Motivational Interviewing to Prevent Childhood Obesity: A Cluster RCT

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abstract

OBJECTIVE: The objective was to evaluate a manualized theory-driven primary preventive intervention aimed at early childhood obesity. The intervention was embedded in Swedish child health services, starting when eligible children were 9 to 10 months of age and continuing until the children reached age 4.

METHODS: Child health care centers in 8 Swedish counties were randomized into intervention and control units and included 1355 families with 1369 infants. Over ∼39 months, families in the intervention group participated in 1 group session and 8 individual sessions with a nurse trained in motivational interviewing, focusing on healthy food habits and physical activity. Families in the control group received care as usual. Primary outcomes were children's BMI, overweight prevalence, and waist circumference at age 4. Secondary outcomes were children's and mothers' food and physical activity habits and mothers' anthropometrics. Effects were assessed in linear and log-binominal regression models using generalized estimating equations.

RESULTS: There were no statistically significant differences in children's BMI (β = −0.11, 95% confidence interval [CI]: −0.31 to 0.08), waist circumference (β = −0.48, 95% CI: −0.99 to 0.04), and prevalence of overweight (relative risk = 0.95, 95% CI: 0.69 to 1.32). No significant intervention effects were observed in mothers' anthropometric data or regarding mothers' and children's physical activity habits. There was a small intervention effect in terms of healthier food habits among children and mothers.

CONCLUSIONS: There were no significant group differences in children's and mothers' anthropometric data and physical activity habits. There was, however, some evidence suggesting healthier food habits, but this should be interpreted with caution.

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WHAT'S KNOWN ON THIS SUBJECT: With increases in the prevalence of childhood obesity, effective preventive interventions are urgently needed. It has been suggested that child health services provide a promising intervention arena and that motivational interviewing is an effective tool for primary prevention.

WHAT THIS STUDY ADDS: This large-scale intervention embedded in regular child health services and targeting early childhood obesity using motivational interviewing showed no significant effect on BMI or physical activity but did have a small positive effect on food habits among 4-year-olds.

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In 2013, it was estimated that 42 million children under 5 years of age worldwide were overweight or obese.[1] In Sweden, there are no systematically collected data nationwide for children under age 5, but based on several county-specific reports, there are large variations by region, and also within regions.[2–6] In Stockholm County, the prevalence of overweight among 4-year-olds is 11.2%, but it ranges from 7.6% to 18.6% in different neighborhoods.[6] Despite signs of stabilization or, in some areas, even a leveling off of the prevalence rate,[2] the prevention of childhood obesity remains one of the key elements in current public health strategies.

Dietary and physical activity habits are established early and become less malleable in later life.[7] Thus, primary preventive efforts are likely to operate optimally if started in early childhood. Next to environmental influences, parental practices, such as feeding styles and making healthy or unhealthy food products available at home, and also parents' nutritional knowledge and health behaviors, are of major importance for young children's emerging dietary and physical activity habits.[8–10] A recent meta-analysis, pooling the results of 50 intervention studies aimed at reducing obesity in early childhood with the involvement of parents, showed an overall significant, but small, effect size.[11] Acknowledged as a promising intervention arena, there have been a growing number of studies in the primary care setting, but they have shown limited effectiveness for obesity prevention so far.[12,13]

It is recommended that intervention efforts have theoretical underpinnings. A well-established approach to behavior change lies in social cognitive theory (SCT).[14] In intervention research, application of SCT is characterized by efforts to increase self-efficacy, that is, people's belief in their capacity to achieve behavior change in a specific domain.[15]

An efficient and brief method for preparing people for behavior change using a client-centered approach is motivational interviewing (MI), which has gained increasing attention in recent years.[16,17] Despite promising results in the treatment of adult obesity,[18] MI as a counseling tool for the prevention or treatment of childhood obesity has shown only a weak or no effect in children and their parents.[19–24] Too brief an intervention or follow-up period, and possibly limited intervention fidelity, have been proposed as explanations for the lack of an intervention effect. There is, however, an exception in 1 recent study, which presents a modest effect of MI compared with care as usual, when targeting overweight and obese preschool children and their parents.[25]

The aim of the current study was to evaluate whether a manualized primary prevention intervention program, delivered by nurses trained in MI and commencing when children were 9 months old, had effects on children and parents at age 4 regarding BMI, waist circumference, prevalence of overweight/obesity, and food and physical activity habits compared with those who had received regular care at child health care centers.

METHODS

The protocol of the PRIMROSE trial, including detailed information on its design, methods and intervention components, has been published elsewhere.[26]

Study Design

In brief, the PRIMROSE trial was a population-based cluster randomized primary prevention trial that started in 2008 at child health care centers (CHCs) in Sweden. The trial was embedded in regular child health services, with the aim of promoting healthy food and physical activity habits among children 9 to 48 months of age and their parents. The trial was approved by the Ethical Review Board in Stockholm, Sweden, and was recorded in the ISRCTN registry (ISRCTN16991919).

Participants and Random Allocation of Child Health Care Centers

Of 1007 eligible nurses, 129 (12.8%) agreed to participate in the trial. After receiving the informed consent of participating nurses and the signing of a contract regulating mutual responsibilities by heads of nurses and the trial's principal investigator (FR), a balanced (1:1) randomization was performed at the CHC unit level in each of the 8 counties that participated. Inclusion of CHCs took place between March 2008 and January 2010. Of the 59 participating CHC units, 31 were randomly allocated to an intervention and 28 to a control arm.

First-time parents receiving preventive services at a participating CHC (n = 2230) were asked by the trial nurses to take part when their children were 5 to 6 months of age. Families were excluded if they did not speak Swedish well enough to benefit from the intervention (n = 172), were about to move, that is, to change their CHC (n = 49), had severe social family problems making it unethical to ask them to participate (n = 67), or for other (including nonreported) reasons (n = 75). A total of 1867 families were eligible for participation. In total, 1355 families with 1369 infants agreed to be included. Detailed information on the randomization and recruitment strategy can be found elsewhere.[26]

The Intervention

As described earlier, PRIMROSE was based on SCT and learning theory.[14] By applying MI and principles of cognitive behavior therapy, intervention nurses assisted parents in promoting healthy food

and physical activity habits in their children and in changing their own health behaviors if needed.[16,17] Nurses at the intervention CHCs attended a 5-day course on MI, learning theory, and the principles of cognitive behavior therapy and on the subjects of nutrition and physical activity, taught by a nutritionist, psychologists, and MI experts. The training and assessment of the nurses' MI proficiency are described in detail elsewhere.[26–28] Families in intervention CHCs took part in 9 sessions (1 group, 6 individual, and 2 individual telephone sessions) in a time frame of ~39 months. The parents, in conjunction with the nurses, formulated goals for changes in unhealthy behaviors and for maintenance of healthy physical activity and food habits. In consecutive sessions, the nurses reinforced the parents' motivation for and commitment to health promotion and behavior change when needed.[26] Families in the control CHCs were only offered the regular age-related health checkups of Swedish child health services, which focus on physical development and immunizations[29] and in which less attention is paid to children's health behaviors.[30]

Outcome Measures

Primary Outcome Measures

The primary outcome measures were children's BMI, waist circumference, and overweight prevalence at 4 years of age. Measurements were taken by study nurses at all visits to the CHCs from recruitment to age 4. BMI was used to indicate overweight status, following gender- and age-specific international specifications.[31] For the children whose BMI was not measured at exactly age 4, we applied growth curve modeling, using nonparametric regression (kernel smoothing) to estimate their BMI at that age.[32]

TABLE 1 Primary and Secondary Outcome Measures

	Baseline (9 Months of Age)	Follow-up (48 Months of Age)
Children		
Height, weight, and waist circumference	Objectively measured at each visit at the CHC	Objectively measured at each visit at the CHC
Food habits		FFQ filled in by mothers
Physical activity habits		7 d wearing accelerometer
Mothers		
Height, weight, and waist circumference	Self-reported in the baseline questionnaire	Objectively measured at final visit at the CHC
Food habits	FFQ	FFQ
Physical activity habits	Baecke questionnaire	Baecke questionnaire

Secondary Outcomes

Secondary outcomes were children's and mothers' food and physical activity habits, and mothers' BMI, prevalence of overweight, and waist circumference. The study protocol contains detailed descriptions of the instruments and measurements used.[26] In brief, food habits were assessed by a semiquantitative food frequency questionnaire (FFQ) validated against a food diary kept for 2 periods of 4 days.[26] The following items were chosen as outcome variables: fruit, vegetables, fish, french fries, sugared drinks, and discretionary calories. According to the Swedish National Food Administration, these food items reflect the quality of dietary intake and are indicators of healthy and unhealthy food habits.[33] Physical activity was measured using the well-validated Actigraph GT3×+ accelerometer.[34] Cutoffs were >3908 cpm for moderate-to-vigorous physical activity, 820 to 3907 cpm for light physical activity, and <820 cpm for sedentary behavior. These cutoffs were specifically developed to measure physical activity and sedentary behavior in 4-year-old children.[35] Non–wear time was defined as 60 consecutive minutes with no counts, allowing for 2-minute interruptions with nonzero counts, and was computed using an algorithm by Choi et al.[36] A valid measurement day was a day with at least 10 wear-time hours. Our analyses of physical activity included children with at least 3 valid days.

Mothers' physical activity habits were assessed using the validated Baecke questionnaire (Table 1).[37,38]

At baseline and follow-up, families also reported on their socioeconomic and sociodemographic circumstances.[26]

Statistical Analyses

Sample size calculations were based on expected meaningful group differences in BMI at follow-up, when the children were age 4. Given a power of 90% and a significance level of 5%, we needed 410 children in the intervention and 540 in the control group at follow-up to detect a mean BMI difference of 0.3 kg/m^2. The calculations were based on Swedish data on 4-year-olds, assuming SD = 1.4, which turned out to be similar in the current study.[39]

To evaluate intervention effects on the primary outcome measures, we applied intention-to-treat analysis in so far as missing data allowed (no imputations were made). We also performed a per-protocol analysis for the primary outcomes, where the sample was restricted to families that had completed all MI sessions (n = 388) delivered by intervention nurses who had fully completed their MI training (n = 35).

Because there were no indications for any differences between the groups at baseline (Table 2), we ran, without additional adjustment for any covariates, linear regressions on continuous variables and log-binominal regressions on binary

TABLE 2 Baseline Characteristics of Mothers and Children in the PRIMROSE Trial

	Intervention, % (*n*) or Mean (SD)	Control, % (*n*) or Mean (SD)
Mothers	*n* = 489	*n* = 550
Age (y)	30.3 (5.1)	29.4 (5.0)
Education		
Primary	2.7 (13)	2.9 (16)
Secondary	30.2 (149)	37.1 (204)
Postsecondary	66.8 (327)	59.7 (328)
Born in Sweden	94.7 (463)	91.1 (501)
Smoking		
Current	8.0 (39)	8.9 (49)
Former smoker	26.4 (129)	27.5 (151)
Never smokers	65.6 (321)	63.6 (350)
BMI (kg/m^2)	24.5 (4.5)	24.7 (4.8)
BMI categories		
Underweight	2.5 (12)	2.7 (15)
Normal weight	60.8 (295)	59.3 (325)
Overweight	24.1 (117)	24.5 (134)
Obese	12.6 (61)	13.5 (74)
Waist circumference (cm)	83.7 (11.3)	84.2 (11.6)
Perceived general health		
Very good	22.1 (108)	23.7 (130)
Good	58.2 (284)	58.2 (319)
Fairly good	17.2 (84)	15.9 (87)
Bad	2.3 (11)	2.0 (11)
Very bad	0.2 (1)	0.2 (1)
Children	*n* = 485	*n* = 556
Gender (female)	48.8 (237)	44.4 (247)
Age at baseline (mo)	6.7 (1.1)	6.7 (1.0)
BMI	17.2 (1.5)	17.4 (1.5)
Current feeding mode		
Breastfeeding only	9.6 (47)	8.6 (47)
Part time	50.5 (247)	49.9 (274)
Not any longer	36.6 (179)	38.3 (210)
Never	3.3 (16)	3.3 (18)

variables using generalized estimating equations with robust variance estimates, taking into account the cluster-randomized study design.[40]

RESULTS

An overview of participant flow is shown in Fig 1. For the 1355 families (1369 children) who consented to participate, we could obtain baseline growth data from their CHC. Of these, 1039 mothers (with 1053 children) filled in the baseline questionnaire on time (Table 2). At follow-up, when the children were age 4, there were 1148 children with data on weight and height, which meant a total attrition rate of 16.1%. At follow-up, the mean age of the children (46% girls) was 4.3 (SD = 0.4) years. The mothers had a mean age of 33.5 (SD = 5.0). At follow-up, 7.3% of the mothers were pregnant and were therefore excluded from the analysis. Although there was twice as high a proportion of dropouts in the intervention group, there were no significant differences in baseline characteristics between completers and dropouts (data not shown).

BMI and Waist Circumference at Age 4 Years

At follow-up, there was no statistically significant group difference in BMI (mean difference: −0.11, 95% confidence interval [CI]: −0.31 to 0.08) or waist circumference (mean difference: −0.48, 95% CI: −0.99 to 0.04) in the intention-to-treat analysis (*n* = 1148) (Table 3). Also, regarding the prevalence of overweight (including obesity), there was no statistically significant group difference (14.8% in the intervention group, 15.5% in the control group, *P* = .80). In the per-protocol analysis, for which the follow-up sample was restricted to families who had completed the entire intervention with nurses who had completed their full training (*n* = 1088), the results for BMI and overweight prevalence remained virtually the same. The difference between the intervention and control group for waist circumference did become statistically significant but reflected a mean difference of merely 0.6 cm (95% CI: −1.19 to −0.07) (Table 4).

Children's food habits

Across the measures of children's food habits, there were differences between the groups in the expected direction, that is, mothers reported a higher consumption frequency of vegetables (*P* = .01), fruits (*P* = .78), and fish (*P* = .21), and a lower consumption frequency of sugared drinks (*P* = .04), french fries (*P* < .001), and discretionary calories (*P* = .01) for the children in the intervention group than in the control group (Table 5).

Children's Physical Activity

There was no intervention effect regarding physical activity (including sedentary behavior) in the 4-year-old children. Children in the intervention group spent nearly the same amount of time as those in the control group in moderate-to-vigorous physical activity (50.6 min/day vs 51.0 min/day, *P* = .81) and sedentary behavior (341.4 min/day vs 340.7 min/day, *P* = 0.87) (Table 6).

Mothers' BMI and Waist Circumference

At time of follow-up, there were data on weight and height for 1050 mothers in the trial. Overall, there were no differences between the intervention and control group regarding BMI (*P* = .67), waist

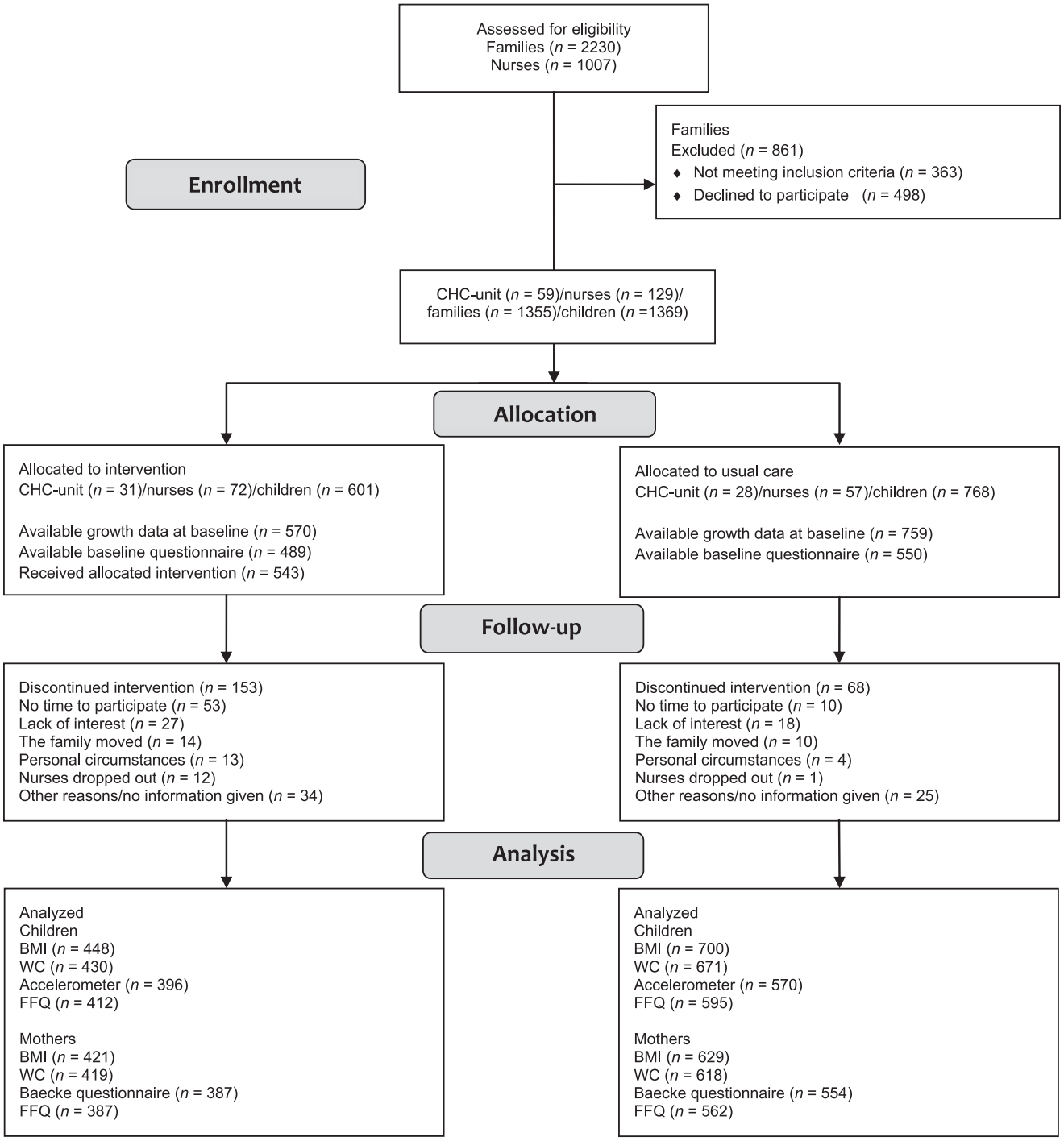

FIGURE 1
Consolidated Standards of Reporting Trials diagram for the PRIMROSE cluster-randomized study.

circumference ($P = .30$), or prevalence of overweight ($P = 0.62$) (Table 3).

Mothers' Food Habits and Physical Activity

As described elsewhere,[26] no statistically significant differences were seen regarding mothers' eating habits and physical activity habits at baseline. At follow-up, as was the case for children, the differences for mothers between the intervention group and the control group regarding food items were in the expected direction, with a higher consumption frequency of fruit, vegetables, and fish, and a lower consumption frequency of french fries, sugared drinks, and discretionary calories in the intervention group than in the

control group. The differences, however, were only statistically significant for french fries ($P = .01$) and discretionary calories ($P = .01$) (Table 5). Regarding mothers' physical activity at follow-up, there was no significant difference between the groups (Table 6).

TABLE 3 Intention-to-Treat Analysis of Anthropometric Data at Follow-up for Children and Mothers in the PRIMROSE Trial

	Intervention	Control		*P*
	Mean (SE)	Mean (SE)	Mean Δ/RR (95% CI)	
Children	*n* = 448	*n* = 700		
BMI	16.0 (0.08)	16.1 (0.06)	−0.11 (−0.31 to 0.08)	.26
WC[a]	52.5 (0.21)	53.0 (0.26)	−0.48 (−0.99 to 0.04)	.07
Overweight[b] (%)	14.8 (0.02)	15.5 (0.01)	0.95 (0.69 to 1.32)	.78
Mothers	*n* = 421[c]	*n* = 629[c]		
BMI	25.0 (0.35)	25.2 (0.19)	−0.16 (−0.95 to 0.61)	.67
WC[d]	83.4 (0.75)	84.4 (0.60)	−0.98 (−2.86 to 0.88)	.30
Overweight[b] (%)	39.9 (0.03)	41.7 (0.02)	0.96 (0.81 to 1.13)	.62

The analysis is based on intention to treat as far as missing data permitted (no imputation). RR, relative risk; WC, waist circumference.
[a] Missing = 47.
[b] Including obesity.
[c] Pregnant women were excluded (*n* = 31 in the intervention, *n* = 51 in the control).
[d] Missing = 2.

TABLE 4 Per-Protocol Analysis of Anthropometric Data at Follow-up for Children in the PRIMROSE Trial

Children	Intervention (*n* = 388)	Control (*n* = 700)	Mean Δ/RR (95% CI)	*P*
	Mean (SE)	Mean (SE)		
BMI	15.9 (0.10)	16.1 (0.08)	−0.15 (−0.35 to 0.05)	.15
WC[a]	52.4 (0.24)	53.0 (0.16)	−0.63 (−1.19 to −0.07)	.03
Overweight[b] (%)	14.5 (0.02)	15.5 (0.01)	0.93 (0.66 to 1.64)	.70

This analysis is based on per-protocol analysis restricted the sample to families who completed the entire intervention with nurses who completed the MI education. RR, relative risk; WC, waist circumference.
[a] Missing = 20.
[b] Including obesity.

DISCUSSION

Our results indicated no significant intervention effects regarding BMI, waist circumference, or overweight prevalence in the 4-year-old children, nor were there any statistically significant differences between children in the intervention CHCs and those in the control CHCs regarding objectively measured physical activity. However, we did find statistically significant differences in children's and mothers' reported intake of some food items. For mothers, we found no significant differences on the anthropometric measures or in physical activity between the intervention and control groups.

The PRIMROSE trial is among the first to evaluate the effects of a preventive intervention based on MI in early childhood. The strengths of our trial include its theory-driven design, its provision for manual-based implementation in routine child health services, its large sample size combined with low attrition, its long intervention period, and its objective measurements of BMI, waist circumference, and physical activity.

Why the Lack of Intervention Effects?

A potential explanation for the absence, in general, of intervention effects may lie in imperfect implementation. Based on the coordinators' monitoring of completed assignments (ie, tasks during sessions and homework),[26] however, it seems, reasonable to assume that the vast majority of nurses closely followed the intervention manual. Yet it is still possible that the absence of effects is partially explained by a certain lack of proficiency in MI among the intervention nurses, despite extensive training and supervision.[27] However, there is currently no validity study of thresholds for proficiency in MI. Another study in a Swedish primary care setting concluded that nurses needed more training, feedback, and supervision in clinical practice to promote MI improvement.[41]

As hypothesized in another study,[42] it is also possible that a lack of intervention effects on BMI and waist circumference is due to a time lag between MI and observable positive changes. However, we are not aware of any study, with reasonably long follow-up, that has found a time-lagged effect on BMI. Indeed washout of an intervention effect over time seems more plausible.[11,43,44] So far, there has been no other study with a comparable long intervention period as in the PRIMROSE trial. A too short intervention period seen in many studies might explain the lack of effect maintenance.

Alternatively, the lack of observed intervention effects may simply be due to an ineffective intervention. Our results are largely in line with recently published intervention studies, showing that behavioral interventions targeting food habits and physical activity, with or without the use of MI, in early childhood have a limited effect on the prevention of childhood obesity.[19–21,23,24,45,46] MI has proven effective when targeting high-risk populations (including those of obese adults) that are reluctant to change unhealthy habits. There is, however, limited evidence on whether MI can also be effective in promoting and maintaining healthy habits. A

recently published study showed positive effects of MI delivered by primary care providers combined with dietary counseling in treating overweight in young children.[25] Yet there is a lack of evidence distinguishing the effects of treating obesity from those of preventing it.[47] In searching for effective tools, it may be of considerable relevance to differentiate between different stages of prevention. The same type of intervention may not have the same effect for different types of prevention strategies.

Even when acknowledging our small intervention effects observed, it is unlikely that the current intervention program could halt or reverse the childhood obesity trend.

Bias in the Assessment of Food Habits?

The PRIMROSE intervention focused more on food habits than physical activity, which may explain our findings of a potentially weak intervention effect on food habits but the absence of any intervention effect on physical activity habits. However, another possibility that must be acknowledged is that the observed weak intervention effect on food habits among children and mothers are mainly due to bias. It is well known that assessment of children's eating habits by a parent-proxy food frequency questionnaire may be subject to recall bias or social desirability bias, and our intervention families may have been particularly vulnerable to these biases. We observed similar results for mothers' and children's food habits, which may reflect similar food habits in households but could also be explained by the fact that mothers filled in both questionnaires. As reported elsewhere,[26] we have assessed the relative validity of the FFQ, which showed that validity is less strong for some food items (eg, french fries). Furthermore, the FFQ was restricted in application to what the children eat together with their family, and we had no information on what they consumed at preschool (which is attended by 92% of Swedish children).[48]

TABLE 5 Intention-to-Treat Analysis of Food Habits at Follow-up of Children and Mothers in the PRIMROSE Trial

	Intervention	Control	Mean Δ (95% CI)	*P*
	Mean (SE)	Mean (SE)		
Children	*n* = 412	*n* = 595		
Fruits (t/d)[a]	1.1 (0.03)	1.1 (0.03)	0.01 (−0.09 to 0.11)	.78
Vegetables (t/d)[a]	1.0 (0.03)	0.9 (0.03)	0.13 (0.04 to 0.22)	.01
Fish (t/wk)[a]	1.6 (0.06)	1.5 (0.06)	0.10 (−0.06 to 0.27)	.21
French fries (t/mo)[a]	1.5 (0.07)	1.8 (0.07)	−0.37 (−0.58 to −0.17)	<.001
Sugared drinks (t/wk)[b]	2.2 (0.18)	2. 7 (0.15)	−0.49 (−0.97 to −0.15)	.04
Discretionary calories (t/wk)[b]	5.3 (0.17)	5.9 (0.12)	−0.60 (−1.01 to −0.18)	.01
Mothers	*n* = 387	*n* = 562		
Fruits (t/d)[c]	1.2 (0.03)	1.1 (0.04)	0.07 (−0.04 to 0.18)	.22
Vegetables (t/d)[c]	1.3 (0.06)	1.3 (0.04)	0.10 (−0.02 to 0.21)	.10
Fish (t/wk)[c]	2.0 (0.07)	1.8 (0.07)	0.18 (−0.01 to 0.38)	.07
French fries (t/mo)[c]	1.4 (0.08)	1.7 (0.10)	−0.33 (−0.58 to −0.10)	.01
Sugared drinks (t/wk)[d]	1.5 (0.14)	1.8 (0.11)	−0.26 (−0.60 to 0.08)	.13
Discretionary calories (t/wk)[d]	7.0 (0.22)	8.0 (0.29)	−1.00 (−1.72 to −0.28)	.01

This analysis is based on intention to treat as far as missing data permitted (no imputation). Sugared drinks included soda with sugar, lemonade, and chocolate drinks. Discretionary calories included savory snacks, sugared drinks, sweets, chocolate, pastries, cake, and ice cream. t/d, times per day; t/wk, times per week; t/mo, times per month.

[a] Missing = 5.

[b] Missing = 14.

[c] Missing = 4.

[d] Missing = 8.

TABLE 6 Intention-to-Treat Analysis of Physical Activity at Follow-up of Mothers and Children in the PRIMROSE Trial

	Intervention	Control	Mean Δ (95% CI)	*P*
	Mean (SE)	Mean (SE)		
Children[a]	*n* = 390[b]	*n* = 546[b]		
Mean wear time (h/d)	12.6 (0.03)	12.6 (0.04)	−0.01 (−0.10 to 0.08)	.87
SB (min/d)	341.4 (2.96)	340.7 (2.46)	0.61 (−6.93 to 8.16)	.87
SB (%/wear time)	45.0 (0.01)	44.9 (0.01)	0.01 (−0.01 to 0.01)	.84
LPA (min/d)	365.8 (2.47)	365.4 (2.10)	0.37 (−5.98 to 6.73)	.91
LPA (%/wear time)	48.4 (0.01)	48.3 (0.01)	0.01 (−0.01 to 0.01)	.88
MVPA (min/d)	50.6 (1.00)	51.0 (0.90)	−0.36 (−3.00 to 2.28)	.81
MVPA (%/wear time)	6.7 (0.01)	6.7 (0.01)	−0.01 (−0.01 to 0.01)	.73
Mothers[c]	*n* = 387	*n* = 554		
Work	2.7 (0.04)	2.8 (0.04)	−0.08 (−0.17 to 0.02)	.12
Sport	2.6 (0.03)	2.6 (0.04)	0.07 (−0.02 to 0.16)	.13
Leisure time	3.0 (0.05)	2.9 (0.04)	0.06 (−0.06 to 0.17)	.32

This analysis is based on intention to treat as far as missing data permitted (no imputation). LPA, light physical activity; MVPA, moderate-to-vigorous physical activity; SB, sedentary behavior.

[a] Assessed by Actigraph GT3× + accelerometer.

[b] Six children in the intervention and 24 in the control group were excluded from the analysis because of invalid measurements.

[c] Assessed by Baecke questionnaire.

Generalizability

The PRIMROSE trial was conducted at regular Swedish CHCs, which are visited by almost all Swedish families with children 0 to 6 years of age, under almost normal working circumstances. The participating control and intervention CHC nurses were from diverse geographic areas, but the study population was restricted to Swedish-speaking families, and >90% of the participating mothers were born in Sweden. In comparison, of first-time mothers in the general Swedish population, 79% were born in Sweden. Also, regarding highest attained education, the PRIMROSE population differed slightly from the general population, in which 37% and 54% had secondary and postsecondary education, respectively, compared with 35% and 61% in the current trial. Therefore, claims of generalizability for the intervention program should be made with caution. Although the PRIMROSE intervention has a potential for implementation given the ecological validity, the large costs of such an intervention cannot be disregarded given the longer meetings between parents and nurses and time needed for training and supervision of nurses in MI. The cost-effectiveness of such an intervention would largely depend on the assumption of maintaining of the small positive, but insignificant, effect on BMI or the value put on the secondary outcome. However, research on cost-effectiveness over the lifetime is scarce in this field.

CONCLUSIONS

Our results suggest no intervention effects of the PRIMROSE primary prevention trial regarding BMI, waist circumference, and prevalence of overweight in children at age 4. However, our results do suggest a small positive intervention effect regarding healthy eating habits, although this must be interpreted with caution. A theory-based and manual-driven approach, combined with the application of MI, is fairly novel in the context of childhood obesity prevention and insufficiently explored. Further research is needed to establish whether the lack of intervention effects regarding BMI and physical activity at age 4 in our study was due to failure of theory, implementation or evaluation, or a combination of these.

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ABBREVIATIONS

CHC: child health care center
CI: confidence interval
FFQ: food frequency questionnaire
LPA: light physical activity
MI: motivational interviewing
MVPA: moderate-to-vigorous physical activity
SB: sedentary behavior
SCT: social cognitive theory
WC: waist circumference

analysis; Dr Rasmussen conceived the study and had main responsibility for its design, coordination, and interpretation of the results as principal investigator; and all authors contributed to the interpretation of results, critically revised the manuscript, and approved the final manuscript as submitted.

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