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EVALUATION OF A SWEDISH UNIVERSAL HEALTH-PROMOTING PARENTING PROGRAM EFFECTIVENESS, COST-EFFECTIVENESS AND PREDICTORS

Malin Ulfsdotter



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**Evaluation of a Swedish universal health-
promoting parenting program
Effectiveness, cost-effectiveness and predictors**

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“Parenting is pleasures, privileges, and profits as well as frustrations, fears, and failures”
(Marc H. Bornstein, 2008 in Promoting Positive Parenting.
An attachment-based intervention, p. viii)

ABSTRACT

Knowledge of universal parenting programs is not as comprehensive as knowledge of targeted parenting programs. Few evaluations of universal programs have to date included a measure of child health and well-being; the focus has rather been on measuring improvement in child behavior problems. Still, many of the existing evaluations of these programs do not show effects in terms of reduced behavior problems in children. Knowledge of potential cost-effectiveness, predictors and moderators of universal programs is also scarce. The present thesis comprises studies of a newly developed universal health-promoting parenting program, with the overall aim of evaluating the effectiveness, cost-effectiveness, and predictors and moderators of the program's effects. **Study I** aimed to describe the trial of All Children in Focus (the ABC program) in a study protocol. A randomized controlled trial was conducted, including 613 parents recruited within the County of Stockholm. Parents were randomized to either an intervention group ($N = 317$) receiving the program directly, or to a control group ($N = 296$) where parents were put on a waiting-list to receive the intervention after approximately six months. **Study II** aimed to evaluate the program's effects on parental self-efficacy and parents' perceptions of child health and development six months post baseline, as well as to test potential moderators. The results showed that the intervention group reported significant improvements in parental-self-efficacy and in parents' perceptions of child health and development compared to the control group. Parents' mental health, educational level, and number of children in the family moderated parental self-efficacy, while parents' mental health and child age moderated child health and development. **Study III** aimed to estimate the costs, investigate the effects, and conduct a cost-effectiveness analysis alongside a randomized controlled trial. The study resulted in a base case incremental cost-effectiveness ratio of €47,290/QALY and sensitivity analyses resulted in ratios between €19,957–145,022 per gained QALY. The probability analysis resulted in a 51 percent probability that the program was cost-effective. **Study IV** concerned the intervention group only. The study aimed to evaluate whether the effect found at six months in child health and development was maintained at the 12-month follow-up, to investigate whether there were changes over time in the secondary outcome measures, and to examine whether changes in the secondary outcome measures predicted change in children's health and development. The results showed significant changes over time (T1-T4) in parents' perceptions of child health and development, parental self-efficacy, harsh and inconsistent parenting, and parents' emotion regulation (the reappraisal scale). Parental self-efficacy was the only variable found to predict child health and development at 12 months. In sum, the current thesis provides support for short-term effects of a universal health-promoting parenting program, as well as for effects being maintained over a longer time perspective. The findings also highlights that families may benefit differently from the program and that further research is needed to establish predictors of the outcomes of universal parenting programs. Finally, the thesis also provides support for the cost-effectiveness of the program, even though further research is encouraged due to the rather low probability of cost-effectiveness found in the current work.

LIST OF SCIENTIFIC PAPERS

- I. Lindberg, L., **Ulfsdotter, M.**, Jalling, C., Skärstrand, E., Lalouni, M., Lönn Rhodin, K., & Enebrink, P. (2013). The effects and costs of the universal parent group program – all children in focus: a study protocol for a randomized wait-list controlled trial. *BMC Public Health*, 13:688.
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LIST OF ABBREVIATIONS

ABC	All Children in Focus (the ABC program)
CEA	Cost-Effectiveness Analysis
CEAC	Cost-Effectiveness Acceptability Curve
CHD	Child Health Development
CUA	Cost-Utility Analysis
ERQ	Emotion Regulation Questionnaire
GHQ-12	General Health Questionnaire 12
HRQoL	Health-Related Quality of Life
ICER	Incremental Cost-Effectiveness Ratio
ITT	Intention-to-Treat
LOCF	Last Observation Carried Forward
MLM	Multilevel Linear Modeling
NMB	Net Monetary Benefit (method)
PPI	Parenting Practice Interview
PSE	Parental Self-Efficacy
RCT	Randomized Controlled Trial
SBU	The Swedish Agency for Health Technology Assessment and Assessment of Social Services
TOPSE	Tool to measure parenting self-efficacy
QALY	Quality-Adjusted Life-Year
VAS	Visual Analog Scale
WHO	World Health Organization
WTP	Willingness-to-pay

1 INTRODUCTION

The Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) published a systematic review of programs to prevent mental ill-health in children in 2010 (1). The report concluded that there was limited international scientific support for parenting programs and a lack of randomized controlled trials (RCTs) based on samples of the Swedish population with follow-ups longer than six months. In addition, the report emphasized the value of health economic evaluations and stated that there was a lack of evidence for universal parental support to be effective. The report further suggested that the goal of municipalities and county councils has eventually to be to provide inhabitants with evidence-based programs only.

In addition, during 2008–2009, several national inventories of methods to prevent mental ill-health in children were carried out. One of them, an inventory of methods in municipalities and county councils, conducted by the National Board of Health and Welfare, reported that 129 different methods of prevention or early intervention were applied (2). However, the report also stated that there was great uncertainty regarding the effectiveness of these methods, and concluded that there was a need for evaluations of methods since most of those applied lacked scientific support regarding effectiveness. Further, a national inventory of methods adopted at preschools for preventing mental ill-health in children (3), showed that the most common programs or structured approaches of parenting support or parental interaction were developed by the preschools themselves. The same pattern was found for schools that also offered their own-developed programs or structured approaches of parenting support or parental interaction (4). For preschools and schools that stated that they offered a program or a structured approach, about half of them stated that they had evaluated the program or strategy (3, 4). Within social services, most municipalities offered both universal and selective parenting programs, which often were manual-based (5). The two programs most frequently offered, both as universal and selective programs, were COPE (the COMMunity Parent Education program) and COMET (the COMMunication METHod). There is one nationally conducted RCT of these programs when offered as targeted interventions (i.e., for children with externalizing problems) (6). However, there is to my knowledge no evidence of the programs being effective when offered universally. At child health care services, parenting programs have been reported to be offered to a great extent, as the International Child Development Program (ICDP) was reported to be used by 15 percent of the nurses at child health care services (7). Until now, there is no RCT conducted on ICDP (1). To summarize, a great number of methods are present in the field of promotion of mental health and prevention of mental ill-health among Swedish children. However, the majority of these methods have still not been subject to efficacy or effectiveness trials, and thereby have not been proven to be effective. This implies that resources, including parents' time, are spent on interventions that we do not know if they work or not.

The use of scientific evidence is of great importance in supporting decision-making, particularly when the implications of a decision are large (8), for example, when

implementing a new parenting program. Trials of effectiveness are needed to show with reasonable certainty that interventions work (9), and are not solely based on subjective experiences, charismatic experts, faith, or assumptions (10). The RCT is viewed as the most rigorous study design for deciding if there is a cause-effect relationship between an intervention and outcome, as well as to evaluate the cost-effectiveness of an intervention (11). In addition, if an intervention is found to be effective in a RCT, further work is needed since the intervention most likely is not equally effective for all participants (12). The RCT can further be used to identify moderators and mediators of intervention outcomes, i.e., include investigation of for whom an intervention works as well as examination of how an intervention works (13). As interpreted by Webster-Stratton and Taylor (14), an intervention evaluated in one controlled trial can be viewed as promising, whereas interventions that have been subject to two or more trials conducted by independent researchers can be reflected upon as well-established. Further, in the criteria for efficacy, effectiveness, and dissemination, Flay et al. (15) have stated that no less than two high-quality trials showing consistent results (i.e., similar effect sizes) are needed as evidence for effectiveness.

2 BACKGROUND

2.1 MENTAL HEALTH

The World Health Organization (WHO) states that health is created by people in everyday life settings, i.e., where people play, love, learn, and work (16). Mental health plays an important role for overall health and social functioning, and an increased interest in the promotion of mental health and well-being has occurred since the beginning of the new millennium (17). Mental health, one among several dimensions of health (18), has been defined by WHO as “*a state of well-being in which the individual realizes his or her own abilities, can cope with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to her or his community*” (19, p. 1). The foundations of mental health across life originate in childhood, and children’s relationships with, for example, parents, peers, and teachers, are important for enabling social, emotional, and cognitive development (20).

2.1.1 Mental health in children

According to WHO, Swedish school-aged children report better health than European and North American children on average (21). However, at the age of 15 there is a shift when Swedish children, especially girls, report poorer health regarding multiple complaints (headache, stomach ache, feeling low, and feeling nervous), compared to other countries. Swedish data show that, during the period of 1985/1986 until 2013/2014, there was an increase in mental health complaints, i.e., feeling low, difficulty getting to sleep, irritable/in a bad temper, and feeling nervous, among 13 and 15 year-olds (22). The level of having two or more complaints, mental and/or somatic, among girls aged 13 and 15 has almost doubled from 1985/86 until 2013/2014 (24% to 46% for 13 year-olds, and 29% to 57% for 15 year-olds). The level of having two or more complaints was lower among boys in the same age groups, but the same trend was seen among boys with a doubled level during the same period of time (27% of the 13 year-olds reported two or more problems and 31% of the 15 year-olds in 2013/2014). The increasing rates of mental health complaints among Swedish school-aged children are viewed as a cause of concern and a growing public health challenge, not only within the scientific field (23) but also among national agencies (22, 24) and within the political field, where more resources are proposed to be allocated due to increased mental health problems among children and young adults (25). Regarding the mental health of younger children in Sweden, aged 0–10 years, knowledge is insufficient and no conclusions can be drawn regarding trends (26).

Furthermore, mental health problems in children, including preschool children, are viewed as an international public health problem (27), and the public health burden of child problems (emotional and behavioral) is extensive (28). In a review by Egger and Angold (29), the prevalence of psychiatric disorders in preschoolers was around 15 percent, and around 25 percent for children and adolescents (aged 5–17 years). The prevalence of antisocial behavior in children, even though viewed as difficult to assess, lies somewhere between 1–10 percent

of all children (30). Regarding the mental health problems of children in the Nordic countries, the prevalence is around 20 percent (31). In addition, about half of the adult population with mental health illness develop the illness before reaching the age of 15 (32), which means that early mental health initiatives, including health promotion, disease prevention, early identification, and treatment may have a substantial impact on public health.

2.2 HEALTH PROMOTION AND DISEASE PREVENTION

Evidence-based prevention and promotion includes the use of current best evidence to decide upon interventions to ensure the best outcomes possible regarding reduction in diseases, and to enable individuals to enhance control over, and to strengthen, their health (8). Health promotion and disease prevention are not synonymous but complementary (33), and are described by the WHO to be activities that are related and overlapping (34). In addition, elements of promotion and prevention frequently exist within the same programs and strategies, and include comparable activities that generate diverse outcomes (35). Saxena et al. (8) describe that the difference between mental health promotion and mental disease prevention lies in the outcomes targeted by the approaches (i.e., the aim of promoting mental health versus the aim of reducing symptoms and ultimately mental disorders). Further, mental health promotion can have as a secondary outcome to reduce the incidence of mental disorders, whereas mental disease prevention can use strategies of promotion to reach the goals of prevention (8). Therefore, distinguishing between health promotion and disease prevention interventions can sometimes be hard and a single intervention may include elements of both approaches.

Promotion concerns improving health and well-being whilst prevention concerns avoiding disease (35). The pathogenic view on health is concentrated on finding causes for ill health and has focused on risk factors, whereas the salutogenic view on health considers reasons for why individuals remain healthy (18). Health promotion entails the determinants of health (34), which are the personal, social, economic, and environmental factors determining the health status of people or populations (36). Further, whilst health promotion has been viewed in terms of interventions occurring outside the health care sector, and considers the general population, disease prevention has instead been viewed in terms of interventions within the health care sector, and targets populations at risk (37). Within the definition of public health lie both the concept of health promotion and that of disease prevention as approaches to promoting health, prolonging life, and improving quality of life (36). Thus, public health includes interventions aiming to promote health and interventions striving to prevent disease.

2.2.1 Health promotion

Health promotion has been defined in many ways, where most of the definitions include the desired goal of improved health/well-being or the goal of health maintenance (33). In 1974, health promotion was defined by Lalonde as a strategy “*aimed at informing, influencing and assisting both individuals and organizations so that they will accept more responsibility and be more active in the matters affecting mental and physical health*” (38, p. 66). WHO later

defined health promotion as “*the process of enabling people to increase control over, and to improve, their health*” (16, p. 1). Further, the inclusion of a primary criterion, empowerment, has been suggested as a way to determine if an initiative is health promotive; i.e., the initiative should involve the process of empowering individuals or communities (33).

2.2.1.1 Key concepts in health promotion

Health promotion incorporates the health and well-being of entire populations (18), and three major strategies for health promotion were identified at the first international conference of health promotion: advocacy, enablement, and mediation (16). Advocacy for health includes actions to gain commitment/support/acceptance for health goals or programs; enablement means taking action in partnership to empower, promote and protect health; and mediation is a process where different interests are combined to promote and protect health (36). During the first conference, five main action areas for health promotion were also listed, namely: build healthy public policy, create supportive environments, strengthen community action, develop personal skills, and reorient health services (16). Furthermore, empowerment is a key concept within health promotion and includes the process where individuals “*gain greater control over decisions and actions affecting their health*” (36, p. 6). Empowerment can include a social, cultural, psychological, or political process in which people have the possibility to express needs, introduce concerns, lay out plans for involvement in decision-making, and take social, cultural and political action to meet the needs (36). Another term included in health promotion is self-efficacy (39). A modified definition (from Bandura 1994) of perceived self-efficacy has been included within the new terms of the health promotion glossary: “*beliefs that individuals hold about their capability to carry out action in a way that will influence the events that affect their lives*” (39, p. 343). How people feel, reason, encourage themselves, and act are regulated by self-efficacy beliefs, and the amount of energy individuals will spend and how much time they will put in when facing obstacles and aversive experiences demonstrate their self-efficacy beliefs (39).

2.2.2 Disease prevention

Disease prevention has been defined in terms of “*measures not only to prevent the occurrence of disease, such as risk factor reduction, but also to arrest its progress and reduce its consequences once established*” (36, p. 4). Disease prevention is viewed as involving actions generally originating from the health care sector, concerning people with risk factors, and often related to risk behaviors (36). Prevention interventions have been divided into universal, selective, and indicated interventions (40). Further, the preventive interventions should, according to Gordon, be applied when individuals are not concerned with suffering from any discomfort or disability (40). The public health concept of disease prevention was earlier also divided into primary, secondary and tertiary prevention, where primary prevention aims to avoid new cases of a disease arising (prevent the disease itself), secondary aims to reduce the consequences of the disease (ameliorate the severity of it), and tertiary aims to stop the progress or reduce the complications (prevent the disability

associated with it) (35, 41). Universal, selective, and indicated prevention interventions are categories of primary prevention (8, 35).

2.2.2.1 Universal, selective and indicated prevention

The division of prevention into universal, selective, and indicated is based on who is offered the intervention (42), where a universal intervention is suitable for everyone and therefore is of relevance for the general population (40). Gordon (40) explains that universal prevention could, for example, imply an intervention regarding use of seatbelts in cars. In addition, with a universal prevention program within a high-risk area, the intervention could still be considered universal since it is not targeting certain groups or individuals (42). A selective intervention is, on the other hand, for individuals belonging to a subgroup recognized by a characteristic that makes them at higher risk of becoming ill; characteristics could be, for example, age, gender, and occupation (40). A selective intervention is advisable for individuals who, on personal examination, are perfectly well, and an example could be an intervention targeting teenage parents. An indicated intervention is for individuals that are identified as having a risk factor, condition or abnormality that, on an individual basis, recognizes them as being at higher risk of future development of a disease (40). Indicated prevention is more commonly applied in a clinical setting, and could, for example, be control of hypertension. The classification system of prevention, which is based on whom an intervention is offered to, can additionally be divided into two kinds; universal and targeted (i.e., selective and indicated) (42). This way of dividing prevention, i.e., targeted prevention includes selective and indicated interventions, will be applied further on in this thesis.

Offord (42) has described benefits and disadvantages of universal and targeted prevention. Some of the benefits of universal prevention are: no stigmatization, makes the area prepared for targeted interventions, and enables the possibility of directing program elements at community-wide risk factors. Also, even though the individual benefit is not predicted to be major, the overall effects at a population level might be considerable. Offord also states several disadvantages to universal prevention; not appealing to the general population, small individual benefit, and the risk of increased inequalities among groups even though the aim is the opposite. Also, there are difficulties in showing overall beneficial effects. Offord states two benefits of targeted interventions: the potential of intervening before problems become severe and the potential of efficiency because resources are allocated to the high-risk group only. However, there are also substantial shortcomings of targeted prevention; stigmatization, difficulties with screening (such as being costly, and those at higher risk tending to refuse screening to a greater extent), high-risk individuals contributing to fewer cases than the group of low-risk individuals, and usually disregarding the social context as a focus of the intervention.

2.2.3 Population reach and risk of promotion and prevention

As described earlier, the targeted outcomes of promotion and universal prevention are different (8), where promotion aims to promote health and well-being whereas universal

prevention aims to prevent ill-health (43). Despite this difference, both promotive and universal preventive interventions are usually aimed for the whole population, as illustrated in Figure 1. Targeted interventions (selective and indicated prevention) are only for subgroups or individuals with a higher risk of disease, meaning that they target fewer people. Further, secondary and tertiary prevention, as well as treatment, reach even fewer individuals since they concern individuals already affected by a disease. The scopes of secondary and tertiary prevention and treatment are beyond this thesis, and will therefore not be further developed.

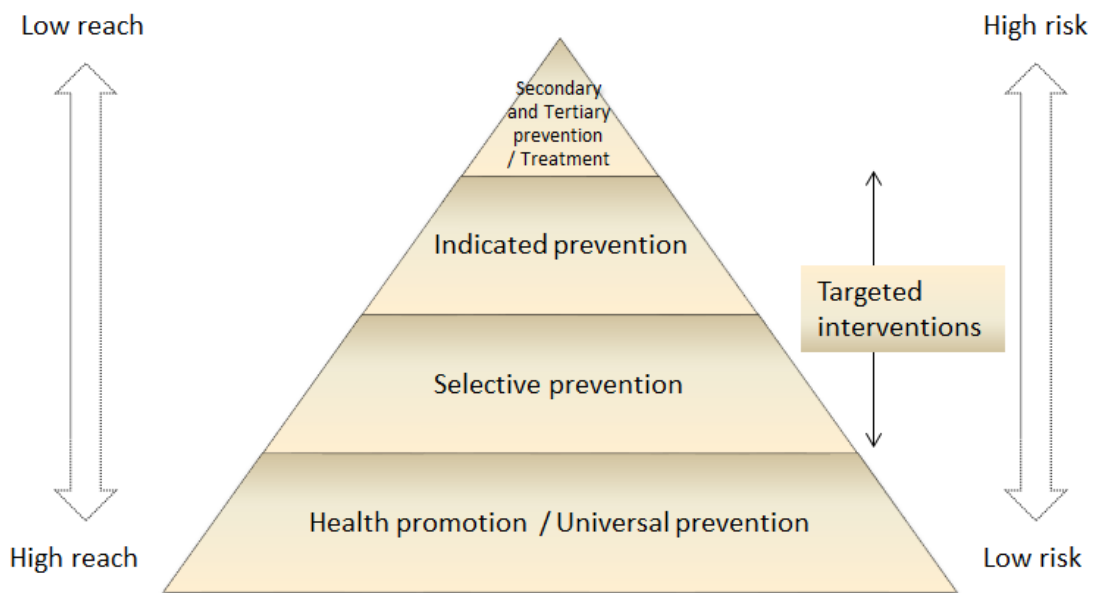


Figure 1. Illustration of population reach and risk of promotion, prevention and treatment.

Further, as also illustrated in Figure 1, the division of interventions into promotion, different levels of prevention, and treatment also illustrates the relation to risk, where lowest risk occurs within the category of health promotion/universal prevention whereas the risk increases further up the pyramid. Figure 1 is to some extent inspired by the mental health intervention spectrum (44), by Ferrer-Wreder et al. (43), by the report *Every child matters* (45), and by Offord (42).

2.3 PARENTING AND CHILD MENTAL HEALTH

Parenting has been described as one of the most overwhelming and significant efforts a great amount of people take on in life (46), and also as being a complicated mission (47). Further, four children are born every second worldwide (estimation from 2015) (48), affecting and exposing lots of human beings to parenting. Children's behavior is, over time, shaped and modeled by parenting strategies and parental behaviors (49). The behavior of a parent is expected, from a theoretical perspective (50), to have a direct impact on children's health and development in ways that can be either positive for the child, or in ways that can be negative, depending on the quality and appropriateness of the parent behavior. Additionally, the impact

of parental behavior on children's mental health could add to the development of child problems (i.e., emotional and behavioral problems) (49).

The impact of parenting on child development has been demonstrated in over half a century of research, and parenting has come to be acknowledged as a highly important determinant of the future health of children, especially their mental health (17, 51, 52). Quality of parenting is viewed as the most powerful risk factor for the development of behavioral and emotional problems in children, and parenting quality is regarded as a highly modifiable risk factor (53). Furthermore, as described by Stewart-Brown (54), parenting seems to influence a wide variety of health aspects, such as: emotional and social development, peer relationships, mental health, healthy eating, obesity, smoking, alcohol and drug misuse, teenage pregnancy, injury, health in general, symptoms of poor health, cardiovascular health, and musculoskeletal problems. Stewart-Brown also highlights aspects of parenting with an impact on health at all ages, including warmth, affection and support, lack of hostility or rejection, conflict management, problem solving, and appropriate levels of control. Meanwhile, behavior management, discipline strategies, and praise are parenting aspects with an impact on health only during preschool and primary school. In addition, parenting has also been found to be predictive of aggression and violence (55), and of educational success and school dropout (56). The influence of parenting is extensive, and parenting is viewed as essential for children, parents and society (17).

Furthermore, regarding younger children in Sweden, it is known that harsher discipline (pushing, grabbing and shaking the child) has increased since 2000, especially in children aged 2–9 (57). In 1980, the prevalence of pushing, grabbing and shaking was 50 percent, which then decreased to 12 percent in 2000. From then, an increase has been noticed: 23 percent in 2006, and over 30 percent in 2011 (57). Reported reasons for harsher discipline used to handle conflicts with children included parents feeling tired or stressed (stress over the general live situation). In addition, it was more common among parents born in Sweden, compared to parents born abroad, as well as among parents who themselves were hit as a child, to report shoving, grabbing and shaking of the child.

2.3.1 Protective and risk factors

Within intervention research, it is of value to consider the level of protection or risk of an individual or a population (43). Andershed and Andershed define a risk factor as *“something—a characteristic, relationship, trait, behavior, mechanism, situation, or circumstance—that increases the probability for a certain outcome”*, and a protective factor as *“something—a characteristic, relationship, trait, behavior, event, situation, or circumstance—that decreases the probability for a certain outcome, in the presence of risk”* (58, p. 413). The occurrence of protective factors can thereby make a child avoid a certain outcome even though being exposed to the risk of it (58). This phenomenon is often referred to as resilience (59), i.e., exposure to risk but still a good outcome (60). Furthermore, most children are at some point exposed to more or less risk, and it is therefore of importance to strengthen and maximize protective factors in children (58).

2.3.1.1 Parenting as a protective factor

The concept of a protective factor is not the same as positive or beneficial experiences because the protective factor might not create a pleasurable happening (an unpleasant event may toughen a person). Also, a protective factor has an interaction component (a modifying role to respond to later adversity), and may not be an experience at all (could potentially be an individual quality, such as being a female) (61). In a review by Eriksson et al. (59), several protective factors related to parenting were identified regarding child externalizing and internalizing behaviors. These were: adequate nurturance and shelter, secure attachment, good parent-child relationships, authoritative parenting (i.e., high in nurturance, maturity demands, control and communication), supportive parenting (such as being involved in the child's education), routines in the family (working parents coming home the same time every day), parental monitoring, and positive family climate. In another review, parental acceptance and responsivity, warmth, secure attachment, positive family relationships, and few infant-caregiver separations were identified as protective factors of psychosocial problems (58). In addition, quality time spent with children was found to be associated with a lower degree of externalizing behavior for children aged eight in a study by Cabaj and co-authors (28).



2.3.1.2 Parenting as a risk factor

There are several parenting risk factors associated with the development of behavior and conduct problems in young children, such as: harsh and inconsistent discipline, poor monitoring and supervision, lack of positive involvement (62), low cognitive stimulation (14), parental rejection/critical parenting, negative restrictive control, lack of positive parenting (49), controlling parenting style, and low parenting efficacy (27). Overprotective parenting and harsh discipline have also been found to be risk factors for internalizing problems (27, 63). Furthermore, children who are quick to anger, have more of an impulsive temperament, and are hyperactive have an increased probability of further conduct problems when their parents respond to their behaviors with harsh or inconsistent parenting (14). Furthermore, Cabaj and colleagues (28) found current absence of positive parenting interactions and low parenting morale (at child age 3) to be risk factors for internalizing behavior problems at child age of eight, whereas hostile parenting (at child age 3) and low satisfaction with parenting sense of competence (at child age 5) were risk factors for externalizing problem behaviors. In addition, Farrington (64) found poor child-rearing, poor

supervision, disrupted family, and father uninterested in the child to be childhood risk factors for an antisocial personality at the age of 18.

Concerning harsh parenting, definitions of the term often include both physical and verbal forms of discipline, such as angry and over-reactive parenting and forms of physical and verbal punishments (65). In a conceptual analysis, negative/harsh parenting was characterized by constructs such as authoritarian (i.e., less nurturing, more psychological control), coercion, conflict, emotional maltreatment, hostile/ineffective parenting, inconsistent/physical discipline, negative interaction, neglect, non-reasoning/punitive strategies, physical abuse, and verbal hostility (66).

2.3.2 Promotion and prevention interventions targeting child mental health through parents

The development of good health starts at an early point in life (52) and it has been argued both by researchers and policy-makers that family supporting interventions, offered at an early stage, are crucial for preventing and improving child behavior problems (67). Support to parents offered early on in parenthood is also viewed as an important approach to empowering parents. Supporting parents in their parenting has, together with actions such as reducing social inequalities and improving schools, been classified as essential when it comes to the promotion of children's well-being (54). Interventions for parents has been described as having great potential to improve child well-being and, thereby, to have a significant impact on public health (54). Additionally, to offer parents interventions targeting parenting behavior is also a central strategy for the prevention of child behavior problems and reducing the risk of later child ill-health (68).

In addition, problems with parenting are not restricted to certain groups of parents but rather exist in the whole of society (54, 69). Support to parents in their parenting should therefore not be restricted only to parents living in, for example, disadvantaged areas but rather be offered universally, contributing to non-stigmatization regarding participation. Further, since there is also a need for tailored support to parents requiring more intensive help than the general population, interventions of both low- and high-intensity are needed to suit a whole population (17).

2.4 PARENTING PROGRAMS

Parenting programs have generally been designed to promote and improve parenting (behaviors, competences, practices, and skills) and to prevent child behavior problems (14, 62, 68, 70). Later, the objectives of parenting programs have also been extended, including the cognitive development of children (71), anxiety (72), and physical health (73). More recently, there has also been a focus within universal parenting programs on objectives such as child well-being (74-76), child emotional knowledge (77), and positive behavior in children (78).

A parenting program can be administered in a group format or individually, in a clinical- or community-based setting and create parental engagement through group discussions, role playing, and homework assignments (79). In addition, programs can also be self-help interventions, delivered as bibliotherapy or in a multimedia format, such as through the Internet or TV (80). Further, it is most common for the parents to participate, even though some programs include the children. Programs may include 10–20 sessions of around 1–3 hours each (81). Programs including fewer sessions also exist, especially universal programs consisting of 1–10 sessions (74, 75, 77, 82-87). Many different names are used within the research literature for a parenting program: parent education program (62), parent management training (88), parenting discussion group (85), parenting intervention (89), parenting program (17, 47, 54), parenting skills program (74), and parent training program (90).

Parenting program is applied as a generic term throughout this thesis, and is used as described by Barlow and Stewart-Brown (62); group-based programs with a standardized setup. In addition, the focus of the thesis is on universal parenting programs, but the literature review also includes targeted programs with the original objective of preventing child behavior problems since most research so far is conducted on these programs.

2.4.1 Development of parenting programs

In the 1960s there was a focus shift in the approach of managing child behavior problems from only changing the behavior of the child, through therapy or institutionalization, to interventions directed at parents (62, 81). The change was initiated by the recognition of parents being able to act as agents of child behavior, previously seen as possible for only highly trained therapists (79); i.e., using behavior modification techniques among parents to produce behavior changes in children was recognized within research (62). The change was also driven by the recognition of parents' behavior contributing to child misbehavior (79, 91). By offering parenting groups, the needs of more parents could be covered, and the groups also seemed to reduce stigma arising from clinical attendance (62). Further development of parenting programs took place later on, from the 1990s, in several countries (62). As described earlier, more than 100 prevention or early intervention methods concerning mental ill-health are now applied in Sweden, a substantial number of these methods are parenting programs (2). Further, several countries (45, 92-95) have also witnessed government interest in supporting parenting to promote child health.

2.4.2 Theoretical framework of parenting programs

Barlow and Stewart-Brown (62) have divided parenting programs into behavioral programs and relationship programs, and programs may also combine elements from both. Many of the parenting programs, especially the behavioral programs, are underpinned by the presumption that behavior problems in children are a function of incidents taking place in the family between parents and children, and that a deficit in parenting skills contributes to behavior problems in children. Behavioral programs, focused on observable and measurable behaviors,

train parents in strategies to increase wanted child behaviors and reduce unwanted ones. In these programs, typically based on social learning theory, parents are encouraged to recognize behaviors that are problematic and to apply positive reinforcement to motivate a wanted behavior. Homework assignments are frequently used to try out newly obtained skills at home.

The relationship programs, also referred to as non-behavioral programs, normally aims at improving the parent-child relationship (81). These programs are instead often based on the humanistic tradition, Adlerian theory, the psychodynamic model, or family systems theory (62). Barlow and Stewart-Brown (62) describe that programs based on the humanistic tradition may include strategies such as use of active listening and sending “I-messages”. The Adlerian theory highlights the importance of understanding of how children work and think and explanations behind child behavior. The psychodynamic model, on the other hand, stresses the significance of understanding the impact previous relationships have on present relationships. Family systems theory includes understanding family behaviors, including one’s own, as well as localizing the behavior of the child within the frame of family relationships. Furthermore, attachment theory has also been the theoretical base for parenting programs (or included as one of several theoretical bases), focusing on the interaction between parents and children and enhancement of parental sensitivity (75, 96, 97).

2.4.3 Effectiveness of parenting programs

Within the field of evaluation of interventions, it is common to distinguish between efficacy and effectiveness trials. Godwin (98) has described that an exploratory trial examines if an intervention is efficacious, meaning that the intervention is tested in an ideal situation with rigorous control of different variables and often conducted by the intervention developers. The participants in an exploratory trial are often coming from a similar group of the population and are also likely to stay in the study. A pragmatic trial, on the other hand, is described by Godwin to examine effectiveness, meaning that the intervention is tested under real-world conditions including participants who represent the whole spectrum of the population for which the intervention is suitable. An exploratory trial results in knowledge regarding whether an intervention works under ideal circumstances, and a pragmatic trial results in knowledge regarding whether an intervention works in real life. An exploratory trial wants to maximize internal validity, i.e., the reliability of the study results, whereas a pragmatic trial seeks a balance between internal validity and external validity, i.e., the generalizability of the results.

2.4.3.1 Targeted programs

Knowledge regarding the efficacy and effectiveness of parenting programs is greater when it comes to targeted programs compared to universal and health-promoting programs. There are multiple reviews of targeted programs (70, 90, 99-103), and it is commonly accepted that parenting programs can be effective (79). Piquero et al. (90) have recently updated their review from 2009 (102), and included 78 studies when investigating the effectiveness of early

family/parent training programs (i.e., with child age under five or mean child age around five years when the intervention started) on child behavior problems. Programs included in the review were home visitation programs and parent training programs. Piquero et al. (90) found a significant positive overall mean effect size of .37 (the effect sizes between the intervention and control group at post-treatment of each study were pooled). Effect size moderators were country of publication, type of program, sample size, and publication bias, where studies published in the USA, parent training programs, studies with smaller samples, and non-published studies had greater effect sizes. A review by Furlong and co-authors (101) considered the effectiveness of behavioral and cognitive-behavioral parenting programs (for parents with children 3–12 years-old) regarding child conduct problems, parental mental health, and parenting skills. In the review, 13 trials were included, and the authors concluded that behavioral and cognitive-behavioral parenting interventions were effective in the short-term (post-treatment and up to 3-months post-treatment) regarding reduction of child conduct problems and in negative and harsh parenting practices. In addition, short-term effectiveness was found regarding improvement in parental mental health and positive parenting skills. However, the review could not draw any conclusions about long-term effects.

Dretzke et al. (100) conducted a review including 57 RCTs of parenting programs (for parents with children to the age of 18 years) targeting children with conduct problems. They concluded that parenting programs were effective regarding reduction in conduct problems in children, both when reported by parents and established by independent observations. Additionally, the parent-reported outcomes were greater compared to independent observations (standardized mean differences of .7 versus .4). In the review by Lundahl and colleagues (70), 63 studies were included regarding the effectiveness of parent training (behavioral and non-behavioral oriented) with regard to child behavior, parent behavior, and parental perceptions of parenting (such as confidence in parenting). The overall effect sizes (Cohen's *d*) for immediate effects were .42 (child behavior), .47 (parent behavior), and .53 (parental perceptions). Behavioral and non-behavioral programs did not differ regarding impact on child or parent functioning. Regarding follow-up effects, results were only presented for behavioral programs and for studies including a control group. An overall effect size of .21 was found for child behavior, .25 for parent behavior, and .45 for parental perceptions of parenting.

Furthermore, parental psychosocial well-being was the outcome of investigation in a review including 48 RCTs of parenting programs (99). Barlow and colleagues found short-term improvements regarding depression, anxiety, stress, anger, confidence, and satisfaction with the partner relationship (standardized mean differences between $-.17$ to $-.79$), whereas only stress and parental confidence continued to be significant at six months. There were no significant improvements found at the one-year follow-ups. In addition, a review (103) examined the effectiveness of prevention programs targeting externalizing problems in children (aged 2–19 years). In total, 38 controlled trials were included covering 25 different programs, and the effectiveness of only five programs was found to be supported by

evidence. Of these, two programs were targeted parent training programs, Incredible Years and Triple-P.

2.4.3.2 *Universal programs*

Until now, there is no review of universal parenting programs to my knowledge. However, there are several universal programs for parents with children aged up to 12 years-old. Some of these are: a brief parenting discussion group (85), “All Children in Focus” (75), “Family Links Nurturing Program” (74), “How-to Parenting Program” (76), “International Child Development Program” (87), “Toddlers Without Tears” (83, 89), and “Tuning in to Kids” (77). In addition, programs originally developed as targeted interventions have been applied as universal programs: “1-2-3 Magic & Emotion Coaching program” (104), “Incredible Years” (86) and “Triple P” (68, 82, 84, 105-107). Several of these programs have been evaluated within RCTs (68, 74, 77, 78, 82-86, 89, 105-108).

In the effectiveness trial of the Family Links Nurturing Program, Simkiss et al. (74) included 286 families with children aged between 2 and 4 years. They investigated negative and supportive parenting as well as child and parent well-being, where no significant changes were found between the intervention and control groups at the 3-month and 9-month follow-ups. However, in 14 of 19 investigated outcomes, a non-significant improvement was found for the intervention group. Tuning in to Kids has been evaluated in both an efficacy (77) and an effectiveness trial (78). Havighurst and co-authors (77) found improvements in parental emotion awareness and regulation, emotion coaching, use of emotion labels and more engagement in emotion exploration, and decreases in emotionally dismissive beliefs and behaviors in the efficacy trial, which included a 6-month follow-up. Regarding the child outcomes, there was an increase in emotional knowledge and decreases in parent- and teacher-reported behavior problems. The effectiveness trial (a pre-post design), which included 128 parents with preschool-aged children, found that emotion coaching practices and positive involvement increased and that emotion dismissive beliefs and practices decreased, whereas no intervention effects were found for the measures of child behavior (78).

Morawska et al. (85) evaluated the efficacy of a brief, one session and two follow-up telephone calls, parenting discussion group including in total 67 parents with children aged 2–5 years. Short-term effects (from pre to post) were found in parent-reported child behavior problems, parenting style, parenting confidence, managing behavior, parenting experience, as well as in social and partner support. The reported effect sizes (Cohen’s *d*) ranged from moderate (parenting style and task-specific self-efficacy) to large (child problem behavior). Further, a 6-month follow-up was conducted for the intervention group, which showed significant time effects, indicating maintained effects, in child behavior, parenting style, confidence, experience, and partner support.

Long-term follow-ups

Until now, there are some longer follow-ups conducted on universal parenting programs. In a 8-year follow-up, involving 56 schools and 1675 children, Averdijk et al. (105) found that Triple-P had an effect on teacher reported aggressive behavior when the children were 15 years; however it was negligible due to an effect size of $-.149$ (Cohen's d). Other articles have been published on the same material (68, 84), where Malti and colleagues (84) found no effects on child externalizing behavior in a 2-year follow-up, and the same result was found when Eisner and colleagues (68) investigated the effect on highly adherent parents, i.e., parents who took part in all four sessions of the program. Nor were any effects found on parenting practices. Several other studies have been published of the Triple-P program when offered universally, such as the study by Sampaio and co-authors (107). The study included an 18-month follow-up of the program, including 355 preschool families, where no effects were found on either child externalizing behavior or parental mental health. Furthermore, a 2-year (82) and a 4-year follow-up (106) were conducted of Triple-P including 280 families recruited from preschools. Both studies concluded that the program was effective regarding reducing dysfunctional parenting practices. However, in the 2-year follow-up, this was true only for two-parent households, since mothers who were single-parents reported no changes in parenting behavior (82). Mothers in two-parent households also reported reductions in internalizing and externalizing child behavior in the 2-year follow-up. A quasi-experimental study including 1610 parents of preschoolers has also evaluated the long-term effectiveness of Triple-P, where Zubrick et al. (109) found decreases in child behavior problems and dysfunctional parenting. However, it has also fairly recently been concluded in a review that the evidence for long-term effects of Triple-P is not convincing (110).

Other programs than Triple-P have been followed over a longer period of time. Lösel et al. (108) evaluated the effects of parent training based on positive parenting offered to 255 families with preschool children. At the 5-year follow-up, the parent training had an effect on externalizing problems and total problems (total problems also included emotional problems). In the 1-year follow-up of a shorter version of Incredible Years, Reedtz and colleagues (86) showed maintained effects of improved positive parenting, sense of competence and reduced harsh parenting. The effects found from pre to post on the child outcome, child behavior problems, was though not maintained at the 1-year follow-up. The program "Toddlers Without Tears" has been evaluated in two long-term follow-ups (83, 89). The program was offered to mothers of infants (6–8 months old) and follow-ups were conducted at the child ages of 18, 24 (83), and 36 months (89). No differences were found between the intervention and control groups at 18 months, but at the 24-month follow-up, parents were less likely to report harsh/abusive parenting and unreasonable expectations of child development (83). Fewer unreasonable expectations of child development were also found in the 36-month follow-up (89), whereas none of the studies found effects on child externalizing behavior or maternal mental health (83, 89).

2.5 PREDICTORS AND MODERATORS IN PARENTING PROGRAMS

Although an intervention is found to be effective on a group level, there are normally differences between subjects in the same group regarding the results of the intervention. Consequently, it is of importance to investigate for whom and under what circumstances a newly developed program works (12, 13). A moderator identifies for whom an intervention is effective and under what conditions the intervention works, while a mediator instead recognizes why and how an intervention works, i.e., identifies mechanisms of change (13). Since the focus of this thesis is not on mediation, it further on will be on moderators as well as predictors. A moderator is a characteristic at baseline or before randomization which has the possibility to show subgroups that are more responsive to an intervention, i.e., contributes to clarification of the individual differences of intervention effects (13). A moderator analysis therefore has the potential to inform whether the needs of certain subgroups, depending on demographics such as ethnic background, are met (111). A moderator is differentially related to the outcomes for the intervention and control groups and is found through a significant interaction effect (13, 112). A predictor is an observed characteristic with which you seek to predict an outcome (43). Predictors can, as moderators, be variables present at baseline which modify the intervention effect, but differ in the sense that they modify the intervention effect irrespective of the condition of treatment (113), i.e., the predictor is tested in an intervention group only or affect an intervention and control group equally. A predictor of outcome may also be measured as the change during an intervention, such as the predictive role of homework compliance in conduct problems (114), or program engagement as a predictor of parenting skills or child behavior problems (115, 116), or parental depression/marital status as predictors of child behavior problems (117), or the predictive role of parental self-efficacy in child health and well-being (75).

Early on, Webster-Stratton and Hammond (117) investigated the predictive role of depression, marital status/adjustment, socioeconomic status (SES), and negative life experiences in parental perceptions of child behavior and in observed behavior. They found that, for mothers, depression made the greatest contribution to maternal perception of child behavior problems; increased depression was associated with increased reports of child behavior problems. At the end of the 1-year follow-up, the greatest contribution was made by number of negative life events, where more negative events during the year were related to more negative perceptions of the child's behavior. For observed maternal behavior, the greatest contribution was made by a combination of SES and marital status, where low SES and single-mother status was related to increased criticism and physically negative behaviors in mothers at both the post-measurement and the 1-year follow-up. For paternal reports of child behavior, the results were the same as for mothers at the post-measurement; depression made the greatest contribution. At the 1-year follow-up, a combination of depression and negative life events made the greatest contribution to predicting paternal reported child behavior. Regarding observed paternal behavior, the greatest contribution at the post-measurement was made by marital satisfaction, where a decrease in marital satisfaction was related to increased paternal criticisms and physically negative behaviors. The greatest

contributor at the 1-year follow-up was SES, where lower SES was related to increased criticism and physically negative behaviors.

Two later meta-analytic studies (70, 91) have investigated the role of predictors and moderators in parenting programs. Lundahl et al. (70) investigated whether family characteristics (age of the child, family SES, severity of child behavior prior to study, and single parents) could explain differences in the outcomes of parenting programs. They found that three of the four studied variables moderated child outcome, family SES, prior problem severity among children, and single parents, whereas child age did not moderate the outcomes. Children in families with low SES benefited less, children with clinically significant levels of disruptive behaviors experienced more change, and children belonging to groups with a fairly high proportion of single parents benefited less. Further, only SES was found to moderate parental outcomes (parent behavior and parental perceptions of parenting) where disadvantaged families did not benefit to the same extent as non-disadvantaged families. Reyno and McGrath (91) studied variables predicting response to parenting programs for child externalizing behavior problems, where low family income resulted in a large standardized effect size, whereas barriers to treatment, source of referral, more severe child behavior problems pre-treatment, and maternal psychopathology resulted in moderate standardized effect sizes. Further, having single parents, increased family size, low education/occupation, treatment attendance, maternal depression, and negative life events resulted in small standardized effect sizes.

Mediators, moderators, and predictors of outcome in a parenting program have been studied by Beauchaine et al. (113). Regarding moderating effects, they found from mother-reported data that low marital adjustment and symptoms of child comorbid anxiety/depression moderated the response to the treatment. From observed data, on the other hand, maternal depression, social class, paternal substance use, marital status, and symptoms of child comorbid attention problems moderated the treatment response (113). Further, child age and gender, maternal education level and number of children in the household did not moderate the treatment response. Regarding the predictive effects of externalizing behavior, maternal age, parental history of substance use, and symptoms of child comorbid anxiety/depression, were found to predict the outcome. Higher scores on a predictor (age, symptoms of comorbidity) and parents' history of substance abuse were related to a larger treatment response. Further, lower reports of problematic parenting; verbal criticism, harsh parenting, and ineffective parenting, were also associated with better child outcome (113).

More recently, Gardner et al. (111, 118) have investigated moderators of outcome. First, moderators of outcome (single and teen parenthood, low education level, alcohol and drug problems, depressive symptoms, perceived hassles, and partner relationship problems) were investigated in a brief family-centered intervention (118). It was found that two variables moderated the outcome with greater improvements in child behavior problems, i.e., mothers with low education and two-parent families, whereas the other variables did not moderate the outcome. In the second study by Gardner et al. (111), moderators and mediators of outcome

were investigated within an effectiveness study of the Incredible Years program. They studied whether single and teen parenthood, very low income, maternal depression, level of conduct problems, gender or age of the child moderated the outcome of conduct problems. Greater improvement was found for boys, younger children, *mistakenly referred to as the opposite in study I* (119), and for more depressed mothers, whereas very low income, single or teen parenthood, high initial levels of problem behavior, and child age did not moderate the outcome. In addition, Duncombe et al. (120) investigated moderators of child outcomes regarding two parenting programs. Investigated moderators were age, gender and initial severity of behavior problems as child factors, whereas education, income, marital status, and mental well-being were investigated as parental factors. It was found that child's age moderated teacher-rated conduct problems, where older children benefited more from the emotion-focused program, and younger children benefited more from the behavior-focused program (120). Further, parents' mental well-being moderated children's threatening/retaliatory behavior, where for the emotion-focused program, children with parents reporting more negative emotions benefited more, i.e., reduced their threatening/retaliatory behaviors to a greater extent, whereas for the behavior-focused program, the opposite was found; i.e., children with parents who initially had fewer psychological problems benefited more.

Knowledge of predictors or moderators in universal parenting programs is much more limited. There is one study by Sherr et al. (87) that investigated the moderating roles of parental self-efficacy, depression, and social support on different outcome measures (positive discipline, activities, engagement, parenting strategy, child management, commotion in the home, and child difficulties). Sherr et al. found greater effects for parents with higher scores of depression compared to parents with lower depression scores. Greater effects were also found for parents who were less satisfied with their social support compared to those with high social support.

2.6 HEALTH ECONOMIC EVALUATIONS AND PARENTING PROGRAMS

Societal resources are scarce, and priorities must always be set. Health economic evaluations can provide decision-makers with important information (121), and are nowadays commonly applied to guide decision-making and inform health policy (122, 123). In addition, a health economic evaluation aims specifically at providing guidance for how society should use its limited resources (124). Economic evaluations, i.e., "*the comparative analysis of alternative courses of action in terms of both their costs and consequences*" (121, p. 9), have the mission to identify, measure, value, and compare costs and consequences (i.e., effects) of the interventions under comparison (121).

2.6.1 Different health economic evaluations and theory

There are several different types of full economic evaluations: cost-effectiveness analysis, cost-utility analysis, and cost-benefit analysis. By full economic evaluation is meant that there is a comparison of two or more interventions and that both costs and consequences of the

interventions are studied (121). Regarding identification and measurement in economic evaluations, the process is similar within the different types of economic evaluations for the costs, whereas the process for the consequences might vary more extensively (121). Health economic evaluations belong to normative economics, which considers how something should be; i.e., recommendations are given based on a certain ethical principle that one condition is better compared to another, as compared to positive economics, which aims to describe and predict the behaviors of individuals and organizations, such as how variation in price and income affects consumption (124). Two central approaches within normative economics are welfare economics and extra-welfarism. Welfare economics, or simply welfarism, aims at maximizing social welfare. For this approach, the well-being of individuals, judged by the individuals themselves, is of importance for the measurement of social welfare (i.e., social welfare must be a function of individual utility) (125). In welfarism, the sum of all individual utilities is considered as the welfare. Cost-benefit analysis is rooted in the theory of welfare economics. The other approach in normative economics, extra-welfarism, or non-welfarism, assumes that social welfare can be based on information that is not individual utility (125). In health economics, the extra-welfarism interpretation is the aim of maximizing health effects, which may reflect both individual and societal preferences. Cost-effectiveness analysis and cost-utility analysis are grounded in the extra-welfarism approach.

2.6.1.1 Cost-Effectiveness Analysis

In a cost-effectiveness analysis (CEA), costs are related to a single consequence that is similar to the alternatives being compared (121). Drummond et al. (121) describe that the consequence of an intervention is measured in the most appropriate natural unit, such as life-years gained, and there are no attempts to try to value the effect. The result of a CEA is presented as a cost-effectiveness ratio, i.e., the cost per unit of effect, such as the cost per life-year gained, or as effect per unit of cost, i.e., life-years gained per money spent. Drummond et al. describes that the incremental cost-effectiveness ratio (ICER), calculated as $C_1 - C_2 / E_1 - E_2$, is the most frequent method for presenting the results of a CEA. The ICER consists of the incremental cost ($C_1 - C_2$) divided by the incremental effect ($E_1 - E_2$). The ICER presents the extra cost per extra health of one intervention compared to another. Further, to be able to make a decision based on a CEA, an external criterion of value must be referred to, such as a published threshold value (121). Drummond et al. present the net monetary benefit (NMB) as another option to report the result of a CEA, i.e., the change in effectiveness (ΔE) multiplied by the willingness to pay (WTP) per unit of increased effectiveness (i.e., the published threshold value), and then subtracting the change in cost (ΔC). A program can be viewed as cost-effective when the formula result is above 1.

2.6.1.2 Cost-Utility Analysis

In cost-utility analysis (CUA) the consequence of an intervention is adjusted, meaning that the quality of the effect is added (121). Drummond et al. (121) describe the outcomes of a CUA as generic (compared to program specific in the CEA), and its most common outcome

measure is quality-adjusted life-years (QALYs). So, for a CUA, effectiveness has to be transformed into a generic measure such as QALYs gained, where changes in quantity (life-years) and quality (health-related quality of life, i.e., HRQoL) are both incorporated. The quality of the QALY is derived from a set of values or weights, often referred to as utilities. As described by Drummond et al., utilities belong to the overall concept of preference, where utilities are measured under uncertainty (through such as standard gamble) and values, on the other hand, are measured under certainty (such as by the visual analog scale). The result of a CUA is often presented as an ICER; i.e., the cost per QALY gained. The CEA and CUA are similar in many ways, such as using the ICER for presenting the result or the NMB method, and Drummond et al. describe that the CUA may be viewed as a specific type of CEA. The CUA is also the recommended framework for many international decision-making authorities (126).

Further on, there is generally an accepted threshold value (i.e., WTP for a gained QALY) for a QALY (127), such as £20,000–30,000 per gained QALY for England and Wales (122). Similarly, threshold values have been derived for other countries based on previous resource allocation decisions; AU\$69,000/QALY in Australia, NZ\$20,000/QALY in New Zealand, as well as proposed by institutions or individuals: US\$50,000/QALY in USA, €80,000 in the Netherlands, and CAN\$20,000–100,000 in Canada (128). In a review of the WTP for a QALY, Ryen and Svensson (129) identified 24 articles including 383 estimates of the WTP for a QALY where the overall mean was €118,839/QALY, with a median of €24,226/QALY (expressed in 2010 Euros). The trimmed mean was €74,159/QALY (where 2.5% of the highest and lowest estimates were excluded) and 80 percent of all the estimates were below €75,000/QALY. Regarding threshold values for a gained QALY in Sweden, no exact limit has been set (123). A governmental authority, the National Board of Health and Welfare, has though suggested that a threshold value below SEK 100,000/QALY (approximately €11,000 in 2014 Euros) is considered as a low cost-effectiveness ratio, below SEK 500,000/QALY (approximately €55,000) considered as a moderate ratio, and over SEK 1000,000 (approximately €101,000) as a high ratio (130). Furthermore, Persson and Hjelmgren (131) have presented a value of SEK 655,000 per QALY based on the value of a statistical life within the traffic sector divided by the loss of remaining life-years from road deaths.

2.6.1.3 Cost-Benefit Analysis

In a cost-benefit analysis (CBA) the consequences of an intervention are instead valued in monetary terms, and the results are often presented as the ratio of costs to benefits or as a sum which represents the net benefit of one program over another (121). An intervention is viewed as worthwhile when the benefits of the intervention exceed the costs of it (121). Further, using WTP techniques, a CBA has the potential to quantify a broad variety of effects including both health- and non-health related effects (121). The rate of return can also be reported for a CBA, which is expressed as the percentage return of an investment over a period of time (132).

2.6.1.4 Perspectives in health economic evaluation

According to the checklist by Drummond et al. (121), the perspective of an analysis should be described. Examples of perspectives in health economic evaluations are the perspectives of the payer, the third party payer, the health care sector, the patient, and society (126). The societal perspective is the broadest and includes all relevant costs and effects irrespective of payer or beneficiary (133). The societal perspective is often recommended, i.e., as the perspective to use in Sweden (123, 134). It is also commonly applied in both formalized and informal health economic guidelines in different countries (126). However, critics of the social perspective propose, for example, that it is not reasonable, rather even unethical, to attach different values to people working compared to those in retirement. Further, it has been stated that the choice of perspective often is guided by available data instead of by whom the relevant payer is and, for example, the productivity losses of parents are often neglected regarding child interventions (135). Difficulties regarding valuing non-marketed resources in monetary terms, such as the time of participants, have also been brought up as an issue within the societal perspective, and Johansson (133) states that it has become customary in Sweden to use 35 percent of the average wage as the valuation of leisure time.

2.6.2 Health economic evaluations of parenting programs

2.6.2.1 Targeted programs

Reduction in child behavior problems has been the measure of effectiveness in most of the conducted health economic evaluations, where two studies have investigated the cost per point reduction of the Eyberg Child Behavior Inventory regarding the Incredible Years program (67, 136). The study by O'Neill et al. (67) resulted in an ICER of €87 per one point reduction in the Eyberg intensity score, with the probability of being cost-effective between 80–90 percent assuming a WTP threshold between €115 and €158. The earlier study by Edwards et al. (136) resulted in an ICER of £73 per one point improvement on the intensity score, with a cost-effectiveness probability of 83.9 percent at the WTP threshold of £100. In addition, O'Neill et al. (67) also conducted a CBA where the outcomes of education, crime, and unemployment in adulthood were combined with the result of the CEA, which resulted in an internal rate of return of eleven percent.

Cost-effectiveness has also been investigated concerning the four programs, COMET, Incredible Years, COPE, Connect, as well as a bibliotherapy, where effectiveness was measured as recovered cases, i.e., children moving from the clinical group to the normal group using the Eyberg Child Behavior Inventory (137). It was found that COMET had a higher proportion of recovered cases, and the ICER was US\$8,375 for COMET compared to bibliotherapy. Further, secondary analyses were conducted where effectiveness was measured as both recovered and improved cases and COPE was the cheapest alternative, with a cost per recovered and improved case of US\$1,937. The same research group has also investigated the effects and costs of Triple-P, where a cost-effectiveness analysis was not feasible because the program was not found to be effective (107).

Other studies have applied modeling techniques to estimate the long-term cost-effectiveness of parenting programs (137-139). Bonin et al. (138) used a decision-analytic Markov model to investigate the costs and long-term savings of implementing different parenting programs to reduce clinical cases of conduct disorder. Their result suggested that implementation of parenting programs was cost-saving for the public sector within 5–8 years. Mihalopoulos and colleagues (139) investigated whether a population-based implementation of a parenting program (Triple-P) would be a wise way of spending public resources. They found that even modest improvements in the prevalence of conduct disorder would be enough to make the program a cost-saving intervention. Lastly, a population-based Markov model has been applied to evaluate the cost per disability adjusted life year avoided where the group format of Triple-P was found to be cost-effective at a threshold value of AU\$50,000, whereas the standard individual format of Triple-P was not found to be cost-effective.

2.6.2.2 Universal programs

To my knowledge, there is to date only one health economic evaluation conducted of a universal parenting program. Simkiss et al. (74) conducted a CUA of the Family Links Nurturing Program alongside a RCT where they applied SF-12 to derive QALYs from SF-6D utilities. SF-12 was used at baseline and at a 9-month follow-up, and the cost per QALY gained was generated with five- and ten-year horizons, based on the effectiveness remaining constant. The cost per gained QALY over five years was £34,913 (with a 36–47% probability of being cost-effective at the threshold of £20,000–30,000/QALY gained) and £18,954/QALY over ten years (with 51–57% probability of being cost-effective). Sensitivity analyses showed that the impact of costs was considerable concerning potential cost-effectiveness, i.e., depending on number of attendees. Further, the result changed somewhat when the effect was assumed to diminish to zero at the end of the time period (£56,885 over five years and £29,664 over ten years). Simkiss et al. (74) concluded that the program was not shown to represent value for money.

2.7 ALL CHILDREN IN FOCUS; A NEWLY DEVELOPED PARENTING PROGRAM

2.7.1 Program development

All Children in Focus (the ABC program or just ABC) was developed during 2010–2011 by psychologists within an organization with experience of program development in the City of Stockholm. The program development was enabled by a governmental investment in universal parenting support (140). The development of the program was conducted in close collaboration with municipalities and city districts within the county of Stockholm and a research group at the Karolinska Institutet. The development was based on: 1) previous research, i.e., research on protective and risk factors, trials of parenting programs, and parenting, 2) the wishes and needs of parents collected through telephone interviews, 3) the ideas and wishes of prospective group leaders, and 4) the child perspective (where parents, during the sessions of the program, will try to take the perspective of the child). Regarding

previous research, one influence on program development was made by the results of the review by Kaminski et al. (79), which showed program components associated with effectiveness in parenting programs. The ABC program was based on social learning theory (141); in the sense of parents being models for their children as well as parental behaviors playing a role in the promotion of a positive relationship (142). Attachment theory (143) is also a basis for the program in that it considers parental sensitivity (75). In addition, the program also considered how family functioning is influenced by the external environment (144), by covering parental stress and other situations occurring outside the family (142). The aim of the program was to promote child health through strengthening the parent-child relationship.

2.7.2 Program content

ABC is a universal health-promoting parenting program for all parents with children aged 3–12 years-old. The program consists of four sessions, offered every other week, with the themes showing love, being there, showing the way, and picking your battles. As illustrated in Figure 2, the theme of the first session, showing love (visa kärlek in Swedish), is a fundamental component of the whole program. The program includes components such as positive attention and warmth, child-directed play, positive parenting strategies, and consistent parenting. Each session is 2.5 hours long, including a break with refreshments, and consists of discussions, role plays, and short films. Parents are also offered a booster session (after approximately two to three months) which includes repetition from the four sessions as well as one of the following three themes: siblings, boys and girls, or teenagers.



Figure 2. The ABC staircase illustrating that the theme of the first session, showing love, is a fundamental component of the program. Illustration by Cecilia Torudd.

2.7.3 Results from a pilot study of the ABC program

An initial evaluation was done of the ABC program based on a pilot study which was conducted in eleven municipalities and city districts within the County of Stockholm, Sweden (75). Parents of 104 children in the ages 2–12 years participated in the study. They took part in the ABC and filled in questionnaires at baseline, at post-measurement, as well as at a 4-

month follow-up. The questionnaire included questions regarding parental strategies, self-efficacy, emotion regulation, mental health, as well as child well-being. Improvements from baseline to post-measurement were found for parental strategies, self-efficacy, mental health, and child well-being. Many of the effects were maintained at 4-month follow-up. The effect sizes were small to moderate. Two predictors of child outcome at four months was found; parental university education and pre-post improvement in parental self-efficacy, whereas the age and gender of the child and income did not predict the child outcome. Further, the pilot study did not include a control group (75).

2.8 SUMMARY OF CURRENT KNOWLEDGE AND RELEVANCE OF THE PRESENT RESEARCH

Parents and parenting have been declared to be of importance when it comes to the health of children. Interventions targeting parents aiming to promote child health and prevent child disease have therefore been urged. Parenting programs have since the 1960s been developed, targeting mainly prevention but to some extent also promotion. The knowledge today of parenting programs, including effectiveness, cost-effectiveness as well as predictors and moderators, is more extensive regarding targeted programs, whereas the knowledge of universal parenting programs is more limited. Regarding universal parenting programs, most of the existing evaluations include a measure of reduction in child behavior problems, where only two RCTs have shown long-term effectiveness (82, 108), whereas knowledge of effectiveness including measures of positive health is scarce. To my knowledge, only one RCT exists (74), which included a measure of child well-being, where no effects were found at the 9-month follow-up. The study by Simkiss et al. (74) is also the only existing study of cost-effectiveness of a universal parenting program and the only cost-effectiveness study of a parenting program using QALYs as a measure of effects. The conclusion of Simkiss et al. regarding the health economic evaluation was that the program did not represent value for money. Finally, even though there is some knowledge of predictors and moderators of outcome in parenting programs, this research is foremost conducted on targeted parenting programs, whereas only one study has investigated moderators of outcome in a universal program (87). Further knowledge is therefore needed of universal health-promoting programs to better understand the potential role of these programs.

3 AIMS OF THE THESIS

This thesis aims to evaluate the effectiveness, cost-effectiveness, and predictors/moderators of the newly developed universal health-promoting parenting program All Children in Focus.

The specific aims of the studies included in the thesis were:

- Study I: to describe the randomized controlled trial of All Children in Focus within a study protocol (written as the Method section in the thesis).
- Study II: to evaluate the program's effects on parental self-efficacy and parents' perceptions of child health and development six months post baseline, as well as to investigate potential moderators. Moderators examined were child age and gender, parents' country of birth, educational level, mental health status, and number of children in the family.
- Study III: to estimate the costs that were associated with implementation of the program, investigate the effects of the program measured in QALYs, and conduct a cost-effectiveness analysis.
- Study IV: to evaluate whether the effect found at 6 months in parents' perception of child health and development was maintained at the 12-month follow-up, and to investigate whether there were changes over time (pre-post and pre-12 months) on the secondary outcome measures, i.e., parental self-efficacy, parental strategies, and parents' emotion regulation strategies. Further, the aim was to examine whether changes between pre- and post-measurement on the secondary outcome measures predicted change in children's health and development at the 12-month follow-up.

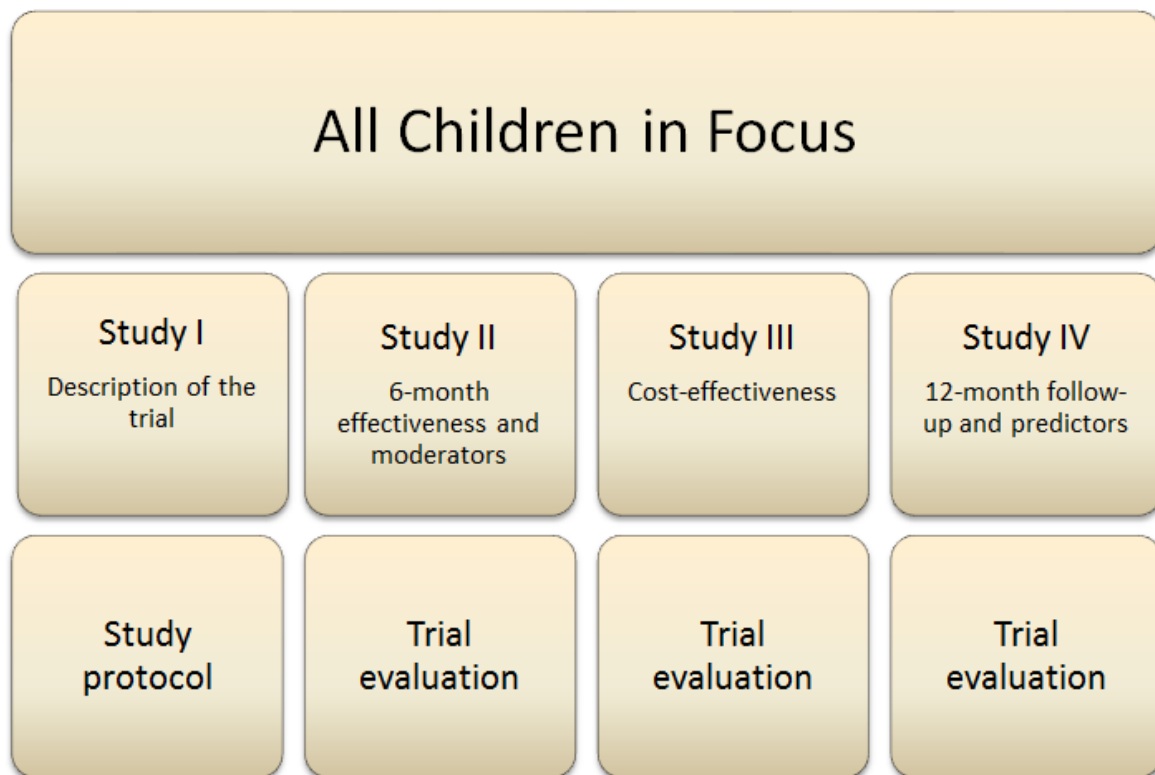


Figure 3. Schematic summary of the studies included in the thesis

4 METHODOLOGICAL CONSIDERATION

The RCT of the ABC program is extensively described in the study protocol (study I) (142). In addition, material and methods applied in studies II–IV are described in each study respectively, and the following section gives an overview of the trial, including information relevant to the thesis. Throughout the thesis, the term “parents” is used rather than “caregivers” since almost all study participants were parents.

4.1 DESIGN

The present thesis is based on data collected in a multicenter pragmatic randomized waitlist controlled trial (RCT) of the ABC program, conducted between 2012 and 2014. Parents with children aged 3 to 12 years-old were recruited in eleven municipalities and city districts within the County of Stockholm (Botkyrka, Haninge, Hässelby-Vällingby, Kungsholmen, Nacka, Norrtälje, Rinkeby-Kista, Sollentuna, Spånga-Tensta, Upplands Väsby, and Vallentuna). Participants randomized to the intervention group received the ABC program (the intervention), whereas the control group was put on a waiting-list to receive the intervention after approximately six months. All parents filled in self-reported questionnaires on three occasions: a baseline measurement (T1), a post-measurement approximately two weeks after the intervention (T2), and a 6-month post baseline measurement (T3). In addition, the intervention group filled in a fourth questionnaire, a 12-month post-baseline measurement (T4).

4.2 RANDOMIZATION PROCEDURE AND POWER

Parents were randomized at individual level at a 1:1 ratio. The randomization was done for each municipality/city district using the function of random sample of cases in SPSS Statistics for Windows, version 20. However, couples were randomized as one unit to ensure that members of the couples did not end up in different groups (to avoid risk of contamination among couples). The randomization procedure resulted in 323 parents being randomized to the intervention group, and 298 parents randomized to the control group. To detect an effect size of .4, with a significance level of $< .05$ at 90% power, and with an intraclass correlation of 0.01, nearly 500 parents were needed in total. In addition, to take into account an attrition rate of approximately 20 percent at the follow-up measurements, an additional 100 individuals were needed. Therefore, the aim was to recruit approximately 600 participants.

4.3 RECRUITMENT

The participating municipalities and city districts each had a contact person who was locally responsible for the recruitment of parents, and who was working in close collaboration with the researchers. Strategies commonly applied to recruit parents were group leader’s personal contact with parents, a recruitment movie produced within the trial and shown at the register at grocery stores, recruitment direct within preschools and schools, and advertisements and information on web pages. About half of the municipalities/city districts also recruited through maternal and child health services. In addition, group leaders in many of the

communities also recruited parents directly within their own setting, e.g., such as preschool teachers inviting parents of the preschool children to participate in the trial.

4.4 PROCEDURE

Parents were recruited to the trial during the spring and fall of 2012. As mentioned above, recruitment was conducted locally in each municipality or city district in close collaboration with the research team. Interested parents within the eleven municipalities and city districts were invited to a locally held information meeting. At the meeting, research staff informed about the trial and group leaders, or the contact person informed about the ABC program. In total, 27 information meetings were held during the spring and fall of 2012. Parents willing to participate in the trial filled in an informed consent form and were thereafter given the baseline assessment. For parents who did not have the possibility to attend a meeting, information was instead sent home. During the fall of 2012, the baseline measurement could also be filled in as a web-based questionnaire, and around 100 parents filled in the first questionnaire online. Parents were after baseline randomized to the intervention or control group, and the intervention group was offered the ABC program (around one month after the baseline measurement). The post-measurement (T2) was sent to all parents approximately 2 weeks after the intervention group received the fourth ABC session. Further, the first follow-up (T3) was delivered to the parents six months after the baseline measurement, and intervention group parents were then offered a booster session. The control group was offered the intervention after the 6-month follow-up. The intervention group also filled in a second follow-up (T4), occurring twelve months after baseline. Most parents filled in the follow-up measurements online where an email was sent to the parent with a link to the questionnaire, although a few parents preferred a paper questionnaire sent home for the follow-ups.

Furthermore, parents were offered incentives. All parents participating in the trial were offered free family entrance to an open-air museum (Skansen) after the first follow-up measurement (T2). Less than half of the families used the free entrance. Also, after filling in the last questionnaire (T4), parents received a gift certificate where they could choose between a paperback book, three movie rentals, an audiobook, or a magazine subscription, and approximately 75 percent of the parents chose to use the certificate. In addition, at a municipal level, it was decided that the control group put on the waitlist should be encouraged. Therefore, parents within the control group of spring 2012 received chocolate bars. This initiative was conducted outside the control of the research group and therefore we do not have knowledge regarding how many of the parents/families actually received the chocolate. For the control group of the fall 2012, it was instead decided to give ABC-reflectors and also here, we do not know how many who actually received the reflectors.

4.5 IMPLEMENTATION OF ALL CHILDREN IN FOCUS WITHIN THE TRIAL

Settings for the ABC groups within the trial were open preschools (i.e., places where parents can go to with their child and meet other parents and their children), preschools, schools, child health centers, family centers, social services, the premises of an educational

association, or other community premises. The most common settings were preschools and schools. In total, 39 ABC groups were held during spring and fall of 2012. Most of the groups were held every other week (could depend somewhat because of school breaks, etc.), and a few groups were run every week. The average number of parents per group was seven and the range was between 4–14 parents per group. Further, 62 group leaders ran the 39 ABC groups (for intervention group parents), and the most common occupations of group leaders were preschool teachers and social workers/counselors (approximately two-thirds). Other backgrounds were other school occupations, such as teachers and school nurses, psychologists, and field assistants. All group leaders were trained (during 4.5 days) where some were trained by the program developers and others by ABC instructors. Regarding the group leaders, important group leader skills are to encourage and empower the parents during the sessions (i.e., validate), to activate the discussion within the group of parents by posing questions (i.e., activate), and to keep the discussion to the topic (i.e., structure) (142). Regarding parental participation in the program, 37 (11.5%) parents did not participate in any of the sessions, whereas a majority of the parents 170 (52.6%) participated in all four sessions, 83 (25.7%) in three sessions, 28 (8.7%) in two sessions, and five (1.5%) parents participated in one session.

The first ABC session (showing love) included creation of personal parental goals, and parents were introduced to components such as positive attention and warmth in the relationship to the child, and positive feedback and reinforcement regarding positive behaviors. Components included in the second session (being there) were parent-child time together with child-directed play. Session three (showing the way) included stress- and anger management among parents to reduce the occurrence of harsh parenting, whereas session four (pick your battles) included consistent parenting and reduction of battles as well as how to handle battles. For an overview of the program components and homework assignments for each session of the ABC program, see the pilot study by Enebrink et al. (75).

The ABC sessions were intended, through positive parenting, to promote child development. An overarching goal of ABC was to promote parental self-efficacy, i.e., “*beliefs or judgements a parent holds of their capabilities to organize and execute a set of tasks related to parenting a child*” (145, p. 390). Parental self-efficacy originates in Bandura’s theoretical framework of self-efficacy (146) and, concerning the ABC program, it was hypothesized as important for a potential process of positive change (75). As described by Sanders (69), having high parental self-efficacy includes having positive beliefs about the possibility of change happening. Also hypothesized as important in driving potential change were parenting strategies (including ones like parental empathy/warmth and positive incentives) and the program provided parents with evidence-based strategies (75). Further, the association between parenting and child functioning (emotional and behavioral) is said to be moderated by parents’ emotion regulation (77). As already mentioned, stress- and anger management was included in the ABC program, and it was hypothesized that enhancement of parents’ emotion regulation also would be of importance for a potential positive change in a health promoting parenting program.

Furthermore, the logical model (147) in Figure 4, illustrates the path from resources (inputs) needed for running the program to the hypothesized impact of the program, in our case corresponding to the outcome of child health and development. The ABC program was the activity, whereas the program implementation was considered as the output. The outcomes in the model were the hypothesized proximal outcomes (parental self-efficacy, parental strategies, and parents' emotion regulation). The implementation process was not included in the research questions of the current thesis.

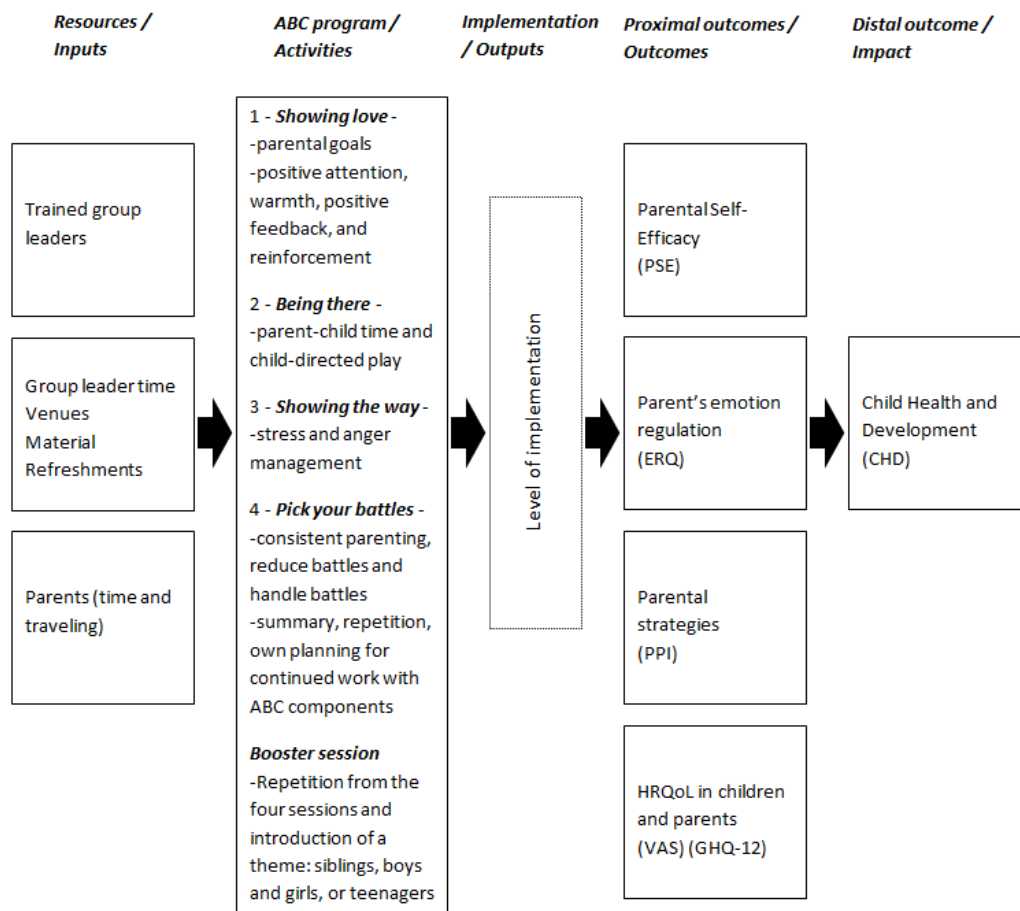


Figure 4. Logical model of the ABC program.

4.6 MEASURES

Baseline characteristics (studies II–IV)

Parents answered questions on baseline characteristics of the child, including the age and gender of the child in focus (i.e., the child the parent was thinking of when filling in the questionnaire). Baseline characteristics of parents included questions on civil status, country of birth, educational level, family income, and number of children in the family. These variables were applied in study II to enable baseline comparison between the intervention and control groups, and in studies III–IV for description of the study sample. Furthermore, five of the characteristics (age and gender of the child, country of birth and educational level, and number of children) were used to investigate moderators in study II.

Child Health and Development (CHD) (studies II and IV)

CHD measured parents' perceptions of health and development in children. The development of CHD was based on an established HRQoL measure (148), and CHD was created to fit the study population of this trial. The questionnaire was tested within pilot studies of the ABC program ($N = 405$), and regarding the validity of the scale, it was found to be acceptable (RMSEA = .074) (119). CHD comprised 35 items aiming to capture six dimensions: children's physical and mental health, their emotional development and independence, as well as family relations and social competence. All items were rated on a 5-point scale (excellent/very good/good/fairly good/bad) (not at all/slightly/moderately/very/extremely) (never/seldom/sometimes/often/always) and combined into a total score. Examples of questions were: "How would your child describe that she/he is doing in general?", "Was your child in a good mood?", and "Did your child feel sad". The total score of the measure ranged between 35 and 175, and a higher score corresponded to better child health. The total score of CHD was used in studies II and IV. Cronbach's alpha was between .914 and .933 for the total score of CHD at the different measurement points in studies II and IV (please see study II and study IV separately for specific values per measurement point).

Parental self-efficacy (PSE) (studies II and IV)

PSE measured parent's self-efficacy, a concept of parent's beliefs in their ability to parent successfully (149). We used an adapted version of Tool to measure parenting self-efficacy (TOPSE) (150, 151) to measure PSE. The adapted version included 48 items aiming to capture eight dimensions: positive emotion, being with your child, empathy, guiding, rules, pressures, acceptance, and experience. PSE was tested in pilot studies of the ABC ($N = 405$) and the validity of the scale was found to be acceptable (RMSEA = .072) (119). All the items of PSE were rated on an 11-point Likert scale which ranged from 0 (completely disagree) to 10 (completely agree). Examples of statements were: "I can show my child tenderness", "I can comfort my child", "I can reason with my child", and "As a parent, I can handle just about anything without losing my cool". The scale was kept as a total score, 0–480, where a higher score was equivalent to higher efficacy. PSE was used in studies II and IV. Regarding internal consistency (Cronbach's alpha), it was between .920 and .942 for the total scale for the measurements in studies II and IV (for specific values per measurement point and study, please see each study separately).

General Health Questionnaire 12 (GHQ-12) (studies II and III)

GHQ-12 (152) measured parents' mental health. GHQ includes six negatively phrased and six positively phrased items. GHQ-12 has been used extensively (153) and has good psychometric properties (152). Items are rated on a 4-point Likert scale (positive items: better - more so than usual /same as usual/less (so) than usual/much less than usual) (negative items: not at all/no more than usual /rather more than usual/much more than usual). An example of a positively phrased item was: "*Felt capable of making decisions about things*", whereas "*Been thinking of yourself as a worthless person*" was a negative phrased item (154). GHQ-12 was

applied in study II where the positively phrased items were used only to measure parents positive mental health (153). The six positively phrased items were coded as 3–0, where 3 was equivalent to more so/better than usual and 0 corresponded to much less than usual. This resulted in a total score on the scale of 0–18, where a higher score corresponded to better mental health. Internal consistency (Cronbach’s alpha) for GHQ-12 was 0.829 for the total scale at baseline.

GHQ-12 was also used for the health economic evaluation (study III), where GHQ-12 scores were converted to indicate QALY weights according to the proposal by Serrano-Aguilar et al. (154). All items of GHQ-12 were used in study III, and to enable the conversion into QALY weights, GHQ-12 scores were coded as 0 and 1. Category 1 (more so/better than usual - not at all) and category 2 (same as usual - no more than usual) were coded as 0 and category 3 (less than usual - rather more than usual) and category 4 (much less than usual - much more than usual) were coded as 1. This resulted in GHQ-12 scores between 0 and 12, which could be converted into QALY weights (153). The internal consistency for GHQ-12 was between .878–.904 at the different measurement points in study III.

Visual Analog Scale (VAS) (study III)

A parent proxy VAS (121) measured parents’ perceptions of children’s HRQoL, which were further converted into QALY weights for children. A horizontal VAS was applied, where parents were asked to estimate in a box their child’s general health state between 0 and 100, where 0 was equivalent to the worst health state and 100 corresponded to the best health state. We then used the formula (raw rating of a health state–raw rating of death)/(raw rating of best health state–raw rating of death) (155), under the assumption of death being equal to 0 and 100 being equal to perfect health, to transform the health state valuations into values (QALY weights) between 0 and 1. The applied scale was inspired by the EuroQol Group’s VAS for children (156, 157) but adjusted after a pilot study of the ABC program (we used a horizontal line and had no intervals marked out along the line). The VAS was applied in study III.

Emotion Regulation Questionnaire (ERQ) (study IV)

ERQ (158) measured two emotion regulation strategies in parents, cognitive reappraisal, i.e., a form of cognitive change (six items), and expressive suppression, i.e., a form of response modulation (four items). All items were measured on a scale ranging from 1 (disagree) to 7 (totally agree) providing a mean score per scale of 1–7. A higher score on a scale was consistent with the strategy being more frequently used. Two examples of items were “*When I want to feel more positive emotion, I change the way I’m thinking about the situation*” (reappraisal) and “*I control my emotions by not expressing them*” (suppression). The validity of ERQ has previously been investigated, where a fairly acceptable model fit was found (159). ERQ was applied in study IV and the internal consistency (Cronbach’s alpha) was between .795 and .851 for the reappraisal scale at the different measurement points, and between .697 and .746 for the suppression scale.

Parenting Practices Interview (PPI) (study IV)

PPI (160, 161) measured parenting practices. PPI is a construct measuring practices such as harsh style (for example verbal and physical aggression), positive style (encouragement, praise, and incentives), and monitoring (i.e., knowing where the child is, degree of supervision) and was adapted from the Oregon Social Learning Center's Discipline Questionnaire (160). In the trial of the ABC program, two subscales were used: harsh and inconsistent discipline (15 items) and praise and positive incentives (11 items). Items were measured on a scale ranging from 1 (never/not at all likely/strongly disagree) to 7 (always/extremely likely/strongly agree), and one item was measured from 1 (never) to 6 (6–7 times). The total score of the harsh and inconsistent scale was between 15–105, and a lower score indicated less harsh parenting. An example of a question from the harsh and inconsistent scale was: "*How often do you show anger when you discipline your child?*", and from the praise and positive incentives scale: "*In general, how often do you praise or compliment your child when your child behaves well or does a good job?*" The total score of the praise and incentives scale was between 11 and 76, and a higher score indicated more positive parenting. PPI was applied in study IV where the internal consistency (Cronbach's alpha) was between .810 and .834 for the harsh and inconsistent discipline scale at the different measurement points, and between .736 and .756 for the praise and positive incentives scale.

Costs (study III)

To be able to conduct the CEA, data on costs were collected from several sources (the program developers, the literature, and the group leaders). The costs were divided into setup costs and operating costs. The setup costs included the fee for group leader training and the time group leaders spent in training (based on the hourly wage including employee benefits). Regarding operating costs, it was further assumed that group leaders would lead several groups in their group leader career, and cost was therefore distributed over ten groups per group leader. The operating costs included an assumption about the time which group leaders spent on recruiting parents as well as group leaders' time for preparing and running the groups. Other operating costs were for venues, material, and refreshments. Lastly, parents' time in sessions and costs for traveling was also included. Please see the corresponding manuscript (162) for a more detailed description of the different costs. Table 1 shows an overview of the included costs and the applied unit costs of each cost. All costs were presented at the price level of 2014 and transformed from Swedish currency to Euros applying the average exchange rate of 2014 (where €1 = SEK 9.1).

Table 1. Overview of the costs included in the CEA and the price per unit.

Type of cost	Price per unit
Setup costs	
Training fee	€1,099/group leader
Time (group leaders)	€26.9/hour
Operating costs	
Time (group leaders)	€26.9/hour
Venue	€11/hour
Material	€7.8/binder
Refreshments	€54.9/group
Time (parents)	€4.5/hour
Traveling transportation (parents)	€0.2/kilometer

4.7 PARTICIPANTS AND ATTRITION

At randomization, 323 parents were randomized to the intervention group and 298 to the control group ($N = 621$). Eight parents were later excluded from the trial, six parents from the intervention group and two parents from the control group, due to wrong age of the child in focus (i.e., the child was not between 3–12 years-old), resulting in an intervention group of 317 participants and a control group of 296 participants ($N = 613$). Of the 613 parents, 49 (8%) did not respond to the post-measurement (T2) and 112 (18%) did not respond to the six-month follow-up. At the 12-month follow-up (T4), when only the intervention group received the questionnaire, 71 did not respond (22%).

There is a bachelor thesis that aimed to investigate whether the study sample within the trial of the ABC was representative of the population of the County of Stockholm (163). Three sociodemographic factors were investigated: ethnicity, income, and education. The result showed that the study population was representative regarding ethnicity; just above 20 percent of the study sample were born outside Sweden, which also was the case for Stockholm County. However, the study sample was not representative concerning income and education, where the study sample had a higher income (SEK 57,000/month versus SEK 42,000/month) and higher educational level (66% versus 47% with university education), compared to the population of Stockholm County.

4.8 STATISTICAL PROCEDURES

All statistical analyses were conducted in SPSS (version 22), except for the non-parametric bootstrap (see section 4.8.2.3) which was conducted in EXCEL. An alpha level of $p < 0.05$ indicated statistical significance.

4.8.1 Study II

4.8.1.1 Sample

The analyses in study II were based on the total study sample of 613 participants (317 randomized to the intervention group, and 296 randomized to the control group). For the whole sample, the mean age of the child in focus was 6 years-old and 57 percent of the children were boys. The average age of the participating parents was 38 years, and a majority were women (73%). Of the participant parents, 77 percent were born in Sweden, 10 percent lived in single-parent households, and 15 percent had one child. The average family income per month before taxation was approximately SEK 58,000, and 58 percent of the participants had completed a university education. Please see Table 1 in study II (119) for the above-mentioned information divided into the intervention and control group. Further, there were no significant differences between the intervention and control groups on any of the baseline characteristics.

4.8.1.2 Missing data

Aside from the attrition of participants, 4–18 responses (0.01%–2.9%) were missing of PSE and 14–67 responses (2.3–10.9%) of CHD due to lack of responses on individual items.

4.8.1.3 Analysis

To investigate baseline differences between the intervention and control groups, chi-square tests and independent samples t-tests were conducted. Multilevel linear modeling (MLM) with a repeated measures design was used to evaluate the effectiveness of the program. MLM was applied to take dependency in data into account. Time-related variables had to be constructed for both the outcome measures (PSE and CHD) due to nonlinear growth trajectories. This was handled by coding T1 as 0 and T3 as 1, and the growth occurring over the whole measurement period (baseline to the 6-month follow-up) was captured (164). The code for T2 was found by the best model fit when generating different specifications (164), where .85 gave the best model fit for CHD and .95 for PSE. Both intercept and time-related variables were used as random effects in the models and unstructured covariance was applied. Effect sizes were calculated by Eta Squared (η^2) by the formula: (residual variance of the intercept model – residual variance with the predictor (the larger model)) / residual variance of the intercept model, when using models without random effects of time (165). An effect size of .02 is considered as a small effect size, .13 a moderate effect size, and .26 a large effect size. In addition, mean, standard deviation, and Cohen's *d* were included in the thesis to enable a more comprehensive comparison. Concerning Cohen's *d*, .20 is considered as a small effect size, .50 a moderate, and .80 a large (166). Regarding the moderator analysis, the potential moderators (child age, child gender, parent's country of birth, parent's educational level, parents' mental health state, and number of children in the family) were all measured at baseline. Separate analyses were run for each potential moderator, with three-way interactions (time, condition, potential moderator), followed by all significant interactions

included in a final model. Also, to reduce multicollinearity, two variables were centered: child age and parent's mental health state.

4.8.2 Study III

4.8.2.1 Sample

The analyses in study III were based on 504 individuals (613-109), 264 in the intervention group and 240 in the control group. The 109 individuals were removed by randomization from the study due to dependency in the data (i.e., both parents participated in 109 families). Of the 504 participants in study III, 82 percent were women, the average age of the participants was still 38 years, and 77 percent were born in Sweden. The mean age of the child in focus was also still 6 years, and 57 percent of the children were boys. The average family income before taxation was approximately SEK 56,000, 12 percent of the participants lived in single-parent households, and 16 percent had one child.

4.8.2.2 Missing data

Missing data for the VAS were 5.4 percent at baseline, 13.3 percent at T2, and 20.2 percent at T3. For the GHQ-12, 2 percent were missing at T1, 7.5 percent at T2, and 17.3 at T3. The last observation carried forward (LOCF) procedure was applied to account for missing data.

4.8.2.3 Analysis

Differences in QALY weights (measured by the VAS for QALYs in children and by GHQ-12 for QALYs in parents) between the intervention and control groups were examined with independent samples t-test. Paired-samples t-tests were used to investigate differences over time within the groups. To derive the change in QALYs over the measurement time (i.e., six months) for the intervention group and the control group separately, the mean of two measurement points (i.e., baseline mean+post-measurement mean/2 and post-measurement mean+6-month follow-up mean/2) was multiplied by 0.25 (3 months was approximately the time between T1-T2 and T2-T3) (127). Further, an assumption of a linear growth trajectory was applied for the QALY change.

A CUA was conducted from a societal perspective, where costs were related to effects to provide the ICER. We used a WTP threshold of SEK 500,000, corresponding to approximately €55,000, following a suggestion by the National Board of Health and Welfare (130). EXCEL was used to conduct non-parametric bootstrapping with 5000 bootstrapped replicates. Individual-level data were applied regarding effects, and the mean regarding the costs. The result of the 5000 replicates was illustrated in a cost-effectiveness acceptability curve (CEAC), which was derived applying the NMB method. Univariate sensitivity analyses were conducted where the distribution of the cost for group leader training and the value of parents' time were changed, and the cost of child care was included. Furthermore, for the thesis, additional univariate sensitivity analyses were conducted on different effect scenarios; i.e., including only significant effects, including changes in effects for the intervention group

only, and for both these cases, also including an assumption of maintained effects over one year.

4.8.3 Study IV

4.8.3.1 Sample

The sample in study IV included just the intervention group. Of the 317 participants, both parents participated in 54 families resulting in dependency in the data. In study IV, we therefore choose to only include one parent per family, based on either more data available for one partner or based on randomization of the couple. Regarding one parent having more complete data, this was the case for 31 couples where 22 mothers and 9 fathers were kept. For the other 23 couples, which had responded to the same amount of measurements, randomization was conducted which resulted in 14 fathers kept and 9 mothers. The analysis in study IV was thereby based on 263 intervention group participants. The mean age of the 263 children was still 6 years, and 38 years of the parents. Of the 263 parents, 79 percent were born in Sweden, 82 percent were women, and 57 percent of the focus children were boys. Further, the average family income before taxation was approximately SEK 55,000, 12 percent of the participants lived in single-parent households, and 16 percent had one child.

4.8.3.2 Missing data

Expectation Maximization (EM) was applied in SPSS to account for missing data. For the four measurement points (T1–T4), we imputed values when a subscale had two or less missing values. In addition, last observation carried forward (LOCF) was applied for non-respondents for T2–T4 (22 were missing at T2 (8.3%), 47 were missing at T3 (17.9%), and 48 were missing at T4 (18.3%). LOCF was also applied for respondents with more than two missing values per subscale at the follow-ups (T2–T4).

4.8.3.3 Analysis

Repeated measures ANOVA was applied to investigate within group changes over time in the outcome measures (CHD, PSE, PPI and ERQ), whereas linear regression and multiple linear regression analysis were applied to investigate potential predictors. Intention-to-treat (ITT) analyses were conducted and compared to results of analyses of study completers. Effect sizes were in study IV calculated as partial eta squared where .02 is considered as a small effect size, .13 a moderate, and .26 a large effect size. In addition, Cohen's *d* was included in the thesis also concerning paper VI for enabling a more comprehensive comparison to other studies (.20 considered a small effect size, .50 a moderate, and .80 a large effect size) (166). The correlation between the pre-measurement and the 12-month follow-up was included in the effect size calculation of Cohen's *d* (167).

4.9 ETHICAL CONSIDERATIONS

The RCT, including the CUA, was approved by the Regional Ethical Review Board in Stockholm (Dnr: 2012/93-31/5). The participants were informed orally and in writing

regarding objectives, procedures of the trial, and the intervention. In addition, they received information about the trial being voluntary and that they could withdraw their participation at any time. All participants signed informed consent forms. The participants were assigned coded identification numbers to secure the confidentiality and the numbers were applied during data entry and analyses of the data. Information about the participants and data were stored in locked safety cabinets at Karolinska Institutet.

The overall aim of the current research project was to evaluate a newly developed parenting program. The benefits that the program potentially could lead to are of importance from a public health perspective. However, the potential harm for parents participating in the trial, including filling in questionnaires, taking time to participate in the intervention, infringement in the parenting role, and having to wait for the intervention for the control group, has to be put in relation to potential future beneficence.

Stigmatization has been described, alongside coercion, as a key concept in health promotion ethics (168). An intervention targeting parenting may impose thoughts as “I’m targeted since I’m a bad parent” or feelings of worthlessness as a parent since offered a parenting intervention. As mentioned in the second paragraph under section 2.2.2.1, a universal approach might reduce the risk of stigmatization since an intervention is offered to everyone (42). In addition, stigmatization could possibly also be avoided through how an intervention is presented or what approach the intervention has. For example, a message regarding the ABC program is that everyone is an expert in parenting meaning that parents can feel that they are as vital as everyone else participating, rather than feeling targeted due to, for example, potential lack in parenting.

Further, Dawson et al. (169) have acknowledged that health promotion has the possibility to change the lifestyles of people, but also pose a question regarding when interventions aiming to change lifestyles are acceptable to conduct? The issues of paternalism as well as responsibility and concern about harm to others are further brought up. The need of balancing between autonomy and paternalism regarding human behavior changes is also raised by Nilstun (170). The governmental interest in promoting child health through parents, by funding both the program development as well as the evaluation of a universal parenting program, indicates a paternalistic approach. The responsibility and concern about harm to others, seems to outweigh the issue of paternalism in a country as Sweden, especially concerning children who are dependent of others regarding nurturing, upbringing, care and so forth. Further, regarding autonomy, participation in a universal parenting program should be voluntary, and was so within the trial.

The potential risk for non-maleficence with a newly developed program also seemed low because the program development was based on earlier research on protective and risk factors as well as knowledge on parenting and earlier prevention trials. In our trial, the risks for participants therefore were considered as smaller compared to the potential beneficence.

5 RESULTS

5.1 STUDY II: EFFECTIVENESS OF A UNIVERSAL HEALTH-PROMOTING PARENTING PROGRAM: A RANDOMIZED WAITLIST-CONTROLLED TRIAL OF ALL CHILDREN IN FOCUS

5.1.1 Effectiveness in parental self-efficacy and parents' perception of child health and development

A significant interaction effect (time x group) was found for parental self-efficacy ($\beta = -15.24$, $t = -5.41$, $p < .001$). Parental self-efficacy increased more over time in the intervention group than the control group and the estimated increase for the intervention group was 24.1 points on the total PSE scale. This corresponded to a moderate effect size ($\eta^2 = .18$). There was also a significant interaction effect for child health and development ($\beta = -2.21$, $t = -2.18$, $p = .03$). Also here, the intervention group increased more across the measurement period compared to the control group, with an estimated increase for the intervention group of 6.7 points on the total CHD scale. This represented an effect size (η^2) of .15, also corresponding to a moderate effect size.

For the mean values and standard deviations of PSE and CHD at the three measurement points (T1, T2, and T3), see Table 2. Furthermore, effect sizes, calculated as Cohen's d , were .27 (T2) and .17 (T3) for PSE, and .17 (T2) and .11 (T3) for CHD.

Table 2. Mean values and standard deviations of PSE and CHD for the intervention and control groups at T1, T2, and T3.

	T1 Mean (SD)	T2 Mean (SD)	T3 Mean (SD)
PSE			
Intervention	363.82 (51.62)	387.68 (43.56)	385.94 (47.80)
Control	366.81 (48.51)	375.48 (46.89)	377.74 (47.93)
CHD			
Intervention	137.16 (13.37)	142.61 (13.09)	143.22 (13.08)
Control	136.96 (14.64)	140.37 (12.81)	141.82 (12.64)

5.1.2 Effects of moderators

Three-way interaction effects (time x group x moderator) were found for three of the six studied variables regarding parental self-efficacy: parents' positive mental health, educational level, and number of children. Intervention group parents who had university-level education had a greater increase in PSE over the measurement period compared to parents without university education ($\beta = 9.44$, $t = 3.67$, $p = .01$). Parents in the intervention group who reported better positive mental health at baseline showed a smaller increase in PSE over time than parents who reported less positive mental health ($\beta = -2.13$, $t = -3.13$, $p = .002$). In addition, intervention group parents who had more than one child, had a greater increase in

PSE compared to parents who had one child ($\beta = 16.17$, $t = 3.09$, $p = .002$). The other investigated variables, i.e., age and gender of the child and parents' country of birth, did not moderate the outcome of PSE. See Table 3 in the corresponding manuscript for details (119).

Regarding moderating effects on child health and development, three-way interaction effects were found for two of the six studied variables: parents' positive mental health state at baseline and age of the child. Intervention group parents who reported better mental health at baseline showed a smaller increase in their perception of CHD over time than parents who initially reported less positive mental health ($\beta = -.92$, $t = -3.93$, $p < .001$). Furthermore, with increased age of the child, there was a greater increase in parents' perception of CHD in the intervention group ($\beta = .52$, $t = 2.14$, $p = .033$). Parents who had older children had a greater increase in CHD over time compared to parents with younger children. No interaction effects were found for parents' educational level, country of birth, number of children in the family, or child gender. Please see Table 4 in the corresponding manuscript for details (119).

5.2 STUDY III: A COST-EFFECTIVENESS ANALYSIS OF THE SWEDISH UNIVERSAL PARENTING PROGRAM ALL CHILDREN IN FOCUS

5.2.1 Costs

The cost to train an ABC group leader, referred to as a setup cost, was estimated at €1,933, and included the training fee and the time group leaders spent on training (i.e., 31 hours). Given that each ABC group was run by two group leaders and with the assumption of group leaders running more than one group (ten groups on average in our base case), the total setup cost was distributed over ten groups and two group leaders. This resulted in a group leader training cost of €386.6 per ABC group, or €53.7 per parent (based on seven parents per group, i.e., the average number of parents/group within the trial). Regarding operating costs (i.e., the time of group leaders, venues, material, refreshments, and parents' time and transportation), the cost per ABC group was €1,962.4, or €272.6 per parent. The total cost (setup and operating costs) for the ABC program was thereby €2,349.4 for one ABC group or €326.3 per parent.

5.2.2 Effectiveness

5.2.2.1 QALYs in children by parent proxies

At baseline, there was no significant difference between the intervention and control groups in QALYs for children measured by a parent proxy VAS ($t[472] = -.455$, $p = .656$). There was a significant difference between the groups at T2 ($t[490] = 2.214$, $p = .027$), whereas at T3, the difference was not significant ($t[492] = -.708$, $p = .479$). Regarding change in QALYs over the whole measurement time (six months), the children in the intervention group had a change of 0.4321 $\left(\frac{((0.8451+0.8709)/2) + ((0.8709+0.8702)/2)}{2}\right) \times 0.25$ whereas the children in the control group had a change of 0.4279 $\left(\frac{((0.8501+0.8479)/2) + ((0.8479+0.8770)/2)}{2}\right) \times 0.25$. The incremental effect was than 0.0042 gained QALYs per child

in favor of the intervention group, which was not a significant change ($t[472] = .900, p = .369$).

5.2.2.2 QALYs in parents

There were no significant differences between the intervention and control group in QALY weights for parents measured by GHQ-12 at baseline ($t[492] = -.677, p = .499$), at T2 ($t[501] = .845, p = .399$), or at T3 ($t[502] = 1.068, p = .286$). Concerning changes in QALYs over the measurement period of six months, intervention group parents had a change of 0.4004 $((((0.7761+0.8086)/2) + ((0.8086+0.8099/2)) \times 0.25)$, and the control group parents had a change of 0.3977 $((((0.7839+0.7997)/2) + ((0.7997+0.7985)/2)) \times 0.25)$. The incremental effect for QALYs in parents was 0.0027 gained QALYs per parent in favor of the intervention group, which was not a significant change ($t[492] = .766, p = .444$).

5.2.3 Cost-effectiveness

A total cost per parent of €326.3 and a total QALY gain of 0.0069 for children and parents (incremental QALY gain in children: 0.0042; and incremental QALY gain in parents: 0.0027) resulted in an incremental cost-effectiveness ratio of €47,290 per QALY gain.

5.2.3.1 Probability and sensitivity analyses

The probability analysis resulted in a probability of 50.8 percent, meaning that the probability of the program being cost-effective at the threshold value of €55,000 was about 51 percent. See Figure 5 for the CEAC.

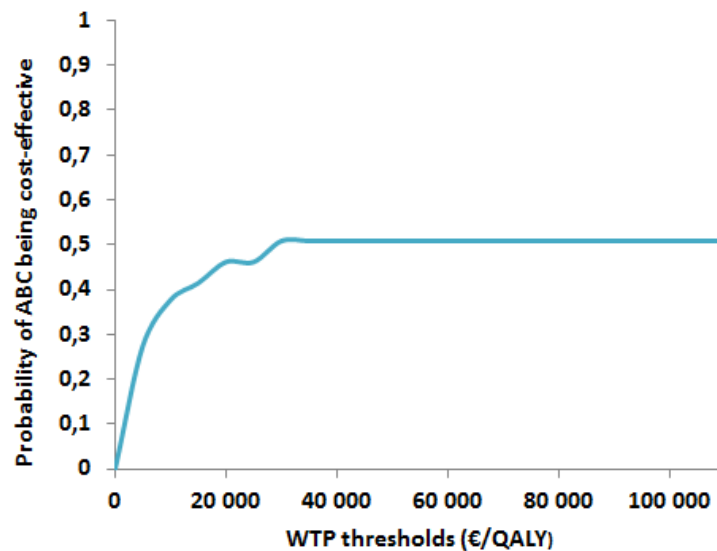


Figure 5. CEAC showing the probability of the ABC program being cost-effective at different WTP thresholds.

Concerning the univariate sensitivity analyses, where costs were adjusted, only one ICER was above the WTP threshold of €55,000; the cost of group leader training distributed over five groups resulted in an ICER of €55,072. When the cost instead was distributed over 20 groups, the ICER was €43,391, and €44,696 for a distribution over 15 ABC groups. When

parents' time was valued at 50 percent of the net wage, the ICER was €51,986, and when the value of parents' time was changed to 0 percent, the ICER instead was €41,739. Finally, including costs for childcare resulted in an ICER of €54,203. The ICERs from the sensitivity analyses were between €41,739 and €55,072 per gained QALY.

5.2.4 Additional sensitivity analyses

The univariate sensitivity analyses in the manuscript (162) only encompassed changes of costs included in the analysis. Therefore, additional sensitivity analyses were conducted where the effects were changed.

Calculating the ICER based on only the significant change in QALYs for children between the pre- and post-measurement resulted in an ICER of €145,022 per QALY gained ($326.3/0.00225$); i.e., it could not be viewed as cost-effective. Further, if still only including the significant change in QALYs for children (T1-T2), but assuming that the effect would last for a year, the ICER would be €36,256 per QALY gained ($326.3/0.009$). In addition, if instead only calculating on changes for the intervention group (VAS+GHQ-12) and assuming no changes over the six months for the control group, the ICER would be €21,052/QALY gained ($326.3/0.0155$). Further, if calculating the effect from pre- to post-measurement for the intervention group (VAS+GHQ-12) and then assuming that the effect would last for a year, while assuming that the control group remained at its baseline value, the ICER would be €19,957 per gained QALY ($326.3/0.01635$). See Table 3 for an overview of the results from the additional sensitivity analyses and for the calculations of the QALY gains.

Table 3. Results from additional sensitivity analyses when changing the effects.

Included effect	ICER	Calculation of the QALY gains
Base case	€47,290	See section 5.2.2.1 and 5.2.2.2
Effectiveness in QALYs for children only (T1-T2)	€145,022	$I (((0.8451+0.8709)/2)*0.25) - C (((0.8501+0.8479)/2)*0.25)$
Effectiveness in QALYs for children only (T1-T2 + remained effect T2-T4)	€36,256	$I ((0.8451+0.8709)/2) - C ((0.8501+0.8479)/2)$
Effectiveness (child + parent) when only including change in the intervention group (T1-T3) and control group remaining stable at T1 value (T1-T3)	€21,052	$I (0.4321+0.4004) - C (((0.8501+0.8501)/2)*0.5) + (((0.7839+0.7839)/2)*0.5)$
Effectiveness (child + parent) when only including change in the intervention group (T1-T2 + remained effect T2-T4) and control group remaining stable at T1 value (T1-T4)	€19,957	$I ((0.8451+0.8709)/2) + ((0.7761+0.8086)/2) - C ((0.8501+0.8501)/2) + ((0.7839+0.7839)/2)$

5.3 STUDY IV: THE UNIVERSAL PARENTING PROGRAM ALL CHILDREN IN FOCUS: TWELVE-MONTH FOLLOW-UP OF CHILD HEALTH AND DEVELOPMENT AND THE PREDICTIVE ROLE OF PARENTING VARIABLES

5.3.1 Changes over time in parents' perception of child health and development and parents' self-efficacy, practices and emotion regulation

The repeated measures ANOVA resulted in significant changes from the pre-measurement (T1) to the 12-month follow-up (T4) in parents' perception of child health and development ($F[1] = 55.95, p = .001$), in parental self-efficacy ($F[1] = 59.04, p = .001$), in harsh and inconsistent discipline ($F[1] = 25.46, p = .001$), and in cognitive reappraisal ($F[1] = 17.14, p = .001$). There were no significant changes from T1 to T4 in praise and positive incentives ($F[1] = 1.18, p = .278$) or in expressive suppression ($F[1] = 3.04, p = .082$). Regarding effect sizes (partial eta squared), they were moderate for child health and development (.19) and parental self-efficacy (.18), and small for harsh and inconsistent discipline (.09) and cognitive reappraisal (.06). When comparing the results from the ITT analysis with study completers, the results were the same except in that a significant change was found for study completers in praise and positive incentives between T1 and T4 ($F[1] = 3.99, p = .047$). See Table 1 in paper IV for means, standard deviations, and results from all the repeated measures ANOVAs. Further, in Figure 6, the significant changes over time are illustrated for child health and development, parental self-efficacy, harsh and inconsistent discipline, and cognitive reappraisal.

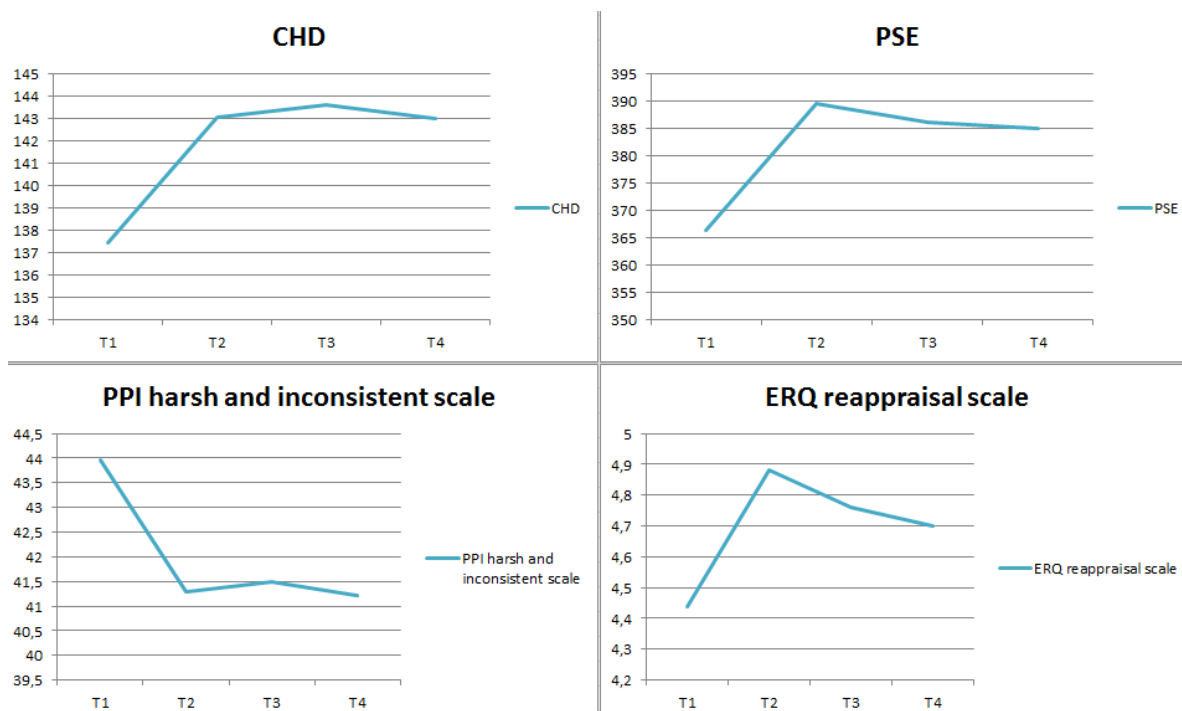


Figure 6. Significant changes found over time (T1-T4) on four outcome measures.

Furthermore, within-group effect sizes between T1-T4, calculated as Cohen's *d*, were .48 for CHD, .48 for PSE, .33 for PPI harsh and inconsistent discipline, and .26 for ERQ reappraisal.

5.3.2 Predictors of child health and development at 12 months

Of the five predictors studied (change between T1 and T2 in parental self-efficacy, the two subscales of emotion regulation, and the two subscales of parenting practices), only one variable predicted CHD at twelve months, namely parental self-efficacy ($\beta = 0.06$, $t = 3.22$, $p = .001$), explaining 2.6 percent of the variance. For more details, please see Table 2 in study IV.

6 DISCUSSION

First, each study is discussed separately (including study hypothesis, main findings, my own reflections, comparison to previous research, and issues/limitations of the study). Then, a general discussion follows, which includes issues, limitations and methodological considerations that concern all the studies. Lastly, implications and future research are discussed.

6.1 STUDY I

Main findings: This study described the RCT of All Children in Focus as well as the intervention.

Reflections: This study introduced me to and gave me the opportunity to develop my skills regarding RCTs, as well as regarding the field of parenting programs and more specifically of universal programs. As a coordinator of the data collection, I received great understanding of this time-consuming work of a trial, including the value of good structure and organization. My experiences of working with an evaluation of a “real-world” intervention also contributed to further developing my sensitivity and flexibility in regards to working with professionals other than researchers. In addition, the work of writing and publishing scientifically was introduced to me as a co-author of the study protocol, giving me valuable experiences for the future work of my doctoral studies.

6.1.1 Issues related to study I

The study protocol provided detailed information regarding the trial and the program under evaluation, and therefore contributes as a primary reference for the conduct of the trial and the content of the ABC program. The purpose and relevance of the trial were also outlined in the protocol as well as the time plan for the trial. Further, the protocol included the research questions for the trial. The current thesis includes half of the research questions, whereas other questions have been taken on elsewhere; a Master’s thesis (171) and a psychotherapist thesis (172).

6.2 STUDY II

Hypotheses: Parents participating in the ABC program (the intervention group) will perceive greater improvements in parental self-efficacy and child health and development compared to the control group. Additionally, parents’ positive mental health, educational level, country of birth, number of children in the family, and age and gender of the child will moderate the effectiveness of the intervention.

Main findings: We found that parents who were offered the ABC program improved significantly more in their ratings of parental self-efficacy as well as in their perception of child health and development compared to the control group, resulting in moderate effect sizes (Eta squared). One variable, parents’ positive mental health, was found to moderate

both parental self-efficacy and child health and development. Regarding parental self-efficacy, two more variables were found to act as moderators: parents' educational level, and number of children in the family. Regarding child health and development, one additional variable was found to moderate, namely child age. Parents, who initially rated their positive mental health lower, had a higher educational level, had more than one child in the family, and older children, benefited more.

Reflections: This study introduced me to statistical data analysis and more specifically multilevel modeling. Through courses, lots of questions posed to the statistics teacher, and hours of reading, I learned how to deal with clustered data through multilevel modeling. My knowledge of moderators were developed, as well as how to investigate moderating variables. As the first author, it was my first time to be responsible for a paper, which developed my skills and abilities in structuring and organizing a paper. Additionally, it gave me experiences of the procedure, including handling review comments and editor contact.

6.2.1 Our results in comparison to other studies

Few other RCTs of universal parenting programs have used a measure focusing on child health and well-being as the child outcome. Simkiss et al. (74) applied PedsQL to measure child well-being, but in contrast to our results, they found no significant change between intervention and control groups. Further, Havighurst et al. (77) applied a measure of child emotional knowledge and found an effect at the 6-month follow-up; however, its result is not comparable to our own result, since we did not include emotional knowledge of the child. In addition, Joussemet and colleagues (76) have conducted a preliminary evaluation (pre-post without control group) of the How-to Parenting Program. They included child reports of positive indicators of mental health (i.e., positive affect, life satisfaction, and self-esteem), and a significant improvement was found in child well-being. Other evaluations of universal parenting programs have found an effect on the child outcome, i.e., reduction in child behavior problems (82, 85, 86, 108). However, nor are these results comparable to our result of effectiveness in a positive health outcome. Regarding parental self-efficacy, Morawska et al. (85) also found an increase from pre- to post-measurement when measuring task-specific parental self-efficacy using the Parenting Tasks Checklist. We found a moderate effect size for PSE while Morawska et al. found a large effect size (Cohen's *d*). In addition, Bloomfield and Kendall (150) also found an increase in parental self-efficacy when using TOPSE, although this study lacked a control group.

Concerning moderators, several studies have previously investigated the moderating effect or predictive role of educational level (70, 91, 111, 113, 117, 118, 120). Several of the studies found that parents with low education/low SES (SES included education) benefited less (70, 91, 117); one study found the opposite, i.e., parents with low education benefited more (118), whereas educational level did not moderate the outcome in two studies (113, 120). Our study result, showing that parents with lower educational level (in our case not having university education) benefited less compared to parents with university education, is in line with several of the earlier studies. There is a well-known association between education and

health, i.e., the well-educated report better health (173), and it is possible that some of the parenting programs might be utilized better by parents with a higher educational level.

Depression (or mental health) has also been investigated as a potential moderator/predictor, where some of the studies found that higher scores of depression were related to worse outcomes (91, 117), whereas some found that higher scores on depression were related to better outcomes (87, 111, 113). Further, in one study, parents with initially fewer psychological problems benefited more when participating in a behavior-focused program, whereas parents with initially higher reports of negative emotions benefited more from an emotion-focused program (120). Our study result, that parents with lower positive mental health benefited more, is in line with the studies showing that parents with reports of depression benefited more (87, 111, 113). Even though these study results are in line with our result, they cannot be viewed as quite the same because we measured positive mental health as the moderator as compared to depression; and we had parental self-efficacy or child health and development as the outcome, as compared to child behavior problems or child management. However, despite these differences in moderating and outcome variables, the tendency was the same: i.e., depressed parents or parents with lower positive mental health benefit more.

Regarding family size and in contrast with the result in our study, Reyno and McGrath (91) found family size to be a predictor of poor outcomes. A possible explanation for the contradicting results could be the difference in outcomes. Family size could in some cases be beneficial (i.e., having several children could possibly promote self-efficacy), whereas in other cases, it could rather fail to enhance the outcome (i.e., when children have problem behavior). Further, we also examined country of birth as a potential moderator, which was not found to moderate either PSE or CHD. This could be explained by important principles of positive parenting being cross-culturally robust (69). In addition, a potential explanation could be that the program developers succeeded in their mission of developing a program suitable for all parents, regardless of, for example, parents' origin.

Regarding child age and gender as moderators, several other studies of parenting programs have also investigated these with varying results (70, 111, 113, 120). We found child age only to moderate CHD where older children benefited more. This result is comparable to that of Duncombe et al. (120) who found that older children benefited more from an emotion-focused program, whereas they also found that younger children benefited more from a behavior-focused program. Further, and in contrast to our results, Gardner and co-authors (111) also found younger children to benefit more regarding conduct problems, which also has been the case in other studies, such as in one study by Ogden et al. (174). In addition, some other studies did not find moderating effects of child age (70, 113). It has been stated that younger children, who are more dependent on their parents to fulfil basic needs, probably are more adoptive of child management skills, which are taught to parents in behavioral programs (175). Regarding older children, who are more independent and possess more advanced abilities of reasoning, non-behavioral programs targeting other skills, such as

communication, have been described as more likely to benefit (176). This could be the case concerning ABC, where the parent-child relationship is targeted. Concerning gender, several other studies did not find gender to moderate the outcome (113, 120), but one study by Gardner et al. (111) did identify gender as a moderator; boys tended to benefit more than girls.

6.2.2 Issues and limitations related to study II

As presented earlier, parents' mental health moderated both the outcome measures (CHD and PSE), where those with lower scores on positive mental health benefited more. This means that families with somewhat more disadvantaged parents, i.e., less positive mental health, not only benefit from the intervention but actually do better. As this could be a group of parents potentially harder to reach and intervene for, the result has to be seen as promising. Further, a next step can be to investigate whether the intervention leads to improved mental health, which has been found in an earlier evaluation of a universal program (109), as well as to study whether potential increased positive mental health predicts or mediates the outcomes in a health-promoting universal program. We also found parents with higher education to benefit more regarding PSE, which might not be completely surprising (due to previous research and the association between education and health). However, this result is important to follow-up because it could potentially lead to a greater increase in the health gap. Further, a potential reason for parents with higher education having a greater improvement in PSE could be that they found it easier to engage in the program. The ABC program is still rather new, and therefore there could be reason to conduct qualitative research to get a more in-depth knowledge of parents' experiences of the program.

6.2.2.1 Limitations concerning study II

An issue regarding study II and the moderating analyses is the question of power. When variables included in an interaction are measured without error, a sample size of 392 is needed to detect a small effect size, and the sample size needed to detect interactions increases when the reliability of the measures included decrease (177). In our case, the power analysis was based on finding potential effects on two outcome measures (CHD and PSE) and was not based on the analyses of moderators. However, as discussed by Gardner and co-authors (111), since so far there are few studies which have investigated intervention moderators and mediators, exploratory studies are worthwhile. For more limitations of study II, see section 6.5.1 under the general discussion.

Further, study II did not include analyses of a full dataset, i.e., did not include a method for imputation of missing data, because MLM was applied. However, it would still have been valuable to conduct imputation of missing data (for example with multiple imputation) to see if the effects remained when running the analyses on full datasets.

6.3 STUDY III

Hypothesis: The ABC program is cost-effective.

Main findings: The cost for the ABC program was €326.3 per parent and the incremental QALY gain was 0.0069 per family (for child and parent). This resulted in a base case ICER of €47,290 per gained QALY. The sensitivity analyses resulted in ICERs between €19,957 and €145,022, and the probability of the ABC program being cost-effective was 51 percent.

Reflections: An important insight gained from performing this study was that the field of health economics differs somewhat from other fields. For example, the health economic evaluation needed to rely on assumptions, there is greater acceptance of the use of non-significant results, and instead a reliance on analysis of sensitivity and probability. In addition, this study was pioneering in the sense that it measured QALYs in both children and parents. From this study, I have learnt that we sometimes need to think outside the box to succeed in our mission. Perhaps the most valuable experience from this study though was the hours of discussion and reflection, not least with my health economics supervisor. Even though the goal of my doctoral studies was to become an independent researcher, I have come to experience the significance of collaboration and the value of input from others.

6.3.1 Our results in comparison to other studies

As described earlier, there is a lack of health economic evaluations of parenting programs including QALYs as a measure of effectiveness. Only one study by Simkiss et al. (74) has used SF-12 to include QALY gains of parents in a CUA, whereas no study so far has included QALYs in children as the effectiveness measure. Their study resulted in an ICER similar to ours, £34,913/QALY gained over a time period of five years compared to €47,290 in our study. However, their ICER was not viewed as cost-effective in relation to the WTP threshold of £20,000–30,000 per gained QALY. In addition, the ICER represented less value for money when the maintained effect was estimated to be zero at five years, i.e., £56,885, which seems fairly likely to represent reality because few evaluations of universal programs have found long-term effects on parents' well-being. Further, reduced problem behavior has been used as the effectiveness measure in other health economic evaluations of parenting programs. These studies have instead reported on the average cost of recovered cases of conduct problems (137) and the cost per point reduction of the Eyberg Child Behavior Inventory (67, 136), and modeled the potential cost-savings over a time perspective of 25–26 years (138, 139). The results of these studies are not comparable to those of our study.

6.3.2 Issues and limitations related to study III

One strength of our CUA was the use of QALYs as the measure of effectiveness, which captures potential gains in both quality and quantity of life, and enables comparison between interventions focusing on any aspect of health. Further, in this paper, we chose to sum the QALY gains of children and parents to illustrate the fact that the intervention does not affect only children or only parents but rather both (compare 178). As stated by Davidson and Levin (179), it is of importance to try to include the effects and costs of relatives in cost-effectiveness analysis, which is especially important for interventions where the costs and effects of relatives are considerable. In our case, it was therefore considered to be essential to

include, beyond the effects on children, also the effects on parents of a parenting program, specifically, since we include costs for parents (time and traveling). As also described by Davidson and Levin, the QALY would also be the appropriate measure for relatives, but there is no well-established method yet for including the QALY gains of relatives in cost-effectiveness analysis. Further, because a QALY theoretically is the same for everyone, i.e., of equal value, it is possible to combine the QALYs of individuals to get the total QALY gain of an intervention. However, it is viewed as a problem if different methods are applied to retrieve QALYs where one is health-related and one is, for example, care-related (179). In our case, both the child and parent QALYs were health-related. So even though the QALY weights were not retrieved with the same measure, we argue for aggregation of our QALY gains in children and parents to capture the total QALY gain, so as more fully to incorporate a societal perspective. In line with Prosser et al. (180), who discuss the role of integrating effects of children's health on the family in future research, I believe that future cost-effectiveness analyses of parenting programs should also consider the potential effects on other family members, such as siblings, and for two parent-households, the other parent, to fully capture a societal perspective.

Further, this study was built on assumptions regarding several of the costs. For example, an assumption was applied regarding the value of parents' leisure time, which was based on another health-promoting activity, namely exercise (181, 182). We reasoned that the valuation of leisure time for another health-promoting activity (in this case exercise) could be closer to the reality (parents' time in the ABC sessions) compared to, for example, basing parents' leisure time on a percentage of the gross wage. As previously mentioned, it has been common in Sweden to use 35 percent of the average wage as the valuation of leisure time (133). However, since this percentage originates from the field of transportation (i.e., the value of transportation time) (183), it was not considered more relevant in the case of valuing parent's time used for attending a parenting program.

6.3.2.1 Limitations concerning study III

It is recommended that extended time horizons are applied to be able to capture all the potential consequences of an intervention (184). The short time perspective in study III was a limitation. We only had data for a time period of six months, and within the manuscript we chose not to make any assumptions regarding effectiveness over a longer time period. Within the thesis though, assumptions were included regarding maintained effects for another half a year which resulted in ICERs of €19,957–36,256 per QALY gained. The additional sensitivity analyses could be compared to the study by Simkiss et al. (74), who estimated effects over a time period of five and ten years.

For most of the effects included in the analyses there were no significant changes between the intervention and control groups, which could be viewed as a limitation. In studies II and IV, that would have meant that we would not have rejected the null hypothesis, i.e., no significant differences between the groups or over time. In this study, however, we continued to work with the mean differences despite non-significance according to several sources (121, 127,

185). Instead, the uncertainty in the data was illustrated in a CEAC which is standard to include in a cost-effectiveness analysis (186). Further, additional analyses were conducted within the thesis, where the effectiveness was calculated on only the significant change in QALYs in children between the pre- and post-measurement. This resulted in an ICER of €145,022 per gained QALY, which could not be viewed as cost-effective. If, instead the calculations is on the significant effect in the child QALYs remaining over a year, the ICER would be €36,256 per gained QALY.

Regarding QALYs in children, VAS was used due to a lack of well-established measures for young children (135). The field of measuring QALYs in children is still developing and further development of calculation methods valid for children are needed (187). Even though the VAS has been used earlier in studies of utility for children and adolescents (187), others have stated that the VAS can be viewed as only the second-best option compared to time trade-off and standard gamble (155), and can be applied only in a limited way (188). However, the potential of applying VAS has been emphasized (189), and the VAS is one of few direct measures of utility weights (155). Apart from the lack of other appropriate measures of QALYs in children, we also needed a simple and user-friendly measure within a rather comprehensive parental questionnaire. Regarding QALYs in parents, we did not use a direct or indirect measure of HRQoL in parents. This was because the questionnaire, as recently mentioned, was viewed as rather comprehensive, and therefore it was not considered ethically acceptable to include more measures. Instead, we chose to retrieve QALY weights from GHQ-12 according to the suggestion by Serrano-Aguilar et al. (154), which was feasible since GHQ-12 was a measure already included in the questionnaire. The QALY weights of parents were in the study by Serrano-Aguilar et al. based on a Canary Island population, and the comparability to our study sample has to be further examined. The choices for obtaining QALY weights within our study could be questioned. However, our belief was that the value of being able to include QALYs as a measure of effectiveness was higher and important for further development within the field. Additionally, the QALY gains in our study should be interpreted with caution and future research has to validate the relevance of a parent proxy VAS and GHQ-12 to retrieve QALYs.

The parent proxy VAS was not applied as a measure where parents made a cross or mark on the VAS. This was due to the fact that this could not be provided within the system, which the web-based questionnaire was built within. Instead, parents rated their child's general health state by filling in a value between 0–100 in a box. Even though this scenario could result in induced memory effects, since parents' stated a number between 0–100, it was believed to be rather unlikely that parents' would remember their previous rating, and additionally, that it would affect their next rating.

6.4 STUDY IV

Hypotheses: Parents participating in the ABC program will rate their perception of child health and development higher over time, as well as report improvements over time in parental self-efficacy, practices, and emotion regulation. In addition, change in parental self-

efficacy, practices, and emotion regulation between the pre- and post-measurement will predict child health and development at 12 months.

Main findings: We found significant changes in parents' perception of child health and development from the pre-measurement to the 12-month follow up. Significant changes were also found in parents' ratings of parental self-efficacy, in parents' practices of harsh and inconsistent parenting, and in the emotion regulation strategy of reappraisal. The effect sizes (partial eta squared) were small to moderate. Regarding these four outcomes, there were also significant changes from pre- to post-measurement. Regarding predictive variables, only parental self-efficacy was found to predict the child outcome at the 12-month follow-up, explaining less than three percent of the variance.

Reflections: This study introduced me to and expanded my knowledge on additional outcome measures within parenting programs. I learned how to handle data with different statistical methods (repeated measures ANOVA and regression analyses) compared to study II. This study also implied development of my knowledge and skills regarding predictor variables. Furthermore, my earlier experiences during my doctoral studies also made the trajectory of this study easier, such as a smoother process of writing the manuscript.

6.4.1 Our results in comparison to other studies

Similarly to our study results, Simkiss et al. (74) did find improvements over time in several of their outcome measures, including child well-being. The intervention group improved more than the control, but the changes were not significantly different between the groups in the study by Simkiss et al. Concerning the other long-term evaluations, which included outcome measures of child behavior problems, the results have varied somewhat. Two RCTs found sustained reductions in child behavior (82, 108). The study by Averdijk and colleagues (105) found a reduction in teacher reported aggressive behavior, but it was viewed as negligible due to an effect size of -0.149 (Cohen's d), whereas no long-term effects were found in the other studies (68, 83, 84, 86, 89, 106). In addition, a quasi-experimental study (109) also found reductions in child behavior problems. As mentioned earlier, these studies with outcome measures focusing on reductions in child behavior problems are not comparable to the results of our trial since we measured change in a positive health outcome, i.e., child health and development. Further, previous RCTs of long-term effectiveness have found improvements in parental outcomes, even though somewhat different outcomes compared to ours (harsh and inconsistent discipline, and praise and positive incentives). Effects have been found in less unreasonable expectations of the child (83, 89), as well as in enhancement of positive parenting and sense of competence (86), and several studies have also found reductions in harsh, dysfunctional, and dysfunctional/abusive parenting (82, 83, 86, 106).

Regarding previous research on predictors of outcome in parenting programs, the pilot study of the ABC program found one dimension of PSE (self-competence) to predict child well-being at the 4-month follow-up (75). This is in line with the result of parental-self efficacy

being a predictor of child health and development at 12 months in the current study. However, another dimension of PSE (knowledge/experience) was not found to be a predictor in the pilot study (75), which contradicts the result of the present study. Furthermore, Sherr et al. (87) did not find a moderating effect of parental self-efficacy on their outcome measures. The pilot study of ABC also investigated the predictive role of ERQ (reappraisal), and, similarly to our current result, ERQ was not found to predict CHD (75). In contrast to our result of not finding harsh and inconsistent parenting to predict CHD, Beauchaine and co-authors (113) have previously found harsh parenting to be a predictor of externalizing problems in children. A reason for the diverse results could be the difference in measures of harsh parenting, as well as the difference in outcome measures (externalizing behavior versus child health and development).

6.4.2 Issues and limitations related to study IV

In study IV, variables were investigated as predictors of outcome rather than as mediators. The reason for not investigating the mediating role of variables lay in the lack of multiple reporters (we only had parental ratings), and we could thereby not overcome the issue of method overlap, where different reports for the measure of the potential mediator and the outcome would be needed (111). Further, a mediator is an influence that occurs during an intervention (13), and, within the trial, we did not collect data regarding potential mediators during the intervention.

6.4.2.1 Limitations

There was no control group within study IV and therefore we cannot say that the changes found over time were actual intervention effects. However, since previous research (RCTs) have found improvements in emotion regulation (77) and harsh parenting (83, 86), we hypothesize that also the changes found in the secondary outcome measures (in PPI and ERQ) in this study could be intervention effects. This though has to be further investigated in a study including a control group. For further limitations of study IV, see also limitations in the general discussion (section 6.5.1).

6.5 GENERAL DISCUSSION

To my knowledge, no other RCT of a universal parenting program has found effects in a parent-reported outcome of child well-being, which is why the results of these studies are of great importance. The vast majority of universal parenting programs are not designed to promote well-being in children. The conducted evaluations of these programs rather focus on measuring reduction in child behavior problems (68, 77, 78, 82-86, 89, 105, 106, 108, 109), and only one RCT has focused on measuring change in child well-being, i.e., a measure focusing on positive health (74). As mentioned earlier, a disadvantage of universal programs is the difficulty in showing overall beneficial effects (42). This is because most individuals in the population will have no or few of the behaviors that the intervention is aimed to prevent, and can therefore show no or only small improvements (42). Earlier research has, in line with this, concluded that a universal parenting program of three sessions is not enough to prevent

externalizing behavior in preschool-aged children (89). In addition, it has been discussed that the low level of problem behavior in children in a general population might be the potential reason for not finding effects in universal parenting programs (106). Reedtz et al. (86) have also pointed out that more research is needed to determine whether a public health approach to the promotion of positive parenting within Scandinavia, where the prevalence of behavior and socio-emotional problems is rather low, can have the potential to reduce the prevalence of child behavior problems.

As suggested by Saxena et al. (8); a reduction in risk factors is likely to be the effect of a preventive intervention for those at greatest risk, whereas those at lower risk might instead, benefit from the same intervention through the effect of strengthened protective factors. Therefore, it could be emphasized that future evaluations of universal parenting programs, especially programs focusing on health promotion, should have a greater focus on measures capturing a salutogenic perspective, i.e., measure potential changes in a positive health outcome such as health and well-being of the child. In line with this, Joussemet and co-authors (76) have included child-reported positive predictors of mental health in their preliminary evaluation of the How-to Parenting Program. Their finding of an improvement in child well-being from pre- to post-measurement is of importance to follow up in a trial with a control group included.

Further, greater effect sizes have been reported in crime reduction when program developers have a high degree of influence in the intervention setting (190). One strength of the current trial was therefore the independence of the research group responsible for the evaluation of the program. Even though there was cooperation between the program developers and the researchers, the evaluation was run strictly by the research group. One of the researchers who was responsible for the trial was additionally responsible for the literature review undertaken at an early phase of the program development. Further, the research group was also responsible for the telephone interviews conducted with parents to capture their wishes and needs for a universal program; which were experiences used by the program developers in the development of the program. Both of these collaborations between the program developers and the research group were assumed not to affect the evaluation in any way.

6.5.1 Issues and limitations related to all studies

6.5.1.1 Lack of normative data

A general issue within our trial was the lack of normative data. Only for two of our outcome measures (two dimensions of PSE and the two subscales of ERQ) were there available norms. The available norms were also not totally appropriate for our sample since our population differed somewhat in age compared to the populations from which the norms originated (159, 191). Therefore, we chose to not include any normative data within the present trial, which should be viewed as a limitation. Further, comparing our data to the existing norms, our means of ERQ and the two scales of PSE were lower compared to the means of the normative

data. Further, the norms for PSE were for parents with children aged 2–5 years-old (191), while ERQ norms were for parents with children aged 10–13 years (159).

Due to the lack of normative data there is no possibility to determine if our study sample is representative regarding outcome measures such as child health, parental self-efficacy, and parenting strategies, compared to the general population of Sweden, or more specifically the population of Stockholm County. Normative data would therefore be beneficial to include in future studies to be able to draw conclusions on how representative the study sample is.

6.5.1.2 Generalizability of the results

Primary variables in generalizability are baseline characteristics of the study sample (age, gender, ethnicity, and so on) (192). As reported earlier, the study sample was representative of the population of Stockholm County regarding country of birth but not regarding income and education (163). This means that our results cannot be generalized to the whole population of Stockholm County regarding income and education; i.e., our results can rather only be generalized to a population with higher income and educational level.

Characteristics of parents who attend or not attend a universally offered parenting program have been studied by Wells et al. (193). They found that parents with a higher education were more likely to attend the program, which is consistent with the sample in our trial. The same pattern was found for mothers when Alfredsson and colleagues (194) studied the parents of adolescents.

Further, the theory of diffusion of innovations (195) could potentially explain why parents with higher family income and educational level participated to a greater extent in our trial. The theory, which tries to explain how and why a new innovation (idea, practice, or object) is spread, divides adopters of a new innovation into five categories: innovators, early adopters, early majority, late majority, and laggards (195). Regarding the innovators (around 2.5% of the involved), they are described as being willing “*to leave the village to learn*” (196) and as being wealthier than the average. Regarding the early adopters (about 13%), they are also explained to have the needed resources and are willing to accept the risks of a new innovation (196). The ABC program was newly developed at the start of the trial, which could potentially also explain why participants in the trial had higher income and educational level (i.e., by being innovators or early adopters).

6.5.1.3 Lack of reporting of program implementation

As mentioned by Hickey et al. (197), knowledge of implementation and its impact on outcomes within the field of group-based early parenting programs is still limited. The aim of the current thesis did not include investigation of the implementation process, i.e., how well the program was conducted during the trial (198). This could be viewed as a further limitation of the thesis. It is of importance to know which parts of an intervention have been delivered as well as how well they were delivered (198). An intervention that is not implemented adequately, or implemented differently than intended, could result in both negative results

and positive impacts (198). Further, it would have been beneficial to pair the outcome evaluation included in the current thesis with a process evaluation (199). Within the trial of the ABC program, program fidelity was investigated through group leaders' own reports as well as by video recordings of the group leaders. The dosage of parents' participation in the trial was also known. Future research should therefore relate these outcomes to the results from the outcome evaluation to investigate the impact of program implementation on the outcomes.

6.5.1.4 Participants and gender perspective

There was a greater number of women participating (73%) in the trial, compared to men. This phenomenon is rather common for parenting programs, and two recent studies (193, 194) conducted in Sweden have shown that mothers are more likely than fathers to participate in universally offered parenting programs. Furthermore, Thorslund et al. (200) found that Swedish mothers were more interested in participating in parenting support compared to fathers. This was true for all types of support (i.e., leader-led, meeting room, individual counseling, and parent phone line) except for a webpage for parents where there was no significant difference between mothers and fathers. In addition, statistics show that Swedish mothers still take more responsibility regarding care of children compared to Swedish men (201). This could potentially be one reason why women are more likely to participate in parenting programs compared to men (202). However, from the perspective of gender equality, the issue of reaching men to an equal extent remains and should be considered in parenting programs. It has been recognized that different factors may influence and motivate women and men's participation (193, 202), which should be considered in future recruitments of parents.

Furthermore, according to Lundahl et al. (203), more positive changes were reported in child behavior when parenting programs included fathers compared to programs which did not include fathers. In addition, they found that mothers and fathers did not benefit equally from parenting programs, where fathers reported fewer changes in their behavior. Our analyses did not consider gender differences and therefore this would be of interest for future work.

6.5.2 Methodological considerations

6.5.2.1 Validity of parental reports

The thesis has been based on reports of parents only. During the pilot studies of the ABC program we invited older children also to fill in questionnaires. However, only three questionnaires were handed in to us, and we therefore chose to exclude the child questionnaire in the RCT. The low response rate among children was not investigated further but could possibly be explained by low interest among children to participate or that children did not receive the questionnaire. Further, the relatively low age of the children (the mean age in the trial was six years) also made child reports harder to obtain, and parent proxies were used instead for all children regarding the child outcomes (CHD and VAS). Studies have reported on discrepancies between parent proxies and child reports of HRQoL (204-207), but

as discussed by Upton et al. (204), the discrepancy is probably not a proof of any of the ratings being right or wrong, but rather evidence of individual beliefs about the health and well-being of the child. Additionally, for children to be able to report on utilities for health economic evaluations, there is also a need for development of reliable and validated measures (135).

Further, due to the lack of multisource assessments in our trial, it was decided to include a non-random sample of parents and children to participate in an observational study. The aim was to be able to verify parents' ratings against observational data on parent-child interactions. In the first analyses of the data, in a psychotherapist thesis, only one correlation was found (of seven studied) between observed negative responses and parents' ratings of harsh and inconsistent parenting (172). This could imply low agreement between the observed ratings and parents' own ratings, but since the analysis was based on a small ($N = 17$) non-randomized sample, it is difficult to draw any further conclusions.

6.5.2.2 Respondents versus non-respondents

As described in studies II and IV, there were differences between the parents who responded to the questionnaires and the parents who did not respond. For study II, parents born outside Sweden failed to complete the questionnaire at the follow-up measurements to a greater extent. This could be a result of the questionnaire only being available in Swedish, and it is therefore vital in future evaluations also to provide the measurement techniques in other languages. For example, in two of the city districts which participated in the trial, 58 and 40 percent of the population have a foreign background (208). Further, the non-respondents in study IV had lower family income and a lower educational level compared to those who did respond (lower family income was also the case for non-respondents in study II). Our findings regarding income, educational level, and country of birth of non-respondents are consistent with other studies (209-211), and the socio-demographic differences between respondents and non-respondents imply selection bias.

6.5.2.3 Control group consisting of a waiting-list

Different types of control groups are applied within trials of effectiveness where the waiting-list control, as applied in the current trial, is one option. The waiting-list control is the most common control group condition within modern research in psychotherapy. However, this condition also brings limitations, such as the control group not needing to make efforts on their own to improve (212). For example, in the field of psychological therapy, it has been found that people who are put on a waiting-list show an overall reduction in psychological symptoms (213). As improvements were also found for the control group in our trial (119), it is of importance to consider what type of control group would be most appropriate in future evaluations of parenting programs.

6.6 IMPLICATIONS OF THE FINDINGS AND FUTURE RESEARCH

Our trial of the ABC program was the first effectiveness study of the program, and the program was shown to promote parental self-efficacy and parents' perceptions of child health and development when compared to a waiting-list control. Thus, the program can now be viewed as promising, but it is still too early to classify the program as well-established (14). According to the older standards of evidence (15), at least one additional high-quality trial is needed to be able to show reliable results in terms of effectiveness. Whereas in the new standards of evidence (214), it is described that to claim effectiveness, a positive average effect throughout effectiveness studies is needed. Further, also within the field of psychosocial treatment, it has been described that the criterion for a well-established treatment is for there to be at least two good experiments conducted by independent research groups (215). At least one additional study of the ABC program is therefore needed before we can talk about the program as being effective.



Results from study III provide support for the cost-effectiveness of the program, which is an incentive for decision-makers to implement the program. Information on cost-effectiveness of a program is viewed as standard and should be included for the effectiveness claim of a program and is needed before scaling-up (214). The result in study III was promising but since the probability of cost-effectiveness indicated great uncertainty, some caution is needed regarding interpretation of the cost-effectiveness. Therefore, more research regarding the potential cost-effectiveness of the program is urged before full scale implementation can be recommended. Future studies of cost-effectiveness need to include a longer time perspective as well as a sufficient sample size to detect probably small effect sizes (the significant change between the intervention and control groups in child QALYs represented an effect size, Cohen's *d*, of .20 in our case). Another important field for future health economic research on interventions for child health is how to measure QALYs in children. There are limited options to date and the field has to develop, and there is a great need for appropriate instruments for measures suitable in child health promotion.

The results of study IV provide support for maintained effects of two of the outcome measures in the trial (PSE and CHD). In addition, this study provides support for changes over time on several other outcome measures. This knowledge has to be viewed as encouraging. Not only does a universal health-promoting parenting program show effects

(study II) but it also seems as the effects are maintained over time (one year), and that a universal parenting program has the potential to impact different outcomes. Future research has to investigate the changes over time to see if these are intervention effects. Further, future research on universal parenting programs is also urged to include mediation analyses to investigate the mechanisms of change in this type of program. Could, for example, the changes in parental self-efficacy, parenting strategies, and emotion regulation work as mediators of child health? In addition, only one variable (i.e., parental self-efficacy) was found to be a predictor of the child outcome in study IV, and future studies could potentially explain the variance to a greater extent.

Further, the fourth session of ABC includes group leaders presenting other available support to parents within the municipality/city district. The organization PLUS, which is responsible for the provision of the ABC program within the City of Stockholm, is also responsible for the parenting program COMET, i.e., a targeted program for parents with children with conduct problems (216). PLUS has noticed that, after more parents have been offered the ABC program, there are more notifications to COMET (personal communication August 2016). This could potentially mean that ABC has the potential to find parents who are in need of more support and channel them further. This experience could be of importance to follow up in future studies and could be of great value for future cost-effectiveness studies.

7 CONCLUSIONS

The evaluated program, All Children in Focus, appears to be effective concerning promoting parental self-efficacy and parents' perceptions of child health and development in a short-term perspective. In addition, families may benefit differently from the program depending on factors such as parents' mental health, educational level, number of children in the family, and age of the child. Cost-effectiveness ratios support the idea that the program can be viewed as cost-effective. However, since the probability analysis showed great uncertainty in the probability of cost-effectiveness, the rationale for full-scale implementation is yet not convincing. In addition, the thesis gives support for maintained effects over a longer time perspective, i.e., twelve months, but regarding predictors of the child outcome, further research is needed since our work explained less than three percent of the variance in child health and development. In addition, there is reason to plan for studies including mediation analysis in future work on universal parenting programs.

The current thesis provide support for the ABC program being promising. Further research is now encouraged to fill in gaps from the current trial as well as to establish if the program can be claimed to be effective.

8 SVENSK SAMMANFATTNING

Bakgrund: Föräldraskap beskrivs som en av de mest överväldigande och viktigaste uppgifter som många människor tar sig an i livet. Likväl är föräldraskap beskrivet som en komplicerad uppgift. Föräldraskap har identifierats som både en skyddsfaktor och en riskfaktor för barn där föräldra-barn relationen klassas som en viktig skyddsfaktor för barns hälsa och välmående. Identifierade som riskfaktorer för utagerande problematik hos barn är bland annat hårt och inkonsekvent föräldraskap och frånvaro av positivt föräldraskap. Att erbjuda föräldrar stöd i föräldraskapet har därför blivit identifierat som en metod för att främja barns hälsa och utveckling. Föräldrastödsprogram delas ofta in i universella och riktade program där de universella programmen vänder sig till alla föräldrar medan de riktade programmen vänder sig till föräldrar som har någon gemensam riskfaktor (antingen på grupp-nivå eller som är identifierad på individuell nivå).

Kunskapen gällande universella föräldrastödsprogram är inte lika stor som den kunskap som finns kring riktade program. Än så länge har också få utvärderingar av universella program tittat på förändring i barns hälsa och välmående. Istället är det vanligare att mäta minskning av beteendeproblem hos barn, detta trots att få av de utvärderingar som finns av universella föräldrastödsprogram har visat effekt gällande just minskning av beteendeproblem hos barn. Då samhällets resurser är begränsade är resultat från hälsoekonomiska utvärderingar ett viktigt beslutsunderlag vid fördelning av resurser. Gällande universella program och hälsoekonomiska utvärderingar så finns idag få studier genomförda. Det är också av betydelse att veta om familjer gynnas olika av föräldrastödsprogram vilket kan studeras genom att analysera så kallade moderatorer. Likväl som det är av betydelse att undersöka om det finns faktorer som kan förutsäga förändring i ett utfall (t.ex. förändring i barns hälsa), vilket undersöks i analys av prediktorer. Kunskapen idag om prediktorer och moderatorer gällande universella program är också mycket begränsad.

Med anledning av den bristande kunskapen kring universellt föräldrastöd består denna avhandling av studier på ett nyligen utvecklat universellt och hälsofrämjande föräldrastödsprogram, Alla Barn i Centrum (ABC-programmet eller kort ABC). Med hälsofrämjande innebär att programmets syfte är att främja hälsa och välmående. Alla föräldrar som har barn i åldern 3–12 år erbjuds programmet. Programmet består av fyra träffar (Visa kärlek, Vara med, Visa vägen och Välja strider) och genomförs av två utbildade gruppleddare. Föräldrarna erbjuds också en boosterträff efter cirka 2–3 månader. Programmet syftar till att främja barns positiva utveckling genom att stärka relationen mellan föräldrar och barn.

Syfte och frågeställningar: Det övergripande syftet med avhandlingen var att utvärdera programmets effektivitet och kostnadseffektivitet samt att studera prediktorer och moderatorer. Studie I syftade till att beskriva studien av ABC-programmet. Studie II syftade till att utvärdera programmets effektivitet gällande föräldrars tilltro till sin föräldraförmåga och föräldrars uppfattning om barns hälsa och utveckling sex månader efter

baslinjemätningen, samt att studera potentiella moderatorer. Studie III syftade till att uppskatta kostnader, undersöka effektivitet, och att genomföra en kostnadseffektivitetsanalys av ABC-programmet. Studie IV syftade till att utvärdera om effektiviteten i barns hälsa och utveckling som vi fann i studie II kvarstod vid 12 månader och undersöka eventuell förändring över tid i de sekundära utfallsmåtten (tilltro till föräldraförmågan, föräldrastrategier, och föräldrars emotionsreglering). Studien syftade också till att undersöka om förändring i de sekundära utfallsmåtten predicerade förändring i föräldrars uppfattning av barns hälsa och utveckling.

Metod: En randomiserad kontrollerad studie genomfördes där 613 föräldrar inom Stockholms län (elva kommuner och stadsdelar) deltog. Föräldrarna fördelades slumpmässigt till antingen en interventionsgrupp ($N = 317$) som fick ta del av programmet på en gång, eller en kontrollgrupp ($N = 296$) där föräldrarna sattes på en väntelista för att erbjudas programmet efter cirka sex månader. Samtliga studiedeltagare fick ta del av ett frågeformulär vid tre tillfällen. Den första gången var före randomiseringen, den andra gången var två veckor efter interventionsgruppen deltagit i ABC och tredje gången var sex månader efter den första enkäten. Interventionsgruppen fick också ta del av enkäten en fjärde gång vilket var tolv månader efter den första enkäten. Frågeformuläret innehöll frågor om barnets hälsa och utveckling, om föräldrars tilltro till sin föräldraförmåga, användning av föräldrastrategier, emotionsreglering (hantering av känslor), föräldrars psykiska hälsa samt bakgrundsinformation om deltagarna (såsom ålder, kön, utbildning etc.). Information samlades också in från litteraturen, programutvecklarna och gruppledarna gällande kostnader för genomförande av ABC-grupper.

Resultat: Resultatet från studie II visade att föräldrar som deltog i ABC-programmet (interventionsgruppen) rapporterade förbättringar i tilltron till föräldraförmågan och gällande uppfattningen om barns hälsa och utveckling jämfört med föräldrar som stod på väntelista (kontrollgruppen). Skillnaderna var statistiskt säkerställda (signifikanta). Föräldrars psykiska hälsa, utbildningsnivå och antal barn i familjen påverkade (modererade) tilltron till föräldraförmågan medan föräldrars psykiska hälsa och barns ålder påverkade utfallet av barns hälsa och utveckling. Att ha längre psykisk hälsa, högskoleutbildning, mer än ett barn i familjen, samt äldre barn gjorde att man gynnades mer av programmet. Studie III resulterade i en kostnadseffektivitetskvot på €47,290 per kvalitetsjusterat levnadsår (QALY) (omkring 430,000 kronor). Med en betalningsvilja på €55,000 per vunnen QALY (500,000 kronor/QALY) kan programmet klassas som kostnadseffektivt. Känslighetsanalysen resulterade i kvoter mellan €19,957–145,022 per vunnen QALY medan sannolikhetsanalysen resulterade i en sannolikhet på 51 procent att programmet kan klassas som kostnadseffektivt. Resultatet i studie IV visade statistiskt säkerställda skillnader över tid (från baslinje till 12-månadersuppföljningen) gällande förbättring i föräldrars uppfattning av barns hälsa och utveckling, tilltron till föräldraförmågan, hårt och inkonsekvent föräldraskap och i en emotionsregleringsstrategi (omvärdering). Endast förändring i tilltron till föräldraförmågan predicerade barnutfallet vid 12 månader.

Diskussion: Enligt min kännedom så har ingen tidigare randomiserad kontrollerad studie av universellt föräldrastöd visat på skillnader i barns hälsa. Ett fåtal studier har tidigare visat på effekt gällande minskning av utagerande problembeteenden hos barn medan de flesta studierna inte har visat på någon effekt. En förklaring som nämnts gällande de uteblivna effekterna är att nivån av utagerande problem hos barn i den generella befolkningen är relativt låg. Med anledning av detta blir avhandlingens resultat viktigt och ett tecken på att framtida utvärderingar av universellt stöd till föräldrar bör innehålla mått på barns hälsa, välmående och utveckling. Vidare har få tidigare studier av universellt föräldrastöd tittat på om familjer gynnas olika av deltagande i universella program. Vår studie visade att flera faktorer påverkade utfallet (föräldrars psykiska hälsa, utbildningsnivå, antal barn och ålder på barnet), vilket innebär att familjer påverkades olika. Studiens utfall påverkades dock inte av barnets kön eller föräldrarnas födelseland utan familjer gynnas lika bra av programmet oavsett föräldrarnas födelseland (Sverige eller utomlands) och oavsett om man hade en flicka eller pojke.

Så vitt jag känner till har endast en tidigare hälsoekonomisk utvärdering av ett föräldrastödsprogram inkluderat QALYs (kvalitetsjusterade levnadsår) som utfallsmått gällande effektivitet för föräldrar medan vår studie är den första som även inkluderar QALYs för barn. Studiens resultat visade på att ABC-programmet kan klassas som kostnadseffektivt men då resultatet också visade på stor osäkerhet i sannolikheten att programmet är kostnadseffektivt rekommenderas ytterligare studier. Då vi fann en liten effekt ($d=0.2$) för barnutfallet så rekommenderas att framtida studier tar det i beaktande för att inte ha för låg power (dvs. för låg sannolikhet att kunna hitta en skillnad om det verkligen finns en skillnad i populationen).

I den sista studien fann vi att effekten, funnen i studie II, kvarstod över längre tid (fram till 12 månader). Resultatet kan klassas som lovande men bör följas upp i jämförelse med en kontrollgrupp för att konstatera att det är en verklig skillnad och inte en effekt av tid. Det är också betydelsefullt att vidare undersöka vad som predicerar förändring i barns hälsa och utveckling och studera mediatorer, som inte varit en del av den här avhandlingen. Vilka är de verksamma mekanismerna, mediatorerna, i ett universellt föräldrastödsprogram som leder till förändring i barns hälsa?

Slutsats: Sammanfattningsvis ger avhandlingen stöd för att ett universellt och hälsofrämjande föräldrastödsprogram har effekt under kort sikt, likväl som det ger stöd för bibehållna effekter under längre tid. Avhandlingen visar också på att familjer kan ha olika nytta av programmet samt att ytterligare forskning behövs för att fastställa vad som predicerar barnutfall i ett universellt program. Avhandlingen ger också stöd för att programmet kan klassas som kostnadseffektivt men med anledning av den låga sannolikheten för kostnadseffektivitet så uppmuntras till vidare forskning på området. ABC-programmet kan i dagsläget klassas som lovande och framtida forskning behövs för att fylla i kunskapsluckor från den genomförda studien av programmet samt för att kunna konstatera om programmet uppnår kraven gällande att klassas som effektivt (då ytterligare minst en studie av hög kvalitet behövs).

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