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# **FAMILY-BASED PREVENTION OF CHILDHOOD OBESITY - LONG-TERM OUTCOMES, CHALLENGES AND IMPLICATIONS FOR FUTURE RESEARCH**

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# Family-Based Prevention of Childhood Obesity – Long-Term Outcomes, Challenges and Implications for Future Research

THESIS FOR DOCTORAL DEGREE (Ph.D.)

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# ABSTRACT

**Background:** Childhood obesity is considered to be one of the most serious health challenges of the 21<sup>st</sup> century. There have been indications that the prevalence has reached a plateau in high-income countries, yet the prevalence is increasing in poorer parts of the world. The same tendencies are seen within richer countries, with higher prevalence in more disadvantaged groups. Despite many ambitious attempts, an effective solution has not yet been found. Family-based early prevention interventions targeting the whole population has been called for, as well as more studies aiming at understanding factors that predispose for childhood obesity or moderate the outcomes of interventions. The cluster-randomized PRIMROSE trial had the aim of primary prevention of childhood obesity. It was based on Motivational Interviewing (MI) and cognitive behavioral principles, and delivered to parents within Swedish child health care services.

**Aims:** The overall aim of this thesis was to investigate the long-term results of the PRIMROSE trial in terms of intervention nurses' MI proficiency and children's weight status at follow-up, and to gain further understanding of the results by exploring the experiences of nurses and study coordinators who had worked in the trial, as well as investigating parental risk factors for children's weight status.

**Methods:** In Study I the MI proficiency level among nurses who had participated in the PRIMROSE trial was explored after the nurses had received the full training package of workshop and supervision. Proficiency at follow-up and potential predictors were also analyzed. In Study II the effect of the PRIMROSE intervention in terms of children's weight status was investigated, as well as potential moderators of the effect. Study III had a qualitative approach and intervention nurses and study coordinators who had worked in the trial were interviewed. In Study IV we explored parental self-efficacy, health behaviors and weight status as potential risk factors for children's weight status.

**Results:** The nurses' proficiency levels after completing the training was generally low, and the results did not change at follow-up. There were no long-term effects of the PRIMROSE intervention on children's weight status, and no significant moderators. The analyses of potential predictors of children's weight status yielded no significant results except for strong associations between parents and children's anthropometry. The interviews with the nurses and study coordinators revealed two overarching themes: "The nurses felt it was rewarding to participate in the trial, but challenging to combine working with the intervention with regular work at the child health care center"; and "The study coordinators felt they were in a difficult position handling the conflicting needs of the research group and the nurses' commitment to usual child health care services". The importance of support, encouragement and clear communication was emphasized, as was adaptation of the training in MI to the setting and target group. Stress and lack of time seem to have been major barriers to delivering the intervention as it was intended.

**Conclusions:** The results of the PRIMROSE trial are in line with previous prevention trials targeting individuals' diet and PA, indicating that we need to shift our focus. Tackling obesity demands a system approach including upstream interventions also targeting the policy level. In addition, the multifactorial etiology of childhood obesity points to the importance of multifactorial solutions, and there's a need for more high-quality research aiming to increase our knowledge about modifiable predisposing factors and moderators. In addition, the often-reported challenges in regards to practitioners' stress levels and difficulties combining regular work duties with working in clinical trials indicates the importance of organizational support.

## LIST OF SCIENTIFIC PAPERS

- I. **Proficiency in Motivational Interviewing among Nurses in Child Health Services Following Workshop and Supervision with Systematic Feedback**  
Enö Persson J, Bohman B, Forsberg L, Beckman M, Tynelius P, Rasmussen F, Ghaderi A  
*Plos One*, 2016 (11(9))
- II. **Prevention of Childhood Obesity in Child Health Services: Follow-Up of the PRIMROSE Trial**  
Enö Persson J, Bohman B, Tynelius P, Rasmussen F, Ghaderi A  
*Childhood Obesity*, 2018 (14(2))
- III. **Experiences of Nurses and Study Coordinators in a Childhood Obesity Prevention Trial Based on Motivational Interviewing within Swedish Child Health Services**  
Enö Persson J, Leo Swenne C, von Essen L, Bohman B, Rasmussen F, Ghaderi A  
*Submitted*
- IV. **Parental Self-efficacy, Health Behaviors and Body Size in Relation to Childhood BMI, Overweight and Obesity at 5 years of age - Prospective Findings from the Control Cohort of the PRIMROSE Trial**  
Enö Persson J, Tynelius P, Bohman B, Rasmussen F, Ghaderi A  
*Submitted*

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## **LIST OF ABBREVIATIONS**

BMI	Body Mass Index
CHC	Child Health Care Center
FFQ	Food Frequency Questionnaire
GEE	Generalized Estimating Equations
ICC	Intra-Class Correlation Coefficients
MI	Motivational Interviewing
MITI	Motivational Interviewing Treatment Integrity code
PSE	Parental Self-Efficacy
PSEPAD	Parental Self-efficacy for Promoting Healthy Physical Activity and Dietary Behaviors in Children Scale
RCT	Randomized Controlled Trial
SCT	Social Cognitive Theory
SE	Self-Efficacy
SEP	Socioeconomic Position
WHO	World Health Organization

# 1 BACKGROUND

## 1.1 CHILDHOOD OBESITY

### 1.1.1 Definitions

The most common way to classify obesity and overweight is the Body Mass Index (BMI), which refers to a person's weight in kilograms, divided by the square of his or her height in meters ( $\text{kg}/\text{m}^2$ ). BMI is not as sensitive as some other measures, and has limited ability to differentiate between body fat and lean (fat free) mass (1). The accuracy of BMI as an indicator of adiposity varies according to the level of body fat, and is more sensitive in indicating excess adiposity in relatively fat children (2). However, BMI is a commonly used, in-expensive, simple and noninvasive measure of overweight and obesity in a population, and correlates to body fat and associated health risks (2).

According to international classification, a BMI greater or equal to 25 is considered as overweight, while a BMI greater or equal to 30 is considered obese. Yet the cut-offs for overweight and obesity used for adults are not reasonable for children, considering that children's normal BMI change over time depending on the age and sex of the child, thus BMI-cut offs for children needs to be adjusted for these variables. The International Obesity Task Force (IOTF) established the most widely used definition of childhood obesity, which corresponds to adult cut-off points for overweight and obesity (3).

### 1.1.2 Prevalence

According to WHO, childhood obesity is one of the most serious health challenges of the 21st century (4). The prevalence of overweight and obesity among children has increased dramatically between 1980 and 2013 (5). In 2013, it was estimated that 42 million children under the age of 5 were overweight or obese (4). There have been indications that the prevalence is leveling off in high-income countries, yet the levels are increasing in poorer parts of the world (6). The same pattern has been reported within high-income countries, with higher prevalence among groups with lower socioeconomic position (SEP) (7-9). SEP is usually defined according to education and/or income, with the strongest evidence for an inverse association between parental educational level and child weight status(7).

There are no current national weight data for Swedish preschool children, but a study conducted in south-western Sweden in 2016 revealed that 10.7 % of boys and 13.2% of girls were overweight or obese at the age of 4(9). Another regional study from 2009 indicated that the prevalence of overweight (including obesity) might be leveling off or declining among preschool children (10) and among 8-12 year olds (11, 12). According to county specific reports, large variations by (and also within) regions exist. According to a study from 2008 11% of 4-year old children in Stockholm born in 2007 were overweight or obese, while in Västernorrland up to 20% of 4-year old children were overweight or obese (13). In Stockholm in 2018, 8.8% of 4-year olds born 2013 were overweight and 1,8% obese(14). As in other rich countries, childhood obesity and overweight in Sweden are more prevalent among children in socially disadvantaged groups (9, 13, 14).

### **1.1.3 Consequences**

Childhood obesity has been linked to a wide range of health consequences, such as metabolic syndrome, dyslipidemia, hypertension, asthma, low self-esteem and decreased quality of life (15, 16). The social and psychological consequences seem to vary in different subgroups and settings, and might depend on cultural norms in the specific context (17). Overweight and obese children are also at higher risk of becoming overweight or obese adults (18, 19) and consequently at risk of obesity-related adult health risks and morbidity (20, 21). However, the majority of obese adults were not obese in childhood or adolescence (19) hence a population-based approach targeting young children may be a preferable target for prevention.

## **1.2 MODIFIABLE RISK FACTORS**

### **1.2.1 Obesogenic environments**

The fundamental cause of overweight and obesity is considered to be an energy imbalance between calories consumed and calories expended, but the reasons for this imbalance are complex and multi-dimensional. In addition to diet and level of physical activity (PA), childhood adiposity have been linked with many other possible predisposing factors such as genetics, epigenetics, intrauterine environment, feeding behaviors, the microbiome, toxic chemicals and more (15, 22, 23).

The almost doubled prevalence of obesity worldwide since the 1980's indicates that environmental factors, and their interaction, play a vital role (24). It has been suggested that changing eating patterns have contributed to the increase in adiposity among children, such as larger portion sizes, increased fast-food consumption, easy access to inexpensive energy-dense foods that are high in sugar and salt, fewer family-meals and lower dietary quality(25). An increase in sedentary behavior and decrease in PA in western societies have also been suggested to contribute to the obesity epidemic(26). There is a lack of convincing evidence regarding the specific dietary components and levels of physical activity (PA) and sedentary behaviors that predicts young children's adiposity (27-29). However, sugared drinks have been consistently associated with childhood overweight and obesity (29, 30).

The "obesogenicity" of an environment has been defined as "the sum of influences that the surroundings, opportunities, or conditions of life have on promoting obesity in individuals or populations"(31). According to this framework, the obesogenic environments are either on the micro-level (e.g. schools, workplaces, homes or neighborhoods) or macro-level (e.g. education and health systems, government, the food industry and the society's attitudes). Food intake and PA are thought to mediate the effect of the broader environments on obesity(31).

### **1.2.2 The obesogenic home environment**

Parents are considered to be important potential contributors to obesogenic home environments, as they have the ability to influence their children by various pathways (32-34). Parental weight status is considered to be one of the strongest predictors of preschool children's adiposity, and this is likely explained by hereditary, environmental and social factors (35-41). Large twin studies indicate that shared environments are the main factor influencing young children's diet, and as the child gets older both genes and shared

environments are important contributors (42, 43). Children might be particularly susceptible to influences by their caregivers during early childhood, a period characterized by plasticity and high level of parental control over children's environments(44).

Studies show consistent findings regarding the associations between parents' and young children's food intake (33, 34, 45) and PA (33, 46). However, these associations are generally in the lower range and based on self-report measures and cross-sectional study designs. The interacting processes that could potentially explain the associations (although modest) between parents and young children's health behaviors remain to a large extent unclear (34, 47-49). Nevertheless, it has been suggested that parents are influencing their children's health behaviors by for example acting as role models for healthy eating and PA (34, 48, 50), and influencing the availability of different foods (34, 50, 51) as well as providing encouragement and social support for engagement in PA(47) and healthy eating(49). Thus, parents' own dietary and PA habits could potentially predict the development of overweight and obesity in their children. However, there's a lack of prospective studies investigating whether parental diet and PA predict young children's weight status, and so far the results have been inconclusive (51-53).

### **1.2.3 Parental self-efficacy**

It is recommended that intervention efforts should be based on underlying theory (54). A prominent theory for behavior change is the social-cognitive theory (SCT), which is the most commonly used in childhood obesity prevention interventions (55). It refers to a dynamic interplay between interpersonal, behavioral and environmental factors. In SCT, individuals are perceived as agents intently influencing their life conditions (56). In intervention research, application of SCT is often characterized by efforts to increase the client's perceived self-efficacy (SE). SE refers to beliefs in one's ability to successfully organize and execute specific behaviors (56). According to SCT, SE is essential to people's motivation to take action, and to stay persistent when facing setbacks. It is not a overall belief about oneself, but differ across domains, and within these domains SE depends on the specific situation (56). In the area of obesity prevention, SE could refer to a person's beliefs in his or her capacity to accomplish health-behavior change in a specific area, for example healthy eating (57).

SE is considered to be a strong predictor of professional behavior, such as attaining goals, persistence when facing obstacles, and managing stress related to work (56, 58). In a study of the role of practitioner SE on implementation of an evidence-based parenting intervention in primary care, SE was positively associated with implementation in terms of proportion of families receiving the full intervention (59).

Parental SE (PSE) can refer to different aspects of parenting, and in this thesis it refers to parents' beliefs in their ability to impact their children's healthy and unhealthy behaviors, which have been positively associated with preschool children's diet and PA (60-63). However, these studies mainly focuses on maternal PSE, and their cross-sectional designs hinder causal inferences. There are a limited number of studies examining the potential relationship between PSE and children's weight status, and these studies are also predominantly cross-sectional, focus on the mother and show inconclusive results (61, 62, 64, 65).

## **1.3 PREVENTION**

It remains to identify suitable, feasible, and sustainable strategies of responding to the burden of adult and childhood obesity. Despite many ambitious attempts by leading researchers, behavioral interventions directed towards adults or children have only been able to demonstrate modest or no sustained effects over time (66-68). In addition, there might be ethical problems associated with letting people go through the possible emotional and physical side-effects of losing and gaining weight multiple times (67). Surgery is considered to be an effective treatment but is costly and with potentially serious side-effects, and have considerable ethical implications when used for youth (67). The limited long-term effectiveness, availability and cost-effectiveness of treatment interventions, indicates the importance of preventive efforts (67). One way of differentiating between levels of prevention is by primary, secondary and tertiary strategies, which can be implemented at both individual and population level.

### **1.3.1 Primary prevention**

Primary prevention refers to interventions to prevent the occurrence of disease before it develops (69). In terms of obesity prevention this could involve campaigns directed to the public about the costs and benefits of different lifestyle choices, taxes on unhealthy food, and public-based programs to prevent unhealthy behaviors. Secondary prevention aims at the early recognition (e.g. screening) of disease to limit its occurrence, for example collecting growth charts on children and counseling on healthy lifestyle behaviors. Tertiary prevention focuses on limiting the consequences of disease (69), for example obesity treatment like diet or surgery.

Due to the health consequences, the lack of effective treatment options, and the potential risk of stigma if targeting specific high-risk groups, primary prevention appears to be the best option to address this growing public health concern (70). In addition, dietary and physical activity habits are established early in life and become less malleable in later life (71).

Reviews and meta-analyses that combine primary and secondary prevention trials in the analyses show inconsistent findings, with most trials conducted in educational settings with school-age children and with short-term outcomes (72-74). A systematic review and meta-analysis of prevention RCTs in primary care showed no effect on weight-related outcomes for children aged 0-5 years (72), and a systematic review of RCTs targeting children under the age of 5 concluded that no study has been able to demonstrate an effect on weight gain or BMI, but in some studies small effects on dietary and/or PA/sedentary behaviors have been reported (75).

In 2011, a Cochrane review combining primary and secondary prevention randomized controlled trials (RCTs) was published (74). However, the majority of the included studies were conducted in school settings with children ages 6-12 years. The authors concluded that prevention among preschool children showed promise, but only eight of the studies included children younger than 5 years. In 2019, an update of the Cochrane review was published, including 39 RCTs targeting children ages 0-5 years (76). The authors concluded that there were moderate-certainty evidence for interventions combining diet and PA to be slightly effective on BMI and zBMI for this age group, however the effect was very small and there

was a lack of long-term follow-ups (77). In addition, subgroup analyses of settings showed that interventions delivered in childcare or preschool (n = 8) had no effect, contrary to interventions delivered at home or in the community (76).

In a systematic review from 2012, only focusing on interventions with the aim of primary prevention, 29 RCTs with weight-related outcomes were identified, of which only two were directed towards preschool children (70). One of these studies showed an effect for girls only, and the other showed no effects (70).

In regards to potential moderators of effect in parental interventions directed towards young children, child age, sex, ethnicity or baseline weight of the child or parent does not seem to influence the outcome (68). The results from two meta-analyses investigating moderators of effect of preventive interventions, suggest that interventions with simple one-mode designs are more effective than more complex methods (68, 78), and that interventions with shorter duration might be more effective than longer interventions (78). In addition, stronger effects have been detected for children and adolescents relative to preadolescents and in studies with self-selected recruitment, but no moderating effect was found for improvements in diet or exercise, sedentary behavior reduction, ethnicity, parental involvement or delivery by trained professional interventionists (78).

### **1.3.2 Family-based prevention**

It has been suggested that preventive efforts are likely to have optimal effects if started in early childhood, and if directed towards the parents. A systematic review specifically exploring parental influence in interventions for 2 - 6 year old children concluded that all interventions reported a positive effect on at least one healthy child behavior and/or child BMI (71). However, the studies in this review were heterogeneous and low in number, and had multiple methodological limitations, which made it hard for the authors to reach any firm conclusions (71). A meta-analysis of RCTs aimed at reducing early childhood obesity with programs involving parents showed a significant, yet small, average effect size, but the effects was not sustained at long-term follow-up (68).

In conclusion, the overall evidence-base for prevention of childhood obesity is weak, with most systematic reviews showing small or no effects (72, 75, 78-81). It has been suggested that new methods for childhood obesity prevention should be evaluated, and one of the suggested methods is Motivational Interviewing (MI) (82).

### **1.3.3 Motivational interviewing**

MI is an efficient and brief method that helps preparing people for behavior change (83). It is a client-centered, collaborative counseling style, which aims to facilitate clients' motivation and commitment to behavior change by helping them to explore and resolve ambivalence about making adaptive changes (83). MI is a style of communicating rather than a set of techniques. The underlying mind-set is called the Spirit of MI, and is characterized by partnership, acceptance, compassion, and evocation (i.e., the belief that people have what is needed for change within them and that the therapist's task is to help evoking it). The focus

on strengthening the clients' confidence in their ability to change their behavior is in line with the concept of SE, and considered to be one of the effective mechanisms of MI (83).

A large body of research on MI has been conducted and generally shows small to medium effect sizes, with the strongest evidence for the treatment of addictions (84, 85). However, there is a high degree of variation in effects across studies, sites, and clinicians, even when the disorder and the target population are the same, and there has been a call for more research on potential moderators of outcome (83-85).

#### *1.3.3.1 Training in MI*

There has been a growing demand for spreading MI into clinical practice, perhaps due to its evidence-base, brevity and applicability. However, long-term acquisition and sustainment of MI proficiency requires extensive training followed by prolonged supervision (86-88) and previous studies show differences regarding practitioners' skills in delivering MI (83). Reviews of MI training show that most studies report increases in participants' MI skills post workshop (86, 89, 90). Nevertheless, available studies show a high degree of diversity in training format, characteristics of participants and outcome measures, (86, 89, 90). A meta-analysis focusing on sustaining skills in MI after workshop showed that studies that did not include training after workshop described eroding proficiency over a six-month period (88). Studies that included supervision or systematic feedback after workshop reported maintained skills after six months. The combination of systematic feedback and supervision was somewhat more effective than supervision only. In addition, increasing the frequency and number of hours of post-workshop training, and the time period during which it occurred, affected skill retention in a positive direction. The authors emphasize the need for more rigorous study designs and longer follow-ups (88).

Few studies have explored what post-training efforts are most effective. In a study comparing different MI training methods (91) further coaching and/or feedback after the workshop led to improved skills. Three different supervisory settings were compared, and outcome in terms of MI skill levels did not differ, and the combination of both coaching and systematic feedback didn't lead to improved results compared to either of the methods alone. Another study comparing tape-recorded supervision and tele-conferences found that the outcomes of the different supervisory conditions were the same (92). Possible moderators of the effect of MI training have been suggested, for example practitioners' counseling skills at baseline, motivation to learn MI, initial level of empathy, educational level, and personality traits (87, 89, 91, 93, 94).

#### *1.3.3.2 MI in childhood obesity prevention*

A systematic review from 2015 of studies using MI components in the treatment of childhood obesity (ages 2 to 11) found six eligible studies, of which half of them had significant results on BMI. The authors concluded that more studies are needed within this field (95). A study within primary care investigated the effect of MI counseling compared to usual care targeting parents of overweight and obese preschool children. The children in the intervention group showed a significant reduction in BMI over two years compared to the control (96).

Although MI also has been suggested to be a suitable method for prevention of childhood obesity (82), few studies have investigated MI as a counseling tool for preventing childhood obesity, and the attempts made so far have shown weak or no effect in children and their parents (97-100). However, it has been proposed that future studies are needed; with more rigorous designs, more comprehensive MI training and higher fidelity (99, 100). In a pilot study exploring feasibility of MI in primary care addressing obesity prevention among 3 to 7 year old children, the results were non-significant. However, the authors conclude that the results still showed promise, and suggest that MI should be evaluated in future, more rigorous studies, with more extensive MI training (100). Taveras and colleagues (99) examined the effectiveness of an MI-based obesity intervention directed toward families of 2 to 6 year old children in primary care. There was no significant effect on BMI after one year(99) or at two-year follow-up(101). The authors discuss potential explanations to the lack of effect, mentioning limited fidelity and the possibility that parents choose target behaviors with low impact on BMI (99). Nyberg and colleagues (97) conducted a cluster RCT to investigate the effectiveness of a preventive parental support program directed towards families of 6 year-olds in Swedish schools situated in socially disadvantaged areas. No effect on BMI was detected, despite satisfactory fidelity and reporting of high MI competence among the practitioners (97, 102).



## **2 AIMS**

The overall aim of this thesis was to investigate the long-term results of the PRIMROSE obesity prevention trial, in terms of intervention nurses' MI proficiency and children's weight status at follow-up, and to gain further understanding of the results by exploring the experiences of nurses and study coordinators who had worked in the trial, as well as investigating parental risk factors for children's weight status.

### **2.1 SPECIFIC AIMS**

- To explore the MI proficiency level among nurses who had participated in the PRIMROSE trial, after they had received the full training package of workshop and nine sessions of supervision, and at 14 months follow-up. A secondary aim was to investigate potential predictors of the outcome.
- To examine the effect of the PRIMROSE intervention in terms of children's weight status at 1 year follow up. A secondary aim was to explore potential moderators of the outcome.
- To explore the experiences of intervention nurses and regional study coordinators who had worked in the PRIMROSE trial. A secondary aim was to propose suggestions to be taken into consideration when planning future similar trials.
- To investigate whether parental self-efficacy, dietary intake, physical activity and anthropometry when the children were 9 months old, predicted children's BMI and weight status at the age of 5, by analyzing data from the control cohort of the PRIMROSE trial.



### **3 THE PRIMROSE TRIAL**

PRIMROSE was a cluster RCT conducted within child health services in eight Swedish counties between 2008 and 2015 (103). The intervention had the aim of primary prevention of childhood obesity and was directed towards first-time parents at child health care centers (CHCs). By the use of balanced (1:1) randomization within each county, 31 CHCs was allocated to the intervention and 28 to the control. Families including 1369 children agreed to participate in the trial and provided written informed consent. Parents who were about to change their CHC, had severe family problems, or did not speak Swedish were excluded. The control group received care as usual, i.e. the regular health check ups at the CHCs, which are attended by nearly all Swedish parents from the birth of their child up to approximately 5.5 years of age.

The intervention was manual-based and delivered to the parents by nurses at the CHCs. It consisted of nine sessions; six individual, two by telephone and one in a group format. The parents participated in their first session when their child was approximately 9-10 months old, and the last session when the child was about the age of 4. The intervention was developed within the theoretical framework of SCT and also included cognitive behavioral principles. It was delivered within the frame of MI. The aim of the intervention was to promote healthy dietary and PA habits among the parents, for them to be healthy role models for their children. During the later sessions the parents were also given more specific advice on how to influence their children's healthy eating and PA. The parents and nurses together formulated home assignments to work with between sessions. The manual contained information and instructions for each session. Information about healthy and unhealthy behaviors was included in some sections, and could be offered to the parents if needed. Please see Table 1 for more details regarding the content of the intervention.

The effects of the intervention (when the parents had attended all the sessions and the children were about four years old) have been evaluated in a previous study(104). The results showed no effect in terms of children's BMI, WC or prevalence of overweight (including obesity). However, there was some evidence of an effect on dietary habits, but the authors conclude that the results should be interpreted with caution due to potential reporting bias (104).

#### **3.1 THE NURSES' TRAINING**

The nurses took part in a five-day workshop that included an overview of nutrition, PA, SCT and cognitive behavioral theory(105). The workshop included 3.5 days of training in MI. The MI training addressed the learning stages 1 to 5 out of the eight suggested learning stages (106): The spirit of MI, client-centered counseling skills, recognizing and reinforcing change talk, eliciting and strengthening change talk, and rolling with resistance. The lectures included didactic presentations, experiential exercises, role-play demonstrations and viewing of video demonstrations, and the nurses also practiced the skills in exercises and role-plays. The manual contained a short summary of the MI skills that the nurses had learned during the training. In addition, the nurses had access to a website which contained the manual,

materials from the lectures, video recordings of the workshop sessions and role-plays of MI-principles.

After the workshop, the nurses received supervision by telephone by professional MI trainers on nine audio-recorded sessions. The first four supervised sessions were self-selected and the last five were based on sessions with randomly sampled parents who took part in the PRIMROSE intervention. Session number 1 and 5 to 9 were coded according to the Motivational Interviewing Treatment Integrity (MITI) code (107), and the supervision was based on the recording and the protocol.

The nurses' proficiency in MI after the workshop and the first four sessions of supervision has been previously published(105). The results revealed that the nurses had not reached the beginning proficiency thresholds on any of the MITI indicators, and effect sizes were small(105).

**Table 1. Overview of the PRIMROSE intervention**

Session	Child age (months)	Type	Duration (min)	Description
1	9-10	Individual	90	<ul style="list-style-type: none"> <li>Information about the intervention</li> <li>Parents as role models</li> <li>Create motivation</li> </ul>
2	11	Group	90-120	<ul style="list-style-type: none"> <li>Repetition of content from previous session</li> <li>Presentation about obesity, nutrition and physical activity</li> <li>Discuss the parents' own health behaviors and what could change/ what impedes change</li> <li>Home assignment: Food registration</li> </ul>
3	12	Individual	45	<ul style="list-style-type: none"> <li>Discuss the parents' health behaviors</li> <li>Formulate goals together</li> <li>Discuss children's health behaviors</li> <li>Formulate goals together in regards to the child</li> </ul>
4	18	Individual	30-45	<ul style="list-style-type: none"> <li>Motivate parents to continue being role models</li> <li>Follow-up of goals</li> <li>Discuss how to be healthy in everyday life</li> <li>Reflect with parents on child's weight development</li> <li>Formulate goals regarding parents' and child's health behaviors</li> </ul>
5	24	Individual	45	<ul style="list-style-type: none"> <li>Increase parental self-efficacy</li> <li>Motivate parents to maintain health behaviors</li> <li>Follow up of goals</li> <li>Reflect with parents on child's weight development</li> <li>Discuss handling of risk situations for unhealthy behaviors</li> <li>Home assignment: Food registration, handout with questions to reflect upon until next session</li> </ul>
6	30	Telephone	15	<ul style="list-style-type: none"> <li>Discuss the home assignment</li> <li>Follow-up of goals</li> <li>Continue motivational work</li> <li>Encourage parents and reinforce successes</li> <li>Support problem-solving of setting limits of children's</li> </ul>

unhealthy behaviors

7	36	Individual	45	<ul style="list-style-type: none"> <li>• Follow-up of goals</li> <li>• Repeat all goals of the intervention</li> <li>• Reflect with parents on child's weight development</li> <li>• Continue motivational work</li> <li>• Increase parental self-efficacy</li> <li>• Discuss challenges and how to address them</li> <li>• Write maintenance plan together with parents</li> <li>• Home assignment: Food registration, handout with questions to reflect upon until next session</li> </ul>
8	42	Telephone	15	<ul style="list-style-type: none"> <li>• Discuss the homework</li> <li>• Follow-up of goals</li> <li>• Continue motivational work</li> <li>• Reinforce parents' confidence and autonomy</li> <li>• Follow-up on the maintenance plan</li> </ul>
9	48	Individual	45	<ul style="list-style-type: none"> <li>• Continue motivational work</li> <li>• Reinforce parents' confidence and autonomy</li> <li>• Discuss how to maintain the child's health behaviors during childhood</li> </ul>



## 4 SUMMARY OF THE STUDIES

### 4.1 STUDY I

In Study I we explored the nurses' MI proficiency levels after they had received the full MI training package of five additional supervision sessions including systematic feedback on observed practice. We also investigated if initial level of empathy, years working in child health services, previous MI training and SE predicted improvement in MI skills. In addition, we explored potential changes in proficiency levels after nine sessions of supervision and approximately 14 months later.

#### 4.1.1 Methods

##### 4.1.1.1 Data collection

Background information in terms of the nurses' sex, age, education, previous experience working within child health services and previous training in MI were collected when the nurses enrolled in the PRIMROSE trial.

MI proficiency was measured using a Swedish version of MITI 3.0(108). MITI is a behavioral coding system that includes both the rater's overall impression of the clinician's competence on 5-point Likert-type scales, and frequency counts of specific behaviors (which can be combined into summary scores). In study I, the following scores were used: MI spirit, empathy, percent complex reflections, reflection – to – question – ratio, percent MI adherent behaviors, and frequency of MI adherent and MI non – adherent behaviors. The inter-rater reliability of the MITI coding in the PRIMROSE trial has been analyzed using intra-class correlation coefficients (ICCs)(105). The ICCs ranged from poor to excellent (from .35 to .85), with percent complex reflections qualifying as poor, empathy and MI adherent behaviors as fair while the remaining scores were either adequate (MI spirit, empathy, MI non-adherent behaviors) or excellent (percent open questions, reflection-to-question ratio, MI adherent behaviors)(105).

The nurses' SE was measured with a questionnaire that was developed for the PRIMROSE trial(109), with the purpose of assessing the nurses' SE in terms of influencing the parents to promote their children's healthy behaviors.

##### 4.1.1.2

The data was analyzed using independent t-tests for group comparisons in the dropout analyses, and paired t-tests for within - subject changes regarding MI proficiency over time. Effect sizes were calculated with Cohen's d. Potential predictors of improvements in MI proficiency between four and nine sessions of supervision were analyzed using linear regression models.

### **4.1.2 Results**

The number of participants decreased during the period of supervision. After the workshop, 51 nurses provided a recorded session for MITI coding, after four sessions of supervision 39 nurses submitted a recording, and after completed training recorded sessions were obtained from 33 nurses. These nurses were all female, had specialist training, and 57.6 % had previous MI training with a mean length of 24.7 hours. At the different assessment points, there were no significant differences between those remaining in the trial and those who had dropped out, in terms of age, prior MI training or MITI scores after workshop. However, after nine sessions of supervision the non-completers had shorter work experience than the completers.

When examining the mean duration between the trial and supervision sessions, it was evident that the time periods between sessions had been longer than intended, e.g. the mean time between session 5 and session 10 (the session following the last supervision session) was 23.2 months instead of the intended 15 months. However, the mean session length (19.61 minutes) was close to the intended 20 minutes.

After having received the whole training package of nine sessions of supervision, the nurses stayed on approximately the same scores on the MITI indicators as reported after four sessions of supervision (mean differences ranged between -1.12 and 0.10). The scores on two of the indicators were significantly different; percent complex reflections had improved and MI adherent behaviors had deteriorated. The percentage of nurses who reached the threshold for beginning proficiency ranged between 18.2 to 54.5 % across indicators. Only one nurse reached the thresholds on all indicators. There were no significant differences between nurses who had reached beginning proficiency on the different indicators, compared to those who had not (in terms of work experience, prior training in MI, initial level of empathy after workshop, or SE at baseline). The results of the regression analyses also showed that none of these variables predicted change in proficiency scores after four and nine sessions of supervision, and neither did the time that had elapsed between these sessions.

There were no significant differences between MITI indicator scores measured after nine sessions and at follow-up approximately 14 months later, except for MI spirit, which showed a significant increase ( $t(27) = 2.52, p = .018, d = 0.49$ ).

## **4.2 STUDY II**

Study II is a 1-year follow-up of the PRIMROSE trial. The primary aim was to investigate if the intervention had an effect on the children's BMI and weight status when the children had reached the age of five. The secondary aim was to examine the potentially moderating effect of parental baseline variables in terms of BMI, weight status, WC, dietary habits, PA and educational level.

## **4.2.1 Methods**

### *4.2.1.1 Data collection*

Nurses working in the trial assessed the children's height and weight using validated scales and stadiometers. Gender and age specific classifications for overweight and obesity were based on internationally established criteria(3). Since BMI was rarely measured at exactly age five, a non-parametric regression method was used to predict the children's BMI at that age(110).

Parents answered a food frequency questionnaire (FFQ) that had been developed for the PRIMROSE trial and validated against an 8-day food diary(103). The results showed good validity in terms of mother's fruit intake, acceptable validity in terms of mothers' intake of discretionary calories (items high in energy but with little nutritional value) and sugared drinks, but less strong validity for mothers' intake of vegetables(103). Healthy and unhealthy intake was classified into two categories based on the recommendations from the Swedish National Food Administration(111). Weekly intake of fruit, vegetables and fish were combined into a variable representing a healthy diet, and weekly intake of French fries, sugared drinks and discretionary calories were combined to represent an unhealthy diet.

Parental PA was measured by the Baecke questionnaire, which has shown adequate construct validity and reliability(112). The questionnaire includes three subscales; PA at work, sport during leisure time and PA during leisure time (excluding sports). In Study II, z-scores of the parents' total scores were analyzed.

Parents also answered questions about their level of education, height and weight, and were asked to measure their WC by using a measuring tape provided by the research team.

### *4.2.1.2 Analysis*

All analyses were conducted using generalized estimating equations (GEE), considering the cluster-randomized design. Differences between the control and the intervention were analyzed using linear regression models on continuous outcomes and Poisson regression models on binary outcomes. Potential moderators were explored with interaction models (group\*moderator) and were adjusted for parental education, age and country of birth. Bonferroni corrections for multiple comparisons were done post hoc.

## **4.2.2 Results**

At post-intervention when the children were 4 years old, anthropometric data of 1148 children were collected. At follow-up one year later, data of 1091 children were obtained, resulting in an attrition rate of 5%. The participants remaining in the trial did not significantly differ from those lost to follow-up in terms of baseline characteristics.

There were no significant differences between the intervention and control group regarding children's BMI, prevalence of overweight (including obesity) or obesity, [BMI difference = -0.13,  $p = 0.29$ , overweight relative risk (RR) = 0.96,  $p = 0.78$ , obesity RR = 0.57,  $p = 0.20$ ].

The results did not differ between boys and girls. No moderator remained significant after correction for multiple comparisons.

### **4.3 STUDY III**

In Study III we had a qualitative approach and explored the experiences of the intervention nurses and regional study coordinators in the PRIMROSE trial. A secondary aim was to generate suggestions to consider when planning future trials.

#### **4.3.1 Methods**

##### *4.3.1.1 Data collection*

Seven to eight years since the start of the PRIMROSE trial, and one to four years after the nurses had delivered their last intervention session, 24 nurses and five study coordinators were asked to participate in Study III. Nine nurses and three study coordinators agreed to be interviewed. The data was based on face-to-face semi-structured interviews, conducted at the participants' places of work. The questions were based on two interview guides with open-ended questions and suggested follow-up questions. The length of the interviews varied between 28 and 48 minutes and were audio-recorded and transcribed verbatim.

##### *4.3.1.2 Analysis*

Content analysis (113, 114) was used to analyze the data. Content analysis involves several steps with the aim to reach a broad and condensed description of a phenomenon(113). The transcripts were repeatedly read and meaning units (text fragments that included some information related to the aim of the study) were identified. These units were subsequently condensed and coded and the codes were merged into categories. From these categories higher order categories were created, in a process of discussion back and forth among the researchers. Lastly two overarching themes(113) were generated, based on an underlying meaning, or latent content of the results.

#### **4.3.2 Results**

All participants were female and had specialist training. The nurses had a mean age of 47 and had worked in child health services for a mean of 9.8 years, and the coordinators were 47, 57 and 58 years old.

The analysis resulted in two overarching themes: The nurses felt it was rewarding to participate in the trial, but challenging to combine working with the intervention with regular work at the child health care center; and "The study coordinators felt they were in a difficult position handling the conflicting needs of the research group and the nurses' commitment to usual child health care services". The reflections from the nurses and study coordinators had a high degree of resemblances, and the results pointed to several challenges during their participation in the PRIMROSE trial:

- The training was by some respondents believed to be deficient, and lacking of examples related to work at CHCs. Long time intervals between the workshop and the first supervision session might have impeded some nurses' skill retention.
- Stress and not enough time to work with the trial seem to have been major barriers for many of the nurses, especially for those with a heavy workload and no available substitute nurses.
- Parents' stress and expectations were also described as challenging. Some parents gave the impression of considering the intervention to be too time consuming, especially during later stages when both parents were back at work. It was also reported that some parents reacted negatively to the MI method, and had expected more direct advice. In addition, it was proposed parents with higher SEP benefitted more from the intervention, that mostly healthy and motivated parents agreed to participate and stayed in the trial, and that stigma might have hindered the parents who would have needed the intervention the most.
- Some nurses' and coordinators described insufficient communication with the research group, e.g. in regards to uncertainties about how to handle practical problems, which led to more work and stress. The coordinators sometimes had a difficult time balancing the conflicting needs of the nurses and the research team. Some nurses expressed that they would have needed more recognition for their hard work, and both nurses and coordinators accentuated the importance of being listened to and supported. The nurses felt that colleagues who also participated in the trial, the MI supervisors, and the coordinators gave them this support. The research team and the CHC manager were also mentioned.
- In addition to external challenges, the respondents also mentioned internal barriers, such as performance anxiety connected to the MI sessions and supervision. However, many nurses also expressed that participation in the trial had been enriching and meaningful, and that MI was useful in their regular work.

## **4.4 STUDY IV**

This study had a prospective design and the aim was to investigate whether parents' PSE, dietary intake, PA, BMI, overweight/obesity and WC when their children were nine months old, would predict the children's BMI and weight status at the age of five. The study sample consisted of the control cohort of the PRIMROSE trial, including 596 mothers and 418 fathers and their children.

### **4.4.1 Methods**

#### *4.4.1.1 Data collection*

In this study, the same measurements as in Study II were used in terms of children's BMI and weight status at age 5. In addition, the same baseline questions, FFQ and Baecke questionnaires were analyzed, although in Study IV dietary intake were categorized into four separate variables to represent healthy (fruit and vegetables) and unhealthy (sugared drinks

and discretionary calories) intake. From the Baecke questionnaire, the subscales sports during leisure time and PA during leisure time (excluding sports) were included.

PSE at baseline was assessed using the self-report questionnaire Parental Self-efficacy for Promoting Healthy Physical Activity and Dietary Behaviors in Children Scale (PSEPAD)(115). PSEPAD covers three subscales which were all analyzed as potential predictors; PSE for promoting healthy dietary behaviors, for limit setting of dietary or PA behaviors, and for promoting healthy PA behaviors. In addition, the z scores of the total scores were also included.

#### *4.4.1.2 Analysis*

Independent t-tests and chi<sup>2</sup>-tests were conducted for group comparisons of parents who had dropped-out and those remaining in the trial. Linear regression models were used for continuous outcomes and Poisson regression models with robust variance were used for binary outcomes. Differential effects in regards to the child's sex were analyzed by including a sex\*predictor interaction term. Children's obesity was not included in the interaction models due to low power (because of few obese children). All models were adjusted for parental level of education.

#### **4.4.2 Results**

The results from the dropout analyses revealed that a higher percentage of mothers who remained in the trial had post-secondary education compared to those lost to follow-up (60% and 39% respectively,  $p = .014$ ), and they were also somewhat younger (mean age 27 years compared to 29 years,  $p = .007$ ). The fathers' baseline factors did not differ significantly.

PSE did not predict children's BMI or weight status, except for fathers' PSE for limit-setting which predicted children's obesity. Neither did parental dietary habits predict the outcome, with the exception of father's fruit intake, which predicted children's overweight. However, the significant results in terms of father's PSE and diet should be interpreted with caution, since multiple comparisons were made. Parental PA did not predict the outcome.

Mothers' BMI, overweight, obesity and WC, and fathers' BMI, obesity and WC were strong predictors of the outcome. There were a tendency of stronger associations between mothers and daughters compared to mothers and sons.

#### **4.5 ETHICAL CONSIDERATIONS**

The Regional Ethical Review Board in Stockholm, Sweden granted approval for the PRIMROSE trial, and all participants in the PRIMROSE trial provided written informed consent.

The participants in the qualitative study were informed that only the main author, who had not been part of the planning and conduction of the primrose trial, would listen to the recordings and read the transcripts, and that their identity would be blinded to the other co-

authors. Nevertheless, some informants decided to share more sensitive information after the interviews, which could not be included in the analyses.

The issue of overweight and obesity can be sensitive due to the associated social stigma. Although all families were invited to participate, parents who were overweight or obese could potentially have reacted negatively when given the invitation. The nurses in the study were therefore instructed to emphasize that all parents were invited. However, this does not rule out potential stigma as the intervention progressed. In the interviews with nurses and study coordinators, it was indicated that parents with excess weight might have been uncomfortable answering questions about their unhealthy habits as well as being weighed and having their waists measured.

Another ethical question is whether the intervention could be harmful if given to parents who are already overly concerned with their weight and health. Maybe the Primrose intervention could influence these parents to become overly concerned with their child's weight. We have tested whether the intervention and control group differed in regards to prevalence of underweight (unpublished results), which showed no significant group difference, but we did not investigate any other possibly harmful effects of the intervention. However, considering that the focus of the intervention was on MI, parental role modeling and positive tools to influence the child (e.g. positive reinforcement and avoiding pressure and punishment), adverse effects are unlikely.

It can be assumed that many parents of young children are under a lot of stress and suffer from guilt for not being "good enough" parents. In addition, it is commonly acknowledged that behavior change is hard, and some groups of parents could have been particularly hindered to make healthy choices, due to contextual and individual factors. Hence it is possible that participation in the trial could have caused additional parental stress and guilt.

It has been argued that prevention strategies directed towards individuals, such as the PRIMROSE trial, could have adverse societal consequences in terms of increased health inequality, since those families who belong to more disadvantaged groups often benefit less from these interventions (116, 117). Also, in the PRIMROSE trial, participants were required to speak Swedish, thus groups that could be potentially at heightened risk of obesity were excluded. However, since the intervention was ineffective, this is probably not an issue, yet should be considered when planning future initiatives.



## **5 DISCUSSION**

The PRIMROSE trial was an ambitious project that was first initiated in 2005, started in 2008 and ended in 2015. The aim of the trial was primary prevention of childhood obesity by delivering an intervention based on MI and cognitive behavioral principles, to families within child health services. When the PRIMROSE trial was initiated, no one had tried to evaluate MI as a tool for primary prevention of childhood obesity before. During the planning phase of the trial, the research team received input from nurses who had previously worked within child health care services, and they also made sure to anchor the trial with managers and policy makers. The trial engaged many experts, researchers, nurses, study coordinators, CHC managers, and families in eight Swedish counties. When I started as a PhD student within the project, the last intervention session had been delivered, and most of the data had been collected.

In the following discussion, I will give a short resume of the findings from the studies included in this thesis, and how they are related to previous research. I will also try to understand how the results relate to each other and how they can give us more knowledge about challenges and opportunities in the area of childhood obesity prevention, and what we can take with us when planning future trials. I will also include some of my own reflections to give the reader the context in which this thesis took form.

### **5.1 SUMMARY AND REFLECTIONS**

#### **5.1.1 Study I**

My first task as a PhD student was to explore the levels of MI proficiency among the intervention nurses in the PRIMROSE trial after they had received nine sessions of supervision, and at 14 months follow-up. The nurses' proficiency levels after workshop and four sessions of supervision had been previously examined (105), and the results from Study I indicated that the nurses' skills had stayed on the same generally low levels, and no significant predictors were found. The study design did not allow for conclusions about causality, since there were no pre-workshop assessments and no control group. Furthermore, the MITI 3.0 thresholds are based on expert opinion and lack validity data to support them (107). Nevertheless, the nurses' scores were generally lower compared to the results of similar evaluations of MI training (90-92), suggesting that the comprehensive MI training were unsatisfactory in teaching the PRIMROSE nurses MI proficiency.

When writing the manuscript for this study, I realized that there were several potential explanations to the low proficiency scores that were related to nurses' challenges when delivering the intervention. The MITI-coders who had coded the recorded sessions informed me of nurses struggling to find target behaviors and demonstrate their MI skills, since the parents already displayed healthy habits or were motivated to make changes. In addition, accompanying children frequently disrupted the conversations. In the manuscript we also discussed other potential factors that could have disrupted the nurses' MI performance, for

example difficulties combining MI with mandatory CHC work tasks and with the PRIMROSE manual, work-related stress, and potential lack of organizational support to engage in the trial. In addition, the low MI proficiency scores could be due to long time intervals between the trial and supervision session, which by far exceeded the intended intervals and might have hindered skill retention.

### **5.1.2 Study II**

My next task as a PhD student was to investigate if the PRIMROSE intervention had an effect on children's BMI, overweight or obesity at follow-up, when the children had reached the age of five. The results from Study II showed no effect on any of the outcome variables, thus we detected no delayed effect of the intervention. The analyses of parental moderators of the outcome did not result in any significant effects that remained after corrections for multiple comparisons. The results were in line with previous obesity prevention studies based on MI (102, 118-120) and studies targeting parents of preschool children (68, 71), as well as childhood obesity prevention studies in general, which show very small or no long-term effects on weight status, regardless of quality, target group or setting (23, 121). The lack of moderating effects in Study II corresponds to the results of meta-analyses (68, 78), however there's few studies examining parents' characteristics as potential moderators (72, 73, 121, 122).

When trying to understand the lack of results, we discussed several possible factors, perhaps the duration of the intervention was too long or with too long time periods between sessions (78)? Or maybe the intervention was too complex, and would have benefitted from including fewer components (68, 78)? Once again questions regarding potential barriers when delivering the intervention came up, as well as the nurses' low levels of MI proficiency shown in Study I. During the process of writing the manuscript for Study II, I started to consider the prospect of conducting interviews with the intervention nurses and study coordinators in the PRIMROSE trial. There were so many questions that needed to be answered by the ones who had actual first-hand experience of the intervention within the CHC context.

### **5.1.3 Study III**

The aim of my third study was to explore the experiences of the nurses and coordinators who had worked in the PRIMROSE trial, and generate suggestions for improvements of future similar trials. The study had a qualitative approach, and I conducted all the interviews face-to-face at the participants' workplaces. It was highly rewarding to meet and listen to the women's stories and reflections. Some of the results were in line with what had been previously indicated, but there were also new perspectives that surfaced from the data.

During the analysis two overarching themes emerged: "The nurses felt it was rewarding to participate in the trial, but challenging to combine working with the intervention with regular work at the CHC"; and "The study coordinators felt they were in a difficult position handling the conflicting needs of the research group and the nurses' commitment to usual child health

care services”. The importance of support, encouragement and clear communication was emphasized in the interviews, as was the need for adaptation of the training in MI to the CHC setting and target group. Stress and lack of time seem to have been major barriers to delivering the intervention as it was intended, and the nurses and coordinators suggested making a future intervention briefer and simpler.

During the process of working with Study III, I became pregnant and had my first child, and started attending the regular health check-ups at the CHC. All the sleepless nights and various concerns and worries (not associated with my son potentially becoming overweight or obese in the future) that characterized this period made me humble when thinking of the parents who had taken the time to participate in the PRIMROSE trial. I think it gave me new perspectives on the responsibilities, stressors and potential guilt associated with parenthood, and how hard it can be to live up to your own standards. As my son grew older, I started to reflect more on my role in directly and indirectly influencing his eating and activity levels, a task that seemed to include many challenges.

#### **5.1.4 Study IV**

In Study IV in this thesis, we explored parental risk factors for children’s BMI and weight status. Mothers and fathers’ PSE, dietary habits, PA, WC, BMI, overweight and obesity when their children were nine months old, were explored as potential predictors of children’s BMI, overweight and obesity when the children had reached the age of five. Mothers’ BMI, overweight, obesity and WC, and fathers’ BMI, obesity and WC were strong predictors, results that were in line with previous research (35-41), however neither PSE nor parental diet or PA predicted the outcome. Few previous studies have investigated PSE in relation to children’s weight-related measures, and these had cross-sectional designs, mainly focused on mothers and yielded mixed results (61, 62, 64, 65). There is also a lack of studies with prospective designs exploring parents’ weight-related behaviors in relation to children’s weight measures, and the results are inconclusive (53, 123, 124).

We discussed several possible explanations to the lack of effect in Study IV; maybe the parents limited their children’s access to unhealthy foods, and perhaps parental support and encouragement of children’s PA are more important than their own PA (125)? Also, other caregivers than the parents might be important. A majority of Swedish children attend public daycare (126) and it has been demonstrated that they are physically most active during preschool hours (127). In addition, preschool teachers’ weight and PA has been shown to be independent risk factors for children’s weight status (128). Yet another factor that we discussed was the long time period between baseline and follow-up, and that much could have happened during this period that may have influenced the parents’ behaviors and perceptions.

The results from this study made me think more about the complexity of the different pathways of parental influence on children’s adiposity. There is obviously a strong link

between parents and children's weight status, but the reasons for this link are yet not fully understood, and most likely related to many interrelated factors.

## **5.2 THE COMPLEXITY OF THE ETIOLOGY**

Although the fundamental cause of childhood obesity is considered to be the result of a long-term imbalance between energy intake and energy expenditure, this simple statement does not take into account all the factors that predispose or add to the energy imbalance (23). By mainly focusing on trying to motivate individuals to eat less calories and more healthy foods and/or increase PA levels, we are assuming that one type of remedy will help all, although the causes of childhood obesity are complex and multifactorial and differ between individuals and contexts (23). It has been recommended that we need to focus more on identifying predisposing factors that moderate the effects of interventions or increases the risk of obesity, and how these factors interact (23, 121). This would enable us to better tailor the interventions to specific subgroups, as well as finding new targets for prevention (23).

PSE is one possible factor that could influence parents' abilities to promote healthy behaviors in their children, and subsequently the children's weight status. Cross-sectional studies have shown associations between PSE and children's health behaviors (60-63), as well as associations between parents' and children's diet and PA (45, 46, 51, 129-134). Although these associations are generally in the lower range, it could be hypothesized that PSE and parental diet and PA also would predict children's weight status, yet this was not confirmed in Study IV. The results may suggest that other risk factors for children's adiposity are more important.

Other pathways by which parents could influence their children have been suggested, for example by feeding practices, parenting strategies, and by encouraging the children's PA and limiting sedentary behaviors (34, 48, 50). However, the ways in which these processes interact with each other and with the child's characteristics are not fully understood (34). There's a tendency in the literature to interpret cross-sectional findings as unidirectional, mostly focusing on the parent influencing the child. However, the relationships are most likely bidirectional, with the child also influencing the parent (51). For example, children with heightened appetite traits and an impulsive temperament are likely more susceptible to unhealthy environmental cues and more challenging to influence in a healthier direction (34). However, more high-quality research is needed to further investigate these assumptions.

## **5.3 WAS MI NOT AN OPTIMAL CHOICE OF METHOD?**

One obvious potential explanation to the lack of effect is the nurses' low levels of MI proficiency. Maybe the intervention would have been effective if they had received more training that was better adapted to work at the CHCs? However, we can't say for sure that the MI scores reflected the nurses' actual skills, since the nurses faced several obstacles during the recorded sessions that the MI scores were based on. The reported difficulties finding target behaviors, staying focused with accompanying children, combining MI with a detailed manual and obligatory work tasks, as well as some parents demanding more advice from the

nurses, indicate that MI may not have been an optimal choice of method within this context. It could be argued that MI is unsuitable for primary prevention, considering that the aim of the method is to solve ambivalence about change (83), and parents agreeing to take part in a prevention program directed towards all parents can be assumed to be fairly motivated. It has been suggested that MI is the most effective with poorly motivated clients (135), and should be avoided with clients who are highly motivated (136). Also, combining MI with a manual has been proposed to interfere with the spirit of MI and lead to smaller effect sizes (84, 85).

Nevertheless, rather than completely discarding MI in the CHC context, an adaptation of the training and use of MI might be an option. The developers of MI suggest integrating MI in all of the practice, to help practitioners use the different MI processes flexibly and when appropriate (83). Not all MI processes aim at strengthening motivation, hence some of them can be helpful in sessions with motivated parents (e.g. engaging, focusing and planning) (83). When the parent show ambivalence about change, the nurse can focus on evocation, a process more unique to MI with the aim of strengthening motivation (83). In addition, the nurse could focus on regular CHC work tasks and giving information or advice to parents when applicable. MI does allow the practitioner to give advice or information, but suggest avoiding expressing unsolicited opinions(83). This kind of flexible use of MI would not require mandatory additional “MI sessions”, hence would not take extra time from nurses’ and parents’ busy schedules. Since it was indicated that the training may have been insufficiently adapted to work at CHCs and the nurses had trouble suppressing their previously learned style of communicating, teaching MI already at the nursing schools might promote a more natural and flexible use of the method.

#### **5.4 NURSES’ STRESS AND LACK OF SUPPORT**

Although the CHCs were financially reimbursed for their participation, the lack of substitutes were not expected, neither was the high degree of stress and time constraints among the nurses, which may have caused digressions from the intended delivering of the intervention.

The problems of time constraints, stress and challenges combining the intervention with regular work tasks have been reported in several other qualitative studies of clinicians’ experiences of working in trials (137-141), thus seem to be part of a general problem. Support and financing of research projects within the organization’s structure instead of dependence on external resources would probably benefit long-term implementation and development of research-based practice. Besides financial and organizational support, it is important to provide practitioners working in clinical trials with emotional encouragement and positive reinforcement for their efforts, as well as involving them in the process of planning, development and evaluation of the intervention (142).

#### **5.5 PARENTAL STRESS AND STIGMA**

Based on the results from Study III, some parents found the PRIMROSE intervention to be too time-consuming, which is in line with the results of several other qualitative studies on parents’ participation in clinical trials (140, 141, 143, 144). There have also been reports

suggesting that parents generally don't consider diet or physical activity as their main concern for their child (145, 146).

Another aspect regarding overweight and obesity is the social stigma associated with these conditions. Healthy behaviors are in today's society mostly regarded as individual choices, thus unhealthy behaviors and subsequent weight problems are seen as personal failures (147). In Study III, it was indicated that parents who were overweight or obese were reluctant to be weighed each session, and answer a lot of questions about their health habits. It has been acknowledged that childhood obesity studies present with additional challenges to recruitment and retention, some of which are related to stigma, and this could potentially be avoided by focusing more on health rather than obesity (148).

## **5.6 SOCIAL INEQUALITIES IN HEALTH**

There is a clear social gradient to childhood obesity, with parents' SEP having an inverse association with children's weight status (7-9). The causal pathways between SEP and weight status are not clear, but has been suggested to be related to factors such as access to recreational areas, healthy foods and leisure time activities as well as stress, knowledge and cultural beliefs (149, 150). It has been argued that the main problem for high-income countries today is inequality in health rather than poverty and health (151).

According to the experiences of some of the intervention nurses in the PRIMROSE trial, parental SEP may have influenced the parents' participation. Parents with lower SEP displayed some difficulty understanding some of the contents of the questionnaires and handouts, and one nurse expressed a concern that the newly arrived immigrants in the community would have needed help but were not able to attend the intervention due to insufficient skills in the Swedish language.

Some nurses who worked with parents with high SEP perceived these parents as highly motivated and more likely to agree to participate in the trial, yet they already had healthy habits, hence there was little room for improvement. This could be related to the concept of "diffusion of innovations", that people with higher SEP tend to adapt earlier to new behaviors, implying that the widening of health inequalities could be temporary and that groups with lower SES will catch up in time (152). The potentially higher motivation among these parents could also be related to a need for "social distinction", people from groups with higher SEP might be more inclined to display their social position by having healthy lifestyles and being normal weight, a need that might be more important in affluent countries where there are fewer material markers of social position, and some of the greatest threats to health are considered to be related to individual choices (152).

Maybe universal prevention strategies directed towards individuals, such as the PRIMROSE trial, could have an adverse effect in terms of increased health inequality, since families who belonged to a more disadvantaged group and were at more risk of their children developing overweight or obesity might have benefitted less from the intervention. It has been acknowledged that socially disadvantaged groups are harder to recruit and retain in clinical

trials (116, 153) and structural measures have been suggested to be more effective for groups who are the most exposed to risk, while measures targeting individuals have greater effects among more privileged groups (116, 117). One could argue that targeting specific sub-groups at heightened risk of obesity would be more desirable than universal prevention, but I think that such an approach might increase stigmatizing already vulnerable groups, especially if the focus is on motivating individual choices.

## **5.7 TARGETING THE OBESOGENIC ENVIRONMENT**

To avoid increased inequality in health, we probably need to shift from focusing mainly on strategies directly targeting individual behaviors, to more structural measures, such as policy changes and changes to the environment with the aim to make it easier for people to make healthy choices (116, 117). Also, the fact that a multitude of obesity prevention trials targeting individuals' diet and PA behaviors have not been able to produce any substantial effects, indicates that we need to shift our focus (23, 121). Most childhood obesity prevention studies do not attempt to influence environments outside homes, child care centers, schools and health care centers, hence more interventions also targeting the macro environment/societal level are called for (54, 75, 76, 154, 155). WHO states the following regarding strategies to address childhood obesity: "The problem is societal and therefore it demands a population-based multi-sectorial multi-disciplinary, and culturally relevant approach"(4). In addition, the preconditions in terms of different recourses of the local community highly influences the residents' opportunities (151) and the degree of successful implementation of structural measures (116), and this needs to be considered when developing new interventions. It's a great challenge to initiate interventions that have the most effect for those worst off in the society, and the reality, experiences and interests of these groups should shape the basis of new initiatives (117).

## **5.8 CONCLUSIONS**

From the results in this thesis we can conclude that a family-based primary prevention intervention based on MI and delivered in child health services had no long-term effects on children's weight status. The intervention nurses displayed generally low levels of MI proficiency that did not improve after they had completed the full training package. However, the nurses and study coordinators reported several challenges associated with delivering the intervention to the parents in the CHC context, which may have contributed to the low proficiency scores. The results of the PRIMROSE trial are in line with previous prevention trials targeting individuals' diet and PA, indicating that we need to shift our focus. Tackling obesity demands a system approach including upstream interventions also targeting the policy level. In addition, the multifactorial etiology of childhood obesity points to the importance of multifactorial solutions, and there's a need for more high-quality research aiming to increase our knowledge about modifiable risk factors and moderators of interventions. Also, the often-reported challenges in regards to practitioners' stress levels and difficulties combining regular work duties with working in clinical trials, indicates the importance of organizational support of research-based practice.



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