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Two-year treatment programme showed that younger age and initial weight loss predicted better results in overweight and obese children aged 2-16 years

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Running title:

Effects of a two-year obesity treatment

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Abstract

Aim: We investigated an outpatient programme that followed the Danish Paediatric Society's recommended multidisciplinary approach to treating overweight and obesity.

Methods: Our cohort comprised 179 participants (55.3% girls) treated from April 2011 until March 2016 at the Hospital of Southwest Jutland, Esbjerg, Denmark. The participant's age ranged from 2.3 to 16.6 years. The body mass index - standard deviation score was registered at inclusion and after three, 12 months and 24 months.

Results: The girls were more obese than the boys at inclusion and the mean reduction in the body mass index - standard deviation score was 0.3 units during the study. Half of the participants achieved a reduction in body mass index – standard deviation score of at least 0.25 units and the frequency of obesity and severe obesity decreased from 69.3% to 47.5%. Predictors of weight loss were younger age and weight loss during the first three months. More than half (53.1%) completed the programme and they were more likely to be younger and male.

Conclusion: The two-year programme reduced the body mass index - standard deviation score and the frequency of obesity. Younger age and early weight loss predicted success and younger age and male sex predicted completion rates.

Key Notes

- This study investigated a Danish outpatient programme that used a multidisciplinary approach to treat overweight and obesity in 179 paediatric patients (55.3% girls) aged 2-16 from 2011- 2016.
- Half of the participants achieved a reduction in body mass index – standard deviation score of at least 0.25 units and the frequency of obesity and severe obesity decreased from 69.3-47.5%.
- Younger age and early weight loss predicted success and younger age and male sex predicted completion.

INTRODUCTION

The prevalence of overweight and obesity has increased enormously over the past two decades. Data from 183 countries showed that childhood overweight increased by nearly 50% from 1980-2013 (1). Moreover, it has been reported that obese children were five-times more likely to be obese in adulthood (2).

Childhood obesity has been shown to have an impact on a multitude of short-term and long term physical and mental health issues (3,4). Cardiovascular risk factors, such as elevated blood

pressure, have been seen in children with obesity compared to normal weight children (5). Even normotensive children with obesity have shown an increased incidence of hypertension in adulthood (6). Obesity has also been associated with impaired glucose tolerance in childhood (7) and type 2 diabetes in adulthood (8).

In 2013 the American Medical Association recognised obesity as a disease requiring targeted treatment (9), a definition that is now widely accepted. In accordance with this, the Danish Paediatric Society recommends clinical guidelines that endorse a chronic care model with a multidisciplinary approach (10), However, these are only implemented in approximately one-third of paediatric departments in Denmark (11). The Department of Paediatrics at the Hospital of Southwest Jutland, which is a secondary healthcare facility, implemented the chronic care model for treating obesity among children and adolescents in April 2011.

This study investigated the effect of the implementation of a two-year, multidisciplinary treatment intervention at the Hospital of Southwest Jutland's paediatric outpatient clinic. The primary outcome was a reduction in the body mass index - standard deviation score (BMI-SDS) after two years. We also wanted to evaluate if age, sex, and the number of visits to a psychologist were predictors for weight loss.

METHODS

Setting

We conducted the study by reviewing the records of patients treated in the outpatient clinic. We obtained data from a quality assurance database, supplemented by electronic and paper patient records, to ensure completeness. Two authors (SD and JPJ) performed double data entry.

Patients were referred to the outpatient clinic from general practitioners or the paediatric department. Patients under the age of 16 years with a BMI above the 97th percentile, according to the national reference (12), were eligible for referral. A small number of children and adolescents with a BMI below the 97th percentile entered the treatment programme after individual evaluation by the responsible paediatrician, in order to prevent further weight gain. As a result, a few adolescents aged 16 -16.6 years of age were included in the analyses. All patients enrolled in the treatment programme have been included in the present study. We excluded patients with obesity secondary to other medical conditions.

The participants in this study were enrolled in the two-year outpatient programme between April 2011 and March 2014 and had completed the treatment programme by the end of March 2016. The dedicated healthcare staff comprised two paediatricians, two nurses, two dieticians, one physiotherapist and one psychologist and the programme consisted of a minimum of 13 visits

(Figure 1). All patients had a minimum of one session with a psychologist and additional sessions if required. Both parents were encouraged to participate during each visit, but this was not a requirement. Each visit lasted 30-60 minutes. This study includes data from the inclusion visit and the visits at three months, one year and two years.

Procedure

At referral, participants were evaluated according to official guidelines from the Danish Paediatric Society (10). The evaluation included their medical history, a physical examination and blood sampling. The guideline recommends either dual-energy X-ray absorptiometry or bio-impedance, but this was not feasible in our setting.

The treatment consisted of advice on lifestyle modifications with regard to nutrition and physical activity, which adhered to the guidelines provided by the Danish National Board of Health (13). Participants were recommended to eat four to five meals per day and were advised to be physically active for 60 minutes daily (13). They were given a diary to record their nutritional agreements, daily exercise goals and achievements, in order to maintain motivation. The diary contained some general recommendations such as: eating breakfast every day, drinking water, having family dinners five times a week, no eating in front of the television or the computer and waiting 20 minutes before optionally refilling their plate. We also asked them to reduce their screen time to a maximum of two hours a day. An image of the healthy plate model was included, in line with the official recommendations from the Danish Veterinary and Food Administration, (10,13).

The healthcare professionals acknowledged that childhood obesity was a chronic disease and that weight loss was especially challenging due to the complex biochemical processes programmed to preserve fat storage. A positive approach to the patient and family was applied, as well as respectful and motivational communication. Long-term lifestyle changes for the entire family were emphasised and encouraged, rather than imposing restrictions exclusively for the child.

Before each visit with the dietician, the family filled out a four-day diet registration, which included three weekdays and one weekend day. No other registration of adherence to the treatment advice was recorded.

The participants' weight and height were measured at the beginning of each consultation while they were wearing light clothes and no shoes. We used a Seca 704 digital scale and a Seca 204 electronic altimeter (Seca, Hamburg, Germany).

Body mass index (BMI) was calculated as weight in kilograms divided by height in metres squared. As BMI changes with age, the BMI-standard deviation score (BMI-SDS) was calculated using the LMS method based on published Danish growth charts (14). The age and sex-adjusted BMI cut-off points of 23, 25, 27, 30 and 35 were used, as proposed by Cole et al (15) at inclusion and the last

visit. Participants could only fall into one group: for example, a cut-off point of 23 was an age and sex-adjusted BMI of 23-25 and a cut-off point 25 related to 25-27.

Statistical analysis

Changes in BMI-SDS during the study period were analysed by regression analysis with BMI-SDS as the dependent variable and time in months as the independent variable. These changes were then investigated separately for four age groups: less than eight years, 8-10 years, 11-12 years and 13-16 years as a *post hoc* analysis, using the same regression model.

Predictors of weight loss were investigated by a regression model, with the change in BMI-SDS during the study period as a dependent variable. The independent variables were age, sex, change in BMI-SDS after three months, cancelling visits or absence of visits and number of consultations with the psychologist. The model was fitted with peri-significant variables ($p < 0.1$) using backward elimination. A similar model was conducted with completion of the programme as a dependent variable. Post estimation analysis was conducted for all models using residual diagnostic.

The chi-square test was used to compare the frequencies of severe obesity, obesity and normal weight at inclusion and at the last visit.

Analyses were carried out for the entire group using an intention to treat analysis with the last observation carried forward. A per-protocol analysis was performed for participants who completed the first and last visit and at least 10 of the 13 scheduled visits. The time from the first contact to the end of the two-year programme or dropout defined the study period.

Summary statistics were provided as means (SDs) for normally distributed data and as medians (ranges) elsewhere. Group comparison tests were conducted using the t-test or a nonparametric analogue. For all statistical analyses, the significance level was defined as $p < 0.05$. The statistical analyses were performed using STATA software, version 10 (StataCorp, College Station, Texas, USA)

Ethics

Permission to gather and store patient information was provided by the Danish Health Authority (3-3013-1613/1/) and the Danish Data Protection Agency (2002-58-0035). Formal consent was not required for this retrospective study.

RESULTS

Study population

A total of 203 children and adolescents were referred for the programme. One was excluded due to secondary obesity and 23 declined participation. In total, 179 children and adolescents aged 2.3 to 16.6 years entered the programme. Of these, 167 (93.3%) completed three months, 137

(76.5%) completed one year and 95 (53.1%) completed the full two-year programme. The descriptive data of the 179 participants included in the analysis are presented in Table 1. The baseline BMI-SDS correlated negatively with age for the entire group, meaning that the youngest children were the most overweight. The baseline mean BMI-SDS differed between sexes, with +2.5 units and +2.8 units for boys and girls respectively (p <0.02)

Adherence to treatment intervention

Of the 95 participants who completed the two-year programme, 89 attended at least 10 of the scheduled visits and these were designated as the per-protocol group. The percentage of boys in the per-protocol group was higher (53.9%) than in the entire cohort (44.7%). Programme completion in the per-protocol group was predicted by younger age (p <0.01) and male sex (p <0.01). In the per-protocol group, more children were in the younger age groups with 18 children (20.2%) under eight years of age, 38 (42.7%) aged 8-10, 18 (20.2%) aged 11-12 and 15 (16.9%) aged 13-16. No other variables had a significant effect on completion.

When we looked at the total cohort, we saw that 36 (1.8%) of all visits were cancelled less than 24 hours in advance and patients failed to attend appointments 29 times (1.5%) without giving notice. The baseline BMI-SDS in the per-protocol analysis correlated negatively with age and male sex, which was similar to the correlations in the entire group.

Development of BMI-SDS

Table 2 shows the development of BMI-SDS and the frequencies of severe obesity, obesity, overweight, slightly overweight and normal weight during the study period for children and adolescents in the intention-to-treat and per-protocol groups. In the total group, mean BMI-SDS decreased -0.3 units (0.5 SD) throughout the study (p <0.01). The decrease in BMI-SDS was associated with a decrease after three months (p <0.01) and younger age (p <0.01), but not with sex and cancelled visits. Psychologist visits correlated negatively (p <0.01) with a decrease in BMI-SDS.

Mean BMI-SDS decreased -0.5 units (0.6 SD) in the per-protocol group, which was significantly more than in the whole group (p <0.05). No differences were observed in predictors of weight loss compared to the entire group.

In the intention-to-treat group, 90 participants, which was 50.3% of the total cohort, achieved a reduction in their BMI-SDS of at least 0.25 units.

When we analysed the age groups individually, we found a significant decrease in BMI-SDS during the study period in the two youngest age groups. The mean BMI-SDS change was -0.7 units (0.6 SD) in children under the age of eight (p <0.01) and -0.4 units (0.5 SD) in those aged 8-10 (p <0.01). In children aged 11-12, the mean BMI-SDS changed -0.2 units (0.4 SD) and in those aged

13-16 it was -0.1 units (0.5 SD), which was not significant. The per-protocol group followed a similar pattern regarding differences between the age groups.

Development in the frequency of obesity

The frequencies of severe obesity, obesity, overweight, slightly overweight and normal weight at inclusion are presented in Table 1. The frequency of severe obesity did not change significantly from inclusion to the last measurement. When we pooled severe obesity and obesity into one group, there was a significant reduction in participants with obesity, from 124 (69.3%) at inclusion to 85 (47.5%) at the last measured BMI (p <0.01). Likewise, the frequency of normal weight increased from one (0,6%) to 14 (7.8%) (p <0.01).

DISCUSSION

The aim of the present study was to evaluate whether a two-year multidisciplinary treatment intervention changes the BMI-SDS in children and adolescents aged 2-16 years with overweight or obesity. Although there is no established consensus for a clinically relevant BMI-SD reduction, a reduction of at least 0.25 units, which was achieved by 50.3% of this study population, has been correlated to clinically relevant outcomes (16,17).

In participants treated per protocol, we found a reduction in BMI-SDS of 0.5 units (0.6 SD) at 24 months. The intention to treat analysis found a smaller, although a clinically relevant, reduction in BMI-SDS of 0.34 units (0.5 SD) at 24 months compared to baseline.

Cochrane reviews have found a comparable effect of behaviour-changing interventions for the treatment of overweight or obesity in children of different age groups (18–20). In preschool children aged 0-6 years, the reviewers found a 0.3 unit reduction in BMI-SDS at the end of the intervention at 6-12 months (20). In children aged 6-11 years, they found a 0.06 unit reduction (19) and in adolescents 12-17 years they found a 0.13 unit reduction (18). In all age groups, the difference between baseline BMI-SDS and BMI-SDS at the most extended follow up was statistically significant. Our results showed a similar effect on BMI-SDS at the end of the intervention. The authors of all three Cochrane reviews conclude that the evidence was low quality, due to study heterogeneity and inconsistencies between the included studies.

Other studies have investigated the implementation of the Danish chronic care model and found similar reductions in BMI-SDS: 0.40 units in boys and 0.25 units in girls (21) and 0.40 units in boys and 0.24 units in girls (22). Our results thus support the principles of the multidisciplinary chronic care model, adapted to local circumstances.

In our study, younger age predicted a reduction in BMI-SDS during the study period, emphasising the importance of treating paediatric obesity early in life. This finding was in accordance with many previous studies (21,23–26) as well as the Cochrane reviews (18–20), which found larger BMI-

SDS reductions in younger children. Another study (22) found no effect of age on the reduction of BMI-SDS.

We found that girls were more overweight than boys were, but the change in BMI-SDS was similar in both groups. This has also been reported by other studies (23,26). Other studies have also reported a sex difference in treatment response (21,22,25), although both boys (21,22) and girls (25) were reported to respond better in different studies. The reason for this was unknown, but differences in demographics, including obesity level, age, sex and interactions between these, may have differed between the studies.

Children who were moderately and slightly overweight were included in our study, when the staff felt that it was necessary. This approach was chosen to avoid them gaining further weight. That practice was also applied in the literature mentioned above.

Drop-outs in childhood obesity treatment programmes are reportedly high (17). In the present study, approximately 50% of the children completed the two-year programme. Although we found that the overall effect of the programme was positive in the intention-to-treat group, a lack of reduction in BMI-SDS at three months and leaving the programme before two years both predicted more reduced responses. In addition, additional psychologist consultations, which could be interpreted as a confounder for emotional stress, were correlated to a poorer outcome. Moreover, the average child was still overweight after completing the programme and it is well known that regaining weight is a problem that faces many children and adolescents after completing a weight loss programme. On the other hand, as we did not have a control group, we can only speculate whether BMI-SDS would have increased more without the programme, even in poor responders. Altogether, these observations support the understanding of overweight treatment as a complex bio-psycho-social discipline. We could ask if we risk doing more harm than good with a weight loss programme if a child shows a high degree of psychological stress and a lack of motivation. We, therefore, suggest that the treatment effect should be evaluated after the initial intervention period and programmes are tailored to meet the individual needs of patients and improve the overall effectiveness.

The present study was conducted as a review of hospital charts for patients enrolled in an obesity treatment programme. We acknowledge several limitations to the presented data, as we have not registered socioeconomic status, parental BMI or any previous treatment attempts by the participants to reduce their weight, all of which are known to affect treatment for overweight and obesity. Furthermore, no control group was included. The reduction in BMI-SDS that was

demonstrated could, therefore, be due to regression towards the mean. However, our results were comparable to other studies.

CONCLUSION

The implementation of a multi-disciplinary chronic care model in an outpatient setting resulted in a decrease in BMI-SDS, a decreased percentage of children with obesity and adherence to the programme, which was comparable to other centres. Along with previous studies, our results emphasise the importance of treating overweight and obesity when children are young. Furthermore, we were able to predict poorer responders after the initial period. As a significant percentage of children did not reduce their BMI-SDS, or dropped out, we encourage further research to identify factors predicting treatment failure and new approaches to achieving weight loss in this group.

Funding

The study did not receive specific funding.

Conflicts of interests

CBJ serves on the Novo Nordisk national board for obesity treatment. All the other authors have no conflicts of interest to declare.

Abbreviation

BMI-SDS: Body mass index - standard deviation score

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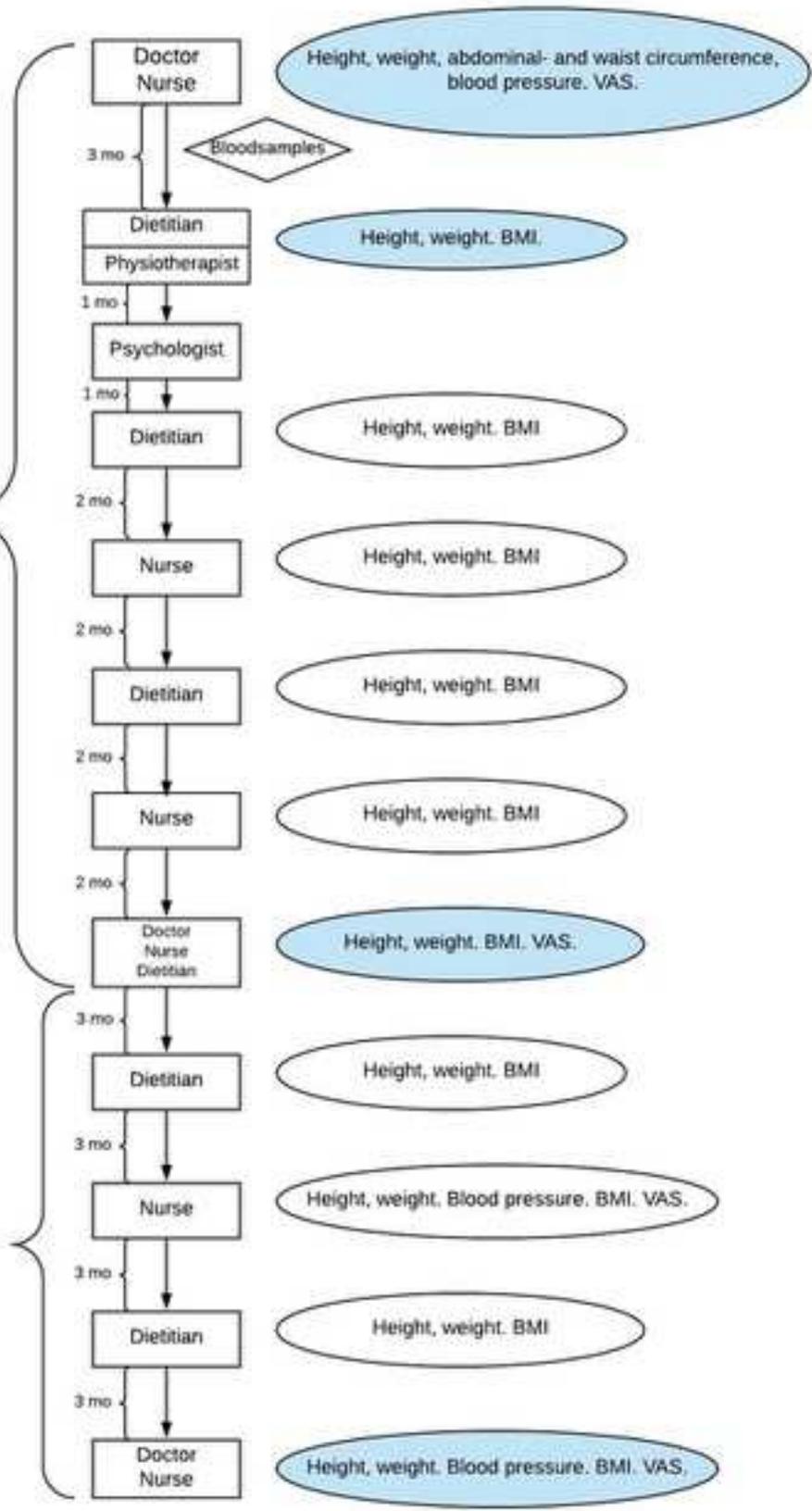
n	179
Age in years, mean (SD)	10.8 (3.0)
Age group < 8 years, n (%)	29 (16)
Age 8-10 years, n (%)	61 (34)
Age 11-12 years, n (%)	43 (24)
Age ≥13 years, n (%)	46 (26)
Boys, n (%)	80 (45)
Height, mean (SD)	150.2 (17.3)
Weight, mean (SD)	61.8 (22.7)
BMI-SDS, mean (SD)	2.7 (0.7)
Severe obesity, n (%)	38 (21)
Obesity, n (%)	84 (47)
Overweight, n (%)	45 (25)
Slightly overweight, n (%)	10 (6)
Normal weight, n (%)	1 (1)
Systolic blood pressure percentile, mean (SD)	67.2 (23.8)
Diastolic blood pressure percentile, mean (SD)	43.3 (20.3)

Table 1: Demographics of the 179 participants defining the study population. Data for weight at inclusion was not available for one subject.

		Baseline	3 months	12 months	24 months
n	ITT	178	163	137	95
	PP	89	89	89	89
BMI-SDS, mean (95 % CI)	ITT	2.70 (1.28-4.12)	2.50 (0.98-4.08)	2.36 (0.76-3.96)	2.36 (0.78-3.94)
	PP	2.70 (1.1-4.3)	2.44 (0.78-4.10)	2.21 (0.57-3.85)	2.22 (0.62-3.82)
Severe obesity (%)	ITT	21.2	16.8	16.7	16.7
	PP	22.5	14.6	13.5	13.5
Obesity (%)	ITT	47.0	36.3	29.0	30.2
	PP	47.2	34.8	25.8	29.2
Overweight (%)	ITT	25.1	32.4	32.4	30.2
	PP	24.7	34.8	32.6	25.8
Slightly overweight (%)	ITT	6.1	11.2	13.4	15.6
	PP	4.5	11.2	15.7	21.3
Normal weight (%)	ITT	0.6	3.3	8.3	7.3
	PP	1.1	4.5	12.4	10.1

Table 2: Development in BMI-SDS and the age and sex-adjusted BMI. Age and sex-adjusted BMI groups: Severe obesity: ≥35; Obesity: 30-34.99; Overweight: 27-29.99; slightly overweight: 25-26.99; Normal weight: <25.

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