

PARTICIPANT INFORMATION SHEET V2 (20-08-2018)

ASSESSMENT OF EXERCISE RESPONSE IN CHRONIC FATIGUE SYNDROME/ MYALGIC ENCEPHALOMYELITIS.

The Escuela Universitaria de Fisioterapia de la ONCE (attached to Universidad Autónoma de Madrid) (EUF ONCE), together with medical specialists from the Hospital Universitario La Paz (HULP), will carry out a study in which you are invited to participate.

The aim of this study is to test whether the 6-min walking test with gas measurement is able to detect the physiological changes of the patient with Chronic Fatigue Syndrome/ Myalgic Encephalomyelitis, and if it avoids the post-exertional malaise produced by the peak incremental cardiopulmonary exercise test with spirometry and cycloergometry used nowadays.

Before you decide, it is important for you to understand why the research is being done and what it will involve. This document gives you important information about the purpose, risks, and benefits of participating in the study. Please take time to read the following information carefully. If you have any questions then feel free to contact the researcher whose details are given at the end of the document. Take time to decide whether or not you wish to take part.

Background to the study

People with Chronic Fatigue Syndrome are at risk of exercise intolerance which helps to determine their diagnosis. Peak cardiopulmonary exercise tests are performed to determine exercise tolerance, sometimes leading to worsening of symptoms. This study aims to determine if the 6-min walking test, is able to determine the intolerance to exercise without causing such worsening.

This study will involve 22 participants with Chronic Fatigue Syndrome. Participating in this study is completely voluntary and you may withdraw at any time. A decisión to withdraw at any time, or a decision not to take part, will not affect the care you receive.

What will happen to me if I participate in this study?

How long will it take?

If you agree to participate in this study, you will be required to visit the internal medicine consultation at HULP on one occasion, the respiratory training laboratory at EUF ONCE on three occasions and the functional laboratory of pneumology at HULP on one occasion. The total time for each visit is 1-2 hours, except the first and last visit that will only take you 30 minutes.



The visit to the internal medicine consultation at HULP will involve:

- Clinical data collection (30 minutes).

The first visit at EUF ONCE will involve:

- Taking consent (10 minutes).
- Clinical data collection, complete of two questionnaires, placement of the activity meter and delivery of activity meter instructions (50 minutes).

The second visit at EUF ONCE will involve:

- Placement of devices (tensiometer and portable ergospirometer) and physiological data collection at baseline (15 minutes).
- Instructions and performance of the 6MWT with spirometry (7 minutes).
- Rest (30 minutes).
- Repeat of 6MWT with spirometry (6 minutes).
- Rest and removal of devices (30 minutes).

The visit to the functional laboratory of pneumology at HULP will involve:

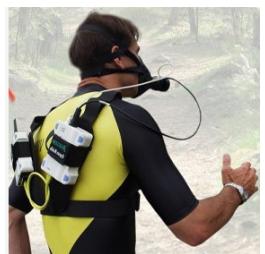
- Clinical data collection (30 minutes).
- Placement of devices and physiological data collection at baseline (15 minutes).
- Instructions and performance of the peak incremental CPET with spirometry and cycloergometry (8-12 minutes).
- Rest and devices removal (30 minutes).

The third visit at EUF ONCE will involve:

- Activity meter removal and complete questionnaires (30 minutes).

Further details on the specific tests?

1-Consent and clinical data collection: We will first give you the informed consent form that you must complete to be part of this study. Then, clinical data will be collected and you will fill in two self-administered questionnaires to assess your quality of life and your degree of multidimensional fatigue, and your weight and height will be measured.



2-6-min walking test with spirometry: this will involve walking fastest you can in a 30 meters long corridor during 6 minutes. Before performing this test a tensionmeter will be placed (a cuff in the arm), a heart rate sensor (elastic band on the chest) and a portable spirometer (small backpack of 750 grams, with a mask and a clip on the ear).



3-Incremental peak cardiopulmonary exercise test with spirometry and cycloergometry: this will involve cycling while we increasing its resistance progressively. The test ends with intense fatigue, reaches maximum heart rate or peak respiratory capacity. Before the test, a tensionmeter (a cuff in the arm), electrocardiograph (adhesive patch on the torax) and stacionary spirometer (a mask and finger clip) will be placed.



4-Activity meter: is a little device placed in the thigh and that is responsible for measuring the amount of physical activity that takes place. You should wear it during 21 days, in three periods of 7 days.

Risk and potential benefits of the study

What risk are involved in participating in the study?

This is a very simple, straight forward study with negligible risks. All tests will be carried out by experienced health professionals. They are carried out routinely to people with CFS/ME both in the Hospital Universitario La Paz and in the Escuela Universitaria de Fisioterapia de la ONCE, either when they start an exercise training programme or as a support diagnostic test. The devices that will be used to perform the measurements are widely used for years in the hospital and research field worldwide. Even so, it is possible that episodes of the so-called "post-exertional malaise" appear after the test, consisting of an increase in the intensity of their symptomatology in the days after the effort was made.

Other consequences of physical exercise, which may appear with very little probability are: muscle or joint injury, episode of myocardial ischemia of greater or lesser intensity and loss of consciousness. To minimize these risks, you will be monitored at all times during the performance of the tests by health personnel.

If I participate in this study, can I also participate in other studies?

This study will perform an evaluation of your condition in a short period of time (30 days) so it is preferable that it does not interfere with any change in your treatment. If you are currently participating in a study or would like to do so, please discuss this with the researcher Ms. Susana García Juez.

What benefits are involved in participating in this study?

You are not guaranteed to get a direct benefit for your participation in the study. The results of your selfless and voluntary participation in this study should improve our understanding and increase scientific knowledge about the effects of your disease. In the future, the 6-min walking test could be used to determine the degree of affection of their disease producing less aggravation of symptoms than current tests.

What if something goes wrong?

If you wish to complain, or have any concerns about any aspect of the way you have been approached during the course of this study, you can approach the EUF ONCE, through the suggestions or claims mailbox whose details appear at the end of this document.

Ending the study

What if I want to leave the study early?

You can withdraw from this study at any time without loss of any non-study related benefits to which you would have been entitled before participating in the study. If you want to withdraw you may do so by notifying the study representative listed in the "Contact Information" section below.

Financial information

Will I be paid for participating?

No, your participation is voluntary.

Confidentiality of subject records

Will my taking part in this study be kept confidential?

The data collected for the study will be identified by a code, so that information that can identify you is not included, and only the Principal Investigator of the study or Collaborators will be able to relate said data to you and your clinical history. Therefore, your identity will not be disclosed to any other person except the Health Authorities, when they require it or in cases of medical emergency. The Research Ethics Committees, the representatives of the Sanitary Authority in matters of inspection and the personnel authorized by the Escuela Universitaria de Fisioterapia de la ONCE, will only be able to access to verify the personal data, the procedures of the clinical study and the compliance of the standards of good clinical practice, but always maintaining the confidentiality of them in accordance with the provisions of Regulation (EU) 2016/679 of the European Parliament and the Council of April 27, 2016 on Data Protection (RGPD) that confers the rights of access, rectification, cancellation and opposition of your data, limit the processing of data that are incorrect, request a copy or transfer to a third party (portability) the data that you have provided for the study. To exercise your rights, contact the principal investigator of the study or direct a written communication to the Data Protection Delegate of the ORGANIZACIÓN NACIONAL DE CIEGOS ESPAÑOLES at the following address: Dirección General de la ONCE, Calle Prado, 24, 28014 Madrid or an email to dpdatos@once.es. We remind you that the data can not be deleted even if you stop participating in the trial to guarantee the validity of the investigation and comply with the legal duties and the medication authorization requirements. You also have the right to contact the Data Protection Agency if you are not satisfied.

The Escuela Universitaria de Fisioterapia de la ONCE is responsible for the treatment of your data and is committed to comply with the data protection regulations in force.

The Principal Investigator and the Escuela Universitaria de Fisioterapia de la ONCE is obliged to keep the data collected for the study at least up to 25 years after its completion. Subsequently, your personal information will only be kept by the Escuela Universitaria de Fisioterapia de la ONCE for the care of your health and for other scientific research purposes if you have given your consent for it and if the law and applicable ethical requirements so permit.

If we transfer your coded data outside the EU to the entities of our group, to service providers or to scientific researchers who collaborate with us, the participant's data will be protected with safeguards such as contracts or other mechanisms by the protection authorities. data. If the participant wants to know more about it, you can contact the Data Protection Delegate of the ORGANIZACIÓN NACIONAL DE CIEGOS ESPAÑOLES at the following address: Dirección General de la ONCE, Calle Prado, 24, 28014 Madrid or an email to dpdatos@once.es

What will happen to the results of the research study?

A summary of the research findings will be sent to the study participants. With the most significant results, scientific communications may be prepared to be presented to congresses and/ or specialized biomedical scientific journals, always maintaining the confidentiality of their personal data at all times.



Contact information

If you require more information about the study, want to participate, or if you are already participating and want to withdraw, please contact:

Study Principal Investigator: Susana García Juez

Email: sgj@once.es

Phone: +0034915894353

Address: Escuela Universitaria de Fisioterapia de la ONCE
C/Nuria Nº42. C.P: 28034, Madrid, Spain

If you have any complaints, please contact:

Secretary: Elena Oliver de la Chica

Suggestions and complain mailbox: <http://euf.once.es/es/mailbox>

Email: euf@once.es

Teléfono: +0034915894500

Record of information provided

You will receive a copy of the information sheet and a signed consent form to keep for your personal records.

Thank you very much for taking time to read this document!

**We appreciate your interest in this study and hope to welcome you at the
Escuela Universitaria de Fisioterapia de la ONCE**

CONSENT INFORMED FOR THE STUDY:

"Assessment of Exercise Response in Chronic Fatigue Syndrome/ Myalgic Encephalomyelitis"

Identification number:

Mr./Ms.....
....., of years old, address at:....., and
National Identity Number:

I DECLARE:

That Mr/ Ms.
has invited me to participate in this study.

That I have read the information sheet that has been given to me, and that I have understood the explanations that have been provided to me in a clear and simple language, and that the researcher who has assisted me has allowed me to make all the observations and has clarified all the doubts that I have raised.

That I understand that my participation is voluntary, and If I do not want to participate in this study will not produce any different treatment in terms of quality of medical assistance or in my treatment.

That, if I decide to participate, I can change my mind at any time and withdraw from the study as soon as I wish, without needing to give any explanation, and therefore I can revoke my consent that I am now giving.

That my personal data will be treated confidentially and will remain anonymous in the publications that are derived from the study.

Therefore, I state that I am satisfied with the information received, I have been able to formulate all the questions that I thought convenient and they have clarified all the doubts raised.

And under such conditions, I freely agree to participate in the study "Assessment of Exercise Response in Chronic Fatigue Syndrome/ Myalgic Encephalomyelitis".

Also (mark with an x as appropriate):

I agree with the use of the data for other investigations: YES NO

I agree on the use of data for teaching: YES NO



In at

Signed: Researcher

Signed: Participant

REVOCATION

Mr./Ms.:.....,

of years old, address in:, and
National Identity Number:

WITHDRAW the informed consent of date and I do not wish to
continue the study, which I give with this date finished.

In at

Signed: Researcher

Signed: Participant