Participant Information Sheet

Exercise, Fatigue and Daily Function in Crohn's Disease and Ulcerative Colitis: A Feasibility Study

This document provides detailed information about the above research study to help you make an informed decision about participating before signing a separate Consent Form. If you have any questions after reading the information sheet, please discuss these with the research team.

What is the purpose of the study?

Inflammatory Bowel Disease (IBD) affects more than 50,000 people in Scotland, with prevalence among the highest worldwide. Fatigue is consistently reported as one of the most debilitating symptoms and many people with IBD experience reduced confidence in everyday physical activity and uncertainty about how their body responds to effort and recovery.

Physical activity is recommended for general health, and existing IBD research relies heavily on self-reported measures of fatigue, with limited physiological data describing how everyday activity is experienced in relation to fatigue and recovery.

This study aims to investigate the relationship between self-reported measures of fatigue, functional capacity, and physiological markers of autonomic function in people living with IBD. The results will be used to inform future research and personalised physical activity guidance.

Why have I been invited?

You have been selected to participate because you are an adult aged 18-65 with ulcerative colitis or Crohn’s disease.

Do I have to take part?

No. Taking part in this study is completely voluntary and it is your decision if you wish to take part. If you decide to take part, you may withdraw from the study at any time without question by contacting the research team via email. Participation is voluntary so no judgement will be made should you decide you do not wish to take part before or during the study. If you decide you do not wish for your data to be used, you have the right to withdraw the data at any point up to two weeks after participation. You do not have to provide a reason for withdrawing and there will be no adverse consequences to you.

What will happen if I take part?

If you decide to take part, you will be asked to attend the Sport and Exercise Science laboratory at the Lanarkshire campus on one occasion (2-3 hours). Before attending, you will be asked to heed the following guidance:

- No strenuous physical activity for 48 hours prior to the visit
- No alcohol consumption for 24 hours prior to the visit
- No caffeine consumption for 12 hours prior to the visit

After giving consent, you will be asked to complete 3 written questionnaires relating to fatigue, health-related quality of life, and habitual physical activity. This should take no longer than 10 minutes per questionnaire and the answers you provide will be completely confidential.

Firstly, you will complete a postural heart rate variability test. This will involve attaching 3 ECG leads to your chest and abdomen so that we may monitor the activity of your heart in more detail. You will be asked to lie at rest for 5 minutes. You will then transition to a standing position and we will continue to record for a further minute.

Your handgrip strength will then be measured on both sides by squeezing a dynamometer as hard as you can.

Following a short rest, you will complete a 30-second Sit-to-Stand Test which simply involves recording the total number of times you can stand up from a chair over a 30 second period.

Finally, you will be asked to complete a progressive submaximal exercise test cycling on a stationary bike. Your heart rate will be monitored continuously through a chest strap. We will gradually increase the intensity at which you are cycling every 3 minutes until you reach 70-80% of your maximum heart rate. This will roughly match a subjective intensity of ‘somewhat hard’. We will then stop the test and continue to measure your heart rate for 2 minutes to monitor how it recovers from this workload.

What are the possible risks of taking part?

You might feel some physical discomfort during and after completing the exercise protocol. This should be temporary and will subside shortly after.

What are the possible benefits of taking part?

You will be contributing valuable preliminary data towards understanding the relationship between physical activity and fatigue among people with IBD. You may also receive the results of your exercise tests if you wish.

Will my taking part in this study be kept confidential and anonymous?

Yes. You will be assigned a unique reference number for the study, meaning you will remain anonymous. When the data is used, it will be collated with that of other

participants and will in no way be linked back to you. Your consent form and questionnaires will be stored in a locked filing cabinet and will only be accessible by the research team. All other data will be stored in password-protected files.

What will happen to the results of the study?

The findings of the study will be presented in a report to Medical Research Scotland and may be published in scientific journals. If you wish, you may request to receive a summary of the findings following the study's completion.

Contacts for further information

Principal Investigators: Dr Mia Burleigh (mia.burleigh@uws.ac.uk)

Ishbel Fraser (b01816388@studentmail.uws.ac.uk)

If you experience a problem and would rather speak to someone out with the research team, you may address this with the ADRI:

Professor Nicholas Sculthorpe (nicholas.sculthorpe@uws.ac.uk)

Formal Complaints

If you believe that you have been subjected to an inadequate level of service, mistreatment or mal-administration by the University, you are encouraged in the first instance to raise the matter with the School or Professional Service area involved in order to address the situation.

Where this does not result in a satisfactory resolution, the matter can be progressed via the University's Complaints Handling Procedure. This may be accessed through the following link:

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