accurate, and many families with risk factors do well whereas families with no risk factors might experience difficulties [16]. Child behavior problems tend to be normally distributed across the population, and many families experiencing problems would be missed by a targeted approach based on risk factors [17]. A universal population-level approach is therefore needed to be able to best prevent child developmental problems [17–19].

There are, however, only a few trials of parenting interventions adopting a universal approach [20–27]. Only one of these trials is in a group format and is delivered only postpartum: the Toddlers Without Tears program that was recently evaluated in a randomized controlled trial (RCT) in Australia [25, 28]. Even though the trial was powered to detect a small effect size, only modest improvements in parenting risks were found, but no impact on child behavior at follow-up time points of 18, 24, or 36 months was found. The authors concluded that, 'A brief universal parenting programme in primary care is insufficient to prevent development of preschool externalising problems' [25]. Compared to the Toddlers Without Tears program, the Incredible Years™ Parenting and Babies Program (IYPB) offers significantly more sessions (eight compared to three), and starts when the infant is younger (preferably between zero and four months compared to eight months). In this pilot trial, a more intensive intervention offered as a universal approach aimed at a community sample of parents with newborns is evaluated.

An important challenge when performing trials with infants is deciding on primary and secondary outcome measures. Often measures yielding important information on how the parent changes over time, such as measures of parent depression, parenting stress, parenting competence or confidence, or parenting practice are used. Observational measures such as the Bayley Scales of Infant and Toddler Development, the Mullen Scales of Early Learning, and the Strange Situation procedure are also frequently used in infant studies. However, despite it being one of the primary areas targeted by parenting interventions, it is not as common to assess infant development, in particular social-emotional development, using parent-report measures. Infant development is arguably the most difficult construct to measure, as it occurs rapidly, dramatically changes within the first years of life, and it is widely influenced by family and culture values [2, 29–31].

Within recent years a few protocols for infant trials have been published [32–37], but none of these are aimed at universal or low risk populations. Given the relatively low numbers of infant program efficacy or effectiveness trials conducted in this emerging field, it is useful for researchers to learn about some of the possible measures that can be used. In addition, it has been common in the published research in the field to only report on measures where there are significant findings, so researchers designing studies do not know which measures to consider or leave out. In the present trial, a wide array of both parent and infant development measures are used, hopefully aiding future researchers to identify appropriate primary and secondary outcomes for trials on infants.

Parent-infant relationships and parenting practices are central to early-onset social-emotional or problem behaviors, such as aggression or disruptive behaviors [3]. Parenting interventions therefore aim to target these two areas and to support parents in providing sensitive

and responsive care to their children. Incredible Years (IY) is a parenting intervention with a focus on strengthening parenting competencies and promoting children's social, emotional, and academic competence. IY was developed by Carolyn Webster-Stratton more than 30 years ago, and offers a range of programs for parents and teachers of children aged from 0 to 12-years-old. The IY programs are used as both universal and targeted interventions in more than 24 countries worldwide.

IY programs have been evaluated in several RCTs and meta-analysis and were found to be effective on both parent and child outcomes [3, 9, 38–45]. A recent meta-analysis of IY interventions for children between three and nine-years-old shows a mean effect size of d = 0.27 for disruptive behavior across informants [38]. Outcomes that were based on parent reporting showed larger effect sizes for targeted approaches (treatment studies d = 0.50) than universal approaches (indicated sample d = 0.20, selective d = 0.13). There were larger effects for children with severe problems. Another recent meta-analysis based mainly on IY studies [9] of children between three and 12-years-old shows standardized mean differences (SMD) of −0.53 for parent reports and −0.44 for independent reports on child conduct problems. Negative or harsh parenting practices were also reduced (SMD: −0.77) and the intervention was cost effective. The only published study on the effects of IY on children younger than three-years-old is an RCT from Wales of the IY Parent-Toddler program that looked at the effects on parental language [46]. The trial indicated positive effects on two out of five language outcomes. Therefore, although there are very positive results of the IY intervention on both parenting and child outcomes for children three-years-old and older, there is very little knowledge on the effects of IY on children younger than three-years-old.

The IYPB is one of the most recent additions to the IY series. It has been evaluated in Wales with a small sample of mothers living in poverty and has demonstrated positive results [47]. The majority of parents appreciated the group format and stated that they had learned how to encourage the babies' development, and how to develop effective routines and manage coping strategies. The group leaders also found the program rewarding because they saw positive changes in parenting skills and a growing attachment between infant and parents. Both parental mental health and parenting confidence improved significantly over time; for parenting confidence the effect size was 0.61 (Ewans S, Hutchings J, Davies S, Williams M. Short-term benefits from the Incredible Years Group Based Programme delivered to Parents and their Babies in Powys. Forthcoming). The effects of the IYPB have, however, not yet been evaluated in the more rigorous RCT design, and have not been analyzed in a universal setting. This pilot trial is therefore the first RCT of the IYPB and the first RCT of a universal parenting intervention for parents with infants in Denmark.

The pilot trial has multiple aims:

1) To estimate the effects of the IYPB program offered as a universal intervention in Denmark on parent and infant wellbeing, development, and relationships, and to establish parameters for a future definitive trial.
2) To provide information on usability on a wide array of parent and infant measures.
3) To test recruitment procedures and to determine rates of recruitment and consent.
4) To investigate the implementation of and parents' acceptance of the IYPB in a universal setting.
5) To provide information on the cost of offering the IYPB as a universal preventive program.

Methods/Design

The trial is a pragmatic, two-arm, parallel, pilot RCT carried out in two municipalities in Denmark. Figure 1 shows the design of the trial. The trial is an external pilot study in the sense that it is a separate trial.

Eligibility criteria

Eligible participants are mothers with infants living in Ikast-Brande or Herning municipalities in Denmark. Ikast-Brande (population 40,620) and Herning (population 47,765) are bordering municipalities located in central Jutland. If a father is present, he is also invited to participate in the trial.

All mothers in Denmark are entitled to 46 weeks of maternity leave after the birth of a child. The first 14 weeks are exclusively entitled to the mother, but the remaining 32 weeks can be shared with the father. Fathers are entitled to two weeks of parental leave after the birth. This means that almost all mothers participating in the study will be on maternity leave with the child when the intervention is being offered, and will remain on maternity leave until the child is somewhere between six and 12 months. At 12 months, around 81 % of children in Denmark attend daycare [48], so most children will be in daycare at the time of the 18-month follow-up assessment. All municipalities offer free home visits by health visitors to families with newborns and children up to the age of six-years-old. Virtually all families (between 97 and 99 %) take up the offer. Most families receive five to six visits within the first year, but the number is suited to the needs of the family. Families are also offered three child health visits at the general practitioner within the first year after birth [49, 50].

Inclusion criteria

Mothers with infants aged up to four months who are able to read and write Danish may be included in the trial. In Ikast-Brande, only primiparous (that is, have

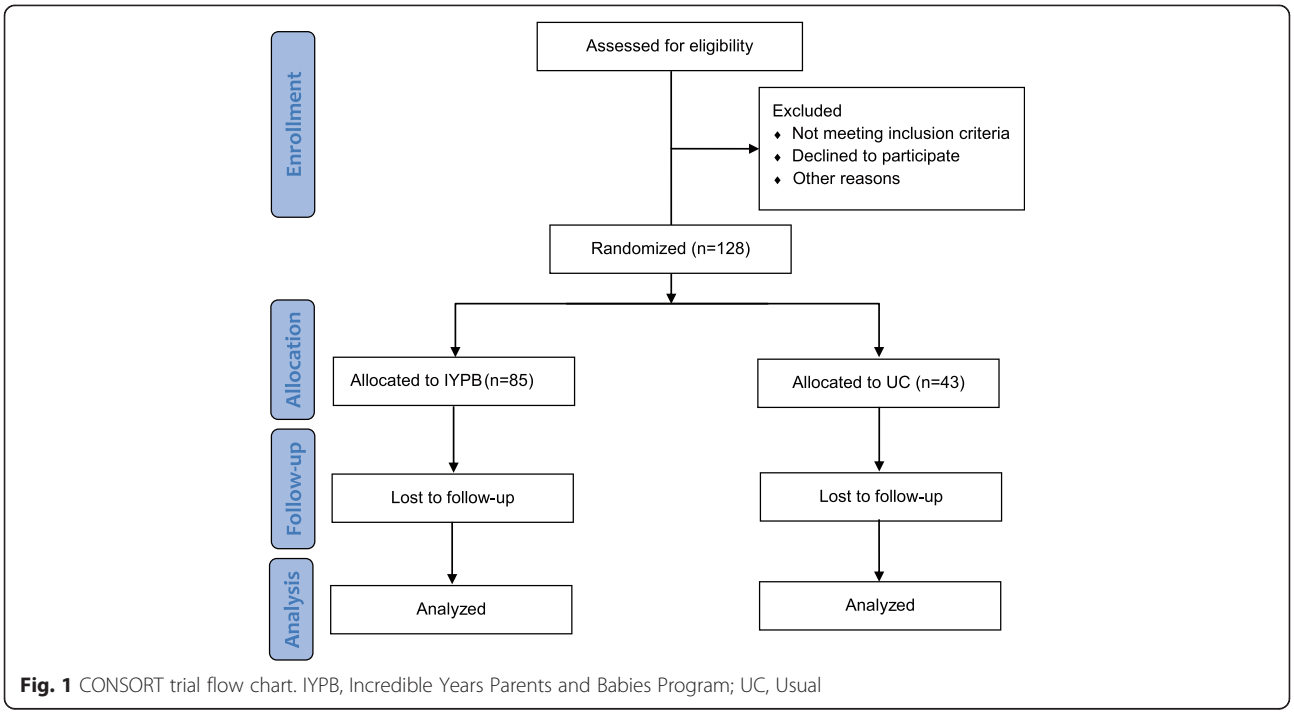

Fig. 1 CONSORT trial flow chart. IYPB, Incredible Years Parents and Babies Program; UC, Usual

given birth for the first time) mothers are invited; in Herning primi- and multi-parous mothers living in certain districts of the city are invited.

Exclusion criteria

Families are excluded if they do not fulfill the inclusion criteria or if they fulfill one or more of the following exclusion criteria: a severe physical or mental disability in parent or child (for example, parents with severe schizophrenia, severe substance abuse, or a child with congenital disease like cerebral palsy) or if the child is placed in out-of-home care.

Intervention care and comparison

Intervention

The families randomized to the intervention group receive the IYPB. The IY programs are based on Bandura's modeling and self-efficacy theories, Patterson's social learning model, and Bowlby's attachment theory. The main foci of the intervention are promoting a warm and nurturing parent–child relationship, enhancing parenting competencies, and encouraging a parent involvement to promote children's social, emotional, and academic skills and reduce conduct problems [51].

Parents learn through the IYPB how to help their babies feel safe, loved, and secure, and how to promote their babies' physical, emotional, and language development. The parenting group format stimulates shared learning and peer support networks. Parents practice new skills with babies within the group and are encouraged to try out ideas at home as part of weekly home assignments. Parents also share updates on their infants' development and activities in a safe and supportive environment [51].

The IYPB uses video vignettes of real-life situations with parents and babies to support the training and to foster discussion in the group. The original American video vignettes are used, with Danish subtitles added. Group leaders also use a Baby Brain Poster with a picture of the brain of a crawling baby to explain to the parents the importance of the development of the infant brain, and how they can strengthen neuron connections and help the brain development of their infant. Parents are furthermore provided with the book *The Incredible Babies* [52], which has been translated into Danish [53]. The book describes how to promote child development and includes a journal section. Before the book was translated, parents were provided with refrigerator notes that included relevant information on, for example, child development or activities the parents could do with their infant to promote child development.

A group is made up of six to eight parents and is led by two trained group leaders. Mothers bring their babies to the sessions, and partners are strongly encouraged to participate. If the mother is single, she can bring a family member such as her mother or sister, if she wants. The program consists of eight sessions of two hours. The parents can arrive half an hour before and eat lunch if they wish. The sessions run every week or every two weeks. The six parts that are covered during the course are: Getting to Know Your

Baby; Babies as Intelligent Learners; Providing Physical, Tactile and Visual Stimulation; Parents Learning to Read Babies' Minds; Gaining Support; and Babies' Emerging Sense of Self. The group leaders follow a manual to ensure that the intervention is delivered with fidelity [51].

Control

The families randomized to the control group receive usual care (UC). UC consists of four to five home visits by health visitors, open consultation hours at a local well-child clinic, voluntary participation in a group of six local mothers, and extra support if needed (for example, extra home visits, family therapy, or video feedback intervention). The intervention group is offered the IYPB on top of UC. UC is consistent with what is offered in the majority of Danish municipalities. The control group families cannot get access to the IYPB, but both they and the intervention group might participate in other infant activities offered by private organizations, such as hymn song at the local church or baby massage classes.

Procedure

The trial is registered by The National Committee for Health Research Ethics (reference number H-2-2013-FSP60, and has received ethical approval from the Internal Research Council at SFI - the Danish National Center for Social Research. The trial is registered at Clinicaltrials.gov (reference number NCT01931917).

Recruitment is performed by health visitor, social workers, or midwifes in the municipalities. Families are provided with oral information, an information sheet, a two-minute YouTube video (available at www.sfi.dk/godtrivsel) with information on the trial, and a consent form. After receiving the initial consent from the family, the contact person in the municipality sends the contact information to the trial coordinator. An interviewer contacts the mother and sets up an interview in the home. At the T1 visit, written informed consent to participate in the trial is obtained from each mother (and father if he wishes to participate in the trial) and T1 measures are collected. All participants are informed that they can withdraw from the study at any time without their rights being affected.

Randomization

An independent researcher computes a random allocation list stratified by municipality and with a block size of three. The allocation ratio is 2:1 (IYPB:UC), as it is important for the municipalities to have enough families in the IYPB intervention arm to start the groups. After the baseline assessment is completed, the interviewer informs a designated research administrator that the interview has been completed. The research administrator then randomizes the family by adding the name to the randomization list in the order the names arrive from the interviewer. Then the contact person in the municipality is informed about the allocation status of the family. Participants are informed by their health visitor as to which arm of the study they have been allocated to. In the case where consent to treatment is withdrawn but the participant agrees to remain in the research study, the participant is followed to completion.

Blinding

Due to the nature of the trial, it is not possible to have a completely blinded design. Participants will know which intervention they are receiving, and the group leaders and health visitors will also know which families are in the intervention arm. Interviewers and coders are blind to group allocation, but participants might reveal allocation status at T2 or T3 assessment. All participants are given an identification number to ensure that the researchers performing the analysis are blinded to allocation status.

Outcomes

Data are collected at three time points: T1 (baseline), T2 (post-intervention, around four months after baseline), and T3 (follow-up, when the child is 18-months-old). Data collection takes place at the parent's home at each of the three time points. All interviewers are trained and experienced in carrying out interviews in participants' homes. The interviewer collects the main part of the background data (for example, education and work status), but the majority of the outcomes are self-reported on computer by the mother. If possible, the father or the partner also completes the questionnaire. Families are compensated by a 200 DKK (approximately 27€) gift card at each visit. The visits are expected to last between 40 minutes (T1) and an hour (T2 and T3). All data are kept at a secure server with password protection. A description of the trial outcomes are outlined below. The timing of the outcomes is shown in Table 1.

Primary outcomes

Parenting

Karitane parenting confidence scale The Karitane Parenting Confidence Scale (KPCS) [54, 55] measures parenting confidence for parents of infants aged 0 to 12-months-old. The KPCS consists of 15 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). A Danish version of KPCS has been developed for the trial by the author and I H Kristensen,

Table 1 Timing of outcomes

		T1 Baseline	T2 Post-test	T3 Follow-up
Parent measures				
Karitane Parenting Confidence Scale	KPCS	√	√	
Parental Stress Scale	PSS		√	√
Major Depression Inventory	MDI10	√	√	√
World Health Organization Well-Being Index	WHO-5	√	√	√
Rosenberg Self-Esteem Scale	RSS		√	
Being a Mother	BaM-13			√
Parental Reflective Functioning Questionnaire	PRFQ-1			√
Parenting Sense of Competence	PSOC			√
Sense of Coherence	SOC13	√		
Background questions: age, education, occupation, ethnicity, number of children, household status, housing situation, household economy, substance abuse		√	√	√
Single items on parent health, parent life satisfaction, support, and network.		√	√	√
Child measures				
Ages and Stages Questionnaire - Social-Emotional	ASQ-SE	√	√	√
Strengths and Difficulties Questionnaire	SDQ			√
Cognitive Development Questionnaire	CDQ			√
Single items on child health and child temperament		√	√	√
Parent–child measures				
Mother and Baby Interaction Scale	MABISC		√	
Video (15 minutes)	EAS/CARE-Index		√	
Single items on interactions with child			√	√

and is administered at T1 and T2, but not at T3 since the child is too old at this time.

Parenting stress scale The Parenting Stress Scale (PSS) [56] measures parenting stress and can be used with parents of children up to 18-years-old. The PSS consists of 18 items that are rated on a five-point scale (Strongly disagree, Disagree, Undecided, Agree, Strongly agree). A Danish version of the PSS developed by the author and T Nielsen is administered at T2 and T3, but not at T1 since the items are not considered relevant for parents of newborns.

Secondary outcomes

Parents

Major depression inventory The Major Depression Inventory (MDI10) [57] measures depressive symptoms present within the last 14 days in adults. The MDI10 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). The Danish version of MDI10 is administered at T1, T2, and T3.

World Health Organization 5 well-being index The World Health Organization (WHO)-5 Well-Being Index [58, 59] measures current mental wellbeing in adults. The WHO-5 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). The Danish version of the WHO-5 is administered at T1, T2, and T3.

Rosenberg self-esteem scale –The Rosenberg Self-esteem Scale (RSS) [60] measures global self-worth in adults. The RSS consists of 10 items that are scored on a four-point Likert scale (Strongly Agree, Agree, Disagree, Strongly Disagree). A Danish version of the RSS is administered at T1 and T2.

Being a mother scale –The Being a Mother Scale (BaM-13) [61] measures a woman's satisfaction and experience with being a mother. The BaM-13 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). A Danish version has been developed for the trial by the author. The BaM-13 was created by some of the developers of the KPCS and is developed within the same framework. The BaM-13 is administered at T3.

Parental reflective functioning questionnaire –The Parental Reflective Functioning Questionnaire (PRFQ-1) (Luyten P, Mayes LC, Nijssens L, Fonagy P. The Parental Reflective Functioning Questionnaire: Development and Preliminary Validation. Submitted) measures reflective functioning or mentalization in parents of young infants and children across three domains: pre-mentalizing modes, certainty about mental states, and interest and curiosity in mental states. The PRFQ-1 consists of 39 items that are scored on a seven-point Likert scale (7 Strongly Agree, 4 Neutral or Undecided, 1 Strongly Disagree). For this trial a shorter version with 18 items is used. The 18 items were selected from a Danish version of the PRFQ-1 developed by M S Væver and J Smith-Nielsen. The PRFQ is administered at T3.

Parenting sense of competence scale The Parenting Sense of Competence Scale (PSOC) [62, 63] measures how parents perceive their own competences as a parent. The PSOC consists of 16 items and two subscales: efficacy and satisfaction. The PSOC is scored on a six-point Likert scale (Strongly Agree, Somewhat Agree, Agree, Disagree, Somewhat Disagree, Strongly Disagree). A Danish version of the PSOC developed by A-M Lange and K K Frantzen is administered at T3.

Sense of coherence –The Sense of Coherence (SOC13) [64] measures how people manage stress and stay well within the salutogenic framework phrased by Antonovsky [65]. The SOC13 consists of 13 items that are scored on a five-point Likert scale (Never, Rarely, Occasionally, Often, Always). A Danish version of the SOC13 developed by T Nielsen is administered at T1.

Single items Single items on parent health, parent life satisfaction, support, and network are administered at T1, T2, and T3. Items are scored on an 11-point scale, with 0 representing Worst possible health/Disagree completely/Often and 10 representing Best possible health/Agree completely/Never.

Children

Ages and stages questionnaire - social-emotional The Ages and Stages Questionnaire - Social-Emotional (ASQ-SE) [31] measures social-emotional problems and competencies in children aged three months to five years. The ASQ-SE 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. A Danish version based on the experimental version of a second edition of the ASQ-SE has been developed for the trial by the author and is administered at T1, T2, and T3, even though most of the infants will be less than three-months-old at T1.

Strengths and difficulties questionnaire –The Strengths and Difficulties Questionnaire (SDQ) [66–68] measures child behavior and psychopathology in children from 2 to 17-years-old. The SDQ 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). The 2014 revision of the Danish two to four year version is administered at T3. The SDQ is used even though the children are 18-months-old and not 24 months as is the recommended lower age limit.

Cognitive development questionnaire The Cognitive Development Questionnaire (CDQ) [69] measures cognitive development of children from 8 to 24-months-old. The CDQ consists of two sections: section one with 19 scripted games for parents to play with their infant, and section two with 16 items asking about everyday behaviors. Items are rated by parents on a yes/no scale supplemented with information on how many blocks were used. A Danish version of the CDQ has been developed for the trial by the author and is administered at T3.

Single items Single items on child health, temperament, height, and weight are administered at T1, T2, and T3. Child health and temperament are scored on an 11-point scale with 0 representing Worst possible health/Disagree completely and 10 representing Best possible health/Agree completely.

Relationship

Mother and baby interaction scale The Mother and Baby Interaction Scale (MABISC) [70, 71] measures the mother-infant relationship. The MABISC consists of 10 items that are scored on a five-point Likert scale (Always, Most of the time, Occasionally, Not often, Never). A Danish version of the MABISC has been developed for the trial by the author. The MABISC is administered at T2.

Video A 15-minute video of the mother and baby is recorded at T2 to assess the mother-infant relationship. The mother is instructed to be with her child on a mat on the floor and to interact with her child as she

normally would. The 15-minute video consists of the following phases: six minutes of free play, four minutes of frustration where the child is given a toy that is challenging, 30 seconds of separation, and three minutes of reunion. The videos will be coded within either the Emotional Availability Scales (EAS) system [72] or the Care Index system [73].

Single items Single items measuring parent/child interaction such as singing songs, dancing, and telling stories are administered at T2 and T3. Three single items are administered at T2. One is scored at an 11-point scale with 0 representing Disagree completely and 10 representing Agree completely, and the other two are scored by marking how many days a week the activity happened. At T3, 14 items are administered. These 14 items were adapted from the evaluation of the Preparing for Life program [74], and are 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).

Background questions

Background questions and socio-demographics are collected at T1, T2, and T3. They measure parent age, education, occupation, ethnicity, number of children, household status, housing situation, household economy, substance abuse, child birth weight, child gestation at birth, and child health.

Recruitment and participation

All levels of parent recruitment and participation will be examined. This includes recruitment procedures (information leaflets, YouTube video, challenges and barriers for the health visitors), consent rates, intervention uptake, and mother and father participation in the IYPB sessions. Parent satisfaction with the IYPB is measured by a questionnaire, and a qualitative study looking into how parents experience participation in the IYPB as a universal prevention will be performed.

Implementation and treatment fidelity

During the trial, a qualitative study of the implementation of the IYPB in one of the municipalities will be performed to look into challenges and successes experienced when moving from using the IYPB as a targeted program to rolling it out as a universal intervention. Treatment fidelity is measured by session checklists completed by group leaders at the end of each session.

Future outcomes

If further funding is obtained data will be collected at later time points (such as 36 and 48 months) to look for long term effects and dropout rates. In Denmark, researchers have access to very rich register data at a relatively low cost on central long term outcomes, such as school performance, education, income, hospitalization, diagnoses, prescription drug use, marriage status, and childbirths. These are key outcomes, but they are usually not easily collected without the access to register data. Participants will be followed up on in central registers at Statistics Denmark at later time points (for example when the children are 20 and 30-years-old) to look for long term effects of the intervention on both parent and child outcomes (for example school performance, work status, and diagnoses). Register data can be collected for all participants and can be compared to the full population if needed.

Data analysis

Sample size

Lancaster *et al.* [75] recommended that the sample size of a pilot study be a minimum of 30 participants to be able to estimate parameters. As a small effect size is expected with a universal sample, the size of the pilot trial is 128 mothers. With a sample size of 128, a power of 0.8, and a two-sided alpha level of 0.05, it is possible to detect an effect size of 0.50 (Cohen's d).

Planned statistical analysis

Analyses are performed using the software packages R 3.2.1 and STATA 13, or later versions. The data analyst will be blinded to allocation arm. Analysis and presentation of data will be in accordance with the CONSORT guidelines, in particular the extensions to pragmatic trials [76] and nonpharmacologic interventions [77]. Standard descriptive statistics (means, medians, ranges, standard deviations, frequencies, and percentages) will be used to report demographics, and baseline and outcome scores. Data will be examined for missing data and multiple imputation strategies will be used if necessary. Missing data are, however, expected to be low as data are collected through home interviews and the families are compensated.

Primary and secondary outcomes will be analyzed using multiple regression for continuous outcomes, and logistic regression for binary outcomes controlling for baseline scores where possible. A two-tailed test $\alpha = 0.05$ will be used and parameters will be summarized using 95 % confidence intervals. If assumptions for parametric analysis are not met, non-parametric tests like the Mann–Whitney *U* test will be used. To account for group or therapist effects, standard errors will be clustered around the group for the parents in the intervention arm.

Analysis will follow intention-to-treat (ITT) principles, but completer analysis (such as complier average causal effects (CACE) based on treatment received will also be performed. To examine how non-compliance affects results two levels of participation will be explored: parents that have participated in at least three of the eight

sessions, and parents that have participated in at least six of the eight sessions.

As larger effects are expected in parents who present difficulties at the time of recruitment, separate analysis will be carried out for the following three groups: parents who have baseline scores in the clinical range of the measures, parents who are scoring within the lowest 25 % of the distribution at baseline, parents who are scoring within the lowest 50 % of the distribution at baseline.

Cost

The economic evaluation will be a cost-effectiveness analysis comparing costs related to IYPB with UC. The effect (benefit) will be calculated in natural units (improvements in the primary parenting confidence measures), while costs will be calculated in monetary units (Danish Kroner). Information about both setup costs (training, further education, time for meetings, and so forth), and operating costs related to delivering the group sessions (staff time, parental time, transport, and so forth) will be collected and included in the analysis. Unit costs for health and social care resources will largely be derived from local and national sources and estimated in line with best practice. If possible, average costs of UC in each municipality and across municipalities will be calculated.

Discussion

This protocol describes a pilot RCT comparing a universal parenting intervention for parents of infants with UC. Infants are dependent on their parents and the quality of their parenting skills, and it is therefore important to support the development of parenting skills in new parents, since lack of parenting skills can have detrimental and long term effects on the infants, such as school failure, behavior problems, relationship problems, substance abuse, and delinquency.

Many parent interventions are expensive because they are intensive and/or long and are offered on an individual one-to-one basis. A relatively brief eight-session group program like the IYPB can therefore be cost effective and possible to roll out to large numbers of families. The intervention is offered at a universal level, making it possible for all parents to participate in an early parenting intervention in a non-stigmatizing way. This trial will provide information on the cost of offering the IYPB in a universal setting, and also important knowledge on the experience of implementing the IYPB in a universal setting.

To the best of our knowledge, this is the first RCT of the IYPB. It is also among the first rigorous evaluations of truly preventive interventions carried out in a real-world universal setting, and will therefore be a valuable addition to the infant intervention literature. Apart from providing information on the effects of the IYPB that can be used to inform a future definitive trial, the pilot trial will provide information on parent recruitment and participation in a trial using health visitors employed by the municipality to recruit mothers, as well as information on experiences with implementing a universal prevention intervention. Furthermore, the trial will yield important information on outcome measures that can be used for the planning and development of future infant trials.

Trial status

The trial started recruiting in August 2013 and is expected to continue recruiting until the end of summer 2015.

Additional file

Additional file 1: Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist. (PDF 57 kb)

Abbreviations

ASQ-SE: Ages and Stages Questionnaire - Social-Emotional; BaM-13: Being a Mother Scale; CDQ: Cognitive Development Questionnaire; EAS: Emotional Availability Scales; IY: Incredible Years; IYPB: Incredible Years Parents and Babies Program; KPCS: Karitane Parenting Confidence Scale; MABISC: Mother and Baby Interaction Scale; MDI10: Major Depression Inventory; PRFQ-1: Parental Reflective Functioning Questionnaire; PSOC: Parenting Sense of Competence Scale; PSS: Parenting Stress Scale; RCT: Randomized Controlled Trial; RSS: Rosenberg Self-esteem Scale; SDQ: Strengths and Difficulties Questionnaire; SMD: Standardized mean differences; SOC13: Sense of Coherence Questionnaire; UC: Usual Care; WHO-5: World Health Organization Well-Being Index.

Competing interests

The author declares that she has no competing interests.

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Paper 5

Short-term Effects of the Incredible Years Parents and Babies Program as a Universal Prevention Intervention for Parents of Infants in Denmark: A Pilot Randomized Controlled Trial

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ABSTRACT

INTRODUCTION
Infancy is an important period in a child's life, and adverse experiences during this stage can have both an immediate and lifelong impact on the child's mental health and well-being. This study sought to evaluate the effects of the Incredible Years Parents and Babies program as a universal intervention for parents with infants.

METHOD
A pragmatic, two-arm, parallel pilot randomized controlled trial, in which 112 families with newborns were randomized to the Incredible Years Parents and Babies program (76) or usual care (36) with a 2:1 allocation ratio. The primary outcome was parenting confidence measured after 20 weeks, using the Karitane Parenting Confidence Scale and Parental Stress Scale. Secondary outcomes include measures of parent health, parent-child relationship, infant development, parent-child activities, network, and economy. Interviewers and data analysts were blind to allocation status. Multiple linear-regression analyses were used to evaluate the effect of the intervention on primary and secondary outcomes.

RESULTS
There was no intervention effect on the primary outcomes. For secondary outcomes, intervention mothers reported a significantly smaller network than control mothers (β = -0.15 [-1.85,-0.28]). There were no effects on any other secondary outcomes. When examining the lowest-functioning mothers, intervention mothers report significantly higher parent stress (β = 4.68 [0.76,8.61]) and worse mental health than control mothers (β = -16.55 [-31.59,-1.51]).

CONCLUSION
No effects of the IYPB as a universal intervention for parents with infants were found. The intervention may need to be adjusted to meet the expectations and needs of a universal group of parents.

TRIAL REGISTRATION
ClinicalTrials.gov NCT01931917 (registration date 27 August 2013)

KEYWORDS
Parenting, parenting interventions, early intervention, early childhood, infants, Incredible Years, randomized controlled trial, universal intervention, prevention.

INTRODUCTION

Increasing numbers of studies with small children suggest that the youngest are at the highest risk of serious developmental harm. During infancy, children are at their most malleable, but are also exposed to more potentially damaging experiences than older children. For instance, the highest rates of child neglect and violent abuse occur when children are under five years old (Corby 2006; Geffner, Igelman, & Zellner 2003), with the most serious injuries and death caused by parental violence against children occurring when infants are under one year old (Grøgaard 2007). Infants are also more sensitive to disruptions in parental care than older children. Infants with mothers who suffer from severe stress or depression can show physiological, biochemical and behavioral deregulations shortly after birth, and have been found to be at increased risk of behavioral and mental problems (Van Doesum, Riksen-Walraven, Hosman, & Hoefnagels 2008). These infants often show avoidance of carers and display high levels of distress and negative emotion (Van Doesum et al. 2008). For many of these children, these effects are the beginning of a trajectory of negative developmental and mental health outcomes throughout childhood and adulthood (Cicchetti, Rogosch, & Toth 1998; Weissman, Warner, Wickramaratne, Moreau, & Olfson 1997). Early parent-child interactions have been shown to be the key predictive factor for many early and late developmental outcomes (Field 1998). Supporting parents in developing and applying positive parenting skills can prevent future problems and encourage healthy child development (Barlow et al. 2011; Barlow, Bennett, & Midgley 2013; Furlong et al. 2013; Heckman & Masterov 2007; Heckman 2008; Olds, Sadler, & Kitzman 2007; Piquero, Farrington, Welsh, Tremblay, & Jennings 2008; Reedtz, Handegård, & Mørch 2011; Welsh & Farrington 2007). This study aims to evaluate a program of parental support based on these child development goals.

The new program is specifically designed for parents with infants, and has been added to the Incredible Years Series (IY) of treatment and prevention programs for children and families. Extensive Scandinavian and international research, both from the program developer and independent research groups, has demonstrated the effectiveness of the IY programs for older children (Axberg, Hansson, & Broberg 2007; Baker-Henningham, Scott, Jones, & Walker 2012; Bywater et al. 2009; Dishion et al. 2008; Drugli, Larsson, Fossum, & Mørch 2010; Furlong et al., 2013; Gardner, Burton, & Klimes 2006; Gridley, Hutchings, & Baker-Henningham 2015; Griffith 2011; Hurlburt, Nguyen, Reid, Webster-Stratton, & Zhang 2013; Hutchings et al. 2007, 2012; Little, Social, & Kingdom 2012; Marcynyszyn, Maher, & Corwin 2011; Menting, Orobio de Castro, & Matthys 2013; Pidano & Allen 2014; Presnall, Webster-Stratton, & Constantino 2014; Scott, Briskman, & O'Connor 2014; Trillingsgaard, Trillingsgaard, & Webster-Stratton 2014). A recent meta-analysis of IY parenting programs for three- to nine-year-old children shows that effect sizes for parent-reported outcomes in treatment studies were higher (d=0.50) than for indicated (d=0.20) and selective studies (d=0.13) (Menting et al. 2013). The universal IY parent program for children aged 3–8 was evaluated in an RCT, which showed reductions in harsh parenting, parent stress, and parent depression, and increases in positive parenting, parent's sense of competence, and quality of life four years after the program ended (Reedtz et al. 2011; Reedtz & Klest n.d.). The IY Toddler Basic program for children aged 1–3 has been evaluated in a couple of trials, with positive results (Gridley et al. 2015; Gross et al. 2003; Perrin, Sheldrick, McMenamy, Henson, & Carter 2014), but we know less about the effects of the IY programs for children under three (Pidano & Allen 2014).

In 2010, the IY series was extended to include the Incredible Years Parents and Babies program (IYPB) for families with infants from birth to one year. IYPB has not been evaluated for effectiveness in a randomized controlled trial (RCT), either in Scandinavia or internationally. One

pre/post evaluation of IYPB in Wales found that both parenting competence and mental health significantly improved over time (Ewans, Davies, Williams, & Hutchings 2015). Another evaluation performed in Wales with a control group also found that mothers in both treatment and control groups significantly improved over time. A significant positive effect on mother sensitivity was also identified, but there was no difference between the two groups on child development, parenting confidence, and parental mental well-being (Jones, Erjavec, Viktor, & Hutchings, n.d.).

During the eight-week course of treatment with IYPB, mothers and fathers attend weekly group sessions with their infants. Group leaders (therapists) trained in IYPB conduct the sessions with eight families. During the sessions, parents learn how to observe, read, and respond in a sensitive manner to their babies' cues and signals. They also learn how to understand babies as intelligent learners, learn about ways to provide physical and tactile stimulation for babies and its importance for brain development, how to take care of their own needs as parents, and how to understand babies' developmental processes and needs.

No programs with strong evidence of effectiveness are available in Scandinavia for the treatment and prevention of developmental problems in infants (e.g. insecure attachment). In the Ungsinn database (ungsinn.no), which is used to catalog and rate programs available for children in Norway, only one parenting program for infants is listed, and at present there is not enough evidence to support its effectiveness. In Denmark, the Circle of Security program is currently being evaluated in a RCT. There are even fewer interventions aimed at a universal sample of parents with infants (Aronen & Kurkela 1996; Bayer, Hiscock, Ukoumunne, Scalzo, & Wake 2010; Dodge et al. 2014; Doherty, Erickson, & LaRossa 2006; Kan & Feinberg 2014; Roia et al. 2014; Santelices et al. 2011; Shapiro, Nahm, Gottman, & Content 2011). Three of these programs are delivered postnatally in a group format like IYPB: 1) Toddlers Without Tears (Australia), with three sessions from eight

months (Bayer et al. 2010; Hiscock et al. 2008); 2) Face to Face (Australia), with five sessions from three months (Vlismas, Malloch, & Burnham 2012); and 3) an American trial of parent training, with eight sessions from age eight months (Dickie & Gerber 1980). None of the studies, however, finds any effects on child development or parent-child relationship. Compared to these three interventions, IYPB offers significantly more sessions than Toddlers Without Tears and Face to Face, and starts at an earlier age than all three of the other interventions. In this pilot RCT, we evaluate a more intensive intervention, offered as a universal intervention aimed at a community sample of parents with newborns.

The aim of the pilot trial was to estimate the effects on parent and infant well-being, development, and relationships of the IYPB program offered as a universal intervention in Denmark, and to establish parameters for a future definitive trial. The secondary aims were to provide information on the usability of parent and infant measures; to test recruitment procedures and determine rates of recruitment and consent; to investigate the implementation and parents' acceptance of IYPB in a universal setting; and to provide information on the cost of offering IYPB as a universal preventive program.

METHOD

Study Design

The trial was a pragmatic, two-arm, 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 (Schulz, Altman, & Moher 2010; Zwarenstein et al. 2008) and registered at ClinicalTrials.gov (reference number NCT01931917).

Participants and Recruitment

The eligible participants were mothers with infants living in the Ikast-Brande or Herning local-authority area in Denmark. Where fathers were present, they were also invited to participate. All mothers in Denmark are entitled to 46 weeks of maternity leave following the birth of a child; the last 32 weeks can be split with the father. Virtually all families receive five or six free home visits by health visitors and three child-health visits to the general practitioner within the child's first year (Foreningen for ledere af sundhedsordninger for børn og unge i Danmark 2013; Sundhedsstyrelsen 2011). Health visitors recruited families between August 2013 and August 2015. After the local contact person received initial consent from the family, the interviewer arranged a home visit, during which written consent was obtained from the mother (and father if applicable).

Inclusion Criteria

The trial included mothers who are able to read and write Danish and had infants aged 0–4 months at the time. Ikast-Brande only recruited first-time mothers, whereas Herning included all mothers. Families could have been excluded in the case of severe physical or mental disability in the parent or the child, or if the child was placed in out-of-home care. However, no families were excluded.

IYPB Intervention

The IYPB program was developed by the American psychologist Carolyn Webster-Stratton. The intervention aims to promote a warm and nurturing parent-child relationship, and to enhance parent competencies in order to promote their babies' physical, emotional, and language development. (Webster-Stratton & Reid 2010). Groups consisted of 6–8 parents and were led by two trained group leaders. Mothers brought their babies to the sessions, and partners were strongly encouraged to participate. The purpose of the group format is to stimulate shared learning and peer-support

networks. Parents practiced new skills with babies within the group, and were encouraged to try out ideas at home as part of their weekly assignments (Webster-Stratton & Reid 2010).

The program consisted of eight two-hour sessions. During each session, group leaders showed video vignettes of real-life situations with parents and babies in order to support the training and foster discussion in the group. The original American video vignettes were used, with Danish subtitles. A baby brain poster was used to explain the importance of infant brain development, and how parents can strengthen neuron connections and help their child's brain development. Parents were also given a Danish translation of the book *The Incredible Babies* (Webster-Stratton 2011, translation 2014), which describes how to promote child development and includes a journal section. The six parts covered during the course were: Getting to Know Your Baby; Babies as Intelligent Learners; Providing Physical, Tactile and Visual Stimulation; Parents Learning to Read Babies' Minds; Gaining Support; and Babies' Emerging Sense of Self. The group leaders followed a manual to ensure that the intervention is performed with fidelity.

Two group leaders were certified IYPB group leaders; two were in the process of gaining IYPB certification. The remaining group leaders were all experienced IY group leaders certified in BASIC Parent Group and 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) consisting of four or five home visits by health visitors, open consultation hours at a local well-child clinic, voluntary participation in a group of six local mothers, and extra support if needed (e.g. extra home visits,

family therapy, or video-feedback intervention). Intervention families received IYPB in addition to UC.

Measures

Outcomes were collected through home visits at baseline (T1) and post-intervention (T2). The mean number of days between T1 and T2 was 146 (SD 28), with a range of 78–207 days. The range was quite large due to the difference in the number of weeks the IYPB program ran. Sometimes, half of the IYPB sessions were offered before the summer or Christmas break, with the other half offered afterwards. Other groups finished within a continuous 12-week period. T2 data was collected between one and three weeks after the IYPB program. Baseline measures and the timing of measures are described in the trial protocol (Pontoppidan 2015). Both mothers and fathers could complete the questionnaire, but only a few fathers did so (50 at T1, 14 at T2). Families received a 200 DKK (~€27) gift card at each visit.

The primary outcomes were the 15-item Karitane Parenting Confidence Scale (Črnčec, Barnett, & Matthey 2008a, 2008b), and the 18-item Parenting Stress Scale (Berry & Jones 1995). Secondary parental outcomes included the 10-item Major Depression Inventory (MDI10) (Olsen, Jensen, Noerholm, Martiny, & Bech 2003), the five item WHO-5 Well-Being Index (Bech 2004, 2011), the 10-item Rosenberg Self-esteem Scale (Rosenberg 1965), and single items on parent health, parent life satisfaction, support, and network. Secondary child outcomes included the 26-item Ages and Stages Questionnaire: Social-Emotional-2 experimental version (ASQ:SE-2e) (Squires, Bricker, & Twombly 2015, 2002), and single items on child health, temperament, height, and weight. Secondary relationship outcomes included the 10-item Mother and Baby Interaction Scale (MABISC) (Hackney, Braithwaite, & Radcliff 1996; Høivik, Burkeland, Linaker, & Berg-Nielsen

2013), three single items measuring parent and child interaction through singing and reading, and a 15-minute video of the mother and baby. The videos have not yet been coded; the results will be presented in a separate paper. Furthermore, we collected characteristics such as parent age, education, occupation, primary language spoken in the home, number of children, whether parents cohabit or the mother lives alone, whether housing is rented or owned, household economy, substance abuse, birth weight, gestational age, and child health. All trial outcomes are described in greater detail in the study protocol (Pontoppidan 2015).

Randomization and Blinding

An independent researcher computed a random allocation list, stratified by local authority, with a block size of three. The allocation ratio was 2:1 (IYPB:UC). Following completion of the baseline assessment, the interviewer informed a designated research administrator that the interview had concluded. The research administrator then randomized the families by adding their names to the randomization list in the order that they were provided by the interviewer. The health visitor informed each family about the arm of the study to which they were allocated. In cases where consent to treatment was withdrawn but the participant agreed to remain in the research study, the participant was followed to completion. Due to the nature of the trial, participants and group leaders could not be blinded. Interviewers, coders and data analysts were blind to group allocation status.

Parent and Group Leader Satisfaction

Parents completed questionnaires after each session, and a final evaluation after the last session. For Ikast-Brande municipality , final evaluation data from 82 parents who participated in the IYPB between January 2014 and July 2015 was analyzed (Rasmussen et al. 2015). Furthermore,

qualitative interviews with group leaders and focus groups with parents were held (Hjælmhof-Larsen & Nielsen 2015).

DATA ANALYSES

Sample Size

We aimed to recruit 128 mothers. With a sample size of 112 (intervention: 76 and control: 36), a power of 0.8, a two-sided alpha level of 0.05, 2:1 and a correlation of 0.6 between T1 and T2, it was possible to detect an effect size of d=0.46.

Statistical Analyses

Categorical data is presented as numbers and percentages, continuous data as means and standard deviations. An independent sample t-test was used to test for group differences at baseline, and a paired sample t-test for total group change over time. The trial included two sets of twins, both in the IYPB group. To account for the lack of independence between twins, we selected the first twin and ignored the other for parent outcomes, but kept both twins for child outcomes. Intention to treat analyses for primary and secondary outcomes was calculated using multiple regression analysis, and included controls for site and baseline score. No further covariates were included, as variables such as the mother's age, education, and parity had no effect on the results.

Of the 112 mothers assessed at T1, eight were lost due to attrition at T2. Depending on the mechanism by which they went missing, this could lead to bias in the estimates. In order to address this, we first tested the assumption of data being missing completely at random (MCAR). This can be tested by creating an indicator variable for observations missing at T2 and fitting it with a logit model. All baseline measures of the outcome variables and other covariates, along with the

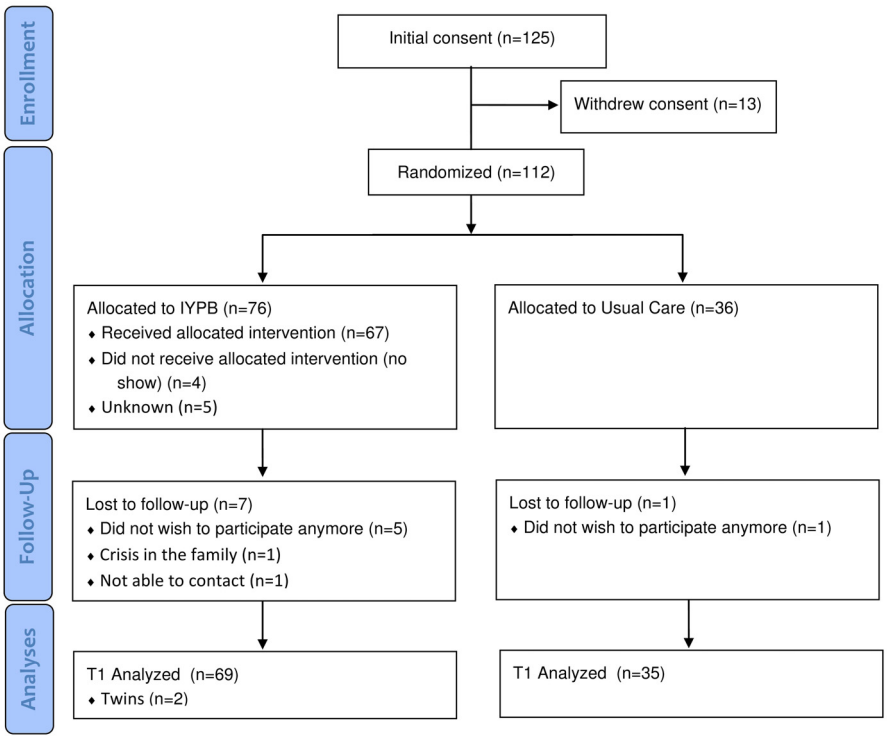
treatment dummy, were included as predictors. We found no significant predictors at the 5% level, but five out of 18 predictors were significant at the 10% level, which therefore indicated that the data was missing at random (MAR). Although the assumption of data missing at random (MAR) is not testable, imputation is still shown to produce less biased results than listwise deletion (Schafer & Olsen 1998). Further, should the data really be MCAR instead of MAR, listwise deletion would lead to unbiased, albeit possibly inefficient estimates. As a result, multiple imputation (Rubin 1987) was performed (using Stata's mi impute procedure) on chained equations. For the analyses, 200 imputed datasets were generated.

Although not all variables were normally distributed, we applied the ordinary least squares (OLS) regression, as it is consistent even without normality. 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. As described in the protocol, differential effects were examined for IYPB compared to UC in three subsamples: 1) parents with baseline scores in the clinical range of the measures; 2) parents scoring within the lowest 25% of the distribution at baseline, and 3) parents scoring within the lowest 50% of the distribution at baseline. Analyses were performed using Stata version 14.

RESULTS

Figure 1 presents the flow diagram of participants in the trial. Of the 125 families who had given initial consent, 13 withdrew consent when the interviewer contacted them to schedule a home visit. Of the 112 families that were randomized, 76 were allocated to IYPB and 36 to UC. Eight families dropped out before T2 assessment. Contrary to many other RCTs, a larger dropout was seen in the intervention group (seven) than in the control group (one). Four out of the seven mothers who

dropped out of the intervention group did not show up or dropped out of the IYPB group. The only significant differences between the dropouts and the non-dropouts were that dropout mothers were older (5.76 years older on average, p=0.0009), had more children (0.80 more children on average, p=0.002), reported having attended more open house sessions with health visitors, and had a larger network at baseline who could help with practical issues in the home.



Figur 1 Trial flowchart

Table 2 presents descriptive statistics for the analysis sample. There were no differences in demographic characteristics between IYPB and UC. The mothers who participated in the trial seem to be relatively representative for the general population in relation to most characteristics, with the exception of education level. When comparing the education level of the mothers in the trial with data from Statistics Denmark for all mothers in this age group (20–39), both in Denmark as a whole

and for the two specific local authorities, it is apparent from Table 1 that the participating mothers generally remained in education longer than the population mean.

Table 1 Distribution of education level (%) for Denmark, Herning and Ikast-Brande, and the trial sample

Education	Denmark total %	Herning and Ikast-Brande %	Trial sample %
Primary school	16.05	17.45	10.00
High school/secondary	20.41	16.75	12.73
Vocational education/secondary	24.96	32.62	26.36
Short tertiary	4.49	7.44	9.09
College/bachelor/tertiary	23.45	21.73	32.73
University/long tertiary	10.24	3.95	8.18
PhD	0.41	0.06	0.91

That the families who participate in research studies have a longer education than the mean is a well-known tendency, but has implications for the generalizability of trial results. Although the education level was higher than that of the general population, the mental health of the mothers appears to be representative of the general population. The total mean of mental health, as measured by WHO5 at T1, is 62.6 at baseline, which is lower than the mean of 67 for Danish women in general (Bech, Olsen, Kjoller, & Rasmussen 2003), but 69.9 at T2. The level of clinical depression in the recruited mothers is 6% at T1, which is in line with the reported 7–8% for the Danish population when the child is five weeks old (Maimburg & Væth 2015).

Table 2 Demographic characteristics for IYPB and UC at baseline (T1)

		IYPB		UC	
		Mean	**SD**	**Mean**	**SD**
MOTHER	Age (years)	29.39	4.88	29.28	4.89
	Number of children	1.4	0.71	1.4	0.77
		N	**%**	**N**	**%**
	Mother living alone	7	9	3	8
Education	Low education	8	11	3	8
	Medium education	26	35	17	47
	High education	40	54	16	44
Smoking	Non-smoker	64	86	32	89
	Daily smoker	10	14	4	11
Alcohol consumption	>1 a week	1	1	1	3
	1 a week–1 a month	21	28	6	17
	Never or <1 a month	52	70	29	81
Employment	Working	54	75	26	72
	Student	10	14	3	8
	Unemployed	8	11	7	19
CHILD		**Mean**	**SD**	**Mean**	**SD**
	Age (months)	1.59	0.88	1.45	0.89
	Birthweight (grams)	3453	644	3549	499
		N	**%**	**N**	**%**
Gender	Boy	41	53	19	54
	Girl	33	45	17	47
Gestational age	28–31 weeks	1	1	0	0
	32–36 weeks	3	4	1	3
	37–42 weeks	64	86	29	81
	>42 weeks	6	8	6	17
FAMILY		**N**	**%**	**N**	**%**
	Danish first language	70	95	36	100
Home-ownership	Own home	45	61	21	58
	Rent home	29	39	15	42

Note: IYPB: Incredible Years Parents and Babies; UC: Usual Care; SD: Standard Deviation

Recruitment

Health visitors had different experiences with the recruitment process. Some found it challenging to ask families to participate in the trial, while others felt confident. During the trial, the more confident recruiters were asked to share their strategies and experiences with the rest. One site adopted a more insistent recruitment strategy, and recruited 62 mothers into seven IYPB groups (8.9 mothers per group). The less insistent site, on the other hand, recruited 50 mothers to 18 groups (2.8

mothers per group). Dropout rates were 10% for the insistent site and 4% for the less insistent site. The two-minute YouTube recruitment video was viewed 88 times.

Participation

Both sites registered parent participation, but only one site provided full information on the number of completed sessions. Ikast-Brande recruited 50 families, of which 33 were allocated to intervention. Thirty mothers participated in the IYPB group, as three did not show up. On average, the participating mothers completed 6.3 sessions. Fathers participated much less than mothers – a total of 17 fathers participated, and completed on average four sessions. There was no difference between IYPB and UC in terms of both the number of extra visits families received from health visitors and the proportion of families who received extra visits in Ikast-Brande. IYPB families received on average 1.48 extra visits; UC families received on average 1.82 extra visits. A total of 33% of IYPB families and 29% of UC families did not receive any extra visits. For Ikast-Brande, IYPB did not reduce the number of extra home visits families received. The protocol describes Complier Average Causal Effects (CACE) analyses for two levels of participation: 1) mothers that participated in at least three of the eight sessions; 2) mothers that participated in at least six of the eight sessions. As we were only able to get detailed participation data from one site, we could not perform these analyses.

Effect Evaluation

Table 3 shows the means for the full trial sample at T1 and T2. All outcome measures based on rating scales significantly improve from T1 to T2, with the exception of self-esteem (RSS). Most single items do not change over time (loneliness, confidants, parent health, child health, overall life satisfaction). One of the single items – parent report of child temperament – improves significantly

over time, whereas mother reports of both family economy and network that can help with practical issues decline significantly from T1 to T2.

Table 3 Means and standard deviations at T1 and T2 for the full trial sample. Change from T1 to T2 with t-test p-value and Cohen's d

	T1 All		T2 All				
	Mean	SD	Mean	SD	Δ	p	*d*
KPCS	41.09	3.21	42.55	2.20	1.46	0.000	0.54
MDI ¤	8.33	5.89	6.22	5.33	-2.11	0.006	-0.39
WHO5	62.62	16.73	69.86	15.70	7.24	0.001	0.47
RSS	24.86	4.52	25.69	4.59	0.83	0.180	0.17
ASQ:SE2e ¤	48.17	23.47	25.54	16.13	-22.63	0.000	-1.15
Single items							
Loneliness	7.06	2.49	7.19	2.44	0.13	0.706	0.01
Network	8.77	2.02	8.03	2.77	-2.74	0.020	-0.28
Confidants	9.43	2.07	9.67	0.94	0.24	0.272	0.16
Overall health self-report	8.61	1.33	8.75	1.27	0.14	0.414	0.11
Life satisfaction	9.13	1.10	9.07	0.99	-0.06	0.691	-0.07
Economy	7.71	1.71	7.05	2.21	-0.66	0.014	-0.39
Child temperament	8.77	1.51	9.26	1.19	0.49	0.007	0.40
Child overall health	9.44	0.90	9.44	1.21	0.00	0.981	-0.01

T1: Time 1; T2: Time 2; SD: Standard Deviation; Δ: T1–T2 change; p: p value of paired t-test; d: Cohen's d; ¤: low score is favorable; KPCS: Karitane Parenting Confidence Scale; PSS: Parenting Stress Scale; MDI: Major Depression Inventory; WHO5: Well-Being Index; RSS: Rosenberg Self-Esteem Scale; MABISC: Mother and Baby Interaction Scale; ASQ:SE-2e: Ages and Stages Questionnaire: Social-Emotional-2 experimental version

Table 4 shows means and regression output comparing IYPB mothers and UC mothers.

The baseline scores for intervention and control mothers do not differ for any of the outcomes apart from one single item (child health), where intervention mothers report significantly better child health than control mothers. However, this difference is not clinically significant, as both groups report a mean above nine on a scale 0–10. When IYPB and UC mothers are compared at program completion, there is no significant difference in any of the outcomes apart from one single item. Mother report of a network that can help with practical issues is significantly lower for mothers in the IYPB group at T2 compared to UC (β=-1.07 [-1.85,-0.28], *d*=-0.18).

Table 4 Comparison of parent and child outcomes in IYPB and UC at T1 and T2 with regression coefficients, 95% confidence intervals, and effect sizes are for multiple linear regressions on imputed data with control for site and baseline score

	IYPB		UC				
	T1	T2	T1	T2			
	Mean	Mean	Mean	Mean	β	CI	*d*
KPCS	41.30	42.60	40.67	42.45	-0.08	[-0.81,0.65]	-0.02
PSS ¤	-	30.76	-	30.05	0.79	[-1.85,3.42]	0.05
MDI ¤	7.65	6.05	9.72	6.56	0.36	[-1.36,2.09]	0.03
WHO5	64.16	69.95	59.44	69.68	-1.48	[-6.55,3.60]	-0.04
RSS	25.35	25.93	23.86	25.19	-0.17	[-1.63,1.29]	-0.02
MABISC ¤	-	11.20	-	11.48	-0.23	[-1.39,0.94]	-0.03
ASQ:SE-2e ¤	47.17	25.73	50.25	25.16	1.33	[-4.98,7.64]	0.04
Child height	56.99	70.39	57.09	70.42	0.01	[-1.31,1.34]	0.00
Child weight (kilo)	4.95	8.40	4.86	8.38	-0.01	[-.31,0.30]	-0.00
Single Items							
Loneliness	7.07	7.15	7.06	7.27	-0.15	[-1.04,0.75]	-0.03
Network	9.07	7.90	8.17	8.28	-1.07	**[-1.85,-0.28]**	-0.18
Confidants	9.61	9.74	9.06	9.51	0.19	[-0.20,0.57]	0.09
Overall health self-report	8.70	8.86	8.42	8.52	0.23	[-0.23,0.69]	0.09
Life satisfaction	9.16	9.13	9.06	8.95	0.15	[-0.20,0.50]	0.07
Economy	7.85	7.29	7.42	6.56	0.33	[-0.29,0.95]	0.07
Child temperament	8.87	9.25	8.56	9.29	-0.12	[-0.58,0.35]	-0.05
Child overall health	9.59	9.45	9.11	9.42	-0.04	[-0.46,0.38]	-0.02
Child enjoys reading	-	6.53	-	6.21	0.34	[-0.59,1.27]	0.07
Days reading	-	3.54	-	2.78	0.80	[-0.15,1.75]	0.15
Days singing	-	6.42	-	6.07	0.35	[-0.32,1.02]	0.11

IYPB: Incredible Years Parents and Babies; UC: Usual Care; T1: Time 1; T2: Time 2; β: regression estimate; CI: 95% Confidence Interval of regression estimate; **Bold** are significant at p<0.05; *d*: Cohen's d; ¤: low score is favorable; KPCS: Karitane Parenting Confidence Scale; PSS: Parenting Stress Scale; MDI: Major Depression Inventory; WHO5: Well-Being Index; RSS: Rosenberg Self-Esteem Scale; MABISC: Mother and Baby Interaction Scale; ASQ:SE-2e: Ages and Stages Questionnaire: Social-Emotional-2 experimental version

Differential Effects

As stated in the protocol, we divided the sample into halves and quarters to look for differential effects. We only performed these analyses on the rating scales (KPCS, PSS, MDI, WHO5, RSS, MABISC, and ASQ:SE-2e), as the single items had very low variation and could not meaningfully be divided into halves and quarters. Table 4 shows regression outputs for the following groups: mothers scoring within the highest 25% and 50% at baseline, and mothers scoring within the lowest 50% and 25% at baseline. Except from KPCS and PSS for the 25% highest, and MDI for mothers in the highest-scoring 25% and 50%, all outcomes favor the intervention group, but no significant

effects were found. For the lowest-performing 50%, parent stress (PSS *d*=0.33) is significantly worse for the intervention group. For the lowest-performing 25%, mental health (WHO5 *d*=-0.49) is significantly worse for the intervention group. Both parent stress and mental health favor the control group, with effect sizes d = 0.33 and d = 0.49, respectively. For both the lowest 50% and 25%, all other outcomes also trend in this direction.

Table 5 Regression results for mothers divided into groups based on baseline (T1) score

	<25 at T1		**<50 at T1**		**>50 at T1**		**>75 at T1**	
	β	95% CI	β	95% CI	β	95% CI	β	95% CI
KPCS	-1.91	[-4.71,0.90]	-0.17	[-1.74,1.40]	0.22	[-0.55,0.98]	-0.39	[-2.02,1.24]
PSS ¤ ±	7.84	[-1.14,16.83]	4.68	**[0.76,8.61]**	-0.80	[-3.99,2.40]	1.18	[-5.15,7.52]
MDI ¤	1.70	[-3.22,6.62]	0.04	[-3.74,3.82]	0.10	[-1.86,2.05]	1.02	[-5.05,7.09]
WHO5	-16.55	**[-31.59,-1.51]**	-4.13	[-12.69,4.44]	0.75	[-5.81,7.31]	3.69	[-7.06,14.43]
RSS	-0.43	[-4.25,3.38]	-0.59	[-3.06,1.89]	0.75	[-0.97,2.47]	0.99	[-1.52,3.49]
MABISC ¤ ±	1.99	[-0.83,4.81]	0.53	[-1.53,2.58]	-0.18	[-1.64,1.29]	-1.27	[-4.25,1.72]
ASQ:SE2e ¤	2.16	[-14.38,18.70]	6.77	[-2.13,15.66]	-2.67	[-11.61,6.26]	-2.12	[-12.73,8.50]

T1: Time 1; β: regression estimate; CI: 95% Confidence Interval of regression estimate; **Bold** are significant at p<0.05; ¤: low score is favorable; ±: KPCS score at baseline used for group; KPCS: Karitane Parenting Confidence Scale; PSS: Parenting Stress Scale; MDI: Major Depression Inventory; WHO5: Well-Being Index; RSS: Rosenberg Self-Esteem Scale; MABISC: Mother and Baby Interaction Scale; ASQ:SE-2e: Ages and Stages Questionnaire: Social-Emotional-2 experimental version

Clinical Levels

Table 5 shows the proportion of mothers within IYPB and UC with clinical levels for outcomes with thresholds for clinical levels. There is no difference in the proportions between IYPB and UC for any of the outcomes. For all outcomes, the proportion of mothers with clinical levels falls between T1 and T2.

Table 6 Proportion of mothers with clinical levels at T1 and T2 for IYPB and UC

	T1		T2	
	% clinical		% clinical	
	IYPB	UC	IYPB	UC
KPCS	24	33	10	6
MDI	5	8	3	6
WHO5	4	11	1	0
RSS	4	3	3	3

KPCS: Karitane Parenting Confidence Scale; MDI: Major Depression Inventory; WHO5: Well-Being Index; RSS: Rosenberg Self-Esteem Scale

Implementation and Treatment Fidelity

After each session, the group leaders completed the checklists provided. Most items were dealt with during the sessions, but sometimes elements were postponed due to time constraints. The group leaders usually included two to four vignettes in each session, but one session included four to six. Based on parent feedback, the group leaders had to change some elements of the program to fit the Danish context. Some vignettes and exercises had to be dropped because parents felt that they were inappropriate. The group leaders also had to space out the sessions so that the infants were old enough for the last sessions to be age-relevant.

Parent and Group Leader Satisfaction

Almost half of the parents stated that attachment to their child was not influenced by IYPB, while 36% stated that it was improved (Rasmussen et al. 2015). Only 1% reported low parenting confidence at the end of the intervention. The elements of the program that parents liked the most were group discussions, talking to others, and sharing experiences. The video vignettes were the most disliked element (only 25% felt that they were appropriate or very appropriate). Less than half of the parents (42%) felt that issues around babyproofing the home were appropriate or very appropriate. Generally, parents preferred the first sessions. Parents mentioned that because their name appeared on the evaluation form, they were not always as critical as they would have been on an anonymous evaluation.

Common reasons for participating in the IYPB program were that parents felt that they might miss out on something if they did not participate, and a general wish to be a good parent (Hjælmhof-Larsen & Nielsen 2015). Expectations were not always fulfilled, as some parents had anticipated

that the sessions would involve more direct teaching and advice from the health visitors. Some parents mentioned that the program structure was a bit too rigid, and they would have sometimes preferred to discuss other issues they felt were important. Furthermore, some felt that the information given was too simple, and not at an appropriate level. Some suggested that the sessions would have been satisfactory had they only involved the mothers, without group leaders. About half of the parents said they would recommend or strongly recommend the program to other parents.

The group leaders generally felt satisfied with running the IYPB groups. The group dynamics differed according to the participants. If parents shared insecurities or worries during the first few sessions, this opened up the dialogue. In groups where parents did not share insecurities and worries, the group leaders found that the more insecure parents stopped coming. The group dynamics were also affected by the participation of fathers. Generally, it was difficult to get fathers to participate. The group leaders also mentioned that they would appreciate more acknowledgement from their leaders.

Cost

We could only obtain cost data for one site. Ikast Brande reports that the cost of IYPB per family is around DKK 7000 (~EUR740) when groups consist of eight families. The price includes training for group leaders, preparation time, housing expenses, food and drinks, supervision, and time for group sessions. It was not possible to get information on the cost of UC. As IYPB was offered in addition to UC, all mothers received UC. Compared to the cost analyses from Wales, the price of running a group in Ikast-Brande is lower than the price for the initial group in Wales, but higher than the price for subsequent Welsh groups (Jones, Hutchings, Erjavec, & Hughes 2012).

DISCUSSION

This is a randomized pilot trial of the IYPB program as a universal intervention for parents with infants. The overall result is that there was no difference between the IYPB and UC groups immediately after the intervention ended, except for one outcome where mothers in the intervention group reported a smaller network to help with practical issues than control mothers. Establishing a support network for mothers is an important part of IYPB, and therefore intervention mothers may become more aware of their own network during the intervention. Network was a secondary outcome measured by a single item, and as we tested in all 20 outcomes at T2 with a 5% significance level, it may also be a spurious effect. Sensitivity analyses included OLS regression without imputation, random effects modeling, and difference-in-differences estimation on the imputed data, as presented in Table 7. The results presented here differ from those in Table 3 only in that for the OLS regression without imputed data, intervention mothers reported reading significantly more days a week than control mothers.

Table 7 Sensitivity analyses comparing OLS regression with and without imputation, random effects modeling, and difference-in-differences estimation at T2 for IYPB and UC mothers

	OLS-I	**OLS**	**RE**	**DiD**
	N=110	N=102	N=220	N=220
KPCS	-0.08	-0.02	-0.48	-0.48
MDI	0.36	0.37	1.57	1.57
WHO	-1.48	-1.48	-4.45	-4.45
RSS	-0.17	-0.07	-0.75	-0.75
PSS	0.79	0.61	-	-
MABISC	-0.23	-0.33	-	-
ASQ:SE-2e	1.33	1.09	3.67	3.67
Single items				
Loneliness	-0.15	-0.10	-0.13	-0.13
Network	-1.07**	-0.95*	-1.28**	-1.28**
Confidants	0.19	0.20	-0.32	-0.32
Overall health self-report	0.23	0.19	0.05	0.05
Life satisfaction	0.15	0.17	0.08	0.08
Economy	0.33	0.31	0.30	0.30
	N=112	N=104	N=224	N=224

Child weight (kg)	-0.01	0.02	-0.07	-0.07
Child height (cm)	0.01	0.31	-0.00	-0.00
Child temperament	-0.12	-0.14	-0.36	-0.36
Child overall health	-0.04	-0.08	-0.44	-0.44
Child enjoys reading	0.34	0.54	-	-
Days reading	0.80	0.94*	-	-
Days singing	0.35	0.41	-	-

* $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$; OLS-I: ordinary least squares regression with imputed data; OLS: ordinary least squares regression without imputed data; RE: random effects, DiD: difference-in-differences

Finding no effect of the IYPB at T2 is consistent with the evaluation results of the IYPB in Wales, where Jones et al. also found no effects apart from improved parent sensitivity in the IYPB group. The baseline means of the primary outcome parenting confidence (KPCS) and the change from T1 to T2 are almost identical to the Jones study (Jones et al. n.d.). The results also resemble those of the Ewans et al. study of IYPB, which found significant improvement over time for parenting confidence (KPCS) and mental health. The baseline means in the Ewans study are lower than in our study (38.66 compared to 41.09), and the change from T1 to T2 is larger (2.26-point improvement compared to 1.76), probably because the sample in the Ewans study consists of a disadvantaged group of mothers. However, the difference is small.

The lack of effect of IYPB as a universal intervention is consistent with some of the previously discussed disadvantages of universal interventions – for example, it is likely that the families with the greatest needs will decline to participate (Fonagy 1998), and it is difficult to detect the overall effects of universal interventions (Offord, Kraemer, Kazdin, Jensen, & Harrington 1998). The results are also similar to the results of the comparable universal trials discussed in the introduction – the Australian Toddlers Without Tears program (Bayer et al. 2010; Hiscock et al. 2008); the Australian Face to Face program (Vlismas et al. 2012); and the American trial of parent training (Dickie & Gerber 1980). The authors of the Toddlers Without Tears program conclude that, "A brief universal parenting programme in primary care is insufficient to prevent development of

preschool externalising problems" (Bayer et al. 2010). Our results indicate that even a more intensive universal intervention, which starts when the infant is younger, does not have any immediate effects after the intervention.

There may be different explanations for why we do not find any effects of the intervention. The sample is a universal sample of mothers with a relatively high education level. As these mothers would be expected to do well without the intervention, it may not be surprising that they do not derive additional benefit from it. Parents seeking advice on how best to take care of infants are often overwhelmed with contradictory information – from both family and friends but especially from the internet. Becoming a parent and taking care of an infant is challenging, and it takes time to gain confidence. It may be that offering an intervention at a time when otherwise well-functioning parents are still not comfortable and experienced in their role contributes to the general sense of information overload that new parents experience, thereby making them even more confused and insecure.

A common issue for measures applied to a universal sample is that there is a ceiling effect (Črnčec, Barnett, & Matthey 2010). This is the case for some of the outcomes in this trial, especially one of the primary outcomes (KPCS). A marked ceiling effect means that improvement over time is difficult to achieve. However, when looking at all mothers in the trial as a whole, we find that almost all outcomes (including the KPCS) significantly improve from T1 to T2. The significant negative effects that we find are related to measures that do not have marked ceiling or floor effects (PSS and WHO-5).

When interpreting the results, it is important to appreciate that the control group did not experience any absence of care, but Danish usual care, which is in itself a relatively extensive intervention. Virtually all families receive five or six free visits from a health visitor and three free scheduled child-health visits to the general practitioner within the child's first year (Foreningen for ledere af sundhedsordninger for børn og unge i Danmark 2013; Sundhedsstyrelsen 2011). In relation to most outcomes, the group as a whole significantly improved over time, which suggests that the universal intervention already offered to families in Denmark is at least as good as the IYPB intervention. However, based on the results from this trial, we cannot conclude whether IYPB would be superior to no intervention at all.

The results indicate that there may be differential effects of the IYPB intervention. Contrary to our hypothesis, we find that mothers with the lowest scores at baseline may experience negative effects due to IYPB. When splitting the sample into the lowest- and highest-scoring halves at baseline, it is striking that all outcomes favor the control group for the lowest-scoring half, whereas the opposite applies to most of the outcomes from the highest-scoring half (except from KPCS and PSS for the 25% highest-scoring group, and MDI for mothers in the highest-scoring 25% and 50% groups). For those in the lowest-scoring half, general well-being (WHO5) is significantly worse for IYPB mothers. For those in the lowest-scoring quarter, parental stress (PSS) is significantly worse for IYPB mothers compared to UC. These results are consistent whether we base the analyses on the imputed data or not.

Group interventions draw strength from being a safe place in which members feel comforted by the fact that others share their concerns and difficulties, and from the group's cohesion, which makes

everyone feel accepted and validated, and gives them a sense of belonging (Joyce, Piper, & Ogrodniczuk 2007; Yalom & Leszcz 2005). If groups comprise parents with very different perceptions of what it is like to be a parent, this may reduce the level of cohesion within the group, and thereby influence the outcomes. We know from other research fields that the lowest-functioning group can experience negative effects if the other members of the group are very different (Carrell S. & West 2013). If a group of parents consists of a majority who feel confident and self-efficacious, and a minority who find parenting challenging, the minority may feel even more insecure and less competent, as they do not experience cohesion, acceptance, and belonging. If this is the case, the intervention may actually contribute to increasing inequality, which is one of the points highlighted in relation to the disadvantages of universal interventions (Offord et al. 1998).

Parent and group leader satisfaction with the program could also influence the results. The general level of satisfaction was not very high, as only about half reported at the end of the intervention that they would recommend it to other parents. Usually, the level of satisfaction with interventions is much higher (around 80–90%). The responses from the parents and group leaders indicate that the program may need to be adjusted to meet the needs and expectations of a universal group of parents. Again, this indicates that the usual care offered to all families is of high quality, and that extra intervention for everyone may not be necessary.

When interpreting the results, we must keep in mind that this is a small pilot sample, and that the results therefore have to be interpreted with caution. Furthermore, the observational data has not yet been coded and analyzed, and we do not know whether there are any effects on the parent-child

relationship outcomes based on observation. Also, the 18-month follow-up data is currently being collected, and may reveal different results than the immediate post-intervention data.

CONCLUSION

This study is the first RCT of the IYPB program as a universal intervention for parents with infants. We find that it is possible to recruit families to an effectiveness trial evaluating a universal intervention, and that the majority of mothers in the IYPB group participated in the intervention, although their level of satisfaction with the program was not high. Apart from one single item (mother report of network, where IYPB mothers report smaller network than UC mothers), which may be a spurious effect, we found no difference between the groups on any outcomes immediately after the intervention ended. When dividing the sample into the lowest- and highest-performing halves at baseline, we found significant negative effects on parental stress and mental health for the mothers in the lowest-functioning groups. All other outcomes also appear to be trending in this direction. Based on feedback from parents and group leaders, the IYPB program may need to be adjusted to meet the expectations and needs of a universal group of parents.

Abbreviations:

IY: Incredible Years; IYPB: Incredible Years Parents and Babies, RCT: randomized controlled trial; UC: Usual Care; KPCS: Karitane Parenting Confidence Scale; PSS: Parenting Stress Scale; MDI10: Major Depression Inventory; WHO5: World Health Organization Well-Being Index; RSS: Rosenberg Self-Esteem Scale; ASQ:SE-2e: Ages and Stages Questionnaire: Social-Emotional-2 experimental version; MABISC: Mother and Baby Interaction Scale; MCAR: missing completely at

random; MAR: missing at random; OLS: ordinary least squares; SD: standard deviation; CACE: Complier Average Causal Effect, CI: confidence interval

Competing interests

The authors declare that they have no competing interests.

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