PARTICIPANT INFORMATION SHEET

Name of Investigators: Dr Alan Sneddon and Ms Karlee Dyck

Name of Study: Crab and Health Study

You are invited to take part in a research study. Before you decide whether to volunteer, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Please do not hesitate to contact us (see below) if there is anything that is not clear or if you would like more information.

What is the purpose of this study?

Crab meat is an excellent source of vitamins, minerals and omega-3 fats. Crab meat contains both white and brown meat and the brown meat especially, may contain high levels of the heavy metal cadmium. Cadmium occurs naturally in the environment. In the non-smoking population, food is the main source of cadmium. Over time, exposure to cadmium causes it to accumulate in the body. High cadmium levels in the body may cause damage to the kidneys, however one study suggested that some nutrients (selenium and zinc) found in crab may protect against kidney damage.

So far, there have been no studies to see if the brown meat from crab increases cadmium levels in the body, and if these levels are associated with kidney damage. In this study, we will be investigating whether those who regularly consume the brown meat from crab have higher levels of cadmium than those who do not consume crab. Therefore, not only are we interested in volunteers who consume crabmeat regularly but also we are equally interested in individuals who do not consume crab as we need to compare cadmium levels in both. Without either group, we cannot conclude whether consuming crabmeat makes any difference to cadmium levels in the body. This research is important to help provide guidance on consumption of crab brown meat.

Who can take part?

We are looking for:
• Healthy male and female volunteers,
• 40 years and older,
• eat Crab/Crab products regularly (especially the brown meat)
• those who never eat crab.
• Non-smokers (never smoked, or have not smoked in the past 5 years).

Those with kidney disease or glomerular nephritis, those with anaemia, those who are pregnant or who work (or have worked) in professions that exposes them to high levels of cadmium are also unfortunately unable to take part in this study. We will carry out a general questionnaire to confirm that you are eligible to take part.

Do I have to take part?
No. It is entirely up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep. You will be asked to sign a consent form and we would like you to complete a short questionnaire. You are free to withdraw at any time and without giving any reason.

**What will happen to me if I take part?**

Before you start the study, we would like you to sign a consent form. We will ask you to sign the consent form and health questionnaire and then complete a crabmeat questionnaire to find out whether you are eligible to take part in our study. If the results from this initial screening indicate that you are eligible, we will invite you to take part in the research study. But again, it is entirely up to you to decide whether or not to take part.

For this study, we will measure your weight/height, and ask you to provide a blood sample of 40 ml (~2-3 tablespoons) and a urine sample (20ml). The urine sample must be from the first morning void, so we will send you a container and instructions to collect this at home. On the same day as your urine sample, we will arrange for you to come to the Human Nutrition Unit at the Rowett Institute, Aberdeen or to meet with a GP in Stromness, Orkney (depending on your location) to collect the blood sample and measure your weight/height. The visit to the Human Nutrition Unit or GP will probably not take more than 20 minutes of your time. If you wish, we will provide you with feedback on your cadmium, zinc, selenium and ferritin levels – for example, if they are deficient, marginal, normal, or elevated.

Your involvement in this study is entirely voluntary. All procedures will be explained to you before the study starts and you will have the opportunity to ask further questions.

**What will happen to the samples I give?**

Once collected, your blood and urine samples will be taken to the laboratory and processed. Processed blood and urine samples will be stored at the Rowett Institute at -70°C in a secure designated freezer for maximum of 5 years after which they will be destroyed. Blood samples will be analysed for cadmium, selenium, and zinc levels, as well as creatinine and ferritin. Urine samples will be analysed for cadmium, B2-microglobulin and creatinine levels. The Rowett GP will inform you and your GP of any out-of-range values and suggest that you follow these up. Samples are only accessible to the research team involved in the study. Confidential information given by you will be accessed by the research team only.

**What will happen to my data?**

All data we obtain from your samples will be coded to ensure confidentiality and will only be accessible to the research team involved in the study. This information will be stored on password-protected computers for a maximum of 5 years. Archiving of data will be in accordance with the Sponsor SOP.

**Expenses and payments**

You will not be paid for the study, but upon completion, you will receive £20 towards travel costs.

**What are the possible disadvantages and risks of taking part in this study?**
During the study, we only take a small amount of blood. There may be slight discomfort when doing the blood sampling from the vein and as with all puncturing of the skin there is a very small risk of infection. Other than this brief discomfort, the risk of taking such a small amount of blood in this study should be minimal.

**What are the possible benefits of taking part in the study?**

This study will probably not help you personally. However, the information we get will help us to understand how brown meat from crab contributes to cadmium levels in the body and if this is likely to increase the risk for kidney damage. This can then contribute to guidance on consumption of brown meat from crab.

**What if there is a problem?**

If you have any complaints about the way you have been dealt with during the study or any possible harm you might suffer, please get in touch with the investigator (Dr Alan Sneddon at 01224 438671 or a.sneddon@abdn.ac.uk) as soon as possible and we will try to address the problem. Alternatively, you may wish to contact Ms Sylvia Stephen, Manager of the Human Nutritional Unit and deputy Chair of the Human Studies Management Committee, at 01224 438607 or sylvia.stephen@abdn.ac.uk.

**Who has reviewed this study?**

This study has been reviewed and approved by the Rowett Human Studies Ethical Review Panel.

**Who is organising and funding the research?**

The funding for this study comes from the Orkney Fishermen’s Society and Macduff Shellfish Group Ltd. This study is sponsored by the University of Aberdeen.

**Will my taking part be kept confidential?**

We will code all of your blood and urine samples to ensure confidentiality. You will not be able to be identified by the samples and your anonymity will be guaranteed in any publication from this study. Identifiable contact information will be kept after the end of the study (with your permission) in order to contact you for future studies that we may be undertaking and this information will be held in accordance with the data protection act.

**CONTACTS FOR STUDY**

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<th>Name: Karlee Dyck</th>
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