Official Title: A combined workplace intervention including exercise and nutrition for health promotion in obese office workers: a randomized controlled study

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1. Objective

Therefore, the main objective of this study is to design, implement, guide and evaluate the efficacy of a 6-month daily supervised workplace (during the working hours) combined intervention program including exercise (flexibility, balance, strength, aerobic capacity) and nutrition on selected health (body fat and circumferences, blood pressure, respiratory function, lipidemic profile), b) functional capacity indices (flexibility, static and dynamic balance, handgrip strength and aerobic capacity) and c) dietary habits (adherence to the Mediterranean diet, daily water consumption amount) of obese office workers. Another important objective of this study is to investigate the individualized responses per participant following the 6-month workplace intervention program. This is of fundamental importance since the individual characteristics of the participants may affect the efficiency of the intervention program and the generalization of study results in the whole population.

2. Methods

2.1. Participants

40 obese office workers (males and females), after announcements by the research team in four workplaces in the region of Western Thessaly in Greece, are expected to express interest in participating in the present study. The participants will be assessed for eligibility according to six inclusion criteria. In more detail, the participants: 1) should have at least 8 h per day in the office, 2) should have BMI value ≥ 30 kg/m^2, 3) should not have chronic diseases (physical or mental), 4) should not use any medication, 5) should not have injuries (in lower or upper body) the last 6 months and 6) should not participate in organized exercise programs or nutrition intervention during the last 6 months. Prior to the start of the study, the demographic, anthropometric, and working characteristics of the participants will be assessed using the American College of Sports Medicine (ACSM) health history questionnaire.

2.2. Intervention

The IG will participate in a supervised 6-month combined intervention program (exercise and nutrition), which took place inside the workplace settings during working hours.

2.2.1. Exercise intervention

The IG will participate, every working day (5 days/week), in a 6-month supervised combined chair-based exercise program (120 training sessions; 25-40 min/day), including chair based seated and chair-assisted standing exercises to improve flexibility, balance, strength and aerobic capacity. The frequency of weekly exercise goals will be altered throughout the 6-month exercise intervention, according to the recommendations of the ACSM.

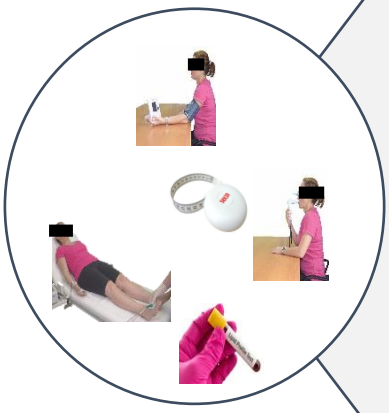
The exercise program will be implemented in small groups (4-5 participants per group), using a stable chair as the basic exercise equipment as well as portable auxiliary exercise equipment such as: a Pilates mini ball, a pair of silicone hand therapy balls, a pair of hand grippers and an exercise band for each participant. Each training session will be consisted of a 3-5 min warm-up, a 19-34 min main part of the program, and a 3-5 min cool-down. The training load gradually will be increased during the 6-month intervention program, according to the recommendation of the ACSM.

2.2.2. Nutrition and hydration intervention

The intervention regarding healthy diet and proper hydration will include 12 sessions (one session every two weeks) with the two nutritionists of the research team. It should be mentioned that for the implementation of the intervention will be used specifically designed educational material such as: a) presentations regarding the importance of healthy diet and proper hydration, b) educational leaflets with tips for healthy diet as well as indicative recipes for healthy snacks at the workplace, c) goal-setting cards for healthy options regarding nutrition and water consumption (Figure 2) and d) free application for proper hydration "Waterful" (https://waterfulapp.com/?from=AppAgg.com) where all the participants of the IG will be downloaded the to their mobile phone during the study.

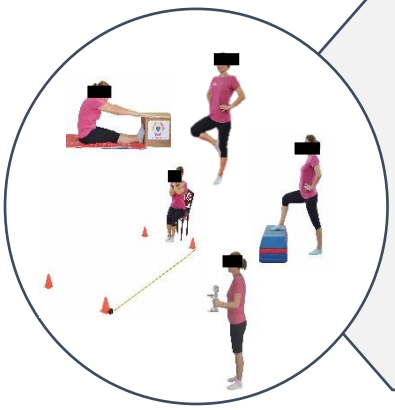
2.3. Measurements

Before and after the completion of the 6-month workplace intervention program selected health and functional capacity indices will be assessed (Figure 1), using widely used, and reliable tests, that have showed high test-retest reliability (ICC = 0.95 - 0.98; SEM = 0.76 - 1.22; SEM% = 2.6 - 4) in office workers. Furthermore, the adherence to the Mediterranean diet was assessed before and after the 6-month time period using specific questionnaire.



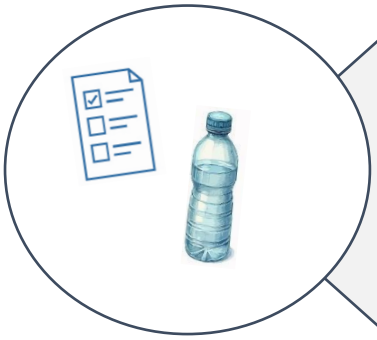
Health indices

- ✓ Body fat (BF): BF% will be assessed using the bioelectrical impedance method (Maltron 900).
- ✓ Body circumferences: The waist and hip circumferences will be measured using an ergonomic circumference measuring tape (Seca 201).
- ✓ Blood pressure: Systolic and diastolic blood pressure will be measured, using an electronic upper arm blood pressure monitor (A&D-UA-851).
- ✓ Respiratory function: Forced vital capacity (FVC) and forced expiratory volume in 1 s (FEV_1) will be measured, using a portable spirometer (Micro, Medical, Micro).
- ✓ Lipidemic profile: A blood sample will be obtained, after overnight fasting (12 h), as previously described. Total cholesterol, high-density lipoprotein (HDL) and triglycerides will be determined using a biochemical analyzer (Clinical Chemistry Analyzer Z 1145; Zafiropoulos Diagnostica S.A., Koropi, Greece), and low-density lipoprotein (LDL) will be calculated using the Friedewald equation.



Functional capacity indices

- ✓ Lower body flexibility: The sit-and-reach test will be performed using a Flex-Tester box (Novel Products Inc., Rockton, IL, USA).
- ✓ Static balance: The single-limb stance test (with eyes opened) will be performed, as previously described by Rinne et al.
- ✓ Dynamic balance: The timed up-and-go test will be performed, as previously described by Rikli and Jones.
- ✓ Handgrip strength: Maximal isometric handgrip strength will be assessed using a portable hydraulic dynamometer (Jamar 5030J1, Horsham, USA).
- ✓ Aerobic capacity: The YMCA 3 min step test will be used [41], which was performed following the metronome cadence (96 beats per minute; 4 steps per cycle). The participants' HR was measured 1 min following the termination of the step test.



Dietary habits

- ✓ The adherence to the Mediterranean diet will be assessed before and after the 6-month period using the specific Mediterranean Diet Score (range of total score: 0-55). The MedDietScore measures the weekly consumption of the following 9 food groups: non-refined cereals (whole grain bread and pasta, brown rice, etc), fruit, vegetables, legumes, potatoes, fish, red meat and products, poultry, full fat dairy products (like cheese, yoghurt, milk), as well as olive oil and alcohol intake.
- ✓ The consumption of water (in ml) per day will be also assessed.

Figure 1. Health, functional capacity and dietary habits measurements before and after the 6-month time period.

2.4. Procedure

The present study will be conducted according to the Declaration of Helsinki and approved by the Ethics Committee of the University of Thessaly. Prior to the start of the study, the participants: (a) will be informed about the experimental procedures and possible risks, (b) will be familiarized with the testing and exercise procedures and (c) will be signed an informed consent form. Following the initial information and familiarization procedure, the baseline measurements will be performed inside the workplace setting (during the working hours) by the same investigators and under the same conditions. The sequence of measurements will be: (1) health indices, (2) functional capacity indices (a. flexibility, b. balance, c. strength and d. aerobic capacity) and (3) dietary habits questionnaire. Before the commencement of the functional capacity tests, the participants will be performed a standardized 8 min warm-up protocol (3 min chair-based aerobic dance, 5 min of static and dynamic stretching for lower and upper body). Following the baseline measurements, the participants will be randomly assigned in two equal groups: the IG and the CG. In the present study, a parallel

randomized controlled design will be used to investigate the efficiency of the 6-month workplace combined intervention program (exercise and nutrition) on health, functional capacity and dietary habits indices in obese office workers. Specifically, a computer-generated list of random numbers will be used for the allocation of the participants in one of the two groups (IG or CG). The main investigator will be blinded for the allocated intervention during the entire period of data collection, and the participants were requested not to discuss their intervention with the main investigator.
During the study, the IG will be prticipate in a daily 6-month (5 times per week) combined intervention program consisting of exercise and nutrition; while the CG did not perform any intervention during the 6 months. The exercise program of the intervention will be supervised by three exercise instructors of the research team, and special exercise attendance books will be filled in to confirm the participants' exercise adherence, while the nutrition part of the intervention will be supervised by the two nutritionists of the research team. After the end of the 6-month period, the baseline measurements will be repeated in the same order and at the same time of day.

2.5. Statistical Analysis

All statistical analyses will be performed using the IBM SPSS Statistics v.31 software (IBM Corporation, Armonk, New York, NY, USA), and the results will be presented as means ± standard deviations. Before the commencement of the study, a power analysis, using software package GPower 3.1, for statistical test "ANOVA: Repeated measures, within-between interaction (2 groups and 2 measures)" and effect size 0.30 (a err prob = 0.05) was performed. The statistical power analysis indicated that a total sample of 32 participants (16 participants in each group) would yield adequate power (0.90). The normality of the data will be examined using the Shapiro-Wilk test. Two-way analyses of variances (2-way ANOVAs) [2 groups (IG and CG) × 2-time points (pre- and post-intervention)] with repeated measures on the "time-point" factor and Sidak pairwise comparisons will be applied to locate the significantly different means within and between groups. Independent t-tests will be also used to compare the percentage change (from pre- to post-measurement) between the two groups (IG and CG). The magnitude of the difference between measurements and groups will be examined using Cohen's *d* effect sizes (ES). The level of significance for all statistical analyses will be set at $p < 0.05$.

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UNIVERSITY of THESSALY
SCHOOL OF PHYSICAL EDUCATION & SPORT SCIENCE
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Research informed consent form

Title of the study: A combined workplace intervention including exercise and nutrition for health promotion in obese office workers: a randomized controlled study

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Purpose of the study: Therefore, the main objective of this study was to design, implement, guide and evaluate the efficacy of a 6-month daily supervised workplace (during the working hours) combined intervention program including exercise (flexibility, balance, strength, aerobic capacity) and nutrition on selected health (body fat and circumferences, blood pressure, respiratory function, lipidemic profile), b) functional capacity indices (flexibility, static and dynamic balance, handgrip strength and aerobic capacity) and c) dietary habits (adherence to the Mediterranean diet, daily water consumption amount) of obese office workers. Another important objective of this study was to investigate the individualized responses per participant following the 6-month workplace intervention program.

Procedures: The present study (measurements and training intervention) will take place at office workplace settings and will be performed by the same investigators with specialization in workplace wellness programs and under the same conditions. Before the start of the study, a familiarization session with experimental testing and training procedures will be carried out. Then, the baseline measurements will be performed on one day for each participant. Following baseline measurements, the participants will be randomly allocated to either an exercise group (IG) or a control group (CG). The IG will participate a 6-month daily supervised workplace (during the working hours) combined intervention program including exercise (flexibility, balance, strength, aerobic capacity) and nutrition; in contrast to the control group which did not follow any intervention program. Each exercise session will last 25-40 minutes and will include three parts: a) warm up, b) main part and c) cool-down. Two days after the completion of the last training session, the pre-training measurements will be repeated.

Risks and inconveniences: All the necessary safety measures will be taken throughout the research so that there is no risk of injury during the measurements and training procedures. However, during the measurements and training there is a possibility of premature (short-term) fatigue of the muscles.

Benefits: By participating in this survey, you will have the opportunity to receive valuable information about your profile and its usefulness in everyday life as well as you will have the opportunity (for the participants of the intervention group) to participate to a 6-month combined intervention program (using exercise and nutrition) for health promotion.

Confidentiality: Participants' data will be kept confidential. For this reason, every effort will be made by the researcher to preserve your confidentiality including the following: a) assigning code names/numbers for participants that will be used on all research notes and documents and b) keeping notes, interview transcriptions, and any other identifying participant information in a locked file cabinet in the personal possession of the researcher.

Compensation: No monetary compensation will be given to research participants.

Contact information: If you have questions at any time about this study, or you experience adverse effects as the result of participating in this study, you may contact the research supervisors whose contact information is provided below. If you have questions regarding your rights as a research participant, or if problems arise which you do not feel you can discuss with the supervisor directly by telephone at +302431047048 / +302431047005 or at the following email address kokaratr@uth.gr / bgerom@uth.gr.

Voluntary participation: Your participation in this study is voluntary. It is up to you to decide whether or not to take part in this study. If you decide to take part in this study, you will be asked to sign a consent form. After you sign the consent form, you are still free to withdraw at any time and without giving a reason. Withdrawing from this study will not affect the relationship you have, if any, with the researcher. If you withdraw from the study before data collection is completed, your data will be returned to you or destroyed.

Consent: I have read and I understand the information provided and have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without cost. I understand that I will be given a copy of this consent form. I voluntarily agree to take part in this study.

Date: __/__/__

Participant's Name: **Participant's Signature:**

Researcher's Name: **Researcher's Signature:**

Observer's Name: **Observer's Signature:**