



## REGULAR ARTICLE

# A family-oriented intervention programme to curtail obesity from five years of age had no effect over no intervention

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## Abstract

**Aim:** To examine the effect of a family-oriented multidisciplinary intervention programme to curtail weight increase in young children with obesity.

**Methods:** Children who weighed more than one kilogram above the 97th percentile for height at the preschool assessment in Oppland County, Norway, were identified. Parents residing in one part of the county were invited to participate in a group-based three-year intervention programme while the rest had no interventions. Body mass index (BMI) and family characteristics at entry and measurements at birth were explanatory variables, and change in BMI standard deviation score (SDS) the outcome measure. For the intervention group, outcome was also related to skinfold thicknesses, waist-to-height ratio and physical ability.

**Results:** The programme was completed by 31 families in the intervention and 33 in the control group. At entry, the respective median (interquartile) age was 5.83 (0.36) and 5.74 (0.66) years, and the BMI SDS 2.35 (1.06) and 1.95 (0.49),  $P = .012$ . The median decrease in BMI SDS was 0.19 in both groups. The decline increased with increasing BMI SDS at entry, but irrespective of group. Social or behavioural factor or other anthropometric measures were not associated with outcome.

**Conclusion:** The intervention programme had no effect on BMI SDS.

## KEYWORDS

body mass index, child, intervention, obesity, standard deviation score

## 1 | INTRODUCTION

The prevalence of overweight and obesity among children has increased throughout the world, and the World Health Organization (WHO) estimates that 41 million children under five years of age are overweight or obese.<sup>1</sup> In Norway,<sup>2</sup> as in some other European countries,<sup>3</sup> the prevalence of overweight and obesity among children may have stabilized over the last 10-20 years. Despite this development,

16% of eight-year-old children,<sup>2</sup> and 13%-17% of children aged 2-19 years<sup>4</sup> in Norway were overweight or obese in studies published during the last decade.

Children with obesity, and in particular adolescents, are at extremely high risk of being affected by obesity as adults,<sup>5</sup> and intervention studies to treat overweight and obesity in childhood have generally had limited or no success.<sup>6-9</sup> Furthermore, studies with some success have usually been evaluated after

**Abbreviations:** Δ BMI, delta BMI; BMI, body mass index; IQR, interquartile range; SDS, standard deviation score; WHO, World Health Organization.

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short follow-up periods and may therefore have limited clinical significance since the risk of relapse may be high.<sup>6-9</sup> However, the majority of studies have addressed children in mid or late childhood, and the chance of success may decrease with increasing age.<sup>10</sup>

Our hypothesis was that intervention to curtail obesity is more effective when addressing young children when parents may have a greater impact on their child's behaviour. In a meta-analysis of children younger than 11 years with obesity, the mean age at entry was less than seven years in only six of the studies, and the interventions tended to be limited in terms of approach and involved personnel.<sup>6</sup> Furthermore, the intervention lasted between 3 and 6 months in 18 of 20 studies, and effects were assessed shortly thereafter. Therefore, our aim was to compare the effect of a three-year, group-based multidisciplinary intervention programme with no intervention in children aged five to six years. The programme only involved the parents, and the purpose was to alter the lifestyle of the family and child. The parents' perceived challenges as the intervention progressed were important in adjusting the programme to their specific needs. Our secondary aim was to identify potential success factors within the intervention group.

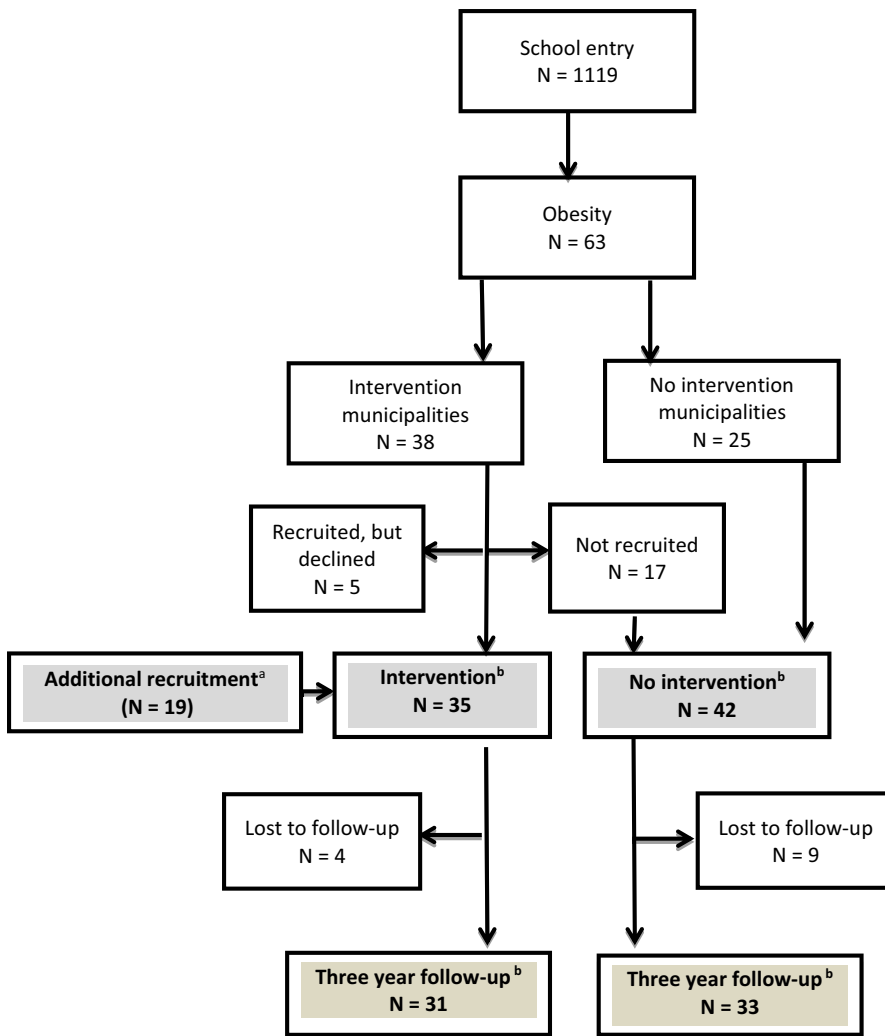
### Key Notes

- Intervention programmes to treat obesity during childhood and adolescence have had limited success, but few studies have involved families of young children.
- This multidisciplinary and group-based programme which addressed parents of five-year-old children with severe overweight or obesity and lasted 2-3 years had no effect over no intervention on the median BMI standard deviation score.
- Anthropometric measures at entry, social or behavioural factors or attendance were not associated with outcome.

## 2 | METHODS

### 2.1 | Study population

We asked the public health nurses in Oppland County, Norway, to invite the parents of all the children who met for the school entry



**FIGURE 1** Recruitment of families of 5- to 6-year-old children with severe overweight or obesity for intervention or no intervention. <sup>a</sup>Included at the request of parents, <sup>b</sup>measurements at public healthcare clinics

health assessment in 2007, to participate in a longitudinal cohort study on health and growth (Figure 1). Virtually all children attend this examination together with at least one of the parents. Of 1895 children who met for the assessment, the parents of 1119 gave written consent to participate. The parents completed questionnaires on health and habits for the children, and on demographic, socioeconomic, health and lifestyle characteristics of the family.<sup>11</sup> The public health nurses measured the child's weight and height and reported these measures together with the recorded weight and length at birth. For children of families who declined to participate, the public health nurse anonymously reported sex, age, height and weight at the time of recruitment, and we have previously reported that the participants were probably representative of the population.<sup>11</sup>

From the cohort, children who weighed at least one kilogram above the 97th percentile for height were identified as eligible for the study. Body mass index (BMI) charts were not available at the public health clinics, but this measure was close to the definition of obesity according to the International Obesity Task Force definition of obesity, although some of the children had a BMI slightly below this limit.<sup>12</sup>

Oppland is one of 20 counties in Norway. It covers 25 192 km<sup>2</sup>, has 26 municipalities and had a population of approximately 183 000 in 2007. On behalf of the research group, the public health nurses in the six municipalities that were geographically closest to the two hospitals in the county were asked to invite the families of eligible children to participate in the intervention programme. These municipalities had approximately 60% of the population in the county. They are mainly rural, but contain the only two cities in the county, each with 25 000-30 000 inhabitants. The other municipalities are rural with towns of variable sizes. The families from the other municipalities and families who were not referred from the intervention municipalities served as controls.

Some families of children with obesity in the intervention municipalities, who were not in the originally recruited group, became aware of the project and asked to be allowed to participate. These children were close in age and were included since a larger group allowed for a more accurate estimate of potential effects of the programme.

## 2.2 | Intervention and control programme

The intervention programme was organised in cooperation with the Learning and Mastery Service at the hospitals. This service is established as part of the specialist health services in Norway, and the purpose is to promote health through group-based patient education programmes aimed at promoting self-management for people living with chronic health challenges.<sup>13</sup> The programme is led by nurses who are trained in providing guidance. Other relevant personnel participate according to specific needs. In this project, only the parents attended the group sessions. In addition to nurses, one or more of the following professions contributed at each session:

paediatricians, nutritionists, physiotherapists and a psychologist. The various professionals participated according to a predetermined schedule early in the programme, but some variation evolved as needs were identified by the groups. The professionals gave practical advice regarding diet and physical activity, but in particular, they encouraged and participated in discussions on experienced challenges in changing lifestyles and on how to deal with them in terms of changing behaviour.

Each group consisted of 5-7 pairs of parents, and each session was scheduled to last 2.5 hours after working hours. The children were occupied in play under the supervision of a preschool teacher while the parents participated in the sessions. The intervention programme was planned to last three years. At the Learning and Mastery Service, the groups were scheduled to meet four times during the first year, twice during the second and one time during the third year. Between each of these sessions, each family (parents and the child) was invited once for discussions and assessments by the study nurses.

The no-intervention control children and their families received no information about the intervention programme and had no scheduled appointments with healthcare services during the three years of the study.

## 2.3 | Measurements

The weight and length at birth were measured by midwives and reported to the public healthcare clinics. Comparisons between the intervention and control group were based on routine measurements of height and weight around school entry and in third grade. Public health nurses performed these measurements according to national guidelines. The children were wearing light underclothes. Height was measured to the nearest millimetre and weight to the nearest 100 g.<sup>14</sup>

In the intervention programme, the children were assessed by two specifically trained study nurses at entry and after each of the three years. The measurements included height, weight, triceps and subscapular skinfold thicknesses, abdominal circumference and maximum walking distance on a 6-minute walk test.<sup>15</sup> Waist circumference was measured to the nearest millimetre, and waist-to-height ratio was calculated as the waist circumference divided by the simultaneously measured height. The skinfolds were measured with a Holtain Tanner/Whitehouse skinfold calliper (Crosswell, Pembrokeshire, UK) and in a way that was identical to how Norwegian references were established.<sup>16,17</sup> On the 6-minute walk test, the nurses recorded the length in metres as the children were able to walk during 6 minutes on a 50 metre lane.

BMI was calculated as weight/height<sup>2</sup> (kg/m<sup>2</sup>). The standard deviation score (SDS) for the BMI, waist circumference, waist-to-height ratio and skinfolds of the children were based on current Norwegian growth references.<sup>17-19</sup> The parents' heights and weights were self-reported.

## 2.4 | Explanatory and outcome measures

The BMI SDS at inclusion was the primary explanatory variable and the change in BMI SDS from entry to the end of the programme the primary outcome measure. In adjusted analyses, we included birth weight, child and family health, lifestyles and other characteristics reported at the study entry as possible confounders. Several of the descriptive ordinal variables were dichotomized in order to do meaningful comparisons.<sup>11</sup> Hospital admissions were admissions for any cause from birth until the preschool assessment. Physical activity per week was reported as frequency of being active enough to experience heavy breathing or sweating.<sup>11</sup> Place of residence was categorised as urban if they lived in one of the two cities. Asthma medication included medication for asthma attacks, inhaled corticosteroids and other maintenance medications.

## 2.5 | Statistical methods

Descriptive statistics are presented as percentages for categorical variables and as medians with interquartile range (IQR) for continuous variables. Correlations are reported as the Pearson's correlation coefficient ( $r$ ). We compared the intervention and control group with Mann-Whitney's  $U$  and Chi-square tests and performed a multiple linear regression analysis across both groups to test whether being in the intervention or the control group had a significant impact on the change in BMI SDS when adjusting for the registered exposures.

The power estimate was based on a Scandinavian study of 10- to 11-year-old children with obesity where children in a family treatment group achieved a mean BMI benefit of 1.7 kg/m<sup>2</sup> after one year compared with a control group with no intervention.<sup>20</sup> The eligible children in our study had a mean (standard deviation) BMI of 20.40 (1.92) kg/m<sup>2</sup>. Although our children were younger and therefore had lower BMIs, an effect of 1.7 kg/m<sup>2</sup> was considered possible since our study was designed to last for three years. With this premise, we calculated that 22 children had to be included in each group to detect such a difference with the statistical significance level of 5% and a power of 80%. However, since the study did not have a true randomised design and the intervention and controls groups varied on some variables, a larger number was desirable. We used intention to treat, in that all who had attended at least one of the sessions were included in the analyses.

Within the intervention group, we used the related-samples Wilcoxon signed-rank test to compare measures at entry and at the end. In order to assess which factors were associated with success, we performed simple and multiple linear regression analyses with change in BMI SDS as the outcome measure. In this model, we included skinfold thickness as the mean of the sum of the triceps SDS and subscapular SDS measurements, and the waist-to-height ratio SDS. Our hypothesis was that relatively high values for a given BMI may suggest a higher fat deposit and therefore true obesity, while relatively low values may suggest a relatively high lean body mass. We used the number of attendances as proxy for motivation to

change lifestyle. The regression analysis was performed in an all-in backward model, and the potential explanatory variables were selected from earlier literature and the strength of association in the post-hoc bivariate analyses. Results are reported as estimated regression coefficients ( $b$ ),  $P$  values and determination coefficient ( $R^2$ ).

$P$  values  $\leq .05$  were considered statistically significant. The SPSS Statistics for Windows, Version 23.0 (IBM Corp., NY, USA) was used for all analyses. The BMI SDS, skinfolds SDS, waist circumference and waist-to-height ratio were calculated in R.2.6.0 (The R Foundation for Statistical Computing, Vienna, Austria) using Norwegian growth references.<sup>16-19</sup>

## 2.6 | Ethical considerations

The study was approved by the Regional Committee on Medical Research Ethics (REK 1.2006.3491) and the Norwegian Data Protection Official for Research (02-2006 SI). One of the patents gave written consent. The study was registered at ClinicalTrials.gov (NCT00458224) before recruitment.

## 3 | RESULTS

### 3.1 | Comparing the intervention and control group

Figure 1 describes the recruitment of subjects. Of 63 originally eligible children, 38 lived in the municipalities of recruitment for intervention. The 25 families from the other municipalities and 17 families from the recruitment area who were not referred for intervention served as controls. An additional 19 children of similar age from the intervention municipalities were included at the request of the parents. Data from both the entry and the end of the programme were available for 31 children in the intervention and 33 in the control group. In the intervention group, three children were born in 1999, 11 in 2000, 12 in 2001 and five in 2002. In the control group, one was born in 2000 and 32 in 2001. The measurements at entry of the children who were lost to follow-up (Figure 1) did not differ from those who completed the comparison study (data not shown).

The children in the intervention group had a higher median weight, BMI and BMI SDS at entry and a higher BMI SDS at the end of the intervention than the control group, but the median increase in BMI ( $\Delta$  BMI 2.02 vs 1.95 kg/m<sup>2</sup>) and decline in BMI SDS ( $\Delta$  BMI SDS 0.19 in both groups) did not differ ( $P = .731$ , Table 1). The fathers in the intervention group had a somewhat higher median BMI, and a higher proportion of the parents were of the opinion that their child looked overweight. Due to the study design, a higher proportion of the families in the intervention group lived in the two cities. The median time interval between the measurements tended to be shorter for the intervention than the no-intervention group (2.05, IQR 1.23 vs 2.59, IQR 1.65) years,  $P = .119$ . There were no other significant differences between the groups (Table 1). The  $\Delta$  BMI and  $\Delta$  BMI SDS did not differ between the controls recruited from the

**TABLE 1** Characteristics of the children with severe overweight or obesity and their families, and change in anthropometric measurements following intervention or no intervention in Oppland county, Norway

Child characteristics	Intervention (n = 31)	No intervention (n = 33)	
<b>Continuous variables</b>	<b>Median (IQR)<sup>a</sup></b>	<b>Median (IQR)<sup>a</sup></b>	<b>P-value<sup>b</sup></b>
Birth weight, kg	3.62 (0.80)	3.72 (0.78)	.466
BMI SDS at birth <sup>c</sup>	-0.11 (1.43)	0.07 (1.35)	.287
Age at entry, years	5.83 (0.36)	5.74 (0.66)	.979
Age at the end, years	7.84 (1.20)	8.42 (1.65)	.066
Height at entry, cm	119.00 (6.00)	118.00 (8.00)	.261
Height at the end, cm	133.20 (10.00)	135.00 (16.00)	.476
Weight at entry, kg	30.00 (7.40)	27.60 (3.00)	.012
Weight at the end, kg	40.30 (14.90)	39.00 (14.90)	.481
BMI at entry <sup>d</sup> , kg/m <sup>2</sup>	20.83 (3.21)	19.32 (1.26)	.005
BMI at the end, kg/m <sup>2</sup>	22.94 (5.24)	21.89 (4.37)	.078
Δ BMI <sup>e</sup> , kg/m <sup>2</sup>	2.02 (3.32)	1.95 (3.76)	.825
BMI SDS at entry	2.35(1.06)	1.95 (0.49)	.012
BMI SDS at the end	2.25 (0.90)	1.86 (0.64)	.018
Δ BMI SDS	-0.19 (0.73)	-0.19 (0.76)	.731
<b>Binary variables</b>	<b>Prevalence (%)</b>	<b>Prevalence (%)</b>	<b>P-value<sup>f</sup></b>
Sex, girls	54.8	57.6	.825
Hospital admissions	50.0	18.2	.007
Screen time > 2 hours per day	33.3	46.9	.277
Physical activity > 2 times per week	70.0	93.5	.017
TV in the child's bedroom	36.7	25.0	.319
Asthma medication after 2 years age	13.3	28.1	.153
Kindergarten since 2 years of age	92.3	81.3	.225
Prematurity,	3.3	3.0	.945
Sleep problems after 2 years of age	10.0	6.1	.563
Breastfeeding > 4 months	61.1	63.2	.898
Dental caries	23.3	27.3	.720
<b>Family characteristics</b>	<b>Intervention (n = 31)</b>	<b>No intervention (n = 33)</b>	
<b>Continuous variables</b>	<b>Median (IQR)</b>	<b>Median (IQR)</b>	<b>P-value<sup>b</sup></b>
BMI mother, kg/m <sup>2</sup>	27.39 (6.64)	26.07 (8.01)	.317
BMI father, kg/m <sup>2</sup>	30.09 (6.30)	27.66 (5.80)	.039
Number of siblings	1.00 (2.00)	1.00 (1.00)	.513
<b>Binary variables</b>	<b>Prevalence (%)</b>	<b>Prevalence (%)</b>	<b>P-value<sup>f</sup></b>
Maternal education above high school	37.9	30.3	.527
Urban living <sup>g</sup>	45.2	18.2	.020
Smoking by family member	56.7	51.5	.682
Parents think child looks overweight	89.3	33.3	<.0005
Living with single parent	36.7	24.2	.283

<sup>a</sup>Interquartile range.<sup>b</sup>Mann-Whitney *U* test.<sup>c</sup>Body mass index, standard deviation score.<sup>d</sup>Body mass index.<sup>e</sup>Body mass index at the end minus at the entry of the study.<sup>f</sup>Chi-square test.<sup>g</sup>Living in one of the two cities.

**TABLE 2** Development of anthropometric measurements and 6-minute walk test in the intervention group during the three-year multidisciplinary intervention programme

Variables (medians and IQR) <sup>a</sup>	Entry (n = 29)	3 years (n = 29)	<i>P</i> <sup>b</sup>
Age, years	6.58 (1.49)	9.61 (1.83)	<.005
Height, cm	125.00 (11.35)	141.20 (8.25)	<.005
Weight, kg	35.50 (8.40)	50.70 (15.80)	<.005
BMI, kg/m <sup>2,c</sup>	21.76 (4.06)	24.54 (6.89)	<.005
BMI SDS <sup>d</sup>	2.36 (0.93)	2.06 (1.06)	.008
Subscapular skinfold SDS	2.20 (1.10)	1.87 (0.67)	.016
Triceps skinfold SDS	2.23(1.28)	2.20 (0.82)	.272
Median mean skinfold SDS	2.08 (1.22)	2.11 (0.77)	.010
Waist circumference SDS	2.51 (1.08)	2.57 (0.55)	.079
Waist-to-height ratio SDS	2.30 (0.94)	2.64 (0.87)	.498
6-minute walking test, metres <sup>1</sup>	540.00 (109.00)	705.00 (129.00)	.001

<sup>a</sup>Interquartile range.

<sup>b</sup>Related-Samples Wilcoxon signed-rank test.

<sup>c</sup>Body mass index.

<sup>d</sup>Standard deviation score.

intervention municipalities and the no-intervention municipalities (data not shown).

In the multiple linear regression analysis of the whole cohort, we included the BMI SDS at birth and at entry to the study, the BMI of parents, relevant measures of health and lifestyles, the demographic variables in Table 1, and the categories intervention vs no-intervention group as exposures, and  $\Delta$  BMI SDS as outcome. A higher BMI SDS at entry was associated with a larger decrease in BMI SDS ( $b = -0.376$ ,  $P = .002$ ,  $R^2 = 0.154$ ), but independent of being in the intervention or no-intervention group. Other variables were of no significance.

### 3.2 | The intervention group

All the measurements at entry and at the end of the programme were available for 29 of the children in the intervention group. The median number of attendances was eight (range 1 to 16); three group attendances at the Learning and Mastery Service (range 0 to 7) and five (range 1 to 9) meetings for individual nurse guidance and measurements. Eleven of the 29 families attended all the planned sessions at the Learning and Mastery Service and the nurse guidance meetings.

The median BMI SDS, but not the median of the mean of the skinfold thickness SDS or waist-to-height ratio SDS, was significantly lower after three years of intervention than at entry (Table 2). The BMI SDS was closely related to the median of the mean skinfold SDS ( $r = 0.864$  at entry and  $r = 0.825$  at the end,  $P < .005$  for both) and to the waist-to-height ratio ( $r = 0.833$  and  $r = 0.785$ ,  $P < .005$  for both). The results for the 11 children of families who attended all the sessions did not differ from those of the rest of the group (data not shown). In the multiple linear regression analysis, a higher BMI SDS at entry was associated with a larger reduction in BMI SDS, but

none of the other exposures were associated with a change in BMI SDS (Table 3).

The parents' weight at entry and the end of the programme was known for 21 mothers and 15 fathers. Their median weight did not change (median difference 0.00 kg).

## 4 | DISCUSSION

In this study of children aged 5–6 years with severe overweight or obesity, a multidisciplinary educational intervention programme with the intention to change family and child lifestyles had no effect over no intervention on the development of BMI. Both the intervention and the no-intervention group experienced the same moderate reduction in BMI SDS, and potential confounders had no significant effects on outcome, neither when comparing the two groups nor within the intervention group. In particular, adherence to the intervention programme and skinfold thickness at entry were not associated with change in BMI SDS, suggesting that motivation on part of the parents and relative fat mass did not affect outcome.

Cochrane reviews of randomized controlled trials suggest that there were no convincing evidence of significant and persistent weight-reducing effects from published studies involving interventions on diet, physical activity or other behaviour in children with a mean age 10 years<sup>7</sup> or adolescents<sup>8</sup> with obesity. In the study of Mead et al, the overall benefit in favour of interventions over usual care was only a BMI SDS score of 0.06, (95% CI 0.10 to 0.02) units at 6–36 months of follow-up. Furthermore, in 13 of the 27 included studies, the SDS score declined as much in the control as in the intervention group.<sup>7</sup> In another Cochrane review, parent-only interventions were as effective as parent-and-child interventions in 5- to 11-year-old children, but minimally more

**TABLE 3** Results from linear regression analyses of differences in body mass index standard deviation score (BMI SDS difference) from entry to the end of the intervention programme after three years in 29 children with obesity aged 5-6 years at entry

Exposure	Unadjusted		Adjusted ( $R^2 = 0.298$ ) <sup>b</sup>	
	Beta <sup>c</sup>	P	Beta <sup>c</sup>	P
Birth weight	0.199	.351		
Age at entry	0.183	.116	0.227	.041
BMI SDS at entry	-0.451	<b>.011</b>		
Mean skinfold SDS at entry	-0.310	.069	-0.340	.031
Waist-to-height ratio SDS at entry	-1.572	.392		
Walking test	0.001	.225		
Number of attendances	0.018	.467		
Adherence in the intervention <sup>d</sup>	0.312	.179		
Sex (girls)	0.502	<b>.029</b>		
Hospital admissions	0.159	.502		
Screen time >2 h daily	0.508	<b>.035</b>		
Physical activity >2 times/week	-0.294	.273		
TV in the child's bedroom	-0.121	.631		
Asthma medication (>2 y age)	-0.510	.172		
Kindergarten since 2 years old	-0.009	.986		
Prematurity (<37 weeks GA)	-0.387	.536		
Sleep problems >2 years of age	-0.530	.155		
Breastfeeding >4 months	-0.018	.918		
Dental caries	-0.443	.141		
BMI mother	0.017	.484		
BMI father	-0.015	.651		
Number of siblings	0.024	.843		
Maternal education above high school	0.142	.528		
Urban area	-0.109	.636		
Smoking by family member	-0.124	.595		
Parents think child look fat	0.376	.339		
Living with single parent	-0.080	.750		

<sup>a</sup>Bold indicates the significant *P*-values in the unadjusted analysis.

<sup>b</sup>After backward stepwise exclusion of variables.

<sup>c</sup>A positive beta means increased risk of a positive BMI SDS, that is an increase in BMI SDS from start to 3 years.

<sup>d</sup>Attended all the sessions (*n* = 11) vs. less (*n*=18).

effective than for waiting list controls.<sup>6</sup> In a meta-analysis of few studies on preschool children, an intervention on diet, physical activity and behaviour had a significant, but slight, beneficial effect at 12-18 months of follow-up.<sup>21</sup> However, the quality of evidence was estimated as low or very low, particularly for the youngest groups. The median decline in BMI SDS in our intervention group of 0.19 was similar to the mean decline of 0.20 in the systematic review by O'Connor et al on weight-reducing trials among children and adolescents.<sup>8</sup> Our results were also similar to the mean decline of 0.22 in a Swedish study on children aged 8-12 years with obesity who attended different treatment programmes.<sup>22</sup> The Swedish study had no controls without interventions, and it is remarkable that our non-intervention control group had the same decline, suggesting that the intervention had no effect over the general public attention on childhood obesity in Norway.

Within our intervention group, the children with the highest BMI SDS score had the largest decline in the SDS score. However, this was equally true for our non-intervention group and was probably not a specific effect of the intervention programme. It is noticeable that presumed risk factors were not associated with failure to decrease the BMI SDS. For instance, limited attendance to the programme, which may imply lack of motivation, dental caries, which may be suggestive of unhealthy dietary and other behaviour, lower parental education, and single parenthood were not associated with outcome. One explanation why extent of physical activity was not associated with outcome may be that physical activity at this young age is mainly related to play. It is likely that the children had similar activity in play since almost all of them were in day care from at least two years of age and thereafter in school where play is an important activity during the first years.

As in most studies, we used changes in BMI SDS as the primary outcome. By using standard deviation scores, the effect of minor differences in age and time interval between measurements was limited. However, it has recently been argued that a decrease in BMI SDS with age in children may not necessarily mean a decrease in the degree of obesity because the SDS of BMI may not accurately correct for age, sex and degree of obesity.<sup>23</sup> Therefore, a reduction in BMI SDS of around 0.20, as obtained in the present and most other studies on children, may not necessarily mean a decrease in degree of obesity.<sup>23</sup>

The referred Cochrane studies conclude that studies to prevent or treat obesity in children are generally of low quality. Likewise, our study has several limitations. The number of participants was limited. However, it is unlikely that a larger study would have shown an effect since the decline in both the median and variation in BMI SDS were almost identical in the intervention and the no-intervention group. The two groups differed somewhat in several aspects, partly due to the recruitment process and partly due to different routines between municipalities related to time of measurements around school entry and in third grade. Unpredictable effects of these differences were reduced by adhering to standard deviations scores in the analyses. It may be argued that the higher median BMI at entry of the intervention group may have masked an

effect. However, the significance of BMI at entry was the same in the two groups. Furthermore, the families who participated in the intervention programme were probably more motivated for treatment than many families in the no-intervention group since most of them, as opposed to the no-intervention group, expressed that their children look overweight. In particular, the families who participated on request expressed a concern for their children's health. It is therefore likely that potential effects of confounding would be in favour of the intervention group. Randomized controlled trials are considered the gold standard when studying effects of interventions, but we chose to include families on basis of geographical closeness to the hospitals for two reasons: the county is large, and the distance to the other municipalities would make it difficult for families to attend. Furthermore, a true randomization could possibly have introduced an unrecognized intervention effect from spill-over within the municipalities. Such concern has been raised in randomized intervention studies where one arm is generally accepted as preferable.<sup>24,25</sup> Despite this concern, we chose to include eligible children in the intervention municipalities who were not referred as controls to account for all eligible children in the county. In these municipalities, a spill-over effect was also unlikely since the intervention programme was conducted outside the municipalities and no information about the programme was publicised during study period. This assumption was strengthened by the finding that their development in measurements did not differ from the rest of the no-intervention controls. The analyses of associations between outcome and factors that were considered potential predictors of success or failure of the programme must be interpreted with caution due to lack of power.

## 5 | CONCLUSION

Our multidisciplinary and relatively long-term approach adds to studies that have failed to significantly decrease severe overweight and obesity in children. The similar reduction in BMI SDS in our intervention and no-intervention groups may suggest that a high national focus on overweight and obesity in children, including societal facilitations to encourage protective lifestyles, is the most important approach to curtail the obesity epidemic among children.

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## CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

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