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Physical exercise in adults for weight loss

Submission date
04/01/2016

Recruitment status
No longer recruiting

Registration date
07/01/2016

Overall study status
Completed

Last Edited
13/02/2024

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aim
When a person is overweight, they carry too much body fat. Over time, this may be damaging to their health, and can lead to a number of serious health conditions including type 2 diabetes, high blood pressure and cardiovascular disease (for example, heart attack or stroke). This study is being carried out to compare the effects of two different ways of helping people to lose weight, improve their quality of life and reduce their risk of developing cardiovascular disease. The main goal is to determine whether a more intensive lifestyle treatment (based on more physical exercise) results in a person losing more weight compared to the conventional treatment over a 24 week period.

Who can participate?
Adults aged 18 to 70 years with a body mass index (BMI) ≥27 to <35 kg/m2. They must not have been diagnosed with cardiovascular disease and should be either non-smokers, or smoking less than six cigarettes per day.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 are given the conventional treatment. This includes a low-calorie diet and an educational programme focusing on how to improve their diet. Those in group 2 also receive the conventional treatment. However, they also do a physical exercise programme, which involves at least 14 hours of supervised brisk walking per week. Before the start of the study and then after 12 and 24 weeks, each participant from both groups have blood and urine tests, their diet assessed, their physical activity recorded, and tests to see how well their muscles oxidise (use) carbohydrates and fats. There are also tests to assess the amount of fat burned during the treatment period. The blood and urine tests together with the assessment of the amount of fat loss are done again two years after the start of the study to check long-term effects.

What are the possible benefits and risks of participating?
The main benefits for the patients included in the study are that they may lose weight and therefore their risk of developing cardiovascular disease. They may also find that there general quality of life improves. The risks are mainly associated with the exercise test, which may cause arrhythmia (abnormal heart beat), coronary ischemia (where not enough oxygen is being delivered to meet the needs of the heart), myocardial infarction (heart attack) and cardiac arrest (where the heart stops beating altogether). Grave complications during exercise test causing

death are extremely rare in patients with a normal electrocardiogram. In the case of patients volunteering to give muscle biopsy samples, there is a risk of mild pain and infection, and a small (0.5-1 mm long) scar in the skin may be visible at short distance in both thighs.

Where is the study run from?
Doctor Negrin University Hospital of Gran Canaria (Spain)

When is study starting and how long is it expected to run for?
June 2014 to December 2019

Who is funding the study?
Ministry of Economy and Competitiveness (Spain)

Who is the main contact?
1. Dr David Morales-Alamo (public)
2. Professor Pedro de Pablos Velasco (scientific)

Contact information

Type(s)
Public

Contact name
Dr David Morales-Alamo

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Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
PI14/01509

Study information

Scientific Title
Feasibility and stability of weight loss elicited by an intensified treatment program in patients who are overweight or obese: neuroendocrine and molecular mechanisms

Acronym
PEAFOWL STUDY

Study objectives
An intensive lifestyle intervention with an energy-restricted diet, high exercise volume, and an educational program in comparison with an intervention based only on an energy-restricted diet, moderate exercise volume, and an educational program will elicit a greater weight loss, weight-loss maintenance, and improved quality of life in middle age individuals with overweight.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee for Clinical Research of the Doctor Negrin University Hospital of Gran Canaria (Comité Ético de Investigación Clínica del Hospital Universitario de Gran Canaria Doctor Negrín), 29/01/2015, ref: 140187

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Overweight and Obesity

Interventions
Participants are randomly assigned to one of two equal groups:
1. High-volume physical exercise intervention with a minimum of 14 hours of supervised brisk walk per week, combined with a low-calorie diet and an educational program to improve the quality of food intake.
2. Conventional intervention, with a low-calorie diet and an educational program to improve the quality of food intake, without specific control on the physical activity program. The diet and the educational program will be similar for both groups.

Intervention Type
Behavioural

Primary outcome(s)
Changes of body weight using a calibrated scale.Measured at baseline, 12 weeks, 24 weeks and 2 years.

Key secondary outcome(s))
1. Changes in fat mass using dual-energy x-rays absorptiometry
2. Changes in quality of life, using SF-36 questionnaire
3. Fasting blood glucose from blood analysis
4. Blood pressure, with a sphygmomanometer
5. Serum lipid profile from blood analysis
6. Resting plasma leptin concentration using ELISA
7. Maximal fat oxidation capacity. Exercise test with indirect calorimetry and (in patients agreeing to, mitochondrial respirometry in needle muscle biopsies obtained from the muscle vastus lateralis at the start of the study and at 24 weeks.

All outcome measures will be assessed at baseline and 24 weeks. At 12 weeks, body fat, quality of life, fasting glucose, blood pressure and lipid profile will be assessed. At two years all outcome measures will be measured except maximal fat oxidation capacity.

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Age between 18 and 70 years
2. Body mass index ≥ 27 and < 35 Kg/m2
3. Steady body mass, with a fluctuation below 3% during the past six months
4. Non-smoker or smoking < 6 cigarettes per day

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Unable or unwilling to give written informed consent or communicate with study staff
2. Inability to attend the scheduled visits (lack of autonomy, lack of a permanent address, travel plans, or other reasons)
3. Impossibility to follow the recommended diet (for religious reasons, swallowing disorders, allergies, or other reasons)
4. Body weight loss > 3% of their body weight during the six months preceding the screening visit.
5. History of very-low-caloric diet during the six months before the screening visit

6. Intention to undergo bariatric surgery in the next six months
7. Prior bariatric surgery
8. Obesity of known endocrine origin
9. Cardiovascular disease including angina, myocardial infarction, coronary revascularization procedures, stroke (either ischemic or haemorrhagic, including transient ischemic attacks), symptomatic peripheral artery disease, ventricular arrhythmia, uncontrolled atrial fibrillation, congestive heart failure, hypertrophic cardiomyopathy, history of aortic aneurism, and pacemaker carriers
10. Major surgery (i.e., surgery requiring hospitalization) during the last twelve months
11. Active cancer or history of malignancy within the last five years (except non-melanoma skin cancer or differentiated thyroid cancer)
12. History of inflammatory bowel disease or small bowel resection
13. Liver cirrhosis or chronic renal failure stages 3B, 4 and 5
14. Immunodeficiency or HIV-positive status
15. Psychiatric disorders: schizophrenia, bipolar disease, eating disorders, depression with hospitalization in past six months
16. History of major organ transplantation
17. Current treatment with systemic corticosteroids, immunosuppressive drugs or cytotoxic agents
18. History in the past six months or current use of weight loss medication, specifically glucagon-like receptor agonist or inhibitors of sodium–glucose cotransporters. The use of metformin in stable dosage is allowed
19. Respiratory insufficiency
20. Current carrier of an orthopaedic prosthesis
21. Illiteracy
22. Alcohol (total daily alcohol daily intake >50 g) or drug abuse within the past six months
23. Any other condition that may contraindicate exercise or interfere with the completion of the study protocol

Date of first enrolment
01/02/2016

Date of final enrolment
01/02/2017

Locations

Countries of recruitment
Spain

Study participating centre
Doctor Negrin University Hospital of Gran Canaria
Barranco de la Ballena, s/n
Las Palmas de Gran Canaria,
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35010

Study participating centre
University of Las Palmas de Gran Canaria (Universidad de Las Palmas de Gran Canaria)
Juan de Quesada, 30
Las Palmas de Gran Canaria
Spain
35001

Sponsor information

Organisation
Ministry of Economy and Competitiveness (Ministerio de Economía y Competitividad)

Funder(s)

Funder type
Government

Funder Name
Ministerio de Economía y Competitividad

Alternative Name(s)
Ministry of Economy and Competitiveness, MINECO, MEC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article		30/11/2021	13/02/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes