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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

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The Effect of Intensive Lifestyle Intervention Applied to Overweight and Obese Patients In Primary Care During The Pandemic Period: Informed Consent For A Randomised Controlled Trial Consent Form

Contact: .....

You have been invited to participate in this research titled **" The Effect of Intensive Lifestyle Intervention Applied to Overweight and Obese Patients in Primary Care During the Pandemic Period: A Randomised Controlled Trial"**, you have been invited to participate in this study. This study is being conducted for **research** purposes. Before you agree to take part in this study, you should understand the purpose of the study and make your decision freely within the framework of this information. Please read the following information carefully, ask any questions you may have and ask for a clear answer. If you agree to take part, you will be given a copy of this form, signed by you and the witness who was with you during the counselling, to keep for yourself. Taking part in this research is entirely voluntary. You can refuse to take part in the research or withdraw from the research at any stage. In both cases, we would like to inform you that you will not be subject to any sanctions or loss of rights.

The aim of this research project is to evaluate the effect of intensive lifestyle intervention to be applied to patients and follow-ups using telemedicine methods (telephone interview) on body mass index (BMI), body composition (height, weight, waist circumference, fat ratio, fat mass, etc.), lipid (cholesterol) values, quality of life and to evaluate different types of interventions designed to increase the frequency of follow-up with intensive lifestyle intervention in order to protect overweight and obese patients from obesity and the diseases caused by obesity during the pandemic process, where the predisposition to obesity (obesity) increased due to changing lifestyle behaviours due to the effect of the pandemic.), lipid (cholesterol) values, quality of life and to evaluate the effects of different intervention types organised as intensive lifestyle intervention and increasing the frequency of follow-up.

A randomised controlled trial is a study model in which people with similar characteristics are divided into research and control groups in order to test a new drug, a treatment or another type of intervention. The intervention method is applied to the research group and the results are compared with the control group. The control group may have different characteristics in terms of intervention. Both groups are followed up regularly for the periods determined by the researchers and the research results are statistically evaluated. In order to take part in this study, it is enough to come twice, and the number of volunteers like you who will take part in the study is 150. The duration of the study is 12 weeks in total and 3 groups will be formed randomly, the participants will be distributed to the research, control 1 and control 2 groups according to the order of outpatient clinic application, no information will be given about which group you are in, your physician will know your group. The first group will be the research arm, the second group will be the control 1 arm, and the third group will be the control 2 arm. All patients will be evaluated face to face at the first visit and at the last visit in the 3rd month. Other interviews will be done by telephone with telemedicine method. The research arm and control 1 arm will be given a calorie restrictive diet programme and exercise programme at the first visit; the research arm will be followed up using telemedicine application (by telephone interviews) on the 15th day, 30th day, 45th day, 60th day, 75th day for 3 months, and the control 1 group will be followed up by telemedicine (by telephone interviews) at the 1st month. The control 2 group will not be given any programme, the necessity of weight loss will be emphasised and their follow-up will be carried out using telemedicine application (by telephone interviews) on the 15th day, 30th day, 45th day, 60th day, 75th day for 3 months. Only telephone interviews will be made as telemedicine application. Telephone interviews are planned to be maximum 10 minutes and compliance with the diet and exercise programme will be evaluated and counselling will be provided. Weight, body composition (fat ratio, fat mass, lean body tissue, waist circumference adipose tissue, waist circumference adipose tissue, visceral adiposity score) and BMI measurements will be performed by the physician in the clinic using the body composition analyser (TANITA) at the baseline and 3rd month visit of all participants. TANITA device is an easy-to-use device and can be used by different people multiple times. TANITA device application is not an interventional application and does not carry any risk. To use the device, after pressing the on button, you will be asked to remove any metal jewellery and accessories you are wearing, stand on the device with your bare feet and hold the device with both hands from the places indicated as "Ellik". After the measurements of your body composition are taken, you will be asked to get off the device. The device is disinfected after each use. Body mass index, body composition and lipid profile will not be checked at interim follow-up. A blood test will be taken from you at baseline and at your 3rd month follow-up to check your lipid values. The blood test will be analysed in the Biochemistry laboratory of Hacettepe University Faculty of Medicine. Risks that may occur during blood sampling: 1) You may feel a little pain due to the needle prick. 2) There is a small risk of prolonged bleeding or infection after the needle stick 3) If a sufficient amount of blood cannot be taken in the first attempt or if errors develop in the test procedures, the procedure may need to be repeated. The diet programme for the intensive lifestyle intervention to be applied in the study will be calculated individually in the form of calorie restriction and will be given by the dietician in the diet clinic. Your diet programme will be given to you by the dietician in the diet clinic. Your exercise programme will be prepared individually for you by a physiotherapist and this programme will be given in the physiotherapy outpatient clinic. The exercise programme will be given to you by the physiotherapist at your first visit. At the first visit in the physiotherapy outpatient clinic, you will be given a 6-minute walk test (6MWT) and your muscle strength will be evaluated. The 6-minute walk test (6MWD) will be used to assess the aerobic capacity and endurance of individuals. The test protocol will be explained to you by the physiotherapist before you start the test. In this test, you will be asked to walk as fast as you can for six minutes in a straight corridor 28 metres long, without running or jumping. If you feel very tired during the test, you will be able to slow down or stop and rest, but the test time will not be stopped. Standard motivational sayings may be used during the test and the time will be monitored with a stopwatch. There are no health risks associated with this test. Blood pressure, heart rate, oxygen saturation (SpO2), perception of fatigue and breathlessness (Modified Borg Scale) will be assessed before and immediately after the test. After a thirty-minute rest interval, the test will be repeated a second time. The best walking distance between the two tests will be recorded in metres (m). Isometric muscle strength will be assessed with a

hand dynamometer. During the measurements, care is taken to repeat 3 times with short intervals. The highest value will be used for analysis. Two muscle groups, grip strength and thigh muscle, will be evaluated bilaterally. Following the initial evaluations, the treatment programme will be determined by the physiotherapist in accordance with the individual for 12 weeks, 3 sessions per week and each session will be 70 minutes. The treatment programme will consist of 5 minutes warm-up exercises, 30 minutes aerobic exercise, 30 minutes strengthening exercises and 5 minutes cooling exercises. Within the aerobic exercise programme, a walking programme will be determined at 65-75% (moderate intensity) of the maximum heart rate (220-age). For strengthening, large muscle groups will be exercised with elastic resistance band. The elastic band will be given to you by the physiotherapist. The exercise recommendations of the control 2 group will be given in accordance with the physical activity recommendations specified in the 2019 Obesity Diagnosis and Treatment Guidelines of the Turkish Endocrine and Metabolism Society. In the treatment of obesity, 150 minutes of moderate-intensity aerobic physical activity (non overloading activities such as walking with regular and frequent steps, cycling, prolonged swimming, garden or field work, tennis) or 75 minutes of high-intensity aerobic physical activity or their equivalent combination is recommended per week. The exercise programme should consist of moderate-intensity physical activity for at least 30 minutes at a time, 5 times a week, muscle-strengthening anaerobic resistance exercises (such as push-ups for arm muscles, sit-ups for abdominal muscles, strength training with weights) two to three times a week, at least one set and 8-15 repetitions.

You are expected to have the requested analyses performed, to answer the investigator's questions appropriately and correctly, and to comply with the follow-up periods.

There is no risk or harm for you in this study. The expected benefits for you are to protect you from obesity and obesity related diseases by enabling you to lose weight, and to provide you with a better quality of life. If there are any developments that may concern you during the research, you or your legal representative will be notified immediately. If there is no clinical benefit targeted in relation to the reasonably expected benefits from the research, you will be informed about this situation.

You can contact your researcher doctor Dilara Canbay Özdemir 24 hours a day at **0542 199 06 52** for additional information about the study or for any problems, unwanted effects or other discomfort related to the study.

In addition, you or your social security institution will not be charged for all examinations, investigations, tests and medical care services within the scope of this study. At your 3rd monthly check-up, you will be reimbursed for your travelling expenses.

The investigator may remove you from the study, with or without your knowledge, for reasons such as not fulfilling the requirements of the intervention scheme, disrupting the study programme or increasing the effectiveness of the treatment. The results of the study will be used for scientific purposes, in case you withdraw from the study or are removed by the investigator, medical data about you can also be used for scientific purposes if necessary. All medical and identifying information about you will be kept confidential and your identity will not be disclosed even if the study is published, but study monitors, surveyors, ethics committees and official authorities can access your medical information when necessary. You can also access your own medical information if you wish. I have read and verbally listened to the information above, which should be given to the volunteer before starting the study. I have asked the investigator all the questions that come to my mind, and I have understood in detail all the explanations given to me in writing and verbally. I have been given enough time to decide whether I want to participate in the study. I know that I am participating in the study voluntarily and that I can leave the study at any time with or without reason. Under these conditions, I authorise the researcher to review, transfer and process my medical information and I voluntarily accept the invitation to participate in the study without any coercion or pressure.

I will be given a copy of this signed form sheet.

Participant

First name, last name:

Signature:

Date:

Interview witness

First name, last name:

Signature:

Date:

Physician interviewing the participant

Name, last name:

Signature:

Date: