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ORIGINAL ARTICLE

## Early intervention for childhood overweight: A randomized trial in general practice

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### Abstract

**Objective.** To evaluate the effect of two intervention modalities concerning overweight and obesity among children in general practice. **Design.** Prospective randomized controlled trial. **Setting.** A total of 60 general practices in the former County of Funen, Denmark. **Subjects.** Overweight children, identified by International Obesity Task Force criteria, aged 5–9 years. **Intervention.** Model 1 with health consultations in general practice during a two-year period or Model 2, an educational programme for the children and their families in addition to the health consultations. **Main outcome measures.** Change in body mass index (BMI) z-score in order to compare the results, independent of gender- and age-related changes over time. **Results.** A total of 80 children were recruited with 35 and 45 children allocated to Model 1 and Model 2, respectively. No significant differences were found in the change in BMI z-score (SDS) between the two groups. A decrease in the mean BMI z-score from baseline to study end of  $-0.20$  (95%CI  $-0.38$  to  $-0.01$ ) in Model 1 and  $-0.26$  (95%CI  $-0.44$  to  $-0.09$ ) in Model 2, respectively, was detected. The majority of the participants (2/3) continued in the study for more than one year in both models, with a mean of 12 consultations in general practice. **Conclusion.** In this particular setting the two intervention strategies against overweight and obesity did not differ significantly with regard to change in BMI z-scores.

**Key Words:** Children, Denmark, family-based, general practice, long-term intervention, overweight, randomized controlled trial

### Introduction

Overweight and obesity in children are increasing health problems in the Western world, including Denmark [1–3], with significant adverse effects on physical and psychosocial health in childhood as well as in adulthood [4,5]. Proactive strategies in childhood to support prevention of overweight and obesity have been advocated [6,7]. A combination of moderation of energy intake, increased physical activity, reduced sedentary activities and family involvement has been reported as successful [8–10]. Only a few reported trials have as yet examined the efficacy of treatment strategies for overweight children and their families in general practice [11,12].

In Danish primary health care *preventive child health examinations* with seven child health examinations

during the first five years of life provide opportunity for an early focus on childhood obesity [13]. The aim of the present study was in a randomized controlled design to compare the effect of two intervention modalities for overweight and obese children and their families in general practice.

### Material and methods

A prospective randomized trial was conducted involving 60 general practices in Funen, Denmark, between August 2007 and November 2010. Participants were randomized using a random number table prepared before recruitment of participants for the study. In order to ensure concealment of the allocated intervention at the time of enrolment of participants,

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- Childhood overweight is a significant health problem and only a few trials have examined the efficacy of treatment strategies in general practice.
- Proactive strategies with an educational programme for children and their families have been advocated.
- In a randomized study a strategy with health consultations in general practice during a two-year period were compared with a more complex strategy comprising an educational programme for the children and their families in addition to the health consultations.
- Comparison of the two intervention strategies showed no significant differences in change in BMI between the two groups.

the participants were randomized in blocks of two for patients enrolled in a single-handed practice, and in blocks of four or six for patients enrolled in a group practice. The size of the blocks and the allocation sequence were unknown to the general practitioners (GPs). Besides information to the patients regarding the study and obtainment of oral and written consent, the GPs did not take part in either the allocation process, or information to the families on results of the randomization. The GPs informed the study investigator about the patient's acceptance of participation in the study. The study investigator allocated the patient according to the random number table and informed the family by telephone or letter.

### Participants

All 168 GPs on the island of Funen (population 472 000), Denmark, were invited to participate through a leaflet or by telephone. The study investigator visited all participating GPs, informed them about the study and introduced them to a lifestyle intervention strategy using a "small steps and realistic goals" approach [14]. In addition they received written material on both study strategy and the lifestyle intervention strategy. A chart, which was used at the monthly consultations in general practice, was introduced in order to ensure that the same themes and thus lifestyle intervention strategy were handled in the consultations. Overweight five- to nine-year-old children were identified in general practice using the International Obesity Task Force (IOTF) criteria [15]. Exclusion criteria were: non-Danish-speaking families, previous or current participation in another project concerning overweight and obesity, mental or

physical disabilities, endocrine causes of obesity, or signs of precocious puberty. Inclusion continued until 80 children and their families were enrolled based on the power calculation.

### Interventions

The children were allocated to one of two models of two-year duration:

*Model 1:* Monthly consultations in general practice during the first study year including focus on lifestyle habits, diet, and physical activity. In the second study year the frequency of consultations was recommended to be every two months, adjusted to the needs of the individual family. All participants received literature on healthy diet and physical activity.

*Model 2:* Intervention as in Model 1, supplemented with three educational programmes, each of three hours' duration, for groups of 2–5 families. The educational sessions in Model 2 were intended to take place at study start, after two months, and after one year and were performed by a dietitian, a physical exercise instructor, and a psychologist with the purpose of promoting a healthy lifestyle through knowledge and inspiration to a healthy diet and enjoyable physical activities.

The strategy of Model 2 was pilot tested with the inclusion of three families. All families were interviewed three times during the first study year by the study investigator. The content and composition of the educational sessions were adjusted according to the feedback from the families.

### Outcome measures

The weight, height, and waist circumference (WC) of the child were measured at each consultation in general practice. It was stressed that the anthropometric measures should be conducted by the same professional [9].

The main outcome measure was the change in BMI z-score in order to compare the results independent of gender- and age-related changes over time. Body weight was measured with the child in light underwear to the nearest 0.1 kg, using the same digital medical scale for the same child. Height was measured in standing position with no shoes to the nearest 0.1 cm using a stadiometer. Danish reference material [16] was used to calculate body mass index (BMI) z-scores (SDS). Change in BMI z-score was defined as the difference between the child's BMI z-score at baseline and the BMI z-score after the two-year intervention. For children with missing data, the latest measurement of the

anthropometric data obtained in general practice was used.

WC was measured as an indicator of abdominal obesity [17] using a measuring tape to the nearest 0.1 cm at the level of the umbilicus. The waist–height ratio (WHtR) was calculated [18].

#### *Sample size*

Sample size calculations were performed for expected changes in variation in BMI. The expected change was minus 1 BMI SD in Model 2, corresponding to stabilization of the weight after a two-year project period. Alpha was set at 0.05 and power at 0.8. Using these assumptions, the estimated sample size was 20 in each group. As a dropout rate of 50% was anticipated, this number was multiplied by two in the final sample size estimate.

#### *Statistical analysis*

A multiple linear regression analysis was performed to assess the influence of the children's baseline BMI, duration of study participation, number of consultations, and randomization on the change in BMI z-scores in the study period.

An unpaired *t*-test was used to compare the change in mean BMI z-score, mean WHtR and mean WC, respectively, in the two randomization groups. A paired *t*-test was used to analyse changes in mean BMI z-score, mean WHtR, and mean WC from baseline to study end within the randomization groups.

Association between change in BMI z-scores/WHtR and duration of study participation, number of consultations, and educational sessions was assessed by multiple linear regression. A full analysis set (FAS) on all analyses available was performed using the statistical package STATA™ (StataCorp, College Station, TX, USA) version 11. A subgroup analysis of participants who were particularly adherent was performed in the subgroup of children with more than one-year project duration, two or more consultations in general practice, and, for children allocated to Model 2, with two or more educational sessions. A lost to follow-up analysis was performed on the group of participants with a complete study participation of two years and the group with study participation of less than two years.

#### *Ethics*

The trial was approved by the Regional Committee for Ethics in Biomedical Research (j.noVF20050116) and the Danish Data Protection Agency (j. no 2007-41-1137).

## **Results**

Sixty general practices accepted to participate in the study. A total of 99 children and their families were invited to participate during the inclusion period August 2007 to December 2009. Eighty (81%) of the eligible children and families were included in the trial; 35 children were allocated to Model 1 and 45 children to Model 2 (Figure 1).

Baseline characteristics appear in Table I. At baseline the mean age and the mean BMI z-scores were significantly lower in girls than in boys. Mean waist circumference was above the 95th percentile at baseline according to British waist circumference percentiles [19]. Mean WHtR was above the cut-off value for definition of abdominal obesity for children more than five years old [20].

Mean duration of study participation was 1.3 years in Model 1 (range 28–925 days) and 1.5 years in Model 2 (range 83–950 days) with no significant differences between the randomization groups (Table II). No influence of the children's baseline BMI, duration of study participation, and number of consultations was found on the change in BMI z-scores between the two randomization groups.

#### *Outcome measures*

No differences were found in change in BMI z-score between the two randomization models (Table III). A significant decrease in BMI z-score was observed for both groups (Model 1:  $-0.20$  ( $p = 0.04$ ) and Model 2:  $-0.26$  ( $p = 0.004$ ), respectively). A difference in WHtR change was detected between the two randomization models, in favour of Model 1 (Table III).

No associations were found between duration of study participation, number of GP consultations, and number of educational sessions compared with changes in BMI z-score and changes in WHtR, respectively. However, in a simple linear regression analysis (data not shown), a strong association was observed between change in BMI z-score and change in WC (regression coefficient 0.03,  $p = 0.007$ ) as well as change in WHtR (regression coefficient 7.3,  $p < 0.000$ ).

A total of 21 participants in Model 1 (62%) and 26 participants in Model 2 (65%) were included in the subgroup analysis of participants who were particularly adherent. No difference was observed in the mean change in BMI z-score between the two randomization models. In contrast to the FAS analyses, no significant difference between the two models in the changes in either WHtR or waist circumference was detected in the subgroup analysis (data not shown).

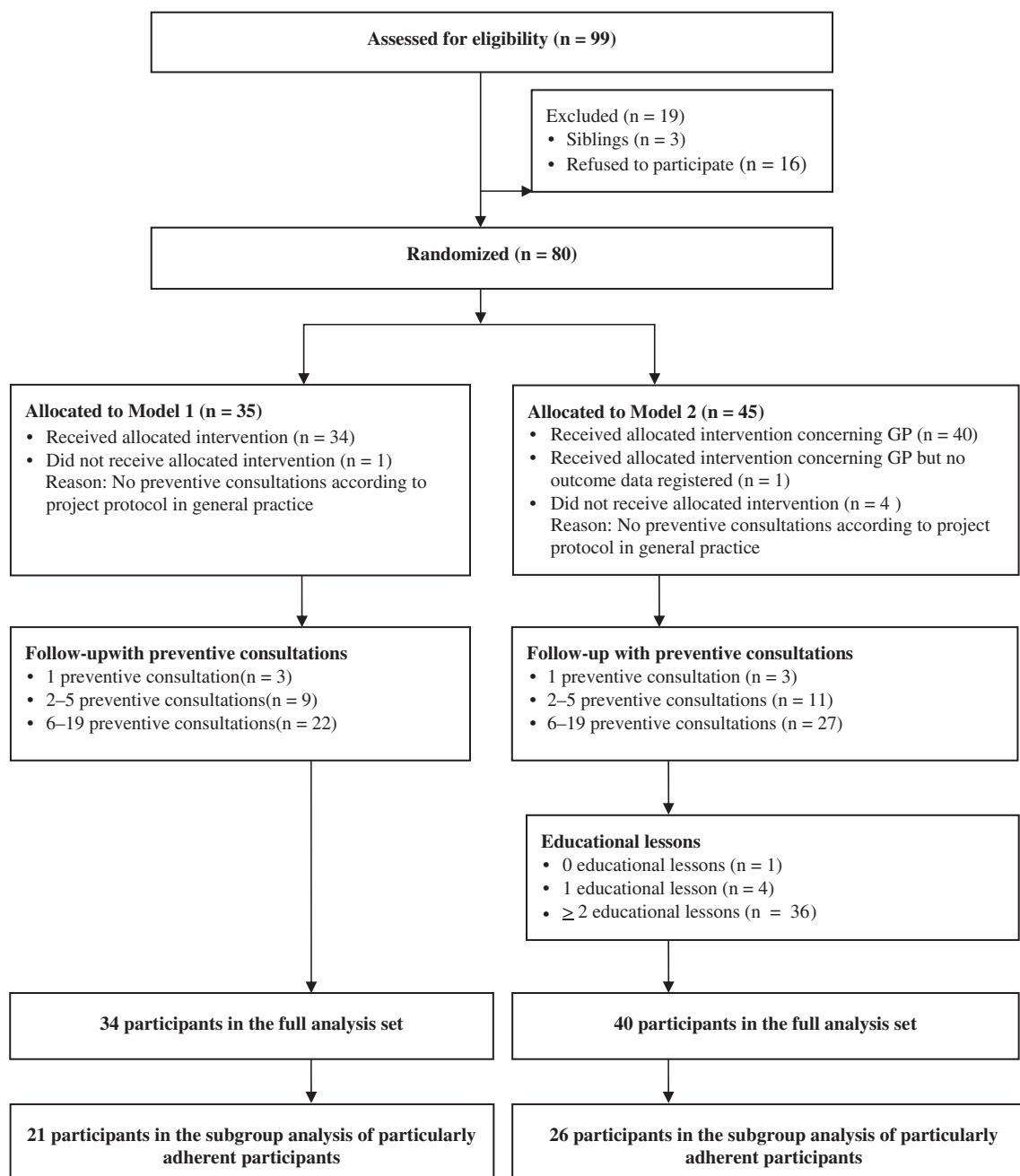


Figure 1. Participant flow and follow-up.

A total of 10 children in Model 1 and 16 children in Model 2 succeeded in a full two-year follow-up. Slightly more girls completed the intervention in Model 1, when compared with Model 2. No differences were found in age or BMI z-score at baseline between the two models. Furthermore, we found no significant differences in change in BMI z-scores during follow-up between the two models, either for the children with less than a two-year follow-up, or for the children with a complete two-year follow-up.

## Discussion

In a prospective randomized controlled trial, two management strategies for overweight and obese five- to nine-year-old children performed in Danish primary health care were compared. A strategy with consultations in general practice (Model 1) and a more complex strategy including educational sessions for the children and their parents in addition to the consultations (Model 2) showed no difference in change of the BMI z-scores. A beneficial



Table I. Baseline characteristics of the participants according to randomization group.

		Model 1 (n = 35)	Model 2 (n = 45)
Females, numbers (%)		22 (62.9 %)	30 (66.7 %)
Age, years	All	6.3 ± 1.3 (5.9–6.8)	6.1 ± 1.1 (5.8–6.5)
	Girls	5.9 ± 1.1 (5.5–6.4)	6.0 ± 1.1 (5.6–6.4)
	Boys	7.0 ± 1.6 (6.1–7.9)	6.4 ± 1.1 (5.8–7.0)
BMI z-score	All	2.79 ± 0.82 (2.51–3.08)	2.88 ± 0.87 (2.62–3.14)
	Girls	2.41 ± 0.58 (2.16–2.67)	2.58 ± 0.54 (2.38–2.79)
	Boys	3.43 ± 0.80 (2.95–3.91)	3.48 ± 1.08 (2.89–4.08)
Waist circumference (cm)	All	n = 31 68.6 ± 9.1 (65.3–71.9)	n = 34 69.9 ± 9.1 (66.7–73.1)
	Girls	n = 20 66.1 ± 7.4 (62.6–69.5)	n = 20 68.0 ± 7.9 (64.3–71.6)
	Boys	n = 11 73.2 ± 10.3 (66.3–80.1)	n = 14 72.7 ± 10.3 (66.8–78.7)
	All	0.554 ± 0.043 (0.538–0.570)	0.563 ± 0.051 (0.545–0.580)
	Girls	0.548 ± 0.046 (0.526–0.569)	0.554 ± 0.539 (0.539–0.570)
	Boys	0.565 ± 0.035 (0.542–0.589)	0.575 ± 0.068 (0.535–0.614)

Note: Values are mean ± SD and (95% confidence intervals) unless otherwise stated.

effect on BMI z-score changes was registered in both strategies.

The strengths of this study were a design based on already existing contact between the GPs and the families, which can enhance the application of the results to daily clinical practice. Furthermore, the two-year duration of the intervention is long, compared with other studies [8,9,21].

Incorporation of a control group without any intervention would have been of benefit in the interpretation of the study results, i.e. as a waiting list group offered the best intervention at the end of follow-up. This was, however, not found ethically applicable due to the long intervention period of two years.

The latest achieved endpoint BMI z-score data were used as carry-forward measure in the analyses due to a high dropout rate and no security for missing data at random. We cannot omit the possibility that

this method could account for some of the beneficial effect found on BMI z-score in both groups. High dropout rates are unfortunately well known in life-style interventions. Dropout rates in this study of 38% in Model 1 and of 35% in Model 2 after one year, respectively, were, however, comparable and even slightly smaller compared with other studies performed in primary health care [22].

Both study models could take advantage of the GP's prior knowledge of the family, and this element may explain why educational lessons three times within the first project year did not demonstrate an additional effect of the counselling in general practice. We can, however, not eliminate the possibility that the three educational sessions might not have been enough to elucidate a possible intervention effect. Sixty GPs were admitted to the study and 80 children were included, which raised the question of

Table II. Duration of study participation, number of preventive consultations, and educational sessions according to randomization group.

	Full analysis set		Subgroup analysis*	
	Model 1 (n = 34)	Model 2 (n = 40)	Model 1 (n = 21)	Model 2 (n = 26)
Duration of study participation:				
Mean number of days ± SD	490 ± 286	539 ± 249	684 ± 161	661 ± 133
(95% CI)	(390–590)	(459–618)	(610–757)	(608–715)
Range (days):	28–925	83–950	379–925	386–862
Preventive consultations in general practice				
Mean number ± SD	9.1 ± 5.7	9.2 ± 5.6	12.5 ± 4.2	11.1 ± 5.2
(95% CI)	(7.1–11.0)	(7.4–11.0)	(10.6–14.4)	(9.0–13.2)
Range (number):	1–19	1–19	2–19	2–19
Mean number of educational sessions				
(95% CI)	NE**	2.55 (2.30–2.81)	NE**	2.85 (2.70–3.00)

Notes: \*Subgroup analysis of particularly adherent participants. \*\*NE: No educational sessions in Model 1.

Table III. Mean change in BMI z-score, in weight/height ratio (WHtR), and in waist circumference (WC) in the two intervention models.

Parameter	Full analysis set			
	Model 1 (n = 34)	Model 2 (n = 40)	Between-group difference in change from baseline	p-values
BMI z-score change				
Mean $\pm$ SD	-0.20	-0.26	-0.07	0.59
(95% CI)	(-0.38, -0.01)	(-0.44, -0.09)	(-0.32, 0.18)	
WHtR change	n = 31	n = 34		
Mean $\pm$ SD	-0.014	0.004	0.018	0.03
(95% CI)	(-0.027, -0.002)	(-0.008, 0.015)	(0.002, 0.034)	
WC change				
Mean (cm) $\pm$ SD	1.92	4.66	2.74	0.03
(95% CI)	(0.24, 3.59)	(2.75, 6.58)	(0.23, 5.27)	

whether the GPs were able to develop routine and competence in treatment of childhood obesity in the study. Not all practices succeeded in recruitment of children though, which may indicate that some barriers exist to recruitment and management of childhood overweight in general practice [23,24]. This issue is discussed in further detail below.

The achievement of a statistically significant reduction in BMI in this study, although modest and similar in the two randomization models, could be interpreted as either a treatment effect or a result of regression towards the mean. However, other studies have shown that BMI z-scores continue to increase in overweight children not receiving any treatment [25,26]. These results support the contention that the findings in this study could be treatment effects.

In the present study an intervention effect in WHtR/WC indicated a favourable outcome of Model 1. This result is in contrast to other studies using WC reduction as a secondary outcome [20,27], where the patterns of change in WC mirrored the changes in the BMI z-score. The regression analysis in the present study also showed a strong association between the BMI z-score change and WC/WHtR change, suggesting caution in the interpretation of the WC/WHtR results. In addition the effect could not be detected in the subgroup analysis.

Previous studies have used study designs and outcome measures comparable to the present study. An Australian and a British study achieved BMI z-score reductions at the same level as the reductions achieved in this study within the randomization groups. No difference between the randomization groups was detected in either of the studies [27,28]. Some studies have achieved larger reductions in BMI z-score [29–31]. However, analyses in these studies were not performed on a full analysis set (FAS) and may have overestimated intervention effects [32].

In conclusion, the study did not reveal any differences between the two intervention strategies against

childhood overweight. A number of limitations in the study should be taken into account, especially recruitment problems and a high dropout rate during the study period. Further investigations of barriers to and facilitators of recruitment and management of childhood overweight in general practice will be beneficial.

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### Declaration of interest

There are no conflicts of interest in connection with the paper. The authors alone are responsible for the content and writing of the paper.

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