

Participant information leaflet

Study title: An uncontrolled open label trial of a nutritional supplement to reduce measures of biological and immune ageing and improve physical function and quality of life in healthy older people.

Invitation to take part

We would like you to take part in a three-month research study to take a nutritional supplement every day and donate a blood sample for the research. The study is being Sponsored by the University of Birmingham. Before you decide, 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 and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

People are living for longer, they are not necessarily enjoying good health in their old age. The number of people aged over 60 in the UK reached 15.5 million (23% of the population) in 2020 and this will continue rising. Changes within the immune system with advancing age, include increased inflammation, and we are investigating if this causes a number of diseases which mostly affect older people, such as heart disease, osteoporosis and dementia. The amount of inflammation in the blood has been shown to indicate how “aged” the immune system is and even how aged a person is overall (called their biological age).

Several food components (nutrients) can reduce inflammation and may reduce the degree of ageing of the immune system and have broad health benefits. However, these nutrients have not been tested in combination to see if their effects are even better.

We aim to test the effect of a nutritional supplement, developed by the company Bayer, which contains eight different nutrients that have been separately shown to reduce inflammation or improve immune function. We will measure inflammation and also whether the supplement improves physical function, quality of life and biological age.

Why have I been invited to take part?

You have been invited to take part because we believe that you are a healthy person, aged 60 or over, a non-smoker and without a chronic inflammatory disease or taking anti-coagulant medicine such as warfarin.

What will the study involve?

The study overall lasts 3 months. If you agree to take part you will be invited to come to the Clinical Research Facility (CRF) in the Heritage Building on the Queen Elizabeth Birmingham hospital site. We will provide the full address with clear directions and transport links, including details of parking. You will be given a 3 months supply of the nutritional supplement, and will ask you to take one tablet every day for 12 weeks.

We will ask you to carry out some simple physical function tests, such as seeing how long it takes you to stand up from a sitting position 5 times.

Lastly, we will ask you to provide a saliva and a blood sample (20ml = 4 teaspoons) so that we can measure inflammation, immune age and biological age. As part of this, DNA will be extracted from the samples to look for specific DNA markers of ageing. The samples will be collected by one of the research team, who will take blood from a vein in your arm using a standard needle. For the saliva sample you will need to produce a small amount of spit into a specifically designed collecting tube. The blood tests will be taken to the university laboratories where they will be processed and stored. The saliva will be sent to a company, Chronomics, to analyse as we do not do this sort of analysis at Birmingham. Chronomics is a company based in the UK that analyses biological samples.

We will ask you to fill in a questionnaire about your quality of life (QoL) and you will take away another questionnaire that asks you to record what you eat for the following week. We will also give you two copies of the QoL questionnaire to be filled in at home, 4 weeks and 8 weeks later, which can be brought to the 12 week visit, and repeat the food diary for the final week.

We will phone you at weeks 4 and 8 of the study to make sure that you are not experiencing any unexpected problems with the supplement and to remind you to fill in the questionnaires.

After 12 weeks we will ask you to return to the hospital and we will repeat all of the tests again. We will not supply further nutritional supplements after the trial has ended.

Do I have to take part?

Taking part is voluntary. It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form which you will be given a copy of. There will be no come back on you if you decide that you do not want to participate in this research. You do not have to explain the reason for your declining to participate.

If you agree to join the study you are free to withdraw from the study at any point and you do not have to give a reason why you wish to do so. If you do decide that you no longer wish to participate, we will keep the data and samples we have already collected.

What will happen to my blood sample?

We will use the blood sample to measure the amount of inflammation in your blood, this will tell us how “aged” your immune system is. We will also do another test which looks at chemical groups on the DNA in your blood cells; this tells us how biologically old you are. If we have any blood left over we would like to store this for up to 5 years for use in future ethically approved research, just in case new tests become available that will help us to understand the benefits of the nutritional supplement.

Although the study is funded by the company Bayer, they will not have access to your personal information and any left over blood will stay at the University of Birmingham. The sample will be destroyed at 5 years

What are the possible side effects of taking part?

The eight nutrients in the supplement (Vitamin D, Vitamin C, Vitamin B3, Omega 3 Poly Unsaturated Fatty Acids (EPA + DHA), Resveratrol, Olive fruit extract, Astaxanthin) have all been shown to be safe in the amounts we are using. Resveratrol is found naturally in grapes, blueberries, raspberries, mulberries, and peanuts. Astaxanthin is a keto-caratinoid that is found naturally in pink shelled sea creatures, such as shrimps. It is manufactured synthetically and is used primarily as a food dye. At much higher doses than we will be using, some of the nutrients affect medicines used for blood thinning, such as warfarin, and so we will not recruit people in to the study who are on this type of medication.

You may develop a bruise on the arm where the blood is taken, this will settle within a few days. There are no other side effects which you are likely to experience.

What are the possible disadvantages and risks of taking part?

None besides the possible side effects noted above.

What are the possible benefits of taking part?

If the supplement does reduce inflammation and biological age you may see an improvement in your physical function and quality of life. You will be told if there is a reduction in inflammation and biological age at the end of the trial as well.

What if there is a problem?

If you have any concerns, please speak to a member of the research team in the first instance, you can get in touch with us using the contact details at the end of this information sheet. We will do our best to answer your questions. If your concerns are not addressed and you wish to make a formal complaint, you can refer to the Patient Liaison Services (PALS) ****Please include details**

Will my taking part in this study be kept confidential?

All information given by you and all results obtained will be treated in the strictest confidence. The blood and saliva samples, and the questionnaires and food diaries, will be assigned a unique code. This code will be used in all experiments so that research staff cannot identify you. We will keep a record that links the unique code for your sample back to you. This record will be kept confidential within the research group.

In general, all personal information about you will remain confidential within the research group and will be stored in accordance with the UK General Data Protection Regulation and Data Protection Act 2018. Your General Practitioner will be informed of your participation only if you agree for us to inform them. No results will ever be released to an insurance company.

The study is funded by the company Bayer who are hoping to market the supplements to older adults in the future if the results are positive. They will be given the overall results, that is - did their supplement reduce inflammation, biological age, and improve physical function - but not have access to any personal data. There are processes in place to ensure scientific independence of the study

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 and contact details. 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 information about you safe and secure.

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.

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 already have.

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

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- HRA leaflet available from www.hra.nhs.uk/patientdataandresearch
- by sending an email to dataprotection@contacts.bham.ac.uk

Will I be paid to take part?

We will offer a one off honorarium of £200 to cover the costs of travel and your time.

What will happen to the results of the research study?

The results of the research study are likely to be published in a scientific journal. Information from the tests carried out on you will be included but you will not be individually identified. We will provide a lay summary of the trial results, and will provide you with a copy if you would like.

Who has reviewed the study?

The study was reviewed by the Health Research Authority and a national Research Ethics Committee.

Professor Lord as key investigator/collaborator of this study declares her role as a Consultant for Bayer Pharmaceuticals. She has received consultancy fees from Bayer Pharmaceuticals during the preparation of the proposed study (to be adapted as appropriate). There are processes in place to ensure scientific independence of the study, and Bayer will not have any role in the testing, result interpretation, or how we disseminate the results.

Contact for Further Information

Should you require further information please do not hesitate to contact either Professor Janet Lord (j.m.lord@bham.ac.uk; 0121 3713234) or Dr Thomas Jackson (t.jackson@bham.ac.uk; 0121 37132XX)

A copy of this information sheet and a signed consent form will be given to you to keep.

Thank you for taking the time reading this information sheet.