Randomized control trials

Long-term effect of the Go4it group treatment for obese adolescents: A randomised controlled trial

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Abstract

Background & aims: Few studies evaluating treatment of adolescent obesity have been published. Therefore, long-term effects of the Go4it group treatment for obese adolescents were examined.

Methods: Obese adolescents (11–18 years) visiting an outpatient paediatric obesity clinic were randomly assigned to 1) intervention group (Go4it) or 2) current regular care i.e. referral to a dietician in the home care setting (controls). Linear mixed models analysis was performed to evaluate intervention effects. Effect modification by sex, age and ethnicity was checked. Outcome measures included body mass index standard deviation score (BMIsds), body composition and metabolic components at 6 and 18 months follow-up.

Results: 122 adolescents, 71 Go4it and 51 controls, with a mean BMIsds of 2.9 ± 0.5 were randomised. At 18 months a modest significant reduction in BMIsds (between group difference: −0.16; 95%CI: −0.30, −0.02; p = 0.028) was observed. None of the other body composition or metabolic components showed significant treatment effects. Ethnicity was a significant effect modifier. Posthoc analysis showed a large significant reduction on BMIsds (between group difference: −0.35; 95%CI: −0.64, −0.07) at 18 months for obese adolescents from western descent, while no effect was observed for adolescents from non-western descent. Significant treatment effects were also observed for systolic and diastolic blood pressure, as well as HDL cholesterol level, but only for obese adolescents from western descent.

Conclusions: Go4it showed promising long-term effects on BMIsds compared with regular care in obese adolescents. Larger benefits were achieved for adolescents of western ethnicity. This trial was registered at www.trialregister.nl with the Netherlands Trial Register as ISRCTN27626398.

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1. Introduction

Overweight and obesity in childhood are associated with negative psychosocial health, orthopaedic complications, asthma, and a strong increase in metabolic abnormalities. Elevated insulin levels are the first metabolic abnormalities observed in obese children. Insulin resistance can lead to glucose intolerance and type 2 diabetes. Child obesity also increases the risk for metabolic syndrome, which is a group of cardiovascular risk factors including increased waist circumference, hypertension, dyslipidaemia and impaired fasting glucose levels. Therefore, the prominent public health goal is primary prevention of child obesity. In addition, effective treatments are required for existing child obesity, since 80% of obese children become obese adults. Notwithstanding the high prevalence of child obesity, little evidence regarding effective child obesity treatments has been published. Most studies included 7–12 year old children, and only a few studies evaluated treatment of adolescent obesity. Cognitive behavioural modification techniques have shown promising results regarding lifestyle changes in child obesity, and were used to develop a new multidisciplinary group treatment for obese adolescents (Go4it).

This study describes the long-term effect of the Go4it group treatment for obese adolescents on anthropometrics, body composition, and metabolic components in a randomised controlled trial.
2. Materials and methods

2.1. Subjects and design

The present study is a randomised controlled trial evaluating the effect of the Go4it multidisciplinary group treatment for obese adolescents, at six and 18 months follow-up.

Adolescents were referred by their general practitioner or school doctor to the outpatient paediatric obesity clinic of the VU University Medical Center Amsterdam. At their first visit the paediatric-endocrinologist interviewed all adolescents concerning their medical history, weight development and ethnicity. Subjects were categorized as of western ethnicity when both parents were Dutch or with at least one parent born outside the Netherlands, but inside Europe (including former Yugoslavia and Soviet Union), North America, Oceania, Indonesia or Japan. Subject with at least one parent born in Turkey, Africa, Latin America or Asia were classified as non-western. The physical examination included height, weight, waist circumference, blood pressure and pubertal Tanner stage.

The subjects and their parents received an information brochure about the study. Within two weeks, the research assistant checked their willingness to participate. Subjects were eligible when they met the following inclusion criteria: 1) age between 11 and 18 years; 2) overweight or obesity according to the definition of Cole et al. Exclusion criteria were: not Dutch-speaking, obesity as a result of a known syndrome or organic cause (hypothyroidism), mental retardation, physical limitations and diagnosed type 2 diabetes mellitus. The research assistant randomly assigned subjects to the intervention (60%) or control group (40%), using SPSS for random selection. This asymmetric distribution was chosen to recruit a sufficient number of adolescents to start the intervention sessions within a reasonable time period. Randomisation was stratified for sex and age group (11–14 y, 15–18 y). The randomisation could not be blinded to the researcher and participants. Recruitment of adolescents occurred from May 2006 to June 2008. The primary outcome was BMI standard deviation score at 18 months follow-up. The medical ethical committee for human studies of the VU University Medical Center Amsterdam approved the protocol. Adolescents as well as their parents gave written informed consent.

2.2. Intervention

Go4it is a multidisciplinary group treatment for obese adolescents based on the programs of Braet et al., Epstein et al., and the educational materials of the Dutch Obesity Intervention in Teenagers (DOIT). During 7 sessions (duration 90 min) with an interval of 2–3 weeks the adolescents received education on healthy diet, sedentary and physical activity behaviour. The group size was 8–12 adolescents. They received cognitive behavioural therapy in which they learned how to improve their lifestyle and how to maintain energy balance. Go4it was carried out in an outpatient clinic involving a dietician, paediatrician/endocrinologist and psychologist.

In addition, two separate parallel sessions for parents were organised corresponding with the first and fourth session of the adolescents. Four booster group sessions were scheduled 6, 14, 26, and 36 weeks after the 3-months intervention period, in order to encourage the adolescents to maintain or further improve their energy balance behaviour and discuss problems and questions. Throughout the program the adolescents remained in the same peer group. The control group received the regular care in the Netherlands (valid for year 2006–2009), consisting of referral to a dietician in the home care setting. Adolescents had to make this appointment themselves. We asked the control group whether they had participated in any other treatment program during the study period. Reasons for non compliance were collected by phone and questionnaire. Details of the intervention, including sample size calculation, have been published elsewhere.

2.3. Anthropometrics, body composition and metabolic components

After an overnight fast, the subjects attended the outpatient clinic. Height was measured with an accuracy of 0.1 cm with an electronic stadiometer (KERN250D, De Grood Metaaltechniek, Nijmegen, Netherlands). Body weight was measured (in under-wear) within 0.1 kg with a calibrated electronic flat scale (SECA861, Schinkel, Nieuwegein, Netherlands). Weight and height were used to calculate BMI (kg/m²). For calculation of BMI standard deviation scores (BMIz-scores) or z-scores, a reference database of Dutch children was used (www.growthanalyser.org; version 3.5). Waist circumference was measured and recorded with a flexible band to an accuracy of 0.1 cm. Body composition was assessed with dual energy x-ray absorptiometry (DXA; Hologic QDR4500-Delphi, Tomp Medical, Cranxium, Netherlands). A standard oral glucose tolerance test was performed by a research nurse. Baseline samples were obtained immediately after measuring fasting plasma glucose and insulin. Glucose was given orally (1.75 g/kg body weight, up to a maximum of 75 g glucose). Blood samples were drawn after 30 and 120 min. Pre-diabetes was defined according the American Diabetes Association (ADA) guidelines as impaired fasting glucose (IFG 5.6–6.9 mmol/l) and/or impaired glucose tolerance (IGT 7.8–11.1 mmol/l). Insulin resistance was estimated by the homeostatic model assessment (HOMA-IR = fasting insulin in mU/l × fasting glucose in mmol/l/22.5). Systolic and diastolic blood pressures were measured at the left arm after a 10-min rest in supine position.

The metabolic syndrome was defined following IDF guidelines. For adolescents aged 10 years or older the metabolic syndrome is diagnosed when waist circumference is above the 90th percentile in combination with the presence of 2 or more clinical features (fasting triglycerides >1.7 mmol/l; fasting HDL <1.03 mmol/l; blood pressure >130 mmHg systolic or >85 mmHg diastolic; fasting glucose >5.6 mmol/l). For adolescents aged 16 years and older the adult IDF criteria were used. The adult definition is the same as for children, except for fasting HDL in females (fasting HDL <1.29).

2.4. Statistics

Baseline characteristics were analysed by t test for continuous variables and Chi square test for categorical variables. Group comparisons were performed according the intention-to-treat principle whereby all subjects were analyzed in the group to which they were randomly assigned. Linear mixed models were applied to assess the effect of the intervention over time. A random intercept and a random slope with time were assumed. Age-, sex- and, ethnicity adjusted analyses were performed with intervention as categorical variable and time as continuous variable, with an interaction term for intervention and time. B coefficients, 95% confidence intervals, and p values were calculated. This approach increases statistical power as it accounts for within-person correlation over time and includes all assessments, at baseline as well as at 6 and 18 months. A p value of < 0.05 was considered statistically significant. Effect modification by sex, age and ethnicity was checked by adding an interaction term between group allocation and the potential moderator. A P value of < 0.1 was considered statistically significant. In case effect modification was found, subgroup analyses were performed. Data were analysed using SPSS software (version 18 0, 2009 SPSS Inc., Chicago, Illinois, USA).
3. Results

Figure 1 shows the consort diagram for the Go4it trial. Of the 219 adolescents who were assessed for eligibility, 122 consented to the trial and were randomly (60:40) assigned to the intervention \((n = 71)\) and control group \((n = 51)\). At 18 months two subjects from the control group were excluded from the analyses, one developed type 1 diabetes and another was diagnosed with acute rheumatism, and therefore met exclusion criteria. Linear mixed models were applied whereby all subjects were analyzed in the group to which they were randomly assigned.

Table 1 shows baseline characteristics of the 122 subjects (56% girls). At six months follow-up 80% were reassessed and at 18 months follow-up 56%. Baseline characteristics were not significantly different between study completers and dropouts.

Table 2 shows the change in anthropometrics and body composition as well as metabolic components. The primary outcome BMIsds was significantly reduced in the go4it group at 18 months follow-up (between group difference: \(-0.16; 95\%\) CI: \(-0.30; -0.02\)). Concretely, in the intervention group \((n = 36)\) BMIsds decreased from 2.96 at baseline to 2.86 at 18 months follow-up, while in the control group \((n = 32)\) BMIsds increased from 2.91 to 2.96. None of the other body composition or metabolic components showed significant treatment effects.

But according to pre-diabetes, there were two subjects less in the intervention group, while in the control group two more subjects were considered pre-diabetic after 18 months follow-up.

Furthermore, the subjects with lower BMIsds were related to the subjects with lower HOMA-IR at 18 months versus baseline \((p = .054)\).

![ consort diagram ]

Table 1
Baseline characteristics in intervention (Go4it) and control group.

<table>
<thead>
<tr>
<th></th>
<th>Intervention group ((n = 71))</th>
<th>Control group ((n = 51))</th>
<th>(p)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td>0.56*</td>
</tr>
<tr>
<td>Male</td>
<td>33</td>
<td>21</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>38</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td>Age, years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>14.5 (1.7)*</td>
<td>14.4 (1.8)</td>
<td>0.73*</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>94.7 (18.4)</td>
<td>92.2 (18.5)</td>
<td>0.47*</td>
</tr>
<tr>
<td>Weight sds</td>
<td>3.03 (0.81)</td>
<td>2.96 (0.88)</td>
<td>0.65*</td>
</tr>
<tr>
<td>Height, cm</td>
<td>167.9 (9.6)</td>
<td>165.0 (8.2)</td>
<td>0.08*</td>
</tr>
<tr>
<td>Height sds</td>
<td>0.17 (1.1)</td>
<td>-0.05 (0.93)</td>
<td>0.24*</td>
</tr>
<tr>
<td>Body mass index, kg/m²</td>
<td>33.3 (4.6)</td>
<td>33.6 (5.1)</td>
<td>0.73*</td>
</tr>
<tr>
<td>Body mass index sds</td>
<td>2.93 (0.41)</td>
<td>2.93 (0.51)</td>
<td>0.99*</td>
</tr>
<tr>
<td>Degree of overweight, n</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overweight</td>
<td>5</td>
<td>7</td>
<td>0.22*</td>
</tr>
<tr>
<td>Obese</td>
<td>66</td>
<td>44</td>
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</tr>
<tr>
<td>Ethnicity, n</td>
<td></td>
<td></td>
<td>0.09*</td>
</tr>
<tr>
<td>Western</td>
<td>36</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>Non-western</td>
<td>35</td>
<td>33</td>
<td></td>
</tr>
<tr>
<td>Prediabetes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Impaired fasting glucose</td>
<td>6</td>
<td>3</td>
<td>0.60*</td>
</tr>
<tr>
<td>Impaired glucose tolerance</td>
<td>4</td>
<td>2</td>
<td>0.63*</td>
</tr>
<tr>
<td>Tanner stage, n</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-pubertal (stage 1)</td>
<td>25</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>Pubertal (stage ≥ 2)</td>
<td>40</td>
<td>34</td>
<td></td>
</tr>
</tbody>
</table>

Note: 4 Values are means (SD).

b For Tanner stage missing values were 6 for intervention and 1 for control group.

c t-test.
d Chi–Square test.

![ consort diagram ]

Fig. 1. Flowchart for enrolment, randomisation, and follow-up of study participants.
The treatment effect on BMIsds was moderated by ethnicity at 6 months ($p = .029$) and 18 months ($p = .057$). Table 3 shows the results stratified for ethnicity. The treatment effect was significant in adolescents from western descent (−0.35; 95%CI: −0.64; −0.07) but not in those from non-western descent (0.004; 95%CI: −0.14; 0.15). Significant treatment effects were also observed for systolic and diastolic blood pressure, as well as HDL cholesterol level, but only for obese adolescents from western descent.

Concerning compliance, 42 of the 71 subjects in the intervention group attended at least five Go4it sessions. The reasons for not attending the Go4it sessions included lack of motivation to change dietary habits, lack of belief of parents in their child's possible success to lose weight, previous unsuccessful dieting experiences, travel distance and the limited time of working parents and schoolchildren. Seven of the 29 subjects who attended less than five sessions never started the Go4it program. Of the parents 72% attended the first parent session and 55% attended the second parent session. At 6 months, 21 (48%) subjects in the control group had never visited a dietician, 4 subjects visited a dietician once, 6 twice, 7 three or more times, and for 6 subjects it is unknown. The main reported reason for not making an appointment was lack of motivation because of previous unsuccessful dieting experiences with or without a dietician.

The participants of the control group had not participated in any other treatment program during the 18 months follow-up.

### 4. Discussion

The multidisciplinary group treatment Go4it significantly reduced the standardized Body Mass Index (BMIsds) at 18 months in obese adolescents. The overall effect was a reduction in BMIsds of −0.16. Ethnicity significantly modified this treatment effect, with a significant BMIsds reduction of −0.35 in obese adolescents of western descent versus no significant treatment effect in those of non-western descent.
The interaction of intervention*time was not significant for any of the outcome measurements, implying that the estimated time effect did not differ significantly by intervention.

The relatively small treatment effect on body size is promising for a number of reasons. First, the intervention aimed to raise energy balance behaviour consciousness of the participants and change their behaviour in a way that would result in long-term beneficial effects. This matter is of particular importance since most initial and short-term results in weight management disappear over time. The present intervention showed a gradual BMIsds change over time, with a larger effect at 18 months versus 6 months, indicating an increase with time rather than a decrease with time. Second, Go4it was intended as a relatively low intensive lifestyle intervention with two additional subjects were considered prediabetic, while in the intervention group two subjects improved from prediabetic to "normal".

There are only 6 comparable randomised controlled trials evaluating treatment programs for obese adolescents. The 2009 Cochrane review on treatment programs for obese children included 64 randomised controlled trials. Seventeen of the 64 studies included adolescents, based on a mean age at or above 12 years. Twelve of the 17 studies were lifestyle interventions with a behavioural component as the main focus of the intervention. Five of the studies included adolescents, based on a mean age at or above 12 years. Twelve of the 17 studies were lifestyle interventions with a behavioural component as the main focus of the intervention.

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The present study can be compared to the randomised controlled trial in obese children 8–16 years of age by Savoye et al.,18,23 although the age group is younger and BMIsds lower (+2.5 vs +3). Savoye et al. compared the effect of an intensive lifestyle intervention program to a control group at 12 and 24 months. The intervention group received a family-based program, including exercise, nutrition, and behaviour modification. Lifestyle sessions were offered twice weekly for the first 6 months, then twice monthly for the second 6 months and no active intervention for the last 12 months. The control group received counselling every 6 months. The intervention by Savoye et al. resulted in a significant long-term (24 months) effect of −0.16 BMIsds, which is identical to the effect of −0.16 for Go4it at 18 months.18 The advantage of Go4it was the lower intensity, and therefore lower cost, with 11 sessions for Go4it versus 60 sessions for Savoye et al.18

Nguyen et al. reported on a randomised controlled trial in obese adolescents of 13–16 years of age, although again with a lower BMIsds compared to the present study (+2 versus +3).26 Nguyen et al. compared the effect of a lifestyle modification program (Loozit) with or without 2-weekly additional therapeutic contact, including telephone coaching and short-message-service. The Loozit intervention consisted of 7 weekly sessions, including parental training, and the initial two months, and 3-monthly booster sessions up to 24 months (in total 14 sessions). The effect of Loozit, with or without additional therapeutic contact, on BMIsds was −0.13 at 24 months. This intervention showed a slightly smaller effect size, while based on a higher intensity (14 vs 11 sessions) and longer intervention period (24 vs < 12 months, including booster sessions). Overall the long-term effect size of the Go4it intervention appears to be in line with, or even more favourable than, other interventions for obese adolescents.

This study has several strengths and original features including: the randomised controlled trial design, long-term follow-up, a relatively easy to implement intervention, and robust outcome measures (including body composition measured by DXA and metabolic components).

The main limitation of the present trial is the high level of attrition, which was 44% (49% in the intervention group and 37% in the control group) at 18 months. Ball et al. recently showed that even on the short term an attrition rate of 20–40% was found in this target group.27 Also, Nguyen et al. reported 38% and Savoye et al. even 56% attrition.18,26 Therefore, this level of attrition is comparable to other studies concerning obesity treatment in adolescents (12–47%).18,21–28 Data imputation was not performed because subjects were in their mid-to-late puberty; therefore increases in height and weight were expected. By imputation of data a somewhat misleading estimate of the intervention effect would be provided.

Another limitations are the asymmetrical randomization. The main reason for this asymmetrical randomization was that to start the group sessions as soon as possible after the first included adolescent was enrolled into the study. Otherwise it would have taken several months before a sufficient number of adolescents had enrolled to start the group sessions.

Disappointing was the lack of a significant treatment effect in non-western obese adolescents, despite tailoring the nutrition education and advice of Go4it to the different ethnicities. Potential explanations are that parents from Turkish or Moroccan descent underestimate the actual weight status of their children as well as the resulting health effects. Thus, cultural norms of healthy body weight and attractive appearance are probable causes of the observed difference.29 Savoye et al. also studied a culturally diverse group of children, but did not report on effect-modification.18

Beforehand, it was intended to develop an intervention that is implementable into the child health care and primary health care setting. This affected choices in the design of the intervention, which had to be evidence based and effective but also practical and affordable. For instance, there was no exercise program provided, but participants were encouraged to seek and participate in existing exercise programs in their own neighborhood. The intervention could have been upgraded with telephone coaching, short-message-service, and email communication at low cost. However, Nguyen et al. showed that this additional therapeutic contact did not improve the outcome at 24 months.30 Since travel distance and the limited time of working parents and schoolchildren was one of the main reasons for non-compliance, implementation of the intervention nearby home or school may improve compliance.

5. Conclusions and implications

In summary, the Go4it intervention showed a significant long-term effect on BMIsds, compared to current regular care in obese adolescents. Implementation of Go4it in a setting nearby home or school may even improve successful treatment of obese adolescents. In addition, development of additional programs aimed at the non-western ethnic group is urgently required.

Ethical approval

This study was approved by the ethical committee for human studies of the VU University Medical Center Amsterdam. The adolescents as well as their parents gave written informed consent.

Contributors

AH, MC, HD and PW provided support in the design of the study and contributed input into the main ideas of this paper. AH conducted the statistical analyses and drafted the manuscript. PW, MC and HD provided support during the development and implementation of the intervention. All authors contributed to the further writing of the manuscript. All authors read and approved the final manuscript.

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Conflict of interest statement

The author(s) declare that they have no competing interests.

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References


