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The Effect of Intensive Lifestyle Intervention Applied to Overweight and Obese Patients in Primary Care During the Pandemic Period: A Randomised Controlled Trial
NCT06321809

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Study Protocol

Objectives

During the Covid-19 pandemic, it is recommended that numerous interventions and management strategies, such as implementing nutritional changes, promoting physical activity, modifying behaviours, administering pharmacological treatment and, if necessary, utilizing surgical treatment for overweight or obese individuals, should be conducted by multidisciplinary teams, as in non-pandemic periods [1,3,7]. Lifestyle modifications, encompassing a decrease in calorie consumption, enhanced physical activity, and behavioural adjustments, assume a pivotal function in aiding overweight and obese individuals in managing their condition for the purpose of disease prevention, management, and treatment [3,7]. When creating a medical nutrition therapy program, it is advised to decrease the total calorie intake by 500 to 1000 kilocalories (kcal) to guarantee a weight loss of 0.5-1.0 kg each week [1,3,8]. Personalized interventions to increase physical activity should consider individuals' abilities and preferences, including engagement in daily activities such as walking and cycling [7,9]. To significantly change the total energy loss and reduce obesity-related risk factors, both resistance and aerobic exercise should be performed [1,3]. For the treatment to be deemed successful, a weight loss of over 5% needs to be attained following the 3-month treatment programme [1,10]. Increasing body mass index (BMI) is also associated with worsening people's quality of life; because these people are more likely to experience pain, functional disability, and decreased muscle strength [11]. Therefore, one of the aims of creating a management plan ought to be to enhance the quality of life.

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The literature review revealed studies on the impact of intensive lifestyle interventions among overweight and obese individuals [12,13]. However, no research has yet examined the effect of these interventions on such individuals in primary healthcare settings during the pandemic period. Upon examining the studies, it was observed that they were mainly assessed in two groups: the intervention group and the control group [12,14,15]. In contrast, this study assessed the participants in three distinct groups. While interventions in many studies involved physicians and dietitians or physicians and physiotherapists, this study incorporated three distinct professionals: a physician, a dietitian, and a physiotherapist [12,13,15].

In this study, lifestyle interventions applied at different intensities and telephone follow-ups applied at different frequencies to overweight and obese individuals applying to primary health care during the pandemic period; It is aimed to evaluate the effect on anthropometric measurements, lipid profile, weight-related quality of life and to observe the differences between interventions.

Design

The study's design is that of a randomized controlled trial, with a single-blind method. It is a clinical intervention study that was conducted between 25.01.2022 and 31.10.2022.

The study's participants comprised of individuals with overweight and obese who made applications between the dates of 25th January 2022 and 31st October 2022 to the Department of Family Medicine at XXX University's Faculty of Medicine. After reading and signing the informed consent form, participants underwent evaluation based on the study's inclusion and exclusion criterias.

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Body mass index (BMI) was computed by the body composition analyser. The classification of overweight and obesity followed World Health Organization (WHO) definitions [10,11].

Intervention group: They were given a calorie-restricted diet and exercise plan by a dietician or physiotherapist at their first visit, and were followed up by telephone calls at weeks 2, 4, 6, 8 and 10 over 12 weeks.

Control-1 group: During the initial medical interview, the participants were given a calorie-restricted diet programme by a dietician and an exercise programme by a physiotherapist; they were followed up over 12 weeks with telephone calls at week 4.

Control-2 group: The participants were not provided with any programme, and the importance of weight loss was emphasised by the family physicians. Dietary and physical activity advice was given according to the recommendations in the Turkish Endocrine and Metabolism Association's 2019 Obesity Diagnosis and Treatment Guide, and was followed up with phone calls at weeks 2, 4, 6, 8 and 10 over a 12-weeks.

Method

i. Assessment of Individual Factors: An assessment of participants' features associated with the sociodemographic and Covid-19 pandemic was conducted through a 24-question survey.

ii. Assessment of Quality of Life: Turkish version of the Impact of Weight on Quality of Life-Lite Version (IWQOL) scale was used. Detailed information about the scale is provided in the supplementary data.

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iii. Body Composition: Height, waist circumference, and body composition measurements (weight, BMI, fat mass, and fat-free mass) were measured for all participants by family physicians using the same body composition analyser.

iv. Lipid profile: Triglyceride, Total Cholesterol, LDL-Cholesterol and HDL-Cholesterol levels were measured.

v. Telemedicine applications: During phone interviews, participants were assessed on their adherence to the diet and exercise programme and encouraged to recognise the significance of leading a healthy lifestyle and losing weight. During the telephone interviews, the family physician discussed the obstacles to improving participants' compliance with diet and exercise, and proposed potential solutions. The participants received motivational speeches from family physician during the phone calls. At the 12-week interview, participants were asked to rate their diet and exercise adherence from 1 (very poor adherence) to 10 (very good adherence). Telemedicine were preferred in order to minimise the risk of transmission of Covid-19 infection.

vi. Diet program: The dietary program for intensive lifestyle intervention was individually calculated as energy restriction and administered to both the study and control-1 group by the dietician during the initial interview. To achieve weight loss through dietary intervention, the energy of the diets to be applied to individuals was calculated by reducing the daily energy requirement by 30%, or 500-750 kcal, to achieve a weight loss of approximately 500 g per week, taking into account individual energy requirements and physical activity levels.

vii. Exercise program: The physiotherapist conducted an individualized exercise program for both the intervention group and control-1 group participants during the initial interview. During the initial interview, participants underwent a 6-minute walk test (6MWT)

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and an assessment of muscle strength. The test outcomes provide valuable insights on the physical condition of the participants. The 6MWT was utilised to gauge aerobic capacity and endurance. For hand grip strength, the Jamar Hydraulic Hand Dynamometer (Jamar, Sammons Preston, Bolingbrook, Illinois, USA) was used for the Quadriceps Femoris muscle group (J-TECH, Medical Commander Powetrack II, USA). Considering the results of the applied tests, the exercise program was determined by the physiotherapist to suit the individual, with 3 sessions per week and each session lasting 70 minutes for 12 weeks. The exercise programme was designed as 5 minutes warm-up, 30 minutes aerobic, 30 minutes strengthening and 5 minutes cool-down. Within the aerobic exercise programme, a walking regime was established at 65-75% (moderate intensity) of the maximum heart rate ($220 - \text{age}$). For strengthening, exercises were applied to large muscle groups with an elastic resistance band.

Statistical Analysis Plan

SPSS 20.0 statistical package software will be used to analyse all data (IBM Corp. Released 2015. IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp.). Means and standard deviations will be used for continuous variables and frequency tables for qualitative data. Chi-square test will be used to examine the relationship between qualitative data. Differences between continuous variables will be analysed using t-test, ANOVA test or their non-parametric equivalents. $\alpha=0.05$ will be accepted as the level of error.

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