Participant Information Sheet

Sampling Sub-group

Title of Project: Impact of the DailyColors™ polyphenol supplement on health markers in older adults: blood and in-person saliva sampling cohort.

Researchers: Prof Anne Corbett, Dr Mary O'Leary, Prof Anni Vanhatalo, Prof Jo Bowtell, Dr Lauren Strusczcak, Dr Esra Bozbas, Joanna L'Heureux, Celeste Lugtmeijer, Jack Pritchard.

Brief summary:

We are inviting you to take part in the sub-group for our research study into the DailyColors™ dietary supplement. You are already registered to take part in the main clinical trial. Being part of the sub-group means that in addition to completing online assessments and providing a saliva sample from home, you will also visit a lab at the University of Exeter. This would be to provide blood and saliva samples on three occasions during the trial. These additional samples will allow us to explore whether taking the DailyColors™ supplement changes markers of healthy ageing, inflammation and metabolism within blood. It will also tell us whether it affects your blood pressure and whether it changes the bacteria that live in your mouth. Participants in this sub-group will be in all three groups (placebo, low dose and high dose).

Taking part in the study is up to you. We thank you for your interest so far. Please take time to read the following information. It may help to discuss it with others.

Purpose of the research:

This study is an extension of the DailyColors™ trial that you are already enrolled in. It will explore whether the dietary supplement causes any changes in your blood, the bacteria in your mouth, your Body Mass Index (BMI) or your blood pressure. There are many components in blood that provide a useful indication of health, including inflammation and how our bodies process food and other substances. These components are linked with health, including brain health and heart health. By analysing blood in the DailyColors™ trial we will be able to explore whether the supplement could affect these components. We also know that the bacteria that live in our mouths are linked to health and ageing. These bacteria change according to our diet. This part of the trial will allow us to explore whether the DailyColors™ supplement causes any changes in our mouths that could affect health. Finally, blood pressure and BMI are important indicators of health and this sub-group will be measured to explore whether the supplement causes any changes.

Why have I been approached?

You have been contacted as you are already enrolled in the DailyColors™ trial and you are living within two hours travel of Exeter. This sub-group has the same criteria as the full trial. These are outlined below as a reminder.

We are looking for people who are aged over 50 years of age with a Body Mass Index (BMI) of 25 or above. Participants will be routinely consuming less than five cups of tea or coffee every day. You will also not be able to take part if you take anti-inflammatory medications (painkillers like ibuprofen) more than three times a week. Those following a vegan diet are also excluded.

What would taking part in the sub-group involve?

If you decide to take part in the sub-group the following steps will take place:

1. After you have given your consent and been allocated to a treatment group in the main trial you will receive a telephone call or email inviting you to take part in the sub-group. You will be directed to the sub-group section on the PROTECT website where all the information can be found.
2. You will be asked to register for the sub-group activities and confirm you have read this Participant Information Sheet A downloadable copy of this is available on the PROTECT website www.protectstudy.org.uk
3. You will be asked to read and sign the consent form. This is to ensure you understand what the subgroup involves and that you are happy to participate. This will include confirming your availability and willingness to travel to Exeter three times over the next 60 days.
4. You will then receive a telephone call from a study team member to arrange the dates and times of your study visits.
5. You will be asked complete your first set of assessments and your first at-home saliva sample kit as per the main study guidance. You will not receive your study capsules in the post. These will be given to you when you come for your visit.
6. You will travel to Exeter for your first visit within 10 days of registering for the trial. We will ask you to fast before this visit, which means you will be asked not to eat or drink anything that morning. We will take one blood sample from a vein in your arm and then we will provide you with your study capsules. You will then be asked to take your first two capsules and remain at the laboratory clinic for two hours. During this wait we will measure your height, blood pressure, waist measurement and body weight. We will ask you to provide a saliva sample. We will then take a second blood sample before you leave. You will be welcome to stay a little longer to have something to eat and drink before traveling home.
7. You will return to the lab clinic in Exeter after 30 days and 60 days. Each visit will be identical to the first visit.

What will happen to my blood and saliva samples?

Blood samples will be stored at the University of Exeter's St Luke's Campus until they are analysed. This will involve measuring the levels of thousands of proteins in your blood. We will also measure the level of the plant nutrient compounds in your blood. This information will be used to find out how DailyColors™ works. It may also tell us which types of people are most likely to benefit from taking the supplement. Some of these analyses will take place at the University of Bristol Proteomics Facility and at the University of East Anglia. Your saliva samples will be used to examine the effect of DailyColors™ on the population of microorganisms in your mouth by extracting the bacteria and analysing their DNA.

When the samples are no longer needed, they be discarded in accordance with the Human Tissue Authority code of practice. This will be a maximum of five years from the date on which they were taken. They may be kept for longer if additional ethical approval is obtained. This allows us to use any remaining tissue for further analyses. You can opt out of these analyses when filling out the consent form.

What are the possible benefits of taking part?

We cannot promise any particular health benefits to taking part in this study.

What are the possible disadvantages and risks of taking part?

Supplementation: As for the main trial, there are no known side-effects of taking plant nutrient rich supplement like DailyColorsTM. Individual sensitivities to the supplement are possible. If this happens to you, you will be free to stop taking the supplement if you wish. This will end your participation in the trial.

Blood Sampling: Blood sampling usually cause some temporary mild discomfort. There is a risk of localised bleeding/bruising, or fainting. In some cases, the first attempt to obtain a blood sample will be unsuccessful. Additional attempts may be made, if you agree. The research team are experienced in this technique. A first aider will be present.

What will happen if I don't want to carry on with the study?

Participation in this subgroup is voluntary. You can choose whether you would like to take part or not. You can stop being part of the subgroup at any time, without giving a reason, but we will keep information about you and samples that we already have. You may withdraw via the PROTECT platform, in person or by contacting the study helpdesk. If you withdraw from the subgroup you do not have to withdraw from the main trial unless you wish to.

How will my data be handled?

In 2018 regulatory changes in the way that data is processed came into force, with the EU General Data Protection Regulation 2018 (GDPR) and the Data Protection Act 2018 (DPA 2018). Since the UK left the EU, the key principles of EU GDPR have been adopted in the UK GDPR (a 'UK-only' version) and the DPA 2018 still applies. We will use information from you for this research project. This information will include your name, contact details and research information about your tissue samples. People will use this information to do this research. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. Once we have finished the study, we will keep some of the data so we can check the results.

The University of Exeter terms its lawful basis to process personal data for the purposes of carrying out research as being in the 'public interest'. The University continues to be transparent about its processing of your personal data. This participant information sheet should provide a clear explanation of how your data will be collected, processed, stored, and destroyed. If you have any queries about the University's processing of your personal data that cannot be resolved by the research team, further information can be obtained from the University of Exeter's Data Protection Officer via the web-link; https://www.exeter.ac.uk/about/oursite/dataprotection/dpo/

You can find out more about how we use your information by contacting a member of the research team or the Sponsor (Contact details at the end of this information sheet).

How will my information be kept confidential?

We will keep all information about you safe and secure. All information collected in this study will be kept confidential. It will be stored either on a password protected computer, on secure 'cloud' storage or in a locked cabinet at the University of Exeter. These locations may only be accessed by the research team. People who do not need to know who you are will not be able to see your name or contact details. Your research data will have a code number instead. Any information from which you could be identified will be stored separately and securely from information obtained from the research. It will only be kept for a limited time (maximum ten years). It will then be destroyed.

Your information may be audited by, the University of Exeter Human Tissue Authority Designated Individual, or representatives of the Human Tissue Authority. This is for auditing the study's compliance with governance requirements. We will write our reports in a way that no-one can work out that you took part in the study. Your data could also be anonymously used in teaching or training materials. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. This will also allow us to provide you with a summary of the study outcomes. It is not necessary for you to give this permission to participate in the study.

Your rights to access, to change or move your information are limited. This is because we need to manage your information in specific ways. This ensures that the research is reliable and accurate. If you withdraw from the study, we will keep the information about you that we already have. To safeguard your rights, we will use as little information about you as is possible.

Will I receive any payment for taking part?

We will reimburse you for your travel expenses and any reasonable costs incurred such as sustenance, but not accommodation. No further payment is available for participants in this study.

What will happen to the results of this study?

The results of this study will be published in a scientific journal. They may be presented at conferences or in media. The results may also be used in teaching or training materials. We will write our reports so that no-one can work out that you took part in the study. This anonymous data may be published in a data repository. This allows other researchers to verify our findings. Your name will not appear on any results. We will also prepare a final report. We will share this with you, if you wish.

Who is organising and funding this study?

The sponsor for this study is the University of Exeter. The study is being funded by DailyColorsTM Health Inc. It is being conducted by the team listed at the top of this information sheet, led by Prof Anne Corbett.

Who has reviewed this study?

This project has been reviewed by the University of Exeter Public Health and Sport Sciences Research Ethics Committee (REF: 2929219)

Contact for any questions or requests regarding your participation in this research

In the event of queries or requests you may contact the study team using the following contact information.
Please email protect.dailycolors@exeter.ac.uk

To contact the Research Ethics Committee
please email shs-rec-admin@exeter.ac.uk

You can also contact the University Research Ethics and Governance Team if you wish to make a complaint or comment

please email cgr-reg@exeter.ac.uk,

or Dr Antony Walsh
Head of Research Governance, Ethics and Compliance
University Corporate Services, University of Exeter
G14, Lafrowda House, St Germans Road, Exeter, EX4 6TJ
DD: 01392 726621 email A.Walsh3@exeter.ac.uk

Consent to Take Part

- I confirm that I have read the information sheet dated 25/09/23, version 2.0 (headed 'Sampling Sub-group') for the above project. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
- I understand that my participation is voluntary and that I am free to withdraw at any timewithout giving any reason and without my legal rights being affected.
- I understand that relevant sections of the data collected during the study, may be looked at by members of the research team, individuals from the University of Exeter,DailyColors or the Human Tissue Authority, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
- I understand that taking part involves taking capsules every day for 60 days.
- I understand that the supplement that I am given may contain grapefruit. I confirm that I have not been advised by a doctor to avoid consuming grapefruit.
- I understand that taking part involves travel to St Luke's campus in Exeter on three occasions in the next 60 days and that I will be reimbursed for this expense.
- I understand that taking part involves donating blood samples on three occasions andI understand what this entails.
- I understand that taking part involves donating saliva samples on three occasions andI understand what this entails.
- I understand that taking part involves having my height, weight, waist measurement and blood pressure measured on three occasions and what this entails.
- I understand that my blood samples may be transported to other laboratories within the UK or overseas for further analyses.
- I give consent for my surplus blood samples to be used for other studies subject to additional ethical approval.
- I understand that my research data (anonymised so that I cannot be identified) may be used for the purposes of publication, shared with other researchers, included in reports and used for teaching or training purposes in University activities including public engagement.
- I agree that my personal data (from which I could be identified) e.g. contact details can be kept securely and used by researchers from the research group to contact me about future research projects. All personal data will be destroyed – at the latest – ten years after completion of this project
- I confirm I consent to take part in the DailyColors subgroup study