Participant Information Sheet

Main Trial Group

Title of Project: Impact of the DailyColors™ Phytonutrient Supplement on Health Markers in Older Adults: A Remote Pilot Clinical Trial

Researcher names: 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.

Invitation and brief summary:

We are inviting you to take part in our research study. We will explore whether taking a dietary supplement called DailyColors™ can change markers of health. These include brain function, wellbeing and how a person's genes work. We will also examine its effects on indicators of healthy ageing in saliva and blood. Some participants will take a placebo (inactive supplement), others will take either a low or high dose of the DailyColors™ supplement which contains a broad range of plant nutrients. These nutrients have been extracted from 16 fruits, vegetables, herbs and spices found in the Mediterranean Diet. These are all thought to reduce inflammation within the body. They could support cardiovascular health, brain health and overall healthy ageing in older adults.

Participants will take DailyColors™ or a placebo twice every day for 60 days (two months). They will complete tests online through the PROTECT website. They will provide a saliva sample for gene analysis through the post. A sub-group of participants will be asked to come to a lab at the University of Exeter on three occasions for blood sampling. You do not have to participate in this sub-group. All participants will have the option to access their gene change data at the end of the study.

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:

DailyColors™ is a unique blend of plant nutrients found in the Mediterranean Diet. This diet has been shown to reduce inflammation, improve brain and heart health and promote healthier ageing. These nutrients have never before been combined in a supplement. It is easier for many people to take a dietary supplement than to completely change their diet. For this reason, we will investigate the effects of DailyColors™ on a wide range of health indicators. These include brain function, heart health, genes, blood proteins and mouth bacteria. These indicators are linked to healthy ageing.

Why have I been approached?

You have been contacted as you are an existing participant in the PROTECT study.
We are looking for people who are:

1. Aged over 50 years of age.
2. With a Body Mass Index (BMI) of 25 or above.
3. Consume less than five cups of tea or coffee every day.

You will not be able to take part if you:

1. Are taking statins, calcium channel blockers (except diltiazem) or some anticoagulants. These may include warfarin, clopidogrel, ticagrelor, ciclosporin, sirolimus, tacrolimus and entocort.
2. You will not be able to take part if you are taking any other medication that has led you to be advised to avoid consuming grapefruit. DailyColors™ contains a grapefruit extract.
3. Take anti-inflammatory medications (painkillers like ibuprofen) more than three times a week.
4. Take a dietary supplement rich in polyphenols (cherry, blueberry, pomegranate or raw cacao).
5. Are allergic to any of the food extracts in the DailyColors™ supplement. These are apple, pomegranate, tomato, beet, olive, rosemary, green coffee, kale, onion, ginger, grapefruit, carrot, grape, blueberry, currant, elderberry, corn starch and sunflower.
6. Have a vegan diet.

What would taking part involve?

If you decide to take part the following steps will take place:

1. You will be directed to the trial section on the PROTECT website. All instructions and assessments can be found here.
2. You will be asked to complete a series of questions to confirm your eligibility. This will include completing a short questionnaire to establish your current health and lifestyle.
3. Provided you are eligible, you will be asked to register with the study. You will confirm that you have read this Participant Information Sheet. A downloadable copy of this is available on the PROTECT website www.protectstudy.org.uk
4. You will be asked to read and sign the consent form. This ensures you understand what the study involves. You will confirm that you are happy to participate in the study.
5. You will then be asked to complete your first (baseline) study assessment. The assessments will be completed online through your PROTECT account. These will take up to one hour and will be:
    a. A set of tests to measure brain function (called a cognitive test battery), which need to be completed in full once at each assessment date.
    b. An Everyday Activities questionnaire. This measures your day-to-day activities.
    c. A Quality of Life questionnaire. This measures your overall health.
    d. A mental health questionnaire. This measures your mood.
    e. A Sleep and Fatigue questionnaire. This measures your levels of tiredness and sleep quality.
    f. A Physical Fitness test battery. This uses short video-led exercises and a brief questionnaire to measure your current physical fitness.
    g. You will then be randomly allocated to receive one of the DailyColors™ doses or a placebo (dummy). The placebo is an identical tablet that does not contain any DailyColors™ content or other active substance. Neither you nor the research team will know which group you are in.

6. You **may** also be invited to take part in the sub-group part of this trial. You do not have to do this. If you are eligible for this sub-group, you will receive a telephone call and/or email. This sub-group will come into a lab at the University of Exeter. You will provide a blood and saliva sample. Your blood pressure will be taken, and your waist measurement will be taken. You will be asked to read a second Participant Information Sheet. You will complete a second consent form.

7. You will be sent your first at-home saliva sampling kit which will contain instructions on how to collect saliva. This needs to be done first thing in the morning before you eat, drink or do any exercise. You will post your saliva sample back to Muhdo Health Ltd, a company that performs genetic profiling.

8. A second pack will be sent to you in the post containing:

    a. Information about how to take your capsules

    b. An activation code to enter in the trial website area so we know you have received your pack.

    c. Your study capsules

9. When you have received your pack containing your capsules you can log into the PROTECT website and activate your study account. You will enter your activation code in the DailyColors™ trial area on the My Studies page. This will let us know you have received your pack.

10. 1You can take your first two capsules in the morning of the first day. You will then take two capsules twice daily for the study period of 60 days. All the capsules will be sent to you at the beginning of the study.

11. One week after you start taking your capsules you will receive a telephone call from our study team. They will check that you are happy with the process. They will answer any questions that you may have.

12. You will be asked to complete the same set of tests as mentioned above after 30 days (except cognitive tests) and again after 60 days. These can all be found on your PROTECT account in the DailyColors™ study area. We will send you an email reminder.

13. You will also be sent a further saliva sample kit to be completed after 60 days (labelled 'Epi 60 days').

14. You will also be asked to complete a report every week to let us know how many capsules you have taken during that time. You will receive a reminder email to do this. You will enter the capsule information into your study account.

15. We would like to have a record of any ill health you experience during the study. You will be asked to answer a set of questions related to your health each time you do the capsule check. This should take 3-5 minutes. If you do report a serious health problem, we may contact you and / or your General Practitioner, (with your permission). If you experience any ill-health you should contact your usual healthcare provider for advice.

16. At the end of the study, we will ask you to complete a survey. You may provide us with suggestions and feedback on your experience of the study. You will also have the option to register with Muhdo Health Ltd to access your DNA and epigenetics data. If you choose to do this we will upload your personal information to the Muhdo portal. You will then receive an email from Muhdo. We will then delete our record of your Muhdo user ID. Any further sampling or data you provide to them will not be accessible to us.

17. We will make the findings of the research available through the study website and newsletter. We will let you know what capsule you were taking.

What will happen to my at-home saliva samples?

You will provide two saliva samples from home during this study. You will post these samples to Muhdo Research Ltd using the pre-paid envelope provided in the sample kit. Muhdo will not receive any other information about you apart from your date of birth and your study ID number. Muhdo will use your samples to extract your DNA. They will analyse them for two outcomes. The first is the genes that make up your DNA. Muhdo specifically analyse genes that are known to be linked to health. The second is your epigenetic profile. This looks at pieces of your DNA that change according to your environment, lifestyle and behaviour. They use these data to provide a profile for your health. This includes your 'biological age', 'eyesight age' and others. This data and the profiles will be uploaded to a web portal. The study team at University of Exeter will be able to download this for analysis. Muhdo will also retain your sample and data as part of their pooled data. This will not be linked to your personal data but they will combine your anonymised data with the data from other participants to conduct analysis and to help develop their research products. You may choose to register with Muhdo at the end of the trial. If this happens, we will provide your personal information to Muhdo so that they can link you up with your genetic information. You can then access your information via a Muhdo account.

What are the possible benefits of taking part?

We cannot promise any health benefits from the DailyColorsTM supplement or the placebo.

If you choose you can access your genetic profile at the end of the study. There is no obligation to do so. However, this data will be available to you at no charge if you wish to register with Muhdo Health Ltd.

What are the possible disadvantages and risks of taking part?

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

Genetic sampling: The saliva sampling process is painless and simple to complete. There are no risks associated with this and no obligation to find out your genetic information.

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

Participation in this study is voluntary. You can choose whether you would like to take part or not. You have the right to withdraw from the study at any time and without giving us a reason. You can do this through the 'Withdraw From Study' link on the website. You can also contact us on the study helpline to withdraw. You may withdraw at any point up until the end of this study. We will contact you to let you know when the study has ended. If you do decide to withdraw from the study we will not collect any further data from you for the purposes of this study. However, all anonymised data collected up until you withdraw will be kept and stored for analysis and regulatory purposes. Withdrawing from this study will not affect your participation in PROTECT or other studies currently affiliated with PROTECT. If you withdraw early, you will still have the choice to be registered with Muhdo Health Ltd.

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 saliva 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 processes personal data for the purposes of carrying out research in the public interest. The University will endeavour to be transparent about its processing of your personal data. This information sheet should provide a clear explanation of this. If you do have any queries about the University's processing of your personal data that cannot be resolved by the research team, further information may be obtained from the University's Data Protection Officer. You can email informationgovernance@exeter.ac.uk. or visit http://www.exeter.ac.uk/ig/

How will my information be kept confidential?

All information collected online in this study will be kept strictly confidential. It will be stored in an electronic database and on an encrypted password protected Microsoft Azure database system at the University of Exeter. This can 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. You will be allocated a unique participant number. This ensures your information is protected and cannot be identified outside of the research team. Any personally identifiable information will be stored separately and securely from information obtained from the research. It will only be kept for a limited time for no more than 10 years after the study has finished. It will then be securely destroyed.

Information collected through Muhdo Health Ltd will be transferred to the University of Exeter using a secure portal. This will use a separate unique participant number to ensure your information is protected. Muhdo Health Ltd will receive your saliva sample and date of birth but no contact details or further personal data. You may choose to register with them after the trial is finished. They will use your anonymised data to support further analysis and research but you cannot be identified in this 'pooled' data.

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?

If you are selected to travel to Exeter to be part of the sub-group then we will reimburse your travel expenses and any reasonable expenses incurred. No other payment will be available to 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 DailyColors^{TM} 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-ethics-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

Thank you for your interest in this project.

Consent to Take Part

- I confirm that I have read the information sheet dated 25/09/2026, version 3.0 (headed 'Main Trial 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 providing a saliva sample at home on two occasions and I understand what this entails.
- I understand that my saliva samples will be transported to Muhdo Health Ltd for analysis and that Muhdo Health will retain my sample and the data arising from the analysis.
- I give consent for Muhdo Health Ltd to process my data for the purposes of this trial and to combine my anonymised data with other participants in this study for internal purposes and for analysis.
- I understand that I have the option to register with Muhdo Health Ltd at the end of this trial to access my genetic information and consent to further use of my data if I wish.
- 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 for the next ten years or as long as I remain in the PROTECT study.
- I confirm I consent to take part in the DailyColors study