Date: September 1, 2021

Title: Comparison Effects Of Blue Prescription Program, Home Exercise Program And Supervised Exercise Approaches On Type 2 Diabetic Women.

Identifiers: NCT05479435

STUDY PROTOCOL

Participants: Individuals diagnosed with Type 2 Diabetes were recruited from Balıkesir Provincial Health Directorate, Edremit District Health Directorate Healthy Life Center. They were 60 people who were assigned to the groups by using a randomization program.

Inclusion Criteria:

Age between 25-65 years.

Diagnosis of Type 2 Diabetes for at least 5 years.

HbA1c value > 6.5% or fasting blood glucose > 126 mg/dL.

Ability to walk independently.

Voluntary participation in the research.

Exclusion Criteria:

Type 1 Diabetes Mellitus.

Use of insulin.

Orthopedic or neurological conditions hindering exercise.

Cardiovascular, pulmonary, or systemic diseases contraindicating exercise.

Recruitment Details: The study commenced on September 1, 2021, at Balıkesir Provincial Health Directorate, Edremit District, Health Directorate's Healthy Life Center in Balıkesir, Turkey.

Evaluated Parameters:

Glycosylated Hemoglobin Change: Hemoglobin A1c is a blood test used to measure the effectiveness of treatment in diabetes, and sometimes to diagnose diabetes. The generally accepted reference range for Hemoglobin A1c (HbA1c) is between 4% and 6%.

Physical Activity Level Change: Assessed via International Physical Activity Questionnaire-short form (IPAQ) to evaluate weekly physical activity levels. The questionnaire provides information about the time spent by the individual in light, moderate, and vigorous activities and sitting in the last 7 days. The MET-min / week score is obtained by multiplying the MET value (metabolic equivalent) by days and minutes for each activity level. Physical activity levels are classified as: Physically inactive (<600 MET-min / week),

Low physical activity (600-3000 MET-min / week), and

Adequate physical activity (> 3000 MET-min / week).

A higher score is associated with a higher physical activity level.

Functional Capacity Change with Timed Up And Go Test: The participant will sit on a chair without armrests, stand up with the command to start, walk 3 meters towards the designated point, turn around and walk to the starting point again and sit. The test is repeated 3 times and the average is taken. The time will be recorded in seconds. As time increases, the risk of falling increases.

Functional Capacity Change with 6-minute Walking Test: It will be performed in a 30 meter long corridor or in an open area. The participant will be asked to walk without running at the highest speed for 6 minutes. Before and during the march, the participant will be verbally encouraged and motivated. How many meters they walked will be recorded as a result of the test. Six-minute walk test results can be interpreted as follows:

Normal: more than 500 meters

Light restriction: 400 to 500 meters

Moderate restriction: 300 to 400 meters

Severe restriction: between 200 - 300 meters

Serious restriction: less than 200 meters.

Fasting Plasma Glucose: Measures blood glucose levels after fasting for 8-12 hours. Assessed at baseline and 12 weeks. The unit of measurement is mg/dL, the reference range is 70-110 mg/dL.

High Density Lipoprotein (HDL): It takes part in the transport of cholesterol from tissues and vessels to the liver and in the synthesis of vitamin D. The unit of measurement is mg/dL, the reference range is 30-96 mg/dL.

Low Density Lipoprotein (LDL): It provides the transport of cholesterol synthesized in the liver to the tissues and blood vessels. The unit of measurement is mg/dL, the reference range is 0- 130 mg/dL.

Total Cholesterol: Total cholesterol is a value that shows the total amount of cholesterol in the blood. In addition to LDL and HDL, triglyceride levels are also used to calculate total cholesterol. The unit of measurement is mg/dL, the reference range is 70-200 mg/dL.

Triglyceride: It is a storage nutrient molecule formed by the combination of fatty acids and glycerol molecules, which form the structure of fats in foods. The unit of measurement is mg/dL, the reference range is 0-250 mg/dL.

C-reactive Protein: It is a protein produced in the liver. It is a protein that is produced by cells and secreted into the blood when the body reacts to conditions such as infection, tumor, trauma, and undertakes various biochemical tasks. The unit of measurement is mg/dL, the reference range is 0-0.5 mg/dL.

Systolic and Diastolic Blood Pressure: Measured with a sphygmomanometer. Baseline and 12 weeks.

Heart Rate: Measured in beats per minute (bpm). Baseline and 12 weeks.

Body Composition Analysis: Assessed using Bioelectrical Impedance Analysis (BIA) and Skinfold Analysis. Baseline and 12 weeks.

Flexibility Measurements: Evaluated using Fingertip-to-floor Distance Measure and Trunk Lateral Flexion Measure. Baseline and 12 weeks.

Quality of Life, Depression, and Contentment: Assessed using various scales (DQOL, Beck Depression Scale, DTSQ). Baseline and 12 weeks.

Anthropometric Measurements: Height, weight, neck circumference, waist circumference, hip circumference, and Body Mass Index (BMI). Baseline and 12 weeks.

Experimental Groups:

Blue Prescription Group: Participants receive a personalized exercise program, motivational support, and follow-up by a physiotherapist. Communication is maintained throughout the study.

Video-Based Home Exercise Group: Participants receive exercise videos, perform exercises independently, and are monitored via phone calls. Assessments are conducted at 12 weeks.

Supervised Exercise Group: Participants engage in supervised exercise sessions led by a physiotherapist. Training and assessments are conducted at 12 weeks.