Title: Effects of an Exercise Program on Physical Functionality and Frailty in Type 2 Diabetic Older Adults. Role of circulating concentration of PDEF and Differential Genes.

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Participant code | | | | | |

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FACULTAD DE CIENCIAS DE LA ACTIVIDAD FÍSICA Y DEL DEPORTE (INEF)
C/ Martín Fierro, 7 – 28040 Madrid

INFORMED CONSENT

Dear volunteer:

Mr./Ms……

You have been invited to take part in a study designed by ImFINE group at Technical University of Madrid with the aim of evaluating the effect of a program of strength training on health outcomes in older adults with diabetes.

This study will be carry out following the current law in a strict way on studies with humans and it has been approved by the Ethical Committee of the Technical University of Madrid.

This research implies the collection of data throughout the following tests:

1. Physical exploration.
2. Questionnaires.
3. Blood analysis.
4. Analysis of body composition and bone density.
5. Physical functionality.
6. Force-velocity profile.
7. Balance.

Test details shown below

Physical exploration: doctors will do this and it will include weight, height, abdominal and hip perimeter, blood pressure and basal heart rate. In addition, sociodemographic data will be collected. Also, it will be collected the presence of other illnesses, surgical interventions, medicines and toxic habits.

Questionnaires: you will answer to questions on your state of frailty (Fried questionnaire), physical functionality and level of disability (Barthel and Lawton questionnaire) and your cognitive function and quality of life (MMSE and EQ-5D-5L questionnaires).

Blood analysis: it is a venous blood extraction to perform an analysis of haematology, basic biochemical and DNA.
It consists in a direct puncture in the venous after fasting overnight and 12 mL of blood will be extracted and distributed in various tubes for further analysis.

Body composition determination:
1. Kineantropometry: it is an assessment of human body skinfolds, perimeters and diameters considered as significant to determine the body composition.

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You will be assessed in weight and heights with the minimum possible clothes with you feel comfortable. Then, the corporal dimensions will be assessed using a plicometer (a type of gripper to assess skinfolds), paquimeter (a calibre to assess the width of your joints) and a measuring tape.

2. Bone densitometry: It is an improved use of X-ray technology to carry out a non-invasive examination. It allows to measure the bone mass, fat mass and fat-free mass of the human body. Does not require the use of contrast. This test generates a minimum of ionizing radiation (less than a tenth of that used in a mammogram), equivalent to the natural radiation received on any given day. The only contraindications this test has for males occur when a contrast has been administered or if it has ever been a recent scan. With the minimum amount of clothing you are comfortable in and without metal objects (jewelry, glasses) you will remain lying on the stretcher of the device. The duration of the test is 10 minutes.

3. Electric bioimpedance: This is a non-invasive test that uses a soft and imperceptible electric current in order to determine the content of water and fat in the body in order to estimate body composition. This test cannot be performed in case of being a pacemaker or metallic prosthesis. You will step on a device similar to a scale and hold the controls with your hands while your bare feet are on a metal platform. The duration of the test is approximately 2 minutes.

Physical functionality
The battery will be used Short Physical Performance Battery (SPPB), consisting of a series of tests that measure the function of the lower extremities, over time that is capable of holding in 3 positions of balance up to a maximum of 10 seconds: feet together, semi-tandem and tandem; the time necessary to walk 4 m at the usual walking speed; and the time necessary to get up and sit 5 times in a chair at the highest possible speed.

Balance evaluation
Using a force platform (Kistler Spain, Spain) to measure the displacement of the pressure center, during different static balance positions.

Force-velocity profile
Determination of maximum muscle power by means of an apparatus (linear encoder), placed in weight machines (chest press and leg press; Technogym, Spain). Repetitions will be carried out at different progressive loads and the muscle power values will be recorded, in order to determine the intensity of the exercise at which you develop your maximum power.

Risks associated to these tests are similar to the risks to participate in a physical exercise lesson. The tests proposed are common at this University and in most of

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the cases the risk is minimum. However, during its performance, if there would be any symptom or rare sensation as losses of breathe, chest pain, dizziness, tachycardia, numbness, loss of balance, nausea, and blurred vision, **you should notify staff**.

Although a previous selection is done by the technicians respect to the people that can take part in the study, we remember that **you must NOT to take part in this study if**:

- your doctor has recommended not to do exercise.
- you have any disability that not allows you exercising in a safe way.
- you have a reduced cognitive capacity (judged by your caregiver).
- you have suffered a heart attack, unstable angina or congestive heart failure.
- you have uncontrolled blood pressure.
- when you do exercise feel pain in your chest, dizziness, chest angina including the following symptoms: stiffness-tightness in the chest, pain or heaviness.
- you have a terminal illness.
- take part in any another study that could interfere in the results of the current study.

This study includes the participation in an exercise program (if you are selected in the exercise group) during 12 weeks or continuing with your normal lifestyle (control group). The inclusion in either group is produced in a randomised way and the researchers that will collect the data ignore the group you are part in.

The exercise intervention consists of a program focused on muscle power, in which upper limb (chest press) and lower (leg press) exercises will be performed. The exercises will be performed on weight machines available at the collaborators' reference institutions. It is very important to note that the intensity in each exercise will be individualized to each patient. The exercises will be performed at that intensity at which they develop their maximum muscular performance, with the performance of 3-4 sets of 8 repetitions of each exercise. From the third week of the intervention, emphasis will be placed on the subjects performing each repetition with an emphasis on the speed of execution. Each session is estimated to last 20-30 minutes.

The treatment of all the data obtained will be carried out within the strictest confidentiality and in accordance with the relevant legislation, including the most recent General Data Protection Regulation (RGPD), Regulation (EU) 2016/679. You will be assigned a 5-digit numeric code. All the data regarding your person will be associated with that code, so that in no case will your name appear (except in the initial questionnaire) and the identity of the data will be kept anonymously. The pseudonymised data will be destroyed after being guarded for a period of 5 years.

Participant code | | | | | |

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At the end of the study we will confidentially provide you with a report with the results obtained in the tests you have carried out.

Please read the attached information after signing the following informed consent.

Participant's name:_____

Identity number: ___

I confirm that:

- I have received oral and written information.
- I have been able to ask questions about the study and resolve my doubts.
- I have received enough information about the study.
- I have understood the purpose of the tests and their possible associated risks.
- I have been informed that there is no financial compensation for participating in this study.
- I have spoken with:…… (researcher's name)
- I understand that my participation is voluntary.
- I understand that for the study I must donate a blood sample.
- I understand that I can leave the study at any time by my own decision without any consequence.
- I authorize to keep a sample of my frozen blood for further study. Otherwise it will be destroyed.

I consent voluntarily to participate as a volunteer in this research.

……., ... of 2019

Volunteer's signature Researcher's signature

Contact:
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Principal researcher: Amelia.guadalupe@upm.es