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Study Protocol: The Feeding Exercise Randomized Trial among Overweight and Obese Adolescents in Greece

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Abstract

Background: This paper describes the study protocol used in the Feeding Exercise Clinical Trial in Adolescents in the region of Larissa in Greece, a randomized controlled clinical trial, among overweight/obese adolescents.

Methods: The main aim of the study was to comparatively evaluate the effectiveness of 2 different clinical interventions among 12 to 18-year-old overweight and obese adolescents. The first group participated in an exercise program and the second group in a combined dietary and exercise program. The third group was the control group. The study was conducted between 2014 and 2015. All adolescents aged 12 to 18 years old from public schools of Larisa and also their parents asked to participate. The effects of the intervention program will be analyzed by repeated-measures analysis of variance or the Friedman test. Changes in lifestyle behaviors from the baseline to the end of the intervention will be assessed using a chi-square test for categorical variables. A Pearson or a Spearman correlation coefficient and a linear regression analysis will be performed to explore any associations between quantitative variables. The following parameters were measured among adolescents: height, weight, body mass index, waist circumference, systolic and diastolic pressure, pulse rate, dietary and exercise habits of the adolescents and their parents.

Conclusion: This is the first clinical trial in Greece investigating the impact of clinical interventions on obesity among adolescents. It is expected that the results will provide useful insights into the effectiveness of clinical interventions among overweight and obese adolescents in Greece.

Keywords: Obesity, Overweight, Adolescents, Clinical Trial, Body Mass Index, Greece

Conflicts of Interest: None declared
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Introduction

Obesity is a common but often underestimated condition of clinical and public health importance all over the world. In Europe and the United States of America, obesity and excess weight constitute an epidemic that is a serious public health hazard and a major risk factor for morbidity and mortality (1-3). Health ed ucators are currently being asked to become involved in child overweight prevention programs (4). Obesity is a significant health problem for adolescents and could be predictive of abnormal body mass index (BMI) among children and adults (5-8). Adolescents represent one of the most vulnerable population group with regard to nutrition and health education (9, 10). Adolescence refers to as a period of major physical and cognitive change and it has been considered as a "critical period" for the development of adult obesity; and adolescents with established overweight or obesity

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↑What is "already known" in this topic:
Obesity among adolescents is an underestimated condition of clinical and public health importance.

→What this article adds:
This is the first clinical trial in Greece investigating the impact of clinical interventions on obesity among adolescents.

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have a moderate to substantial risk of remaining so in adulthood (11). Adult diseases related to obesity are now becoming more prevalent among the youth (12, 13). The growing economic impact of obesity is also a concern (14-16). Key health and medical organizations (16, 17) in several countries have recommended that research should be conducted on the effectiveness of well-designed interventions to combat overweight and obesity in children and adolescents (18, 19).

In addition, there is evidence that over 60% of young people eat more than the recommended amount of fat, while only 34% of boys and 33% of girls consume the daily suggested servings of fruits and vegetables (17). Nearly 25% of the calories that adolescents consume are from low nutritional value foods (20). Moreover, it is estimated that the vast majority of girls and boys consume more than 10% of their calories from saturated fat (21, 22). Despite their natural tendencies, adolescents have become less physically active in comparison to those who were children 50 years ago (23). The Center for Disease Control reported that less than 50% of adolescents are physically active on a regular basis, with a sharp decline in activity from childhood. It has been suggested that 20% of adolescents are not engaged in any leisure time physical activity (24, 25). In order to improve the health of the adolescent population, effective intervention programs focused on modifying unhealthy lifestyle behaviours are needed (18, 19, 25). Regular physical activity in teenagers and adolescents has been shown to improve strength and aerobic endurance, bone mass and density, blood glucose regulation, and reduce body fat (26, 27). In Greece, various researches have been conducted on the frequency of overweight and obesity among children. On the contrary, only few studies investigated overweight and/or obesity among adolescents (28-31). In addition, to the best of our knowledge, no clinical trial has been conducted in Greece investigating the impact of clinical interventions on obesity among adolescents.

Consequently, the Feeding Exercise Clinical Trial in Adolescents (FETA) program aims to compare and evaluate the efficacy of two different clinical interventions among overweight and obese adolescents 12-18-year-old.

Methods

Study Design

The study consisted of 2 parts.

Part 1. Descriptive Study: The first part included the measurement of the following parameters among12 to 18 year-old students in public high schools of Larissa: height, weight, BMI, waist circumference, systolic and diastolic blood pressure, and cardiac rate. In addition, information was obtained on dietary and exercise habits of the adolescents and their parents. All the overweight or obese students detected in the first phase of the study were invited to take part in the randomized control trial.

Part 2. Intervention Program (Clinical Trial): In the clinical trial, 2 different intervention groups and 1 control group were employed. The first group participated in an exercise program and the second group in a combined dietary and exercise program. The third group was the control group. Each group comprised of 50 individuals, aged 12 to 18, of both sexes. All groups completed a 50-m speed trial and filled out a questionnaire concerning their nutritional and exercise habits, both at the start and at the completion of the program. The students participated in a 50-m speed trial. The same test took place both at the start and at the finish of the program. The implementation of the program will start with the speed trials for all the 3 groups. The first group participated in an exercise program (duration: a 3-month program, training 3 times a week for 45 minutes at a time). The second group underwent a combined training and nutrition program for 3 months, meeting 3 times a week, for 45 minutes at a time. The first 10 minutes of each session included discussion regarding dietary issues, aiming at supplying knowledge and changing habits. The remaining time was used for the exercise program. The third group, the control group, only completed the questionnaires and participated in the speed trial tests at the beginning and the completion of the program. The intervention program lasted for 3 months, with 45 minutes per week. Measurements (weight, height, BMI, and waist circumference) continued for 3 months after the completion of the program (total duration of the program: 6 months).

Inclusion criteria

All students from the 15 public middle schools in the city of Larissa in central Greece were invited to measure their weight and height to calculate their BMI. All the overweight or obese students were invited to take part in the study.

Exclusion Criteria

Those who had an organic cause for their obesity and those who received any medication that could interfere with growth or weight control were excluded from the study.

Participants

To detect a 0.28 standardized effect size from the baseline to 6 months in the BMI score, with a power of 80% at 2-sided 5% level of significance and assuming a dropout rate of 20%, a minimum sample size of 65 participants per group was required. Analyses were conducted on a modified intention-to-treat basis, which included all randomized participants who had a baseline and at least 1 post-baseline completed questionnaire, with the last observation carried forward.

Outcome Measures

The following parameters were measured pre- and postintervention.

(i) Adiposity: Weight will be measured by the use of children barefoot and wearing light clothing, with Tanita HD646 scales (Tanita Corporation of America Inc) to 0.1 kg. In addition, the parameter of height will be measured using the stretch stature method and PE87 portable stadiometers (Mentone Educational Centre). Nonextensible steel tapes will be used to assess waist circumference, which is measured at the mid-point level between the low-

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er costal border and the iliac crest. Anthropometric measures are conducted using the International Society for the Advancement of Kinanthropometry procedures (32). With regard to the BMI, it will be calculated via measuring weight and height. Moreover, we will use the Cole scale to establish a definition for children's overweight and obesity (33). Last, the waist circumference will be measured by the use of a tape measure.

(ii) Metabolic Profile Measures: Systolic and diastolic blood pressure and cardiac rate will be measured using an automated blood pressure monitor.

(iii) Dietary Intake: Two questionnaires will be administered to the students: the modified version of the Parental Authority Questionnaire (PAQ) (34, 35) and the modified version of Parent-Initiated Motivational Climate Questionnaire-2 (PIMCQ-2) (36). Another questionnaire (modified version of the Family Eating and Activity Habits Questionnaire (FEAHQ) (37-39) will be administered to parents and children to investigate the dietary intake of children. The modified version of the PAQ includes 30 items for every parent, presented in a 5-level Likert scale. The first 10 items of the data describe parental authority behaviour examples, the next 10 are of parental authoritarian behaviour, and the last 10 are of parental permissiveness. This questionnaire is based on the work of Baumrindi (34) and Buri (35) in order to study the 3 types of parental authority which are (a) permissive, (b) authoritarian, and (c) authoritative.The modified version of the PIMCQ-2 is a 36-item questionnaire containing 3 subscales: Learning/Enjoyment Climate, Worry Conductive Climate, and Success Without Effort Climate. In addition, we investigated the relationship between parental style and perceived motivational climate of parents through the use of a questionnaire based on an idea presented by White and Duda in 1992.

Program Evaluation: Over a 6-month period, the followings were evaluated in each group:

1. Performance in the speed trial
2. Height, weight, BMI, waist circumference, and heart rate
3. Dietary intake using the modified version of the Family Eating and Activity Habits Questionnaire by Golan.

Ethical considerations

The Medical School of University of Thessaly and Ministry of Education and Religious Affairs, Sport and Culture has approved the protocol of this study. Written informed consent from all parents was obtained before their enrolment into the study.

Data analysis: Epi Info software will be used for data entry and SPSS software for the statistical analysis. Qqualitative variables will be presented as absolute (N) and relative frequencies (%). Quantitative variables will be presented as mean with standard deviation or median with interquartile range. Kolmogrov-Smiranov test and Levene test will be used to test the normality and the equality of variances of the quantitative data, respectively. An analysis of variance (ANOVA) or the Kruskal-Wallis test will be used to analyze differences in age, body weight, and BMI among participants before the intervention. A One-way ANOVA, with Bonferroni corrections for multiple comparisons, will be conducted to explore differences among groups at the baseline for parents and children's data. The effects of the intervention program will be analyzed by the repeated measures ANOVA or the Friedman test. Changes in life style behaviours from the baseline to the end of the intervention will be assessed using a chi-square test for categorical variables. A Pearson or a Spearman correlation coefficient and a linear regression analysis will be performed to explore any associations between quantitative variables. The Cronbach alpha coefficient will be used to estimate the internal consistency of the PAQ, the PIMCQ, and the FEAHQ. A p value < .05 will be considered as statistically significant.

Quality Control

Monitoring the quality of the FETA program is considered to be essential to ensure a robust study and to maintain internal validity. Several procedures are employed to ensure that the quality of the study will be optimal. These procedures are described below.

(i) Assessor Blinding: Data collection personnel will be blind to participants' group allocation. Children and their parents will be asked not to inform the data collection personnel of their group allocation status.

(ii) Training: A trained physical education teacher and accredited practising dieticians will run the project. Data collection personnel who are involved in the assessments will be trained by full-time study members before the assessments.

Ethics

The protocol of the study has been approved by the General Assembly of the Medical School of University of Thessaly and also by the Ministry of Education and Religious Affairs, Sport and Culture. Written informed consent from all parents will be obtained before their enrolment into the study.

Discussion

This paper describes the protocol of the Feeding Exercise Randomised Clinical Trial in Adolescents (FETA) in the region of Larissa in Greece, a randomized controlled trial, among overweight/obese adolescents. The FETA program consists of 2 parts. The first part of the project (descriptive study) is expected to provide useful information about the prevalence and the risk factors of obesity among adolescents in the region of Thessaly, Greece. The second part consists of a clinical trial, the first clinical trial among obese adolescents in Greece, which is expected to provide useful information on the effectiveness of clinical interventions among overweight and obese adolescents in Greece.

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Conflict of Interests

The authors declare that they have no competing interests.

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