University Hospitals of Derby and Burton NHS Foundation Trust

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# Participant Information Sheet
# Version 2.0

## Effect of immuno-nutrition on markers of sarcopenia and systemic inflammation in a haemodialysis population: a feasibility randomised controlled trial

### We invite you to take part in a research study

- Before you decide whether to take part, 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. Discuss it with friends and relatives if you wish.
- You are free to decide whether or not to take part in this study. If you choose not to take part, this will not affect the standard of care you receive.
- Ask us if there is anything that is not clear or if you would like more information.

### 1. Why are we doing the study?

Low muscle mass and strength (this is called sarcopenia) are common problems in people receiving haemodialysis which lead to poor quality of life and a higher risk of death.

Inflammation, caused by the body's defence (immune) system being activated in response to infection or injury, is another common factor that causes loss of muscle mass and strength in people on haemodialysis.

Standard food supplements are not effective at increasing muscle mass and strength in people on haemodialysis. This is because inflammation limits protein from food being converted into muscle.

"Immuno-nutrition" is a new form of food supplement that provides calories and protein like other standard food supplements but also contains extra nutrients that reduce inflammation. In previous studies, immuno-nutrition has been shown to benefit people with cancer, another patient group with high inflammation.

Recently, we showed that immuno-nutrition improved muscle strength and decreased inflammation in a small study of 14 people on haemodialysis.

Therefore, the aim of this research is to test the study methods and procedures, and to collect information that will help us design a larger, more detailed study in the future.

## 2. Why am I being invited to take part?

You are being invited to take part because you are receiving three haemodialysis sessions per week for at least 3 hours, your blood tests show that your potassium levels are normal, and you are not taking any medication that inhibits your immune system. We are inviting 70 participants like you to take part.

## 3. Do I have to take part?

No. It is completely up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. If you withdraw or decide not to take part, it will not affect your legal rights or the standard of care you receive in any way.

## 4. What will I need to do if I take part?

Once you have agreed to take part in the study and signed the consent form, you will be randomly assigned (similar to picking names from a hat) to the **intervention group** ("immuno-nutrition" supplement) or the **usual care group** (standard food supplement). You will be asked to take **one supplement daily for 24 weeks**.

If you are assigned to the **intervention group**, you will be asked to dissolve the immuno-nutrition supplement sachet in **125 ml (4 oz)** of water. You will be provided with a shaker with markings in ml & oz to ensure the supplement is accurately mixed in 125 ml (4 oz) of water. The immuno-nutrition supplement is made with **cow's milk** and contains **fish oil** and **soy** ingredients. It has **Halal diet certifications,** but it **does not have Kosher diet certifications,** and it is also **not suitable for vegetarian or vegan diets.** The flavour of the immuno-nutrition supplement will be tropical fruit, as this is the only available flavour in the UK.

If you are assigned to the **usual care group**, you will be asked to take **one bottle (125ml)** of a standard food supplement. This supplement is also made with **cow's milk** and contains **soy** ingredients. It has both **Halal and Kosher diet certifications,** and it is **suitable for vegetarian and vegan diets.** The available flavours of the standard food supplement are vanilla, mocha, strawberry and peach mango.

You will receive detailed oral advice on how and when to take the food supplement you were assigned to (i.e., immuno-nutrition or standard food supplement).

Consumption of the food supplements will be supervised during your haemodialysis sessions, and you will be asked to self-report consumption on non-dialysis days by returning empty sachets or bottles.

You will continue to receive advice regarding your diet by your usual NHS renal dietitian.

At the start of the study, the research team will access your medical records to collect information about your age, ethnicity, civil status, religion or belief, socioeconomic status, medical conditions and the drugs you are taking.

The following assessments will be made at the **start of the study** and after **12, 18 and 24 weeks** of taking the supplements. They will be conducted when you attend the dialysis unit to receive your usual treatment. We estimate that it will take approximately 60 minutes to complete them.

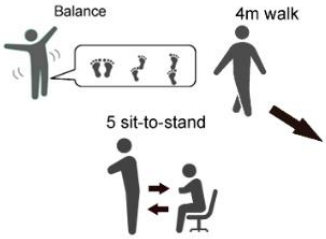


**Handgrip strength (a measure of muscle strength)**



**Levels of fat and muscle within the body using a specialist scale**

Please note this assessment will not be conducted if you have a pacemaker, implanted defibrillator, or other electronic life-sustaining device




**Physical function (walking speed, ability to stand from a chair and balance)**

Please note this assessment will not be conducted if you are unable to stand (e.g., wheelchair users)




**Quality of life via a questionnaire**



**Food diaries 1 dialysis day, 1 non-dialysis day and 1 weekend day**



**Blood tests to monitor blood chemistry and inflammation**

The research team will collect the results of the blood tests that you usually have done every month as part of your treatment.

We will also collect approximately two teaspoons of your blood and remove the plasma from it. Plasma is the straw-coloured liquid part of blood that contains many important molecules including those that indicate inflammation, which is what we will measure in this study. We will make sure to take the blood on a day when you are not having any routine blood tests done, and before your usual treatment so no extra needle puncture will be required. The plasma samples will be stored in a freezer at the University of Nottingham until they are analysed in a laboratory.

If you decide to withdraw your consent from the study, plasma samples may still be retained and used in the final analysis.

If you agree, we will also store any remaining plasma for future research. If you do not agree to the future use of your samples, they will be destroyed after we complete the analysis of molecules that indicate inflammation. Your samples will be destroyed following guidance from the Human Tissue Authority.

Finally, after 24 weeks of taking the supplements, we will ask you some questions about the taste, smell and consistency of the supplements, and your opinion about continuing taking the supplements for longer than 24 weeks.

Once we have finished the study, your usual haemodialysis sessions and all other treatment for your medical conditions will continue as normal.

## 5. Expenses and payments

You will not be compensated for your participation in this study. Study assessments will be arranged to take place when you attend for your haemodialysis treatment. If you do have to make any extra visits for the study, travel expenses will be offered.

## 6. What are the possible disadvantages and risks of taking part?

This study will involve taking either an immuno-nutrition supplement or a standard food supplement and following your normal diet; therefore, this study is not expected to be associated with any risks. However, if you experience anything untoward, the research team will record this, and you will be closely monitored until it has resolved. You will also be monitored regularly to ensure that you are taking the food supplement you were assigned to.

Although what you say to us is confidential, should you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons.

## 7. What are the possible benefits of taking part?

We cannot promise the study will help you but the information we get from this study will help us design and conduct a larger, more detailed study to test the effect of immuno-nutrition on muscle mass and strength, inflammation, and associated beneficial outcomes.

## 8. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers' contact details are given at the end of this information sheet.

If you remain unhappy and wish to complain formally, you can do this by contacting the Patient Advisory & Liaison Service (PALS) at:

Office: 01332785156
Text: 07799 337 500
Email: uhdb.contactpalsderby@nhs.net

University Hospitals of Derby and Burton NHS Foundation Trust has in force the relevant insurance policies which apply to this study. In the event that something does go wrong and you are harmed during the research, then you may have grounds for a legal action for compensation, but you may have to pay your legal costs.

The normal National Health Service complaints mechanisms will still be available to you.

## 9. How will we use information about you?

We will need to use information from you for this research project.

This information will include your:

- Name
- Contact details
- Age
- Civil status
- Religion/belief
- Socioeconomic status
- Medical conditions
- Medications

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all personal information about you safe and secure.

Once we have finished the study, we will keep some data so we can check the results. We will write our reports in a way that no one can work out that you took part in the study.

**University Hospitals of Derby and Burton NHS Foundation Trust are the sponsor of this research and responsible for looking after your information.**

We will keep all information about you safe and secure by:

- Storing any personal or identifiable information about you (e.g. name) on a secure password-protected folder away from the research data.
- Using data storage systems recommended as secure by NHS organisations and universities that are routinely backed up and GDPR compliant.

## 10. International transfers

Your data will not be transferred outside the UK.

## 11. How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a minimum of 5 years after the study ends, in accordance with national legislation. The study data will be fully anonymised, securely archived and then destroyed.

## 12. What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we have already collected.

You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do this research. If so, we will tell you why we cannot do this.

## 13. Where can you find out more information about how your information is used?

You can find out more about how we use your information via:

- The HRA leaflet www.hra.nhs.uk/patientdataandresearch
- The Sponsor's website www.uhdb.nhs.uk/research-how-we-use-your-information
- By sending an email to our Data Protection Officer at uhdb.dataprotectionofficer@nhs.net
- By asking a member of the research team

## 14. Involvement of your General Practitioner/Family doctor (GP)

We will inform your GP via a letter that you have agreed to take part in this study. We will let them know whether you have been assigned to the intervention or usual care group.

## 15. What will happen to any samples I give?

We would also like to seek your consent so that any remaining samples may be stored and used in possible future research – **this is optional** (please indicate whether you agree to this on the consent form).

The samples will be stored with a code unique to you and securely at the University of Nottingham under the University's Human Tissue Research Licence (no. 12265). Some of these future studies may be carried out by researchers other than the current team of Dr Daniela Viramontes Hörner, who ran the first study, including researchers working for commercial companies.

Any samples or data used will be anonymised, and you will not be identified in any way. If you do not agree to this, any remaining samples will be disposed after they have been analysed, and this will be in accordance with the Human Tissue Authority's codes of practice.

## 16. Will any genetic test be done?

No genetic tests will be performed as part of this study.

## 17. What will happen to the results of the research study?

The results of this study will be submitted to scientific journals for publication as soon as data analysis is completed. The results will also be presented at conferences. You will not be identified in any publications.

We will organise an event to inform you about the results of this study. If you are unable to attend the event, the Chief Investigator Dr Daniela Viramontes Hörner will provide you with a written lay summary of the results.

We will also liaise with kidney charities and patient groups (e.g., Kidney Care UK and National Kidney Federation) so that the results are published on their websites.

We may share our research data with researchers in other Universities and organisations involved in research in health and social care. Data shared in this way will be anonymised.

## 18. Who is organising and funding the research?

This research is being organised by University Hospitals of Derby and Burton NHS Foundation Trust and is being funded by the National Institute for Health and Care Research as part of the Research for Patient Benefit Programme.

## 19. Who has reviewed the research?

All research in healthcare is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by East Midlands – Nottingham 2 Research Ethics Committee.

## 20. Further information and contact details

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Email: mszdv@nottingham.ac.uk

**Thank you for taking the time to read this information sheet. Please ask any questions you may have.**