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Informed Consent Form

Title: The role of physical activity and diet within Pulmonary Sarcoidosis

Ethics Code: NCT03336736

Date submitted: 07/11/2017

Study Information sheet and consent form



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Information Sheet: The role of physical activity and diet within Pulmonary Sarcoidosis

Ethics Code: 1617/040

Thank you for considering being a participant in this project.

Below you will find a short background to our work, and an outline of what you will be required to do as a participant in this study.

The primary aim of the study is to ascertain the physical activity patterns in those with pulmonary sarcoidosis with regards to perceived physical activity and actual physical activity. The secondary aim of the study is to understand the effect of pulmonary sarcoidosis in relation to muscle strength and exercise capacity against physical activity, lung function and oxygen saturation and how these differ from normative values. Unfortunately, Sarcoidosis has a chronic shortage of research. This lack of research is coupled with current researchers' focus solely on results of tests such as lung function, at the expense of patient feedback on the condition, despite lung function being shown to be a poor indicator of overall health, including primary and secondary symptoms within Sarcoidosis, and current treatment methods (corticosteroids) causing several detrimental side effects. Therefore, the purpose for the current study and its future applications are to better understand physical activity and other measurements such as muscle strength as indicators of health within Sarcoidosis as well as identifying possible areas for future study in relation to non-pharmacological treatments.

Am I eligible to take part in the study?

You are eligible to take part in the study if you have been diagnosed with pulmonary sarcoidosis (this can be in addition to other forms of sarcoidosis) and aged 18-65 years.

Inclusion criteria: A diagnosis of sarcoidosis will be accepted provided the participant has diagnosed pulmonary sarcoidosis ascertained by self-reporting according to ATS/ERS/ WASOG criteria statement. Additional criteria include, aged 18-65 years old (both males and females) and able to give written informed consent. Clinically able to carry out exercise testing and have access to a computer with internet.

Exclusion criteria: Contraindications to (not able to perform) physical tests or exercise testing e.g. unstable cardiovascular disease, oncological, cardiac, neurological or orthopaedic history. An injury in the past 6 months that inhibits ability to perform exercise testing. Patients with a concurrent and predominant diagnosis of another significant respiratory disorder (for example: asthma, chronic obstructive pulmonary disease (COPD), cystic fibrosis, or lung cancer).

What is expected of me?

The study will involve you visiting the Human Performance laboratory, Penrhyn Rd, Kingston University, London on two occasions at least one week apart. The visit will consist of physical measurements including exercise capacity and muscle strength as well as completing questionnaires regarding fatigue and your physical activity levels. Between visits you will be asked to wear an accelerometer (a pedometer-like device) attached to your hip by a belt clip to measure your physical activity for 7 days.

You will also be asked to complete a 7-day food diary. On completion of the lab visits, participants will be invited to voluntarily participate in a follow-up semi-structured interview or focus group (either through skype, face-to-face or over the telephone).

Your results will be anonymous and you will not be identifiable.

Travel cost reimbursement will be offered to all participants who attend lab visits.

What are the benefits of taking part?

The benefits of this study will be to establish the effect sarcoidosis has on numerous physical measurements such as exercise capacity and muscle strength in relation to normative values as well as better understanding the role of physical activity within the condition. The study will not only add knowledge to the current body of research but also help identify potential future areas of research that may have been overlooked before or lacked scientific support. Participants will also benefit from anthropometric, exercise and strength testing as this will give them information on their own health and fitness status.

What are the risks of taking part?

No identified risks other than those of typical computer uses and physical activity.

Only participants who are medically stable and clinically able to carry out an exercise programme on a regular basis will be included in the study, this will be assessed when the criteria are applied to potential participants (as indicated in the inclusion/exclusion criteria). Prior health screening of participants minimises risk and allows exclusion of participants unsuitable for testing on health grounds. This will ensure that at-risk individuals will not be included for the purposes of this study, thus minimising the risk of injury when performing independent exercise. Involvement in an exercise programme could potentially cause discomfort, pain or injury.

The participant will be taught the procedures and observed carrying out the testing under the supervision of a trained professional (the principal investigator), including technical support and first aiders will be on site. The participants will be instructed to exercise at a medium rate of perceived exertion, and not continue if they become very fatigued. They will be educated on potential risks and advised to constantly monitor for adverse effects and report any if experienced. In the case of adverse effects, an appointment will be made with their GP/Consultant for a medical review.

Participants may feel discomfort or breathlessness while performing the exercise tests during the assessment. The discomfort associated with exercise testing is only that typically experienced during normal exercise (e.g. breathlessness, sweating and possible minor short-term post-exercise muscle soreness; however it should also be noted that as with any form exercise there is a very rare risk of disordered heart beats, abnormal blood pressure, fainting and vomiting). If this occurs they will be advised to take a rest till they recover, this test will be carried out by a trained clinician (the principal investigator). Participants are able to stop testing at any time if they wish.

What if I have a question or a query?

We are happy to answer any queries that you may have regarding the study. Please note that your GP/health professional will be informed of your participation in this study. In the event of having any health concerns, we will advise you to contact your GP for further screening and advice.

What if I decide to withdraw?

Participants are permitted to withdraw from the study at any time and data from them will not be used.

What about my Confidentiality?

Any information given to us by you will remain confidential and all data will be kept anonymous. All data will be coded and saved as encrypted password protected files on a PC. Results of testing and analysis along with age, gender will be recorded. Participants will remain anonymous throughout the research, including the publication of the research which may result in availability of the research at the University Learning Resources Centre, through scientific journals and conference presentation. Any hard copy versions will be kept in locked offices/cabinets of lead applicant.

The only personnel authorised to access the data will be the researcher, principle investigator and the project participants (their individual data only).

If you have any questions or problems, please do not hesitate to contact the researchers or project supervisor:

Name of Researcher: Luke Morton-Holtham

Email: K1214556@kingston.ac.uk

Name of Supervisor: Dr Hannah Moir

Senior Lecturer in Health & Exercise Prescription
Kingston University, London

Email: H.Moir@kingston.ac.uk

Tel: 020 8417 2876

Thank you for your time & contribution to this study.

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Statement by participant

I give my consent to the research procedures that are outlined above, the aim, procedures and possible consequences of which have been outlined to me

- I confirm that I have read and understood the information sheet/letter of invitation for this study. I have been informed of the purpose, risks, and benefits of taking part.

Study title: Establishing the existence of non-pharmacological multifactorial patterns within Pulmonary Sarcoidosis: The role of physical activity and diet within Pulmonary Sarcoidosis.

- I understand what my involvement will entail and any questions have been answered to my satisfaction.
- I understand that my participation is entirely voluntary, and that I can withdraw at any time without prejudice.
- I understand that all information obtained will be confidential.
- I agree that research data gathered for the study may be published provided that I cannot be identified as a participant.
- Contact information has been provided should I (a) wish to seek further information from the investigator at any time for purposes of clarification (b) wish to make a complaint.

Participant Signature:Date:

Participant Name:

Participant ID:

Statement by investigator

- I have explained this project and the implications of participation in it to this participant without bias and I believe that the consent is informed and that he/she understands the implications of participation.

Researcher Signature: Date:

Researcher Name: