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The placebo effect on aerobic fitness test results is preserved following a multidisciplinary intervention program for treating childhood obesity

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Background: The aim of the study was to examine the placebo effect on fitness test results in trained and untrained overweight and obese children.

Methods: Twenty pre-pubertal overweight children performed two pairs of progressive treadmill exercise tests before and 12 weeks into a multidisciplinary program for the treatment of childhood obesity. In each test pair, at random order, participants received different types of information regarding a water drink consumed prior to testing—standard information (water) vs deliberate positive information (presumed energy drink, placebo).

Results: The intervention led to a significant change ($P < .05$) in BMI%ile (95.6 ± 4.4 vs 93.6 ± 6.9), % fat (35.4 ± 6.0 vs 31.6 ± 5.8), baseline heart rate (104.2 ± 11.6 vs 94.0 ± 7.0 bpm), total leisure activity score—Godin (9.3 ± 8.8 vs 41.5 ± 15.2), total screen time (6.9 ± 5.8 vs 3.1 ± 1.4 h/d), and a significant improvement in fitness. Following the placebo drink, both groups achieved a significantly higher peak heart rate (untrained: 176.1 ± 13.7 vs 167.5 ± 16.8; trained: 170.7 ± 11.6 vs 166.2 ± 11.4 bpm) and longer running time (untrained: 559.9 ± 151.0 vs 434.4 ± 140.3 seconds; trained: 728.3 ± 177.3 vs 667.1 ± 176.1 seconds). Despite longer exercise duration and higher peak exercise heart rate, average, and peak RPE were lower after the placebo drink (untrained: 12.1 ± 2.3 vs 13.6 ± 2.1; trained:10.0 ± 1.8 vs 11.6 ± 2.1), recovery time was shorter (untrained: 119.2 ± 25.3 vs 133.2 ± 23.7 seconds; trained: 92.6 ± 18.9 vs 102.7 ± 18.3 seconds). The placebo-induced change in running time and peak RPE were significantly greater prior to training.

Conclusion: The significant information placebo effect is preserved in trained overweight children. Information, as well as other motivating aids and fatigue distractors may be useful in enhancing physical performance in obese children.

KEYWORDS

fitness, information, obesity, sham effect, training

1 | INTRODUCTION

In recent decades, more children and adolescents from all socioeconomic levels in both developed and developing countries are becoming overweight and obese.[1] Recent studies have found that Israel has one of the highest rates of childhood obesity in Westernized countries.[2]

Obese children are at a heightened risk for developing cardiovascular manifestations such as hypertension, hyperlipidemia, endothelial dysfunction, insulin resistance, and diabetes[2,3] as well as social and psychological difficulties which may have an enormous impact on their quality of life.[4]

The mechanisms behind the increased prevalence of childhood obesity are not completely understood, but the adoption of a modern lifestyle of increased caloric intake and decreased energy expenditure likely plays a crucial role.[5,6]

Multidisciplinary weight-loss programs that include dietary counseling, behavioral intervention, and physical exercise and involve the child's family seem to be the most promising tool to treat childhood obesity.[7] Intervention programs centered on physical exercise have been shown to improve health results in overweight children, including weight loss, reduced fat percentage, and improved fitness metrics.[2,8]

In recent years, researchers have investigated the effect of perception on exercise and health,[9] trying to figure out whether this effect could be used to promote exercise and physical activity. One example of the use of perception is the placebo effect. Recent studies demonstrated that placebos have their own treatment potential[10] and may be used to improve physical exercise results.[11-13]

While placebo responses in children and specifically in the field of physical exercise are less studied, we recently tested the effect of information placebo on aerobic fitness test results in normal weight[14] and overweight children.[15] We found that the use of deliberate positive information before an aerobic test led to a significant increase in running duration and maximal heart rate and to a significant decrease in recovery time. We also found that the use of placebo led to a decrease in the rated perceived exertion (RPE) during exercise.

The goal of the current study was to examine whether the use of positive information is still effective following 12 weeks of multidisciplinary weight-loss program focused on improving physical fitness in overweight children. We hypothesized that when an obese child is more familiar with physical exercise and is better trained, sham procedures, that is, placebos, would be less effective, if at all.

TABLE 1 The effect of the 12 wk' multidisciplinary program on anthropometric measures and physical activity of the study participants

	Obese—untrained pre n = 20	**Obese—trained post n = 20**
Gender (F/M)	7/13	
Age (mo)	125.2 ± 25.1	128.2 ± 25.2*
Weight (kg)	55.8 ± 10.9	54.8 ± 10.5
Height (cm)	146.7 ± 8.6	147.9 ± 8.8*
BMI (kg/m^2)	25.8 ± 3.7	24.6 ± 3.6*
BMI percentile (%)	95.6 ± 4.4	93.6 ± 6.9*
Fat percentage (%)	35.4 ± 6.0	31.6 ± 5.8*
Intense PA (h/wk)	0.5 ± 0.9	3.6 ± 1.5
Moderate PA (h/wk)	0.7 ± 0.9	1.4 ± 1.0
Light PA (h/wk)	0.5 ± 0.9	1.3 ± 0.9*
Total leisure activity score—Godin	9.3 ± 8.8	41.5 ± 15.2*
TV Screen time (h/d)	3.5 ± 4.5	1.5 ± 1.0
Computer + phone time (h/d)	3.6 ± 4.4	1.6 ± 1.3
Total screen time (h/d)	6.9 ± 5.8	3.1 ± 1.4*

*$P < .05$.

2 | METHODS

2.1 | Participants and recruitment

Twenty (seven girls and 13 boys) overweight children participated in the study following informed consent signed by their parents/guardians. Participants' characteristics are presented in Table 1. The study was approved by the Institutional Review Board of the Meir Medical Center. Upon recruitment, participants were examined by the attending physician at the Child Health and Sports Center. Only pre-pubertal (Tanner stage 1) children were included. None of the subjects had an organic disease, and none of the subjects were taking any medications that might interfere with growth, weight control, or exercise tolerance (eg, corticosteroids, thyroid hormone substitution, and recombinant growth hormone.).

The participants were tested four times (two session pairs separated by 12 weeks) with each child being his/her own control.

2.2 | Design and procedure

We tested the influence of positive information on physical fitness metrics in overweight children before joining the

multidisciplinary program for the treatment of childhood obesity and 12 weeks into the program.

When first joining the program, participants performed a treadmill exercise stress test twice under identical conditions except for the difference in the information provided regarding a drink (water) consumed prior to testing: standard information vs deliberate positive information (placebo). Before each testing session, the participants drank a glass of a drink. In one session, they were informed they were drinking water whereas in the other session, the drink was described by the examiner as a drink that increases energy levels, strengthens muscles, and is therefore likely to improve exercise performance. The drink bottles were also styled differently for the two sessions—during the standard information session, plain transparent water bottles were used; whereas during the deliberate positive information sessions, the water bottles were opaque and blue-colored and included a label proclaiming the content to be an energy drink that strengthens muscles and improves athletic performance. Tests were performed at random order (half the children performed the first test following standard information and half following deliberate positive information). Twenty minutes after consuming the drink, the participant went on the treadmill and started the exercise test. After 12 weeks in the program, participants were asked to perform two additional exercise tests under the same previous conditions one test with standard information and one with deliberate positive information.

2.3 | Multidisciplinary program

Following the initial exercise test, all children participated in the Child Health and Sports Center multidisciplinary program for the treatment of childhood obesity. The program includes a dietary intervention, an exercise component, and behavioral therapy and involves the child and his family.[8]

2.3.1 | Dietary intervention

The participants met with the dietitian six times during the intervention. Children were invited with both parents to all meetings. Each family was instructed to come to the first meeting with a 24-hour dietary recall. The first appointment, 45-60 minutes long, was dedicated to acquaintance, learning about the reasons for childhood obesity, receiving information about food choices, dietary and cooking habits, understanding the motivation for weight loss, and trying to enroll the whole family to the treatment program. The following appointments, 30-45 minutes each, were devoted mainly to nutritional education. In addition, children and families received dietary information by working sheets/flyers on important nutritional issues. Subjects received a balanced hypocaloric diet. The diet consisted of 1200-2000 kcal depending on the age and weight of the child, or of a caloric deficit of about 30% from the reported intake, or 15% less of the estimated daily required intake.

2.3.2 | Exercise program intervention

Subjects participated in a twice-weekly exercise training program (1 hour per training session). Children exercised in groups according to their age. The intervention was designed to mimic the type and intensity of exercise that children normally perform. These activities varied in duration and intensity throughout the program and were designed primarily as games to encourage enthusiasm and participation of the subjects. Endurance-type activities accounted for most of the time spent in training (about 50% team sports and 50% running games), with attention to coordination and flexibility skills. In order to encourage personal responsibility of the participants, subjects were instructed to add an extra 30-45 minutes of walking/other weight-bearing sport activities at least once a week. These activities were reported to the coach at the end of the last training session each week. Subjects were encouraged throughout the program by the physicians, nutritionist, and coaches to reduce sedentary activities.

2.3.3 | Behavioral intervention

All children were evaluated by the program psychologist. In this age group, our behavioral intervention is divided into parental intervention and movement therapy. The parents met with the psychologist every 2 weeks to discuss issues related to their coping with difficulties arising with their children during the intervention. In addition, subjects and parents participated in a weekly 45 minutes movement therapy session. This meeting was directed by the movement therapist of the Child Health & Sports Center. Although this session includes additional movement, its major purpose was to achieve positive nutritional and physical activity behavioral and lifestyle changes and bonding with parents.

2.4 | Measures

2.4.1 | Anthropometric measurements

Standard calibrated scales (Seca 767) and stadiometers (Seca 240) were used to determine height, weight, and body mass index (BMI-kg/m^2). BMI-for-age percentile was calculated using the Center for Disease Control growth charts[16]. Fat percentage was evaluated by bioelectrical impedance analysis, using the Tanita BC-418 Segmental Body Composition Analyzer, following the consumption of a glass of drink (250 cc).

2.4.2 | Fitness assessment

Fitness was assessed using a progressive treadmill exercise test to determine exercise endurance.[2] Tests were performed in a well-lighted, clean, and well-ventilated room, with a controlled temperature of 22-23°C. Subjects were familiarized with the treadmill for 5 minutes and performed a warm-up of 1 minute at a speed of 2.2 miles per hour, with no incline. Exercise started at a speed of 2.2 miles per hour, with an incline of 10 degrees. The exercise intensity was enhanced every 2 minutes (exercise test stage) by increasing the elevation of the treadmill by 2.5 degrees (up to an incline of 22.5 degrees). Then, the treadmill speed was increased by 0.6 miles per hour every 2 minutes. As stated, each subject performed the test twice, using the same protocol, at the same time of the day—once believing they drank water, and once believing they drank an energy drink, at a random order. Subjects were encouraged throughout the test by the staff and exercised to the limit of their tolerance. Endurance time was measured from the end of warm-up to exhaustion. Heart rate was measured using Polar H10 heart rate monitor. Recovery time was measured as the time from the end of exercise until heart rate reached 100 bpm. Rate of perceived exertion was evaluated using the Borg scale.[17]

2.4.3 | Habitual activity & screen time assessment

Weekly habitual physical activity of the participants was assessed using the Godin leisure time physical activity questionnaire.[18] Each type of activity was scored according to an estimated MET score, and the final weighted score was calculated according to the formula (9 × frequency of strenuous activity) + (5 × frequency of moderate activity) + (3 × frequency of light activity). In addition, each participant was asked to list his/her weekly time spent watching television and playing smart phones and computer games (screen time).

2.5 | Statistical analysis

ANOVA for repeated measurements was used to assess the effect the multidisciplinary program on BMI percentiles, Fat percent, baseline heart rate, running time, RPE, and recovery time. Paired *t* test was used to assess the effect of placebo administration on exercise test results before and following the multidisciplinary intervention. Paired *t* test was also used to assess the percent placebo-water difference before and following the intervention Data are presented as mean ± SD. Significance was set at an alpha level of $P < .05$.

3 | RESULTS

The effect of 12 weeks multidisciplinary weight-loss program on anthropometric measures, physical activity, and fitness among the participants is summarized in Table 1. The intervention was associated with a significant decrease in BMI percentile and fat percentage and was associated with a significant reduction in total screen time and a significant increase in total leisure activity (Godin). As expected in pre-pubertal children, no significant sex differences were found.

The water vs placebo exercise test results before and following 12 weeks of the multidisciplinary program are presented in Table 2. Training led to a significantly lower baseline heart rate, longer running time, reduced RPE during the exercise test, and reduced recovery time from exercise. Following consumption of the placebo drink, overweight children before and after training demonstrated significantly higher peak heart rate, reached a higher exercise test stage, and running time. Although the exercise duration was longer and the peak heart rate was higher, the reported average and peak RPE were significantly lower following the placebo consumption, both before and following training. The recovery time for the placebo consumption was also significantly shorter before and following training. Since the placebo trial represents the true maximal result, a comparison of placebo vs placebo results, before and after intervention is presented in Table 2. A significant decrease in baseline heart rate, significant increases in exercise test phase, and running time with no difference in peak heart rate were noted. The intervention also led to a significantly reduced peak RPE and faster recovery.

Placebo-water percent differences before and following training are presented in Figure 1. Percent increase in maximal heart rate and improvement in running time with placebo were significantly greater prior to training. The reduction in peak RPE with placebo was significantly greater following training. Training had no effect on the placebo-water percent differences observed in the average RPE and in recovery time. The placebo and water differences in fitness metrics were not related to the order of tests, age, gender, or child habitual physical activity level.

4 | DISCUSSION

We examined the effect of information placebo on the results of aerobic fitness tests in overweight children before and after a 12-week multidisciplinary weight-loss intervention. In contrast to our hypothesis, the information placebo effect was preserved in trained overweight children.

Consistent with our previous findings in overweight children,[15] the present study demonstrated that the use

TABLE 2 Effect of the water vs "placebo" on physical activity (PA) measures of the study participants before and after 12 wk of multidisciplinary program (n = 20)

	Untrained—pre		Trained—post	
	Water	Placebo ("Energy")	Water	Placebo ("Energy")
Initial heart rate (bpm)	104.2 ± 11.6	104.6 ± 12.8	94.0 ± 7.0[b]	92.7 ± 7.0[c]
Ergometry phase	3.9 ± 1.2	5.1 ± 1.2[a]	6.1 ± 1.4[b]	6.6 ± 1.4[a,c]
Running time (s)	434.4 ± 140.3	559.9 ± 151.0[a]	667.1 ± 176.1[b]	728.3 ± 177.3[a,c]
Maximal heart rate (bpm)	167.5 ± 16.8	176.1 ± 13.7[a]	166.2 ± 11.4	170.7 ± 11.6[a]
Peak RPE	19.1 ± 1.5	18.0 ± 1.1[a]	16.9 ± 2.2[b]	15.1 ± 2.0[a,c]
Average RPE	13.6 ± 2.1	12.1 ± 2.3[a]	11.6 ± 2.1[b]	10.0 ± 1.8[a]
Recovery time (s)	133.2 ± 23.7	119.2 ± 25.3[a]	102.7 ± 18.3[b]	92.6 ± 18.9[a,c]

[a]$P < .05$ placebo vs water.

[b]$P < .05$ pre vs post training.

[c]$P < .05$ placebo pre vs placebo post training.

of deliberate positive information led to a significant improvement in physical fitness metrics including higher maximal heart rate and longer running time. In addition, although participants performed longer and more intense exercise, the peak and average RPE were lower and recovery time was significantly shorter. The main finding of the present study was that the significant effect of placebo was maintained following a 12-week weight management program that was associated with a remarkable improvement of fitness, although the percent placebo-water difference was lower.

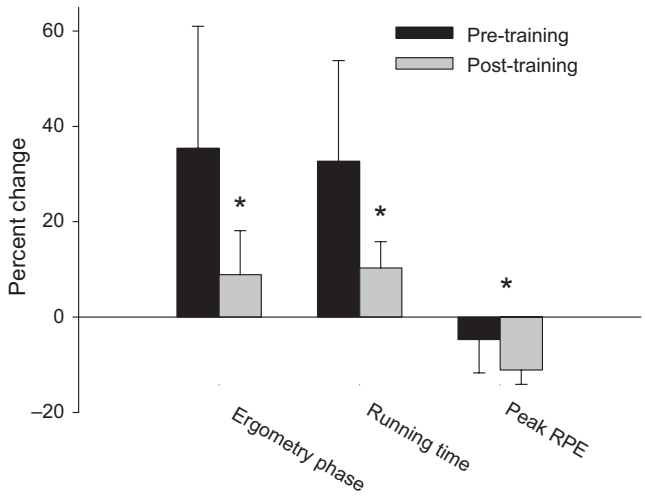

FIGURE 1 Percent change in ergometry phase, running time, and rate of perceived exertion before and following intervention. Percent increase in ergometry phase and running time with placebo were significantly greater prior to training. In contrast, reduced peak RPE with placebo was significantly greater following training

The 12-week multidisciplinary weight-loss program was associated with a significant decrease in BMI percentiles and fat percentage. Moreover, there was a significant decrease in sedentary behavior as determined by screen time, and a significant increase in leisure time physical activity measured by the Godin leisure activity score. The program was associated with a remarkable improvement in the overweight children's physical fitness metrics as shown by reduced resting heart rate and longer running time, as well as by reduced average and peak rating of perceived exertion during the exercise test and shorter recovery time despite performing a significantly more intense exercise test. The results demonstrating the effectiveness of the multidisciplinary program are in line with previous studies.[2,7] However, multidisciplinary weight-loss interventions may have some drawbacks. First, the motivation of obese children to participate and sustain a prolonged and continuous exercise programs is low. In addition, morbidly obese children (BMI% >97)[19,20] and overweight and obese adolescents[21-23] are less likely to succeed in such programs. Thus, additional tools are needed to encourage participation, improve cooperation and adherence that will lead to long-term success of multidisciplinary weight-loss intervention programs.

In recent years, the use of placebos in the context of weight loss and physical activity has been examined in studies focused mostly on adults. Very few studies have tested adolescents,[24] pre-pubertal normal weight,[14] and overweight children.[15] Consistent with previous findings, the present study demonstrated that when overweight children perform an exercise test following deliberate positive information they achieve higher maximal heart rate, run for significantly longer time,

and despite the more intense exercise, they perceive exercise as easier as demonstrated by lower peak and average RPE and a significantly shorter recovery time. The deliberate positive information placebo effect on the exercise test results persisted even after weight reduction and a remarkable improvement in fitness measures. This finding is important, as it suggests that overweight children may perform exercise better if properly encouraged and that encouragements should be used throughout intervention programs as a possible available, harmless and inexpensive tool to improve their effectiveness, particularly in children in which the regular program was less effective. It is important to note, however, that the effect of placebo on maximal heart rate and running time was lower when overweight children became more fit. We assume that the improvement in general physical fitness following the 12 weeks of training allowed participants to come closer to their upper physical exertion limits during the control (water) session, leaving less room for improvement, for supplementary aids.

One of the mechanisms behind the motor performance improvement following the administration of placebo is the expectation mechanism, especially when this expectation is induced verbally.[25] The term expectation describes the phenomenon in which, for instance, the hope for improvement facilitates its occurrence. The subject holds this expectation consciously, based on past experience or other reasons, such as being convinced, holding a belief, and learning or receiving an explanation.[26] Expectation was found to reduce pain, diminish anxiety, and lead to clinical improvements.[27]

In addition to the expectation that our participants had due to being primed regarding the supposed effect of the "energy drink" they were about to consume, it is likely that they remembered the beneficial effect of using the "energy drink" for exercise performance prior to their participation in the program. A positive past experience effect may have also contributed to the improved placebo effect on performance.

The subjects' past experience with the placebo "energy drink" probably also modulated their anxiety and lowered their perceived exertion. Whether positive past experience effect is long-lasting, needs further research.

While deliberate positive information was still significantly effective after the improvement in fitness, the percent placebo-water difference in maximal heart rate and running time was significantly lower following training in the overweight and obese children. These results are consistent with other modalities commonly used to improve exercise performance like music. Previous reports have demonstrated that music effects on nexercise test performance are inversely related to the participant's fitness level and had significantly greater enhancing effects in untrained subjects, during initial stages of training programs.[28] Several mechanisms may explain the reduced or even lack of impact of supplemental aids during phases of increased fatigue. Physical exertion results mainly from the exercise intensity and duration. During markedly intense exercise, the participant experiences a variety of exertion feelings, ranging from discrete symptoms to extreme general fatigue, and exhaustion. The supplementary aid (deliberate positive information, music, etc) distracts the participant from the exercise-associated sensation of fatigue (The parallel processing model[29]). It is suggested that this mechanism operates mainly during low-intensity levels of exercise, when external signals can compete with internal signals. During high-intensity exercise, internal cues, such as fatigue, have a stronger impact on mental status.[30] Therefore, the effectiveness of external aids/distracters is greater in untrained individuals performing low-moderate intensity exercise and is limited in more fit individuals and during intense efforts.

Our study demonstrates that the use of placebo information as well as other motivating aids and fatigue distractors may improve children's performance. The effect of placebo on running time in the overweight children prior to intervention was remarkable (about 30%), a change that is hard to achieve in intervention programs. This raises the question of a possible interpretation bias when trying to evaluate children's fitness using a "maximal" exercise test. In fact, the "true" (or closer to "true") fitness characteristics of the participants (prior and following the intervention) were those achieved during the placebo trial. The training intervention was associated with significant favorable changes in running time, RPE, and recovery time even when we calculated the placebo pre-post training differences.

Our study carries some limitations; a relatively small sample size that did not allow us to differentiate further within the overweight and obesity subgroups. Moreover, our study tested the effect of placebo on a single exercise before and after training among obese children. The possible effects of placebo consumption on physical activity during the rest of the day, or on food consumption and food choices following exercise are unknown.

In summary, deliberate positive information was associated with a significant improvement in physical fitness metrics in overweight children. This beneficial effect was maintained, although to a lesser extent, following a 12-week weight management intervention program that was associated with a remarkable improvement in fitness.

5 | PERSPECTIVE

If properly encouraged while exercising, obese children may better perform. Encouragements should be an integral tool in enhancing physical activity, exercise performance, and fitness in intervention programs for the treatment of childhood obesity.

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