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Effects of the Healthy Start randomized intervention on dietary intake among obesity-prone normal-weight children

Jeanett F Rohde[1,2,*], Sofus C Larsen[1], Lars Ängquist[3], Nanna J Olsen[1], Maria Stougaard[1], Erik L Mortensen[4] and Berit L Heitmann[1,2,5,6]

[1]Research Unit for Dietary Studies at the Parker Institute, Bispebjerg and Frederiksberg Hospital, the Capital Region, Nordre Fasanvej 57, entrance 5, ground floor, 2000 Frederiksberg, Denmark: [2]National Institute of Public Health, University of Southern Denmark, Copenhagen, Denmark: [3]Institute of Preventive Medicine, Bispebjerg and Frederiksberg Hospital, the Capital Region, Frederiksberg, Denmark: [4]Department of Public Health and Center for Healthy Aging, University of Copenhagen, Copenhagen, Denmark: [5]The Boden Institute of Obesity, Nutrition, Exercise & Eating Disorders, The University of Sydney, Sydney, NSW, Australia: [6]Section for General Practice, Department of Public Health, University of Copenhagen, Copenhagen, Denmark

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Abstract

Objective: The study aimed to evaluate the impact of a 15-month intervention on dietary intake conducted among obesity-prone normal-weight pre-school children.

Design: Information on dietary intake was obtained using a 4 d diet record. A diet quality index was adapted to assess how well children's diet complied with the Danish national guidelines. Linear regression per protocol and intention-to-treat analyses of differences in intakes of energy, macronutrients, fruit, vegetables, fish, sugar-sweetened beverages and diet quality index between the two groups were conducted.

Setting: The Healthy Start study was conducted during 2009–2011, focusing on changing diet, physical activity, sleep and stress management to prevent excessive weight gain among Danish children.

Subjects: From a population of 635 Danish pre-school children, who had a high birth weight (≥4000 g), high maternal pre-pregnancy BMI (≥28·0 kg/m^2) or low maternal educational level (<10 years of schooling), 285 children completed the intervention and had complete information on dietary intake.

Results: Children in the intervention group had a lower energy intake after the 15-month intervention (group means: 5·29 *v.* 5·59 MJ, $P = 0·02$) compared with the control group. We observed lower intakes of carbohydrates and added sugar in the intervention group compared with the control group after the intervention ($P = 0·002$, $P = 0·01$).

Conclusions: The intervention resulted in a lower energy intake, particularly from carbohydrates and added sugar after 15 months of intervention, suggesting that dietary intake can be changed in a healthier direction in children predisposed to obesity.

Keywords
Dietary intake
Diet quality index
Intervention
Obesity prevention
Pre-school children

The increasing prevalence and incidence of obesity is one of the major challenges to good health worldwide[1]. Particularly the high obesity rates among children of all ages are a major concern, because of the immediate and long-term adverse psychosocial and health-related consequences (including reduced survival) of being overweight or obese in childhood[2–9]. Preventive efforts to avoid obesity early in life and maintain the prevention effects over time are warranted to secure a healthy childhood and adulthood. It is clear that obesity is under the influence of both genetic and environmental factors (including diet and physical activity (PA))[10–12], which complicates efforts to prevent development of obesity among children. In this regard, studies have shown that some groups may be at increased risk of becoming overweight and obese later in life, such as those children with obesity among their first-degree relatives[13], children born with high birth weight (≥4000 g)[14] and children from socially disadvantaged families[15]. Furthermore, research also suggests that low birth weight and rapid catch-up

*Corresponding author: Email jeanett.friis.rohde@regionh.dk

growth together, as well as maternal smoking during pregnancy, are associated with childhood overweight[13,16]. Targeting such predisposed groups of children for obesity prevention may be more effective than targeting unselected population subsets of children[15,17].

Since dietary intake and PA are modifiable risk factors, they are of particular interest when it comes to obesity prevention. It is well documented that a healthy dietary intake is associated with lower risk of certain diseases such as overweight and obesity, type 2 diabetes and CVD[18–23]. Especially vegetables, fruit, whole grains and fish have been associated with lower risk of diseases[18–20]. Evidence[24] also indicates that diet patterns that are high in energy-dense, high-fat- and low-fibre foods are related to later development of overweight and obesity in young people. Moreover, it has been shown that a high consumption of sugar-sweetened beverages (SSB) is associated with weight gain in children[25]. In addition, there is some evidence to indicate that examining multiple dietary factors within a diet pattern may better explain the association between dietary intake and obesity development than individual nutrients or foods[24]. Dietary habits are established in early life[26] and securing healthy dietary habits throughout life by intervening as early as possible and before overweight and obesity is established is therefore important. One such target group is those yet of normal weight, but predisposed to future development of obesity.

On this background, the objective of the present study was to evaluate the impact on dietary intake of a 15-month weight gain intervention focusing on diet, PA, sleep and stress management among normal-weight children predisposed to future obesity. Specifically, we examined if intervention children improved their (i) energy intake and diet composition of macronutrients, (ii) intakes of fruit, vegetables, fish and SSB and (iii) diet quality, compared with children from the control group.

Methods

Study design

Healthy Start was a randomized controlled primary weight-gain prevention intervention study conducted between 2009 and 2011[27]. The study consisted of children aged 2–6 years from eleven municipalities in the greater Copenhagen area of Denmark, born between 1 January 2001 and 31 December 2007, who were all considered predisposed for later development of obesity. Children were considered predisposed if they had a high birth weight (≥4000 g), a mother who was overweight prior to pregnancy (BMI ≥ 28·0 kg/m^2) or came from a family with low socio-economic status (maternal educational level ≤10 years). After selecting the children in Danish registries and administrative birth forms (*n* 5902), they were randomized into three groups: the intervention, control and shadow control groups. All siblings were allocated into the same group. A total of 1159 parents to children accepted to participate in the study. Information from the shadow control group is not used in the present study because information about dietary intake was not obtained in this group (*n* 524). Parents to children who accepted to participate in the study were invited with the child to meet with a health consultant (*n* 635). At the first consultation height and weight of the child were measured and BMI calculated. Children classified as overweight, according to the international cut-offs developed by Cole *et al.*[28], were excluded from the study (*n* 92). If the child was of normal weight, he/she was included and had additional anthropometric measurements taken. Only children with full information on dietary intake at baseline and follow-up were included in the per protocol (PP) analyses (*n* 285; Fig. 1).

Children in the intervention group were assigned to a health consultant trained in nutrition and dietetics, and most children were followed by the same consultant throughout the 15 months of follow-up. Each child and his/her family were seen on a regular basis, with up to ten consultations during follow-up. The frequency of the meetings and the agenda were based on individual needs and resources of each family. The consultations in the intervention were focused around four themes: optimizing diet and PA in accordance with the official Danish national recommendations, together with sleep and stress management.

The dietary advice used for guidance in the consultations was based on the Nordic Nutrition Recommendations from 2004[29], which were converted into the Danish national recommendations, 'The 8 Dietary Guidelines'[30]. Each of the eight dietary guidelines was included in the intervention and adjusted to the age of the target group (Table 1). Furthermore, all children were given a Y-plate that was visually divided into three spaces: 1/5 (fish, meat, poultry and eggs), 2/5 (pasta, rice, potatoes and whole grains) and 2/5 (fruit and vegetables)[31]. The intervention families were also invited to participate in group-based bimonthly cooking classes and monthly play and activity events. The purposes of the cooking classes were to help the parents convert theory obtained from the consultations into practice and to encourage them to involve the children in meal preparation. The classes took place around dinner time and lasted approximately 2·5 h. Each class had a different theme, such as how to create a healthy lunch box, how to include more fish in the diet, creating healthy fast food, healthy salads and desserts, preparation of dishes without meat and making healthy soups. At the beginning of the class, families received a brief brush-up on the theory of the day's topic and recipes. Afterwards, each family prepared a dish and presented it for the other participating families during the joined intake of the meal by the end of the class. Beside the consultations and cooking events, the families could get inspiration for cooking healthy meals on the Healthy Start primary

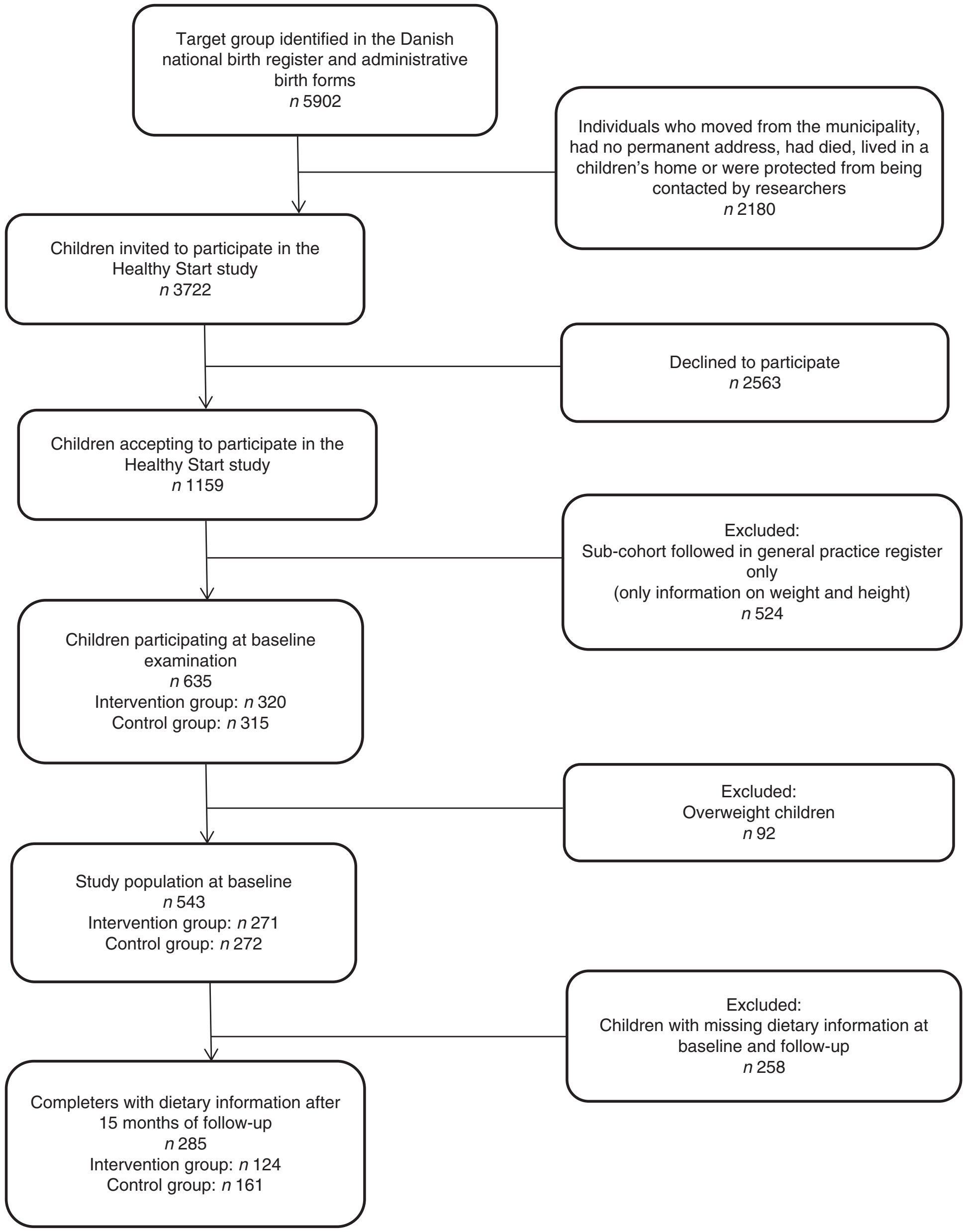

Fig. 1 Flowchart of the study population

Table 1 The Danish national recommendations: 'The 8 Dietary Guidelines'*

1. Eat fruit and vegetables (minimum 300–500 g/d, depending on age)
2. Eat fish or fish filling several times per week (minimum 200–300 g/week)
3. Eat potatoes, rice or pasta and wholegrain bread every day (minimum 200–300 g/d)
4. Limit sugar, especially from soft drinks, sweets and cake (maximum 10 E%)
5. Limit fat (maximum 30 E%), especially from dairy products and meat (maximum 10 E%)
6. Eat from all food categories every day, choose various products within each food category
7. Quench your thirst with water (1–1½ litres/d)
8. Be physically active (minimum 1 h/d)

E%, percentage of energy.
*Based on the Nordic Nutrition Recommendations from 2004[29] and adjusted to the age of the target group.

intervention webpage (www.sundstart.nu). Children allocated to the control group met with a health consultant twice; at the beginning of the study and at follow-up approximately 15 months after their first visit.

Diet assessment

At baseline and follow-up, the parents were asked to fill out a 4 d record of their child's dietary intake from Wednesday to Saturday. These days were specifically chosen to gain information on the dietary intake on both weekdays and weekend days. To help the families estimate portion sizes of the foods eaten, the diet records were accompanied by a picture book including seventeen series with foods and portion sizes[32]. The software Dankost 3000, used for nutrition calculation (http://dankost.dk), was based on the official Danish national food composition database (version 7.01) developed by the National Food Institute at the Technical University of Denmark[33].

Outcome

One of the components of the diet intervention was to improve the composition of macronutrient intake. Recommendations were based on the Nordic Nutrition Recommendations from 2004[29], as follows.

- Fat: maximum 30 % of energy (E%).
- Saturated fat: maximum 10 E%.
- Carbohydrates: maximum 55 E%.
- Added sugar: maximum 10 E%.
- Protein: minimum 15 E%.

The intake of several food and beverage groups was considered of particular interest based on 'The 8 Dietary Guidelines' and was examined in more detail. These groups included fruit, vegetables, fish and SSB (intake units: g/d) and were defined as follows.

- Fruit: fresh, canned and frozen (excluding jam, fruit juice, dried fruit and fruit products with added sugar).
- Vegetables: fresh, canned and frozen (excluding fried onion, ketchup, pickles and potatoes).
- Fish: fatty fish, lean fish and shellfish.
- SSB: soft drinks, squash, chocolate milk, milkshake and drinking yoghurt.

A diet quality index (DQI) based on guidelines related to dietary intake was developed to evaluate the overall quality of the children's diet. The DQI was adapted from Knudsen *et al.*[34]. The following nutrients and food items were included in the index.

- Fat: maximum 30 E%.
- Saturated fat: maximum 10 E%.
- Added sugar: maximum 10 E%.
- Fish: minimum 200 g/week.
- Fruit and vegetables: minimum 300 g/d.
- Potatoes, rice or pasta (wholegrain bread not included): minimum 200 g/d.

The two dietary guidelines 'Quench your thirst with water (minimum 1 – 1½ litres/d)' and 'Be physically active (minimum 1 h/d)' were not included in the DQI due to the lack of accurate data corresponding to these guidelines. For each child, a DQI score was calculated at baseline and follow-up, based on the six nutrients/food groups, as a function of the relationship between the recommended intake and the reported intake. For the food groups with a minimum recommended intake, the group score would be based on the ratio (R/R_T) between the reported (R) and the recommended (R_T) intake, where the score was set to 1 for intakes with $R \geq R_T$. For the food groups with a maximum recommended intake, the score was instead derived as $1-(R-R_T)/(R_{max}-R_T)$, where the score was set to 1 for intakes $R \leq R_T$. In the latter equation R_{max} is the maximum value possible, or attained, which for example would be 100 for the variables based on E%. For example, if a child had a fruit and vegetable intake of 100 g/d and a fat intake of 32 E%, the corresponding scores were calculated as $100/300 = 0{\cdot}33$ and $1-(32-30)/(100-30) = 0{\cdot}97$, respectively. Hence the score for each of the food items and nutrients ranged between 0 and 1, with 0 representing a score the furthest away from the recommendation and 1 a score fully complying with the recommendation. Finally, total scores were generated by summing the six individual scores; hence, by construction, the DQI was derived as a continuous variable ranging from 0 to 6.

Covariates for multiple imputations

Information on the child's native municipality, gender and age was obtained from the Medical Birth Registry[35]. Furthermore, by linking the civil registration number for each of the children included in the intervention to the Danish Health Visitors' Child Health Database, information on the number of months the child was breast-fed without supplements, maternal and paternal highest education (primary school or above primary school), maternal and paternal ethnicity (Danish, or first-, second- or third-generation immigrants, including reunited families) was obtained. These data were collected by health visitors and retrieved from the Danish Health Visitors' Child Health Database. The Database Steering Committee approved of and provided the data.

Information on the child's PA level was obtained from a questionnaire completed by parents at baseline and was based on the question: 'How physically active is the child compared to other children at the same age?' The parents could indicate if they perceived their child as being 'fairly active', 'very active', 'not so active' or 'do not know'. Moreover, information on the parents' height and weight was self-reported in the parental questionnaire at baseline and was used to calculate BMI. Child BMI was calculated based on height and weight which were measured at baseline by a trained health professional. Height was measured to the nearest 0·1 cm using a stature meter (Soehnle 5,002 or Charter ch200P). The children had bare feet or wore socks. Body weight was measured to the nearest 0·1 kg using a mechanical or beam-type weighing scale (Tanita BWB-800 or SV-SECA 710). Children were measured in underwear and were asked to urinate, if possible, before weighing. If the child was using a diaper, a new one was put on before weighing. BMI *Z*-scores were generated using the Lambda-Mu-Sigma method, which summarizes the changing distributions of the dependent variable by the median, the CV and the skew expressed as Box–Cox power[36]. A gender- and age-specific power transformation in increments of 0·1 years was used, applying national reference *Z*-scores to the study population rather than internal reference *Z*-scores[37].

Statistical methods

Per protocol analyses

Linear regression models were used to evaluate the effect of the intervention on dietary intake, with adjustments for baseline level. We corrected for heteroscedasticity using the robust (or sandwich) estimator of variance. Possible gender interaction was explored for all analyses by adding a product term to the models. Significant interactions were further evaluated through stratified analyses. A few children, in the PP analyses, participated together with at least one sibling. Sensitivity analyses were conducted where siblings (*n* 15) were excluded. Furthermore, sensitivity analyses looking at changes as well as analyses on food groups adjusted for baseline energy intake were conducted. Analyses of dropouts were performed to investigate if completers differed from non-completers with regard to the selection criteria (birth weight, maternal pre-pregnancy BMI and maternal education level).

Intention-to-treat analyses

To investigate whether selection bias or dropout may have affected the results in the completer analyses, any child who dropped out after the baseline examination was included in the intention-to-treat (ITT) analyses (*n* 543), following modified ITT principles[38]. Multiple imputations were used to impute missing values in the ITT analyses. In the multiple imputations, $m=10$ complete data sets were first generated. In each set of data, the missing value was then replaced with the imputed values, which were constructed based on predictive distributions for each of the missing values. Afterwards each of the completed data sets was then analysed, and the results from the ten analyses were combined to create a single set of estimates that comprised the variability associated with the missing values. The imputations were made using chained equations as implemented in Stata through the commands *ice* and *mim*[39] and based on the following set of imputation variables: information on allocated group, municipality, BMI *Z*-score at baseline, gender, age at baseline (years), number of months breast-fed without formula, PA level at baseline ('fairly active', 'very active', 'not so active' or 'do not know'), total energy intake (kJ) at baseline, macronutrients (intake of protein, carbohydrates and fat; E%) at baseline, food groups (intake of fish, SSB, fruit and vegetables; g/d) at baseline, maternal and paternal ethnicity (non-Danish/Danish), maternal and paternal education (years of schooling), and maternal and paternal BMI at baseline (kg/m^2). As in the PP analyses (*n* 285), linear regression analyses were used to examine the differences between the intervention and control group in the ITT analyses with baseline adjustments (*n* 543). Furthermore, sensitivity analyses without siblings (*n* 39) were performed. Analyses were run using the statistical software package Stata version 14.0 (www.stata.com).

Results

In total 124 children from the intervention group and 161 from the control group had complete information on dietary intake both before and after the intervention. The baseline characteristics of these children are presented in Table 2. Analyses of dropouts based on the selection criteria showed a higher maternal educational level among the participating children compared with children who dropped out. No differences were observed in relation to birth weight and maternal pre-pregnancy BMI (see online supplementary material, Supplemental Table 1).

In the PP analyses, a higher total energy intake was observed at follow-up in the control group (group mean: 5·29 MJ) compared with the intervention group (group mean: 5·59 MJ; $P=0·02$; Table 3). No significant differences in percentage of energy from fat, saturated fat, carbohydrates, added sugar or protein were observed after the 15-month follow-up. However, the intervention group had a lower absolute energy intake of carbohydrates (group means: 2·93 *v.* 3·15 MJ) and added sugar (group means: 0·35 *v.* 0·43 MJ) after the intervention compared with the control group ($P=0·002$, $P=0·01$; Table 3). No differences were seen for intakes of fruit, vegetables, fish, SSB or DQI between the two groups in the PP model (Tables 3 and 4).

We found a significant interaction between gender and allocation group in relation to protein intake in the PP analyses ($P=0·01$), but the further analyses stratified by gender did not reveal any significant differences in relation to protein intake for boys (intervention group: 15·2 E%, control group: 15·7 E%) or girls (intervention group: 15·5 E%, control group: 16·0 E%) between the intervention and control groups (boys: $P=0·07$, girls: $P=0·08$).

Sensitivity analyses conducted without siblings included (*n* 15) gave essentially similar associations to the PP analyses, although, without the siblings, the association between allocation group and total energy intake was borderline significant only ($P=0·05$; see online supplementary material, Supplemental Tables 2 and 3). Looking at changes in total energy intake also revealed a significantly lower total energy intake among children in the intervention group (group means: 0·4 *v.* 0·7 MJ) compared with children in the control group ($P=0·02$; Supplemental Table 4). Moreover, looking at changes in food groups

Table 2 Baseline characteristics of the included participants stratified by intervention status*: obesity-prone normal-weight Danish pre-school children, Healthy Start study, 2009–2011

	Intervention group			Control group		
	n	Median	P5, P95	*n*	Median	P5, P95
Age (years)	124	4·0	2·6, 5·5	161	3·9	2·4, 5·7
Gender (% boys)	124	58·1		161	57·8	
BMI *Z*-score (SD)	124	0·1	−1·2, 1·2	161	0·2	−1·0, 1·2
Total energy intake (MJ)	124	4·87	3·53, 6·51	161	4·74	3·39, 6·81
Fat (E%)	124	29·8	22·8, 36·9	161	28·9	22·3, 38·3
Fat (MJ)	124	1·42	0·97, 2·06	161	1·34	0·84, 2·17
Saturated fat (E%)	124	11·2	7·6, 14·4	161	10·8	6·9, 14·5
Saturated fat (MJ)	124	0·50	0·31, 0·83	161	0·50	0·28, 0·84
Carbohydrates (E%)	124	54·9	47·6, 62·3	161	55·5	44·7, 62·5
Carbohydrates (MJ)	124	2·76	1·90, 3·85	161	2·80	1·93, 3·93
Added sugar (E%)	124	7·1	1·7, 13·2	161	7·2	1·8, 14·1
Added sugar (MJ)	124	0·34	0·07, 0·72	161	0·33	0·09, 0·75
Protein (E%)	124	15·1	12·2, 20·2	161	15·5	12·5, 19·4
Protein (MJ)	124	0·75	0·50, 1·02	161	0·74	0·53, 1·09
Fruit (g/d)	124	86	12, 213	161	91	23, 195
Vegetables (g/d)	124	93	20, 181	161	88	25, 180
Fish (g/day)	124	12	0, 47	161	10	0, 47
SSB (g/d)	124	34	0, 213	161	50	0, 263
DQI (units)	124	4·3	3·4, 5·1	161	4·3	3·6, 5·3
	n	%		*n*	%	
Birth weight above cut-off (≥4000 g)						
No	34	27·4		46	28·6	
Yes	90	72·6		115	71·3	
Maternal educational level						
≤10 years	2	2·7		3	3·2	
>10 years	71	97·3		91	96·8	
Maternal pre-pregnancy BMI above cut-off (BMI ≥28·0 kg/m^2)						
No	56	53·4		76	58·0	
Yes	48	46·2		55	42·0	

P5, 5th percentile; P95, 95th percentile; E%, percentage of energy; SSB, sugar-sweetened beverages; DQI, diet quality index.
*Results presented as median and P5, P95 unless otherwise stated.

revealed no significant differences between the intervention and control group (Supplemental Table 5). Furthermore, looking at the food groups adjusted for baseline energy intake revealed no significant differences between the intervention and control groups (Supplemental Table 6).

Similar to the PP analyses, the ITT analyses showed a lower total energy intake among the children from the intervention group (group means: 5·21 *v.* 5·46 MJ) compared with the children in the control group; however, the difference no longer reached significance ($P=0·06$). A lower carbohydrate intake (group means: 53·1 *v.* 54·2 E%) was observed in the intervention group compared with the children in the control group ($P=0·05$; Table 3). No significant differences were observed, in the ITT model, between allocation groups for fat, saturated fat, added sugar, protein, fruit, vegetables, fish, SSB or DQI (Tables 3 and 4). However, similar to the PP analyses, lower intakes of energy from carbohydrates (group means: 2·93 *v.* 3·09 MJ) and added sugar (group means: 0·36 *v.* 0·42 MJ) were observed in the intervention group compared with the control group at the 15-month follow-up ($P=0·01$, $P=0·05$; Tables 3 and 4). Lastly, sensitivity analyses looking at changes in dietary intake and food groups adjusted for energy intake gave essentially similar results (see online supplementary material, Supplemental Tables 2–6).

Discussion

The present study evaluated the impact of a 15-month intervention on dietary intake and quality among pre-school children predisposed to obesity. The results indicated that after the intervention the children in the intervention group had a lower mean total energy intake compared with the control group, mainly as the result of lower intakes of energy from carbohydrates and added sugar.

The observed lower added sugar intake could indicate a better diet quality and may, together with the reduced total energy intake, be beneficial in relation to primary prevention of excessive weight gain and later potential development of overweight and obesity.

When comparing our results with those from other obesity prevention intervention studies among young children (0–5 years), few of these previous studies reported positive changes in dietary intake[40–44]. One of these studies, conducted among African-American

Table 3 Effects of the intervention on intakes of energy and macronutrients at 15-month follow-up*: obesity-prone normal-weight Danish pre-school children, Healthy Start study, 2009–2011

		Intervention group		Control group		
	n	Mean	95 % CI	Mean	95 % CI	*P* value
Total energy intake (MJ)						
PP	285	5·29	5·11, 5·46	5·59	5·41, 5·76	0·02
ITT†	543	5·21	4·98, 5·44	5·46	5·29, 5·62	0·06
Fat (E%)						
PP	285	31·1	30·3, 32·0	30·2	29·5, 31·0	0·12
ITT†	543	31·0	30·1, 31·9	30·0	29·2, 30·9	0·07
Fat (MJ)						
PP	285	1·66	1·58, 1·74	1·70	1·63, 1·78	0·39
ITT†	543	1·64	1·54, 1·73	1·66	1·59, 1·74	0·59
Saturated fat (E%)						
PP	285	11·2	10·7, 11·6	11·0	10·7, 11·4	0·70
ITT†	543	11·1	10·7, 11·5	11·0	10·7, 11·3	0·58
Saturated fat (MJ)						
PP	285	0·59	0·56, 0·62	0·62	0·59, 0· 66	0·18
ITT†	543	0·60	0·56, 0·64	0·61	0·58, 0·64	0·56
Carbohydrates (E%)						
PP	285	53·1	52·1, 54·0	53·9	53·2, 54·6	0·14
ITT†	543	53·1	52·2, 54·0	54·2	53·5, 54·9	0·05
Carbohydrates (MJ)						
PP	285	2·93	2·83, 3·03	3·15	3·05, 3·24	0·002
ITT†	543	2·93	2·83, 3·02	3·09	2·99, 3·18	0·01
Added sugar (E%)						
PP	285	6·7	6·0, 7·3	7·4	6·9, 7·3	0·09
ITT†	543	6·8	6·1, 7·6	7·5	6·8, 8·1	0·18
Added sugar (MJ)						
PP	285	0·35	0·31, 0·39	0·43	0·39, 0·47	0·01
ITT†	543	0·36	0·31, 0·41	0·42	0·38, 0·46	0·05
Protein (E%)						
PP	285	15·9	15·4, 16·3	15·8	15·4, 16·3	0·78
ITT†	543	15·7	15·3, 16·1	15·8	15·4, 16·1	0·87
Protein (MJ)						
PP	285	0·83	0·80, 0·87	0·88	0·84, 0·91	0·12
ITT†	543	0·82	0·77, 0·88	0·86	0·83, 0·90	0·14

PP, per protocol; ITT, intention-to-treat (unadjusted model); E%, percentage of energy.
*The difference between groups was tested using linear regression modelling with adjustment for baseline levels. Results presented as mean and 95 %CI.
†Imputations on allocated group municipality, BMI *Z*-score, gender, age at baseline, number of months breast-fed without supplements, physical activity level at baseline, total energy intake (kJ) at baseline, macronutrients (intake of protein, carbohydrates and fat; E%) at baseline, food groups (intake of fish, SSB, fruit and vegetables; g/d) at baseline, maternal ethnicity, paternal ethnicity, maternal education, paternal education, maternal BMI at baseline and paternal BMI at baseline.

children, reported a difference between intervention and control children regarding percentage of energy from saturated fat, 11·6 *v.* 12·8 % at 1-year follow-up, but no differences were observed post-intervention or at a 2-year follow-up[40]. Moreover, no differences were observed for intakes of total fat and fibre. Additionally, the changes observed for intake of saturated fat were confined to the African-American children, but were not observed among the Latino participants[41]. In our study, we did not see differences in saturated fat intake between the intervention and control groups, but the mean intake was above the recommendation of 10 E% in both groups. Our PP analyses showed a slightly lower intake of energy from carbohydrates in the intervention compared with the control group at the 15-month follow-up, potentially stemming from less added sugar and soft drinks. However, individual changes in soft drinks did not differ between intervention and control children. This reduction in discretionary energy together with a lower intake of sugared drinks has also been observed in a Swedish intervention study among 9–48-month-old children[45]. Also, in another intervention study[42] among children with impending overweight, lower total energy intake and percentage protein intake were reported among children in the intervention group compared with the control group after the intervention[42]. These results for total energy intake are in good agreement with our results also showing a lower total energy intake among the children from the intervention group compared with the controls. This observed lower total energy intake may indicate a positive effect of the intervention with regard to obesity prevention. In an earlier 10-month obesity prevention intervention programme focusing on diet and PA strategies among Australian children aged 3–6 years[46], a higher intake of fruit and vegetables was seen after the intervention among children from the intervention group compared with the controls, and the intervention children were less likely to have unhealthy food items in their lunch boxes[47]. We

Table 4 Effects of the intervention on diet quality and intakes of fruit, vegetables, fish and sugar-sweetened beverages (SSB) at 15-month follow-up*: obesity-prone normal-weight Danish pre-school children, Healthy Start study, 2009–2011

		Intervention group		Control group		
	n	Mean	95 % CI	Mean	95 % CI	*P* value
Fruit (g/d)						
PP	285	99	89, 109	101	92, 110	0·76
ITT†	543	98	87, 109	97	84, 109	0·89
Vegetables (g/d)						
PP	285	115	103, 128	116	106, 125	0·96
ITT†	543	110	97, 123	113	102, 123	0·75
Fish (g/d)						
PP	285	20	16, 25	15	13, 18	0·07
ITT†	543	19	15, 24	15	11, 19	0·21
SSB (g/d)						
PP	285	71	57, 86	81	66, 95	0·33
ITT†	543	72	54, 89	90	74, 105	0·16
DQI (units)						
PP	285	4·3	4·2, 4·5	4·4	4·3, 4·5	0·41
ITT†	543	4·3	4·2, 4·4	4·4	4·3, 4·5	0·17

PP, per protocol; ITT, intention-to-treat (unadjusted model); DQI, diet quality index.
*The difference between groups was tested using linear regression modelling with adjustment for baseline levels. Results presented as mean and 95 % CI.
†Imputations on allocated group municipality, BMI *Z*-score, gender, age at baseline, number of months breast-fed without supplements, physical activity level at baseline, total energy intake (kJ) at baseline, macronutrients (intake of protein, carbohydrates and fat; percentage of energy) at baseline, food groups (intake of fish, SSB, fruit and vegetables; g/d) at baseline, maternal ethnicity, paternal ethnicity, maternal education, paternal education, maternal BMI at baseline and paternal BMI at baseline.

generally did not see significant intervention effects on the various elements of the diet like fruit, vegetables and fish, or on overall diet quality; however, trends were generally in a healthier direction. Both groups had a DQI above the mean (4·3 on the scale from 0 to 6), which may indicate good compliance with the Danish national dietary guidelines before the intervention and hence potentially less room for improvement. The intervention focused on various elements and on average the families had four consultations during the study, which may have made the intervention too complex to promote larger changes in dietary intake. As far as we know, no previous obesity prevention intervention programme among young children (0–5 years) has examined effects on overall diet quality[43], so our results cannot be compared with previous findings.

To the best of our knowledge, the Healthy Start intervention programme is the first study that aimed to prevent excessive weight gain among yet normal-weight pre-school children predisposed to future obesity[48], and not only aimed at improving diet and PA, but also to improve sleep quality and quantity and reducing stress. The strengths of the Healthy Start study are the randomized design, which minimizes the possibility that any of the observed associations were due to confounding, and a relatively long intervention period compared with previous interventions[43]. The use of validated measurements for dietary intake is also a strength of the present study. However, we do acknowledge that even though dietary intake was assessed using a validated tool, biased reporting may still have been present. In total, 96 % of all Danish children aged between 3 and 6 years spend more than 7·5 h/d in day care[49] and since the caregivers were not instructed to fill out dietary registration for the children or did not have the time to inform parents about the children's dietary intake, there is a possibility that the children may not have eaten all food provided and hence the parents may have over-reported their intakes. Nevertheless, this bias in reporting would be expected to be present in both the intervention and the control groups and should therefore most likely not affect the comparison of the groups. On the other hand, parents of the intervention children may, as a consequence of the intervention, have given more biased information on dietary intake at follow-up than control parents. Indeed, at follow-up, 8 % in the intervention and 2·5 % in the control group under-reported intakes[50] and we cannot exclude that this may have contributed to the observed effects on overall energy intake of the intervention. A higher maternal education level among the participating children was observed, which could indicate that some selection bias has been introduced. This could partly explain the lack of observed effects of the intervention on the specific nutrients and foods, since previous research has indicated that there may be less space for improvement in diet for children from families with high socio-economic status, and that children from families with low socio-economic status may benefit most from participating in intervention programmes[51]. Likewise, observer bias may potentially also be a concern in the Healthy Start intervention study, as it was not possible to blind the health consultants concerning the group assignment of each child. However, to attempt to reduce this problem, detailed manuals and guidelines were developed on the practical conduction of the consultations with the families in both the intervention group and the control group.

The generalizability of the results is subject to the limitation that our study population was confined to obesity-prone children and our results may not apply to children without a predisposition to obesity. However, the intervention was truly a primary obesity prevention intervention, as all included children were of normal weight at baseline. In this way, and to the best of our knowledge, the present intervention differs from all previous obesity prevention interventions conducted to date as previous interventions generally included groups of children of mixed weights and the present study was conducted among children who were all normal-weight[48]. Moreover, due to a higher maternal education level among the participating children these results may potentially not be generalizable to children from all families.

From a public health perspective, the findings from the current study emphasize that targeting the family's individual needs and resources may have positive impact on the development of healthy dietary intake among pre-school children.

Conclusion

In this primary prevention intervention study targeting obesity-prone 2–6-year-old children, a decrease in total energy intake was obtained among children in the intervention group after 15 months of intervention. Overall the composition of macronutrients and food intakes were not different before and after the intervention, but the overall intervention effect on energy intake resulted from lower absolute intakes of carbohydrates and added sugar. The observed lower total energy intake may be beneficial in the attempt to prevent excessive weight gain and later potentially the development of overweight, and the lower added sugar intake is an indicator of a better diet quality.

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Supplementary material

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