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Original article

7-Year follow-up of a lifestyle intervention in overweight children: Comparison to an untreated control group

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SUMMARY

Background & aims: We present the 7-year follow-up analysis in overweight children and adolescents, who had participated originally in a randomized control trial of a lifestyle intervention. We compared them to an untreated population-based control group to demonstrate the effectiveness of the intervention.
Methods: Degree of overweight (BMI-SDS) was determined in 32 overweight children (mean age 11.5 ± 1.5yrs, 65.6% females, mean BMI 23.7 ± 1.5 kg/m^2) at onset of intervention (T0), end of 6-month intervention (T1), 12 months (T2) and 7 years after end of intervention (T3). A total of 76 overweight children derived from a representative national population survey served as control group.
Results: The participants in the intervention group reduced significantly their BMI-SDS between T0-T1 (mean ± standard deviation −0.28 ± 0.28, p < 0.001) and demonstrated no significant changes between T1-T2 (mean ± standard deviation −0.10 ± 0.34) and between T2-T3 (median +0.07; interquartile range: −0.54–0.62). BMI-SDS at T3 was significantly (p = 0.015) lower compared to T0. At T3, 46.8% of the participants in the intervention were normal-weight. The reduction in BMI-SDS between T0-T3 was significantly (p = 0.043) greater in the intervention group (median −0.26; interquartile range −0.87 −0.23 BMI-SDS) compared to the control group (mean ± standard deviation −0.05 ± 0.77).
Conclusions: The lifestyle intervention led to a significant reduction of overweight in the 7-year follow-up period. This decrease in BMI-SDS was significantly greater than the changes in BMI-SDS in a control group.
This study is registered at clinicaltrials.gov (NCT00422916).

1. Introduction

Overweight and obesity in childhood is a major health problem [1]. Even overweight children have an increased mortality [1]. Lifestyle intervention based on a combination of physical exercise, nutrition education, and behaviour therapy are regarded as treatment of choice for obese children [2–5]. Only very few studies analysed the changes in weight status ≥5 years after the end of treatment in this age-group [6–9]. These reported that the achieved weight loss in the interventions was sustained after 5–10 years in contrast to studies in adults reporting weight regain in the majority of the participants [10].

However, all available long-term studies have focused on obese children and adolescents. Therefore, the effectiveness of these interventions is largely unknown especially in overweight children and adolescents. We have previously demonstrated in a randomized controlled trial (RCT) that the lifestyle intervention "Obeldicks light" was effective to improve weight status in overweight children and adolescents in the short-run [11,12]. We performed the following 7-year follow-up study to evaluate the long-term effect of this lifestyle intervention in those children, who were originally part of the pilot study or in the RCT. We compared their changes in BMI-SDS between onset of intervention and 7-year follow-up to the changes in BMI-SDS of overweight children and adolescents from a population based cohort. We hypothesized that the decrease of BMI-SDS was significantly greater in the intervention group compared to the control group.

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2. Materials and methods

Overweight was defined by a body mass index (BMI) > 90th percentile and <97th percentile using German percentiles [13].

2.1. Subjects

2.1.1. Intervention group

We aimed to re-evaluate in the time period between July 2015 until December 2015 all overweight children (n = 57), who had participated in the randomized controlled trial (RCT) comparing the intervention "Obeldicks light" to an untreated control group as well as all overweight children, who had participated in the pilot study for this RCT (n = 19). Details of the randomized controlled study and the pilot study have been published previously [11,12]. The children were randomized to direct participation or after a 6-months waiting period.

All these children were contacted by letter, mail, and telephone for re-assessment of their weight status. If no response was achieved, the children were contacted by letter, mail and telephone at least four times. If addresses were not correct any more their registration offices were contacted to get the actual address.

All children who had dropped-out during the intervention were excluded from the study.

2.1.2. Untreated control group

Untreated overweight children were recruited from the population based modular study Motorik-Modul (MoMo) of the German Health Interview and Examination Survey for Children and Adolescents (KiGGS) [14]. Details of the recruitment process have been published previously [15]. A total of 4528 children were measured between 2009 and 2012 (baseline), while 2178 children were followed up 6 years later. All participants of the MoMo study, who were overweight and aged between 8 and 16 years at baseline and who had participated in the follow-up measurement, served as control group (n = 76). Pregnant girls and adolescents/young adults with an officially recognized disability were defined as ineligible.

2.2. Intervention

The six-month outpatient lifestyle intervention "Obeldicks light" is based on behaviour counselling, nutrition education, physical activity, and including individual psychological training of the child and his/her family [9]. The intervention was performed in sex- and age-specific group sessions. Details have been reported previously [11,12,16,17]. A training book of the intervention has been published [16].

2.3. Measurements

In the intervention group, height and body weight were measured at onset of intervention (T0), after 6 months (T1 = end of intervention), after 18 months after onset of intervention (T2 = 12 months after end of intervention) and in the time period from July 2015 to December 2015 (T3 = 6.4–8.2 years after onset of intervention). In the control group, height and body weight were measured at baseline and after 6 years.

Height was measured to the nearest centimetre using a rigid stadiometer. Weight was measured unclothed to the nearest 0.1 kg using a calibrated balance scale. Body mass index (BMI) was calculated by weight [kg]/height [m]^2. Since BMI is gender and age dependent in childhood, reduction of overweight was defined by reduction of standard deviation score of BMI-SDS. We used Cole's least mean square method to calculate BMI-SDS to normalize the BMI skewed distribution [18]. Reference data for German children were used [13].

2.4. Statistical analysis

We used two sided significance tests on an alpha = 0.05 level throughout. Data are presented as mean and standard deviation or as median and interquartile range if variables were not normally distributed. All variables were normally distributed except changes of BMI-SDS between T0 and T3 and BMI-SDS at T3 in the intervention group as tested by Shapiro–Wilk-tests.

Negative values for changes in BMI-SDS imply loss of BMI-SDS since changes were calculated by later observation minus previous observation.

Baseline characteristics of the participants of the lifestyle intervention and with available follow-up were compared to baseline characteristics of participants of the lifestyle intervention without follow-up by t-test for unpaired observation and chi-square tests as appropriate.

The BMI-SDS values over time were compared by Kruskal–Wallis test in the intervention group as global test followed by subsequent paired student t-tests and Wilcoxon test as adequate.

Baseline characteristics of the participants in the intervention group were compared to baseline characteristics of subjects of the control group by t-tests for unpaired observation and chi-square tests as appropriate. Furthermore, we compared the changes in BMI-SDS in the follow-up period between the participants of the intervention and the control group by Mann–Whitney U test.

Multiple linear regression analyses were performed with reduction in BMI-SDS between baseline and the end of follow-up as dependent variable and the independent variables age, gender, and baseline BMI-SDS both in the intervention group and in the control group.

All calculations were carried out using Winstat for Exel® (R. Fitch Software, Bad Krozingen, Germany).

The local ethics committee of Bielefeld University approved this study. Written informed consent was obtained from all subjects and their parents prior to study start.

3. Results

The mean time period between onset of intervention and follow-up examination was 7.6 ± 0.6 years (=7.1 ± 0.6 years after end of intervention) in the intervention group, while the time period between baseline and follow-up was 6.2 ± 0.1 years in the control group. A total of 32 children of the intervention group could be re-evaluated (see Fig. 1). None of the children in the intervention group participated in any further lifestyle intervention in the follow-up period.

The characteristics of the study population are presented in Table 1. While the participants of the intervention group demonstrated a larger evaluation period as well as a slightly higher BMI-SDS and BMI compared to the control group, the subjects did not differ significantly according to age or gender.

The children of the RCT or pilot study not participating in the follow-up study did not differ in respect from their gender (p = 0.964), age (p = 0.255), and BMI-SDS (p = 0.355) at onset of intervention, or their changes in BMI-SDS between T0 and T2 (=12 months after end of intervention; p = 0.159) from the children with follow-up at T3.

The children in the intervention group changed significantly their BMI-SDS between onset of intervention and end of follow-up (p = 0.005; Kruskal–Wallis test). They reduced significantly their BMI-SDS in the intervention period between T0 and T1 (see Fig. 2). Furthermore, this degree of weight loss remained stable both 12

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