PARTICIPANT INFORMATION SHEET

SUNLIGHT EXPOSURE AND VITAMIN D STATUS IN THE UK'S AGEING POPULATION

You are invited to take part in a research study being sponsored by The University of Manchester. Before you decide whether or not you wish to take part, it is important that you understand why the study is being performed and what it would involve for you. Please take time to read the following information carefully. One of our research team will go through it with you and answer any questions you have. Discuss the study with your friends, family or General Practitioner if you wish. Please ask if anything is not clear or you would like more information. Thank you for taking the time to read this.

What is the purpose of this study?
The purpose of this study is to see how effective sunlight is at increasing your vitamin D level. We get most of our vitamin D through exposure to ultraviolet (UV) in sunlight and a small amount from our diet. We want to see much vitamin D you make through the natural sunlight exposure you receive during your normal daily life, and how much you can make when given a course of simulated sunlight (UV) exposures. This will take place between September 2016 and March 2017. After the initial recruitment visits you will make 19 visits to the Photobiology Unit, Salford Royal Hospital. You will undergo UV exposures and be asked to provide blood samples.

Why have I been invited to take part?
This study will involve 125 healthy male and female adults aged 65-84.

Do I have to take part in this study?
Participation in this study is entirely voluntary and will require you to agree to take part. If you do decide to take part you will be given this information sheet to keep and you will be asked to sign a consent form. You can withdraw from the study at any time without giving a reason. If you do withdraw from the study, information gathered to that point may still be used in the research (with your consent) but no additional information will be collected. Should you lose the capacity to consent during the course of the study, you will be withdrawn from the study. Your data and samples already collected (including identifiable data) will be retained for use in the study but no further data or samples would be collected.

What will taking part involve?
This study has two parts. First, all 125 volunteers will take part in a summer and winter assessment of personal sunlight exposure, diet and vitamin D levels. In Part 2, volunteers will receive a course of simulated sunlight exposures with weekly blood samples for measurement of vitamin D levels. Blood samples will be about 20 ml (just over one tablespoon) and will be used to assess vitamin D and your general blood biochemistry including liver, kidney and bone function. For logistical reasons, only 85 volunteers can

participate in Part 2 of the study and those meeting the inclusion/exclusion criteria will be invited to continue

Part 1. Summer and Winter assessments

For 1 week in September 2016 and one week in January 2017 you will wear a small plain square badge on your clothing to measure how much sunlight you receive. There will be 2 badges, one for during the week and one for the weekend. During the same week you will complete a simple daily sun exposure diary to record when you are outdoors, and a diet diary to record any vitamin D-containing food you eat. The following week you will attend the Photobiology Unit to provide a blood sample. We will also ask you to complete a short lifestyle questionnaire regarding sun exposure behaviour.

Part 2. Course of simulated sunlight exposures

This will be a randomised controlled trial where we will measure how vitamin D levels change over a course of UV exposures compared to a course of control or 'mock' exposures which appear identical but do not contain UV. This will take place between January and March 2017. You will be invited to attend the Photobiology Unit before this on two consecutive days (approximately 1 hour each day) for measurement of your sunburn threshold and height and weight, detailed assessment of your sun sensitivity/skin type, and to provide a blood sample. During the first visit, the researcher will mark a site on your upper buttock for UV exposure. The area will then be exposed to UV. You will be asked to return approximately 24 hours later so we can assess your sunburn response by measuring the redness of the skin.

We will then randomly allocate you to either the UV group or control group but you will not know which group you are in. Randomisation is akin to drawing lots or the toss of a coin to decide which group you are in. The UV group will receive a course of low dose (below your sunburn threshold) UV exposures and the control group will receive a course of 'mock' exposures. You will attend the Photobiology Unit 3 times a week (at approximately the same time of day) for 6 weeks where you will be given the exposures in a whole body cabinet. You will be required to wear clothing, which we will provide, representing a T-shirt and shorts such that your hands, arms, lower legs and face are exposed. These areas may tan during the course. You will be asked to provide a blood sample and have your skin colour measured before the first exposure of each week and after the final exposure. These will be short visits of up to 30 minutes each. You will also be asked to attend twice more, 3 and 6 weeks after the course to provide another blood sample to assess how well your vitamin D levels are maintained. Blood will be taken on 10 occasions in total throughout this part of the study. During the first and last week of the course you will be asked to complete a simple daily diary of vitamin D-containing foods you have eaten.

With your consent, anonymised blood samples and data collected during the study may be used in future related research, subject to further ethical approval

Study flow diagrams:

Part 1. Summer and winter assessments

In each of the 2 seasons:

Week 1 - visit Photobiology Unit: Assessment of skin type, height and weight measurement, receive badges and diaries.

Week 2: Wear badges and complete diaries.

Week 3 - visit Photobiology Unit: Return badges and diaries, blood sample taken.

Part 2. Course of simulated sunlight or mock exposures

Sunburn threshold testing/baseline assessments

Visit 1: Blood sample taken, sun sensitivity/skin type assessed, skin exposed to UV.

Visit 2 (24 hours later): UV response threshold determined.

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Course of exposures

Visit 3: - Blood sample taken, skin colour measured.

- Exposure in an irradiation cabinet.

Visit 4 (48 hours after visit 3): Exposure as on Visit 3.

Visit 5 (48 hours after visit 4): Exposure as on Visit 3.

Visits 6-20: Repeat of Visits 3-5 each week for 5 weeks.

Visit 21 (72 hours after Visit 20): Blood sample taken, skin colour measured.

Visits 22 & 23 (3 & 6 weeks after visit 21): Blood sample taken.

What are the possible disadvantages or risks of taking part?

We do not expect there to be any disadvantage from taking part. There may be slight discomfort and bruising following the blood sample. Volunteers taking part in the simulated sunlight part of the study may experience some redness of the skin for a short while after their sunburn threshold has been tested.

What if something goes wrong?

If you have any concerns or there is a problem then please contact the research team on 0161 2060457.

Statement of Indemnity
In the event that something does go wrong and you are harmed during the research you may have grounds for a legal action for compensation against the University of Manchester or NHS Trust but you may have to pay your legal costs.

What are the possible benefits of taking part?
You will not benefit directly from taking part in this study. However, if you are found to have vitamin D deficiency your GP will be informed in order to offer advice and/or treatment.

Will I be reimbursed for this study?
Volunteers taking part in the whole study (summer/winter assessment and course of simulated sunlight or mock exposures) will receive reimbursement of up to £310. Volunteers not having the course of exposures will receive up to £40. Reimbursement is for travel costs, which is made at a flat rate, and for the time and inconvenience of taking part. If a volunteer does not complete the study, reimbursement will be pro-rata based on the number of visits made and samples provided.

What will happen to the results of the study?
The results of this study will help guide future research and may help inform national guidance on sunlight exposure. The results will be published and you will be able to obtain a summary of this from the study team. You will not be identified in any publication of these results.

Will my taking part in the study be kept confidential?
All information given to us and results obtained will be kept in the strictest confidence and will only be accessed by the researchers working on this study, including our collaborator at University College Cork, Ireland, and by people from regulatory authorities and The University of Manchester to check the study is being carried out correctly. Your name and other personal information will not be disclosed other than to inform your GP that you are taking part in the study. Blood samples will be stored under the Human Tissue Authority licence of the University or NHS Trust as appropriate.

Who has reviewed and approved this study?
This study has been reviewed by the Dunhill Medical Trust, the charity which is funding this research. The study has also been reviewed and approved by a University of Manchester Research Ethics Committee.

Contact for further information
If you have any questions at any time during the study you can contact one of the study investigators at Salford Royal Hospital on 0161 2061150.

What if I want to make a complaint?

Minor complaints
If you have a minor complaint then you need to contact the researcher in the first instance:
Mrs Joanne Osman. Tel: 0161 2060457. E-mail: joanne.osman@manchester.ac.uk

Formal complaints

If you wish to make a formal complaint or if you are not satisfied with the response you have gained from the researcher in the first instance then please contact the Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: **research.complaints@manchester.ac.uk** or by telephoning **0161 275 2674** or **275 2046**.

What do I need to do next?

If you are interested in participating in this study, please contact Joanne Osman on 0161 2060457 or by email to joanne.osman@manchester.ac.uk

Thank you for taking the time to read this information.
If you decide to take part in the study please keep a copy of this for your information.