**Study of Low Intensity UV Room Lighting to Prevent Seasonal Vitamin D Insufficiency in Desk Based Clerical Staff (V6 18/01/21)**

**Patient Information sheet**

**Chief Investigator: Dr David Wright, Prof Ann Webb**

Dear Participant

You are being invited to take part in a study of a free standing desk light which has been modified to provide a very small dose of ultraviolet light as well as its normal desk lighting function. This form of lighting has not been tried before and we would like to know if it is well tolerated and whether it improves vitamin D during the winter. The study is being carried out by researchers from the South Tyneside and Sunderland NHS Foundation Trust. Before you make a decision about 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 this information carefully, and discuss it with others if you wish.

Vitamin D is essential for people’s general health. Sunlight, through its ultraviolet light, delivers the most efficient route to sufficient vitamin D levels. Unfortunately, modern lifestyles in urban and often indoor environments lead to a lack of UV exposure. Since 90% of the vitamin D in the body is usually produced via the sunlight absorbed by the skin, and only 10% by the intake of food, very low doses of artificial ultraviolet light supplemented in general room lighting may be a simple, safe way to maintain vitamin D during the winter.

The lighting gives a very low dose of ultraviolet light similar to spending about 15minutes outdoors during a British summer, but spread over 7.5 hours,. The actual dose of ultraviolet light you receive will on depend how long you spend at your desk, and its efficiency for vitamin D synthesis will also depend on how much skin you expose. In this office setting we would like your face and forearms to be uncovered while the light is switched on, and for you to spend your work shift sat at your desk. During the study we will measure how much ultraviolet light you receive using a wrist band and badge, and we will take blood tests to measure vitamin D during the eight weeks you use the lighting and eight week when you are not exposed.

The lights were made and modified by Signify Lighting (Eindhoven), and have been re-tested at the University of Manchester to make sure of safety. It is important that you maintain the correct distance from the light while it is switched on, and avoid looking directly into the lighting. The lights are also fitted with an automatic timer which starts the light at 8.30am and finishes at 4pm. You have been invited to participate in the study because you work at the location where we will conduct the trial, and are otherwise fit and active. Before the study we will perform a score of your skin type based on your skin tone and any history of tanning or burning, called the Fitzpatrick score, to ensure your skin type is safe and likely to respond to low doses of ultraviolet light.

Whether or not you take part in the study is your decision. 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 are free to withdraw from the study at any time without giving a reason. All identifying information will be kept confidential, and each participant will receive up to 50 Euros for personal expenses and inconvenience, depending on expenses incurred. Please contact us if there is anything that is not clear, or if you would like more information (contact details for the research team are at the end of this information sheet).

**What will happen to me if I take part?**

We will arrange for you to meet our Researcher who will assess your skin type using a questionnaire and to have a blood test to measure vitamin D. We will perform a questionnaire to measure general health at a baseline visit and arrange to set up the low intensity desk light, and measuring badge. We will provide you with instructions on how to use this device over the following 8 weeks.

You will complete further questionnaires before and after the eight weeks period you use the light and the control period when you are not using the light. These questionnaires will be used to assess if there is difference in your health status following exposure. You will return after 4, 8, 12 and 16 weeks to have a blood sample to recheck your vitamin D level. After completion of the study, you will be invited to an interview at Sunderland Royal Hospital with a member of the research team to help us understand your experience of using the UVB lamp at work. The audio recording will be transcribed electronically and analysed for common themes. Direct quotes (made anonymous) may be used in study reports.

**What do I have to do?**

If you decide you would like to take part, please contact the researcher named at the end of this information sheet and they can arrange to discuss this study with you in more detail.

**What are the possible disadvantages or risks of taking part?**

Exposure to too much sunlight can cause sun burn, premature skin aging and skin cancer, but the dose of ultraviolet used in this study is extremely small in comparison to normal summer exposure in the UK. UV light therapy is widely used in psoriasis and skin dermatitis, and has a proven safety record. The low intensity UV treatment dose for psoriasis and skin dermatitis is significantly greater than that proposed in this study we consider the risk of premature skin aging and skin cancer is negligible with the dose used in this study. There is a very small risk of skin irritation up to 48 hrs after exposure. This is usually mild, but may require topical treatment with Betnovate cream for 3 days on the arms if a severe reaction occurs (available free of charge to recruits). Any adverse effects such as skin irritation should be reported to the study coordinator using the telephone helpline.

You will have some extra blood tests, with the usual minimal risks and possible associated discomfort but there are no other disadvantages.

**What are the possible benefits of taking part?**

You will find out what your vitamin D status is, and be provided with advice to improve further your vitamin D (if necessary) at the end of the study.

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

You are free to refuse to join the study and may withdraw at any time during the study. This will not affect your care in any way. If you choose to withdraw from this study we will keep and use any data collected about you anonymously as part of the study up until that point. This data will be used in the same way as described in the ‘What will happen with my information and will it be kept confidential?’ section below.

**What will happen to the results of the research study?**

A summary of findings will be made available to all research participants who will be invited to take part in the study

**How will we use information about you and how will it be kept confidential?**

South Tyneside and Sunderland NHS Foundation Trust is the sponsor for this study and is based in the United Kingdom. We will use your information in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information, using it properly and disposing it after the study. Research staff at South Tyneside and Sunderland NHS trust (STSFT) will collect information from you for this research study in accordance with our instructions. STSFT will keep your name, hospital number, date of birth and contact details confidential. STSFT will use this information as needed, to contact you about research, and make sure the relevant information about the study is recorded, and to oversee the quality of the study. STSFT will create a unique code assigned to you for this study. Manchester University will only receive information with your unique study code without any identifying information (such as name, hospital number, date of birth). Data collected as part of this study will be anonymised, and stored on a secure database. If we share the data with other researchers working on this study, it will contain only your unique code with no identifiable information.

All electronically stored data (e.g. blood tests) will be named using your individual study number to ensure confidentiality. Blood samples from participants will be sent to the clinical laboratory at Sunderland Royal Hospital for processing. The sample will be destroyed in the usual way once data from the blood sample has been recorded.

If you consent for us to contact you in the future for further information about this study, the information collected (name, address, telephone number, NHS number) will be kept securely in a secure database and be held by STSFT. Only relevant individuals from the study team will have access to this information.

If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at

* [www.hra.nhs.uk/information-about-patients/](https://www.hra.nhs.uk/information-about-patients/)
* <https://www.stsft.nhs.uk/research-and-innovation/research>
* <https://www.stsft.nhs.uk/patients-and-visitors/caring-our-patients/how-we-use-your-information>
* By sending an email to james.carroll@chsft.nhs.uk, or
* By ringing us on 01915656256 Ext 49906

STSFT will destroy identifiable information about you after the study is finished. We will seek your consent to inform your GP of your participation in the study. A Data Monitoring Committee (DMC) made up of the sponsor, chief investigator and commercial partner (Signify) will be held on a bi monthly basis. The DMC is responsible for reviewing the data, performing interim analyses and advising on any safety issues

**Who is organising and funding the research?**

The study is being carried out by researchers from South Tyneside and Sunderland NHS foundation Trust. The study is being jointly funded by the NHS trust and Signify Lighting.

**Who has approved the study?**

The study has been approved by HSC Research Ethics Committee B.

If you have any problems with the study, you can contact the researchers (see contact details below)

**Complaints procedure**

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 on 0191 5656256 Ext 42232/42247

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

In the event that something does go wrong and you are harmed during the research and this is due to someone’s negligence then you may have grounds for a legal action for compensation against South Tyneside and Sunderland NHS Foundation Trust but you may have to pay your legal costs.

The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

NHS Indemnity does not offer no-fault compensation (i.e. for non-negligent harm) and Sunderland Royal Hospital is unable to agree in advance to pay compensation for non-negligent harm. The Trust may, however, consider an ex-gratia payment in the case of a claim.

**Research Team Contact details**

Helen O’Neil

Sunderland Royal Hospital

Kayll Road

Sunderland

SR4 7TP

0191 5656256 ext 42232/42247

**Thank you for taking the time to read this. You may keep this information sheet.**