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Original article

Three-year follow-up of 3-year-old to 5-year-old children after participation in a multidisciplinary or a usual-care obesity treatment program

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SUMMARY

Background & aims: Little is known on the long-term effects of obesity intervention programs in preschool-aged children. We compared the long-term effects of a multidisciplinary treatment program with a usual-care program in seventy-five 3- to 5-year-old overweight or obese children who had participated in a randomized controlled clinical trial.

Methods: A follow-up study collecting data at 18 and 36 months after starting both programs. The multidisciplinary program consisted of diet counseling, exercise sessions teaching motor skills and focusing on an active lifestyle, and psychoeducation for parents. Outcome measures were changes in anthropometry and body composition, determined by bioelectrical impedance analysis and ultrasound. Results: At the end of the 16-week treatment program, the multidisciplinary intervention showed a greater decrease in body mass index z score (BMI-z) (mean (SD) 0.2 (0.1)) and waist circumference z score (WC-z) (mean (SD) 0.3 (0.1)), than usual-care. During the 36-month follow-up, a significant overall treatment effect of the multidisciplinary intervention program was demonstrated on BMI-z (0.28, 95% CI 0.03–0.54) and abdominal subcutaneous fat (SCF) (0.23, 95% CI 0.01–0.45), compared with the usual-care program.

Conclusions: A multidisciplinary intervention program in 3- to 5-year-old overweight and obese children shows greater long-term effects on reductions in BMI-z and SCF, compared with a usual-care program.

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1. Introduction

In the Netherlands, the prevalence of childhood obesity has increased by two to three times between 1980 and 2009. In 2009, the prevalence of overweight in Dutch boys between the ages of 3—5 years was 7.8—12.8% and in Dutch girls 12.8—18.1%. For obesity, the prevalence in Dutch boys and girls aged 3—5 years was 0.8—2.0% and 1.6—3.3%, respectively. For comparison, in 2010 the prevalence of obesity in the same age category of children from the United States was 12.4% in boys and 10.0% in girls. In obese

children, a decreased insulin sensitivity and dyslipidemia have been described at a young age.^{3,4} Childhood obesity may persist into adulthood,⁵ potentially leading to the development of cardiovascular disease (CVD) and type 2 diabetes (T2D).^{6,7}

Prevention of childhood obesity should have a high priority.⁸ When efforts to prevent the development of obesity have failed, it is important to intervene. A Cochrane review has shown that family-based, multidisciplinary lifestyle intervention programs for children under the age of 12 years with overweight or obesity can be successful in reducing weight.⁹ Literature reporting on long-term effects of lifestyle intervention programs is limited. These long-term effects are important since maintenance of beneficial effects of obesity intervention programs would indicate the persistence of a reduced life-time risk on CVD and T2D.

At present, the longest follow-up period of obesity treatment programs was published in 1994. ¹⁰ Epstein and colleagues reported 10-year outcomes of 4 randomized studies in 185 children aged 6—

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Non-standard abbreviations: BF%, body fat percentage; (z-)BMI, body mass index (z-score); CVD, cardiovascular disease; FFM, fat-free mass; (z-)HC, hip circumference (z-score); SCF, subcutaneous fat; T2D, type 2 diabetes; VF, visceral fat; (z-)WC, waist circumference (z-score).

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12 years. ¹⁰ The authors concluded that the results obtained in the first 5 years of treatment were predictive for the outcome at 10 years. The importance of positive results during the intervention period on maintaining these effects on the long-term was also emphasized by an obesity intervention study in 663 children with a mean age of 10.6 years. ¹¹ A 5-year follow-up study in 31 obese children with a mean age of 8.4 years, in which eight follow-up visits were included, showed a persistent decrease in BMI-SDS and WC, together with improved family habits towards a healthy lifestyle and decreased total energy intake. ¹²

Little is known about the long-term outcome of obesity intervention programs in preschool-aged children. The aim of this study was to evaluate the long-term effects of a multidisciplinary intervention program in overweight or obese children aged 3-5 years and in children receiving usual-care. Primary outcome measure was the change in body mass index z score (BMI-z) at 18 and 36 months after the start of the intervention. Secondary outcome measures were the changes in body fat percentage (BF%), visceral fat (VF) and abdominal subcutaneous fat (SCF), WC z score (WC-z), hip circumference z score (HC-z), and fat-free mass (FFM).

2. Materials and methods

Details of the programs and effects until 12 months after the start of both programs have been described previously.¹³ In short, children and parents participated in a randomized, controlled clinical trial at the "Groningen Expert Center for Kids with Obesity (GECKO)-Outpatient Clinic". Children aged 3–5 years were referred to the outpatient clinic if they had a BMI-*z* >1.1. After exclusion of medical causes for obesity, eating disorders, mental retardation and behavioral problems, children were randomly assigned to the multidisciplinary lifestyle intervention or usual-care programs. Enrollment took place from October 2006 to March 2008. A total of 75 children started with the study. They all were Dutch, except for five children from former Dutch colonies (two Suriname and three Dutch Antillean children) and one child from Morocco. Children lived in rural as well as in urban regions.

The multidisciplinary lifestyle intervention program included dietary advice for children and parents (6 sessions of 30 min each), physical activity sessions for children (12 sessions of 60 min each) and psychological counselling for parents only (6 sessions of 120 min each). Dietary advice was given by a dietician and aimed at improving eating behavior by using personal goals. Physical activity sessions under guidance by a physiotherapist mimicked elementary school exercise. For example, children were supervised on dancing to music and ball playing, aiming at developing motor skills and having fun during exercise. Furthermore, the parents were asked to stimulate the physical activity of their child at home, for at least 60 min per day, according to the Dutch Standard of Healthy Activities. Psychological counselling sessions were given by a psychologist who taught the parents how to be a healthy role model to their child. In the usual-care group, children and parents were followed up by a pediatrician (3 sessions of 30-60 min each) who advised on healthy eating and an active lifestyle. Both programs lasted 16 weeks. Written informed consent was obtained from the parents or legal caretakers. The study was approved by the Medical Ethics Committee of the University Medical Center Groningen.

Between the anthropometric measurements and assessment of body composition at 12 months after the start of the intervention and visits at 18 and 36 months from baseline, no follow-up visits or interventions were done. Height and weight were measured in duplo using standard calibrated stadiometers and scales. BMI was calculated and age- and gender-specific *z* scores were determined using the web-based program Growth Analyser 3 (http://www.

growthanalyser.org/). WC and HC were measured in duplo using a standard measuring tape. WC-z and HC-z were calculated as described for BMI. Bio-impedance analysis (BIA-101, Akern S.r.l./RJL Systems) was used to assess BF% and FFM,¹⁴ and ultrasound (SonoSite Titan, SonoSite, Inc) to measure VF and SCF.¹⁵

Pedometers (Yamax Digi-Walker SW-200, Yamax USA, Inc) were used to assess the children's physical activity and were worn, at a minimum, three weekdays and one weekend-day. The average number of steps was calculated. During two weekdays and two weekend-days, specially developed diaries were used to document the type and amount of food consumed. The diaries were analyzed by a dietician using a validated computer program (Vodisys Medical Software, IP Health Solutions) containing the 2006 Dutch food composition database, and the intake of nutrients was calculated.

Statistical analysis was done using PASW Statistics version 18.0. Distribution of normality was tested using the 1-sample Kolmogorov—Smirnov test. The statistical analysis for testing a treatment effect, implemented a population-averaged linear mixed model on the repeated measurements after intervention for each end point separately. Follow-up time was treated as a categorical variable to avoid a specific and possibly unrealistic parametric time profile per individual. The analysis was corrected for its baseline value to eliminate possible random differences in the response at baseline. The intervention was implemented as a main effect and as interaction effect with time, to be able to investigate a possible effect of the intervention at different time points. The effect size per time point and an overall or average effect size over time are provided accompanied with a 95% confidence interval. An unstructured correlation matrix was selected to describe the dependency among the repeated measurements after intervention. Restricted maximum likelihood was applied to estimate the populationaveraged model to be able to address the missing data appropriately. The significance level of all tests was P < .05.

Due to loss to follow-up, data on anthropometry and body composition from 48 (64.0%) children were available 18 months after the start of the intervention, 25 of 40 (62.5%) children from the multidisciplinary intervention group and 23 of 35 (65.7%) children from the usual-care group. At 36 months after starting the intervention, anthropometric data and data on body composition from 29 (38.7%) children were available, 17 of 40 (42.5%) children from the multidisciplinary intervention group and 12 of 35 (34.3%) children from the usual-care group. Not all children and parents used the pedometers and diaries to assess physical activity and food consumption. At 18 and 36 months from baseline respectively, in children from the multidisciplinary intervention group, data from 12 and 12 pedometers and 16 and 14 diaries were available respectively. In children from the usual-care group, this was 10 and 5 and 8 and 6, at 18 and 36 months from baseline.

3. Results

Table 1 shows the descriptive and anthropometric characteristics of the study population at baseline. Figure 1 provides details about inclusion and dropout from the study. Mean (SD) age of the children in the multidisciplinary intervention group 18 months after the start of the intervention was 6.0 (0.8) years and 7.3 (1.1) years at 36 months. In the usual-care group, mean (SD) ages at 18 and 36 months from baseline were 6.2 (0.9) years and 7.4 (1.3) years, respectively.

Table 2 shows the estimated effect sizes and their 95% confidence intervals of the multidisciplinary intervention program, compared with the usual-care program, on the anthropometric parameters of obesity and body composition at the different follow-up moments. It should be noted that none of the outcome variables demonstrated a significant interaction effect between the

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