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# Sunlight exposure and vitamin D in the ageing po

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 07/11/2016 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 16/11/2016 | Completed | [_] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 14/01/2021 | Skin and Connective Tissue Diseases | [_] Record updated in last year |

## Plain English summary of protocol

Background and study aims
Vitamin D is essential for healthy bones and muscles, particularly in older people where low levels contribute to weak bones and falls. Sunlight exposure of the skin is the major source of vitamin D. Older adults may have reduced capacity of the skin to make vitamin D, but it is unknown how this, or their sun-exposure behaviour, influences their vitamin D levels. This study will examine vitamin D production in 65-84 year-olds following exposure to low amounts of simulated sunlight that mimic national policy on UK summer exposures. In addition, it will compare naturally-gained sunlight exposure levels and vitamin D. The aim of this study is to find out whether exposure to simulated (artificial) summer sunlight while casually dressed can produce a sufficient rise in vitamin D levels in older adults compared to natural sunlight exposure.

Who can participate?
Healthy white Caucasian older adults.

What does the study involve?
In the first part of the study, participants are randomly allocated to one of two groups, with six times more participants being allocated to the first group. Those in the first group are exposed to artificial sunlight containing UV radiation (UVR) three times per week for six weeks. Those in the second group are exposed to sham light (artificial sunlight with the UVR filtered out) three times a week for six weeks. In both groups, the UVR exposure is performed in a horizontal irradiation cabinet (like a tanning bed) and takes approximately 6 minutes. Participants are followed up during the 6 week course of UVR exposures, providing a blood sample at the beginning of each week, as well as being asked to keep a record of their diet for the first and sixth week of the study to assess dietary vitamin D intake.
In the second part of the study, for one week in September and January participants are asked to wear a special badge to measure their sunlight exposure. In the same week, participants use a simple diary to record their time spent outdoors, clothing and sunscreen use, and complete a diet log to estimate dietary vitamin D intake. The following week, participants attend the Photobiology Unit to provide a blood sample to test for vitamin D levels.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating.

Where is the study run from?
Salford Royal Hospital (UK)

When is the study starting and how long is it expected to run for?
March 2015 to December 2017

Who is funding the study?
Dunhill Medical Trust (UK)

Who is the main contact?
Dr Mark Farrar
mark.farrar@manchester.ac.uk

# Contact information

### Type(s)
Scientific

### Contact name
Dr Mark Farrar

### ORCID ID
http://orcid.org/0000-0001-8602-7279

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
30640

# Study information

### Scientific Title
Sunlight exposure and vitamin D status in the UK's ageing population

## Study objectives
The aim of this study is to determine if exposure to simulated summer sunlight while casually dressed can produce a sufficient rise in vitamin D levels to avoid deficiency in older adults (65 years and over) in comparison to vitamin D acquired through natural sunlight exposure.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
1. University of Manchester Research Ethics Committee 1, 05/05/2016, ref: UREC16143
2. North West (Haydock) Research Ethics Committee, 05/07/2016, ref: 16/NW/0467

## Study design
Randomised; Both; Design type: Prevention, Education or Self-Management, Complex Intervention, Cohort study

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Not specified

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied
Specialty: Dermatology, Primary sub-specialty: Dermatology; UKCRC code/ Disease: Musculoskeletal/ Disorders of bone density and structure

## Interventions
Interventional study:
Participants are randomised to one of two groups (active or control) with a 6:1 allocation using a computer-generated randomisation sequence.

Active group: Participants receive exposure 1.3 standard erythemal doses of solar-simulated ultraviolet radiation (UVR) three times per week for six weeks.

Control group: Participants receive sham exposure of irradiation cabinet fitted with filters to block UVR three times per week for six weeks.

In both groups, each UVR exposure is performed in a horizontal irradiation cabinet and takes approximately 6 minutes. Participants wear clothing that reveals the arms and lower legs during the exposure.

Participants are followed up during the 6 week course of UVR exposures, providing a blood sample at the beginning of each week. Participants also complete a diet log during the first and last week of the course to estimate dietary vitamin D intake.

Observational study:
For one week in each of September and January, participants will wear a dosimeter badge to measure their sunlight exposure. In the same week, subjects will use a simple diary to record their time spent outdoors, clothing and sunscreen use, and complete a diet log to estimate dietary vitamin D intake. The following week, subjects will attend the Photobiology Unit to provide a blood sample. The observation period is one week with follow-up one week later.

### Intervention Type
Other

### Primary outcome measure
Serum 25-hydroxyvitamin D concentration measured by liquid chromatography/tandem mass-spectrometry at baseline, 1, 2, 3, 4, 5 and 6 weeks (intervention study) and in September and January (observation study).

### Secondary outcome measures
1. Serum parathyroid hormone measured at baseline and week 6 (intervention) and in September and January (observation)
2. Bone turnover markers measured at baseline and week 6 (intervention) and in September and January (observation)
3. Dietary vitamin D intake assessed thorough diet logs at baseline and week 6 (intervention) and in September and January (observation)
4. Sun exposure measured by dosimeter badges and diaries in September and January (observation only)

### Overall study start date
01/03/2015

### Completion date
31/05/2019

## Eligibility

### Key inclusion criteria
1. Healthy, ambulant, male and female adults aged 65-84 years
2. White Caucasian
3. Willing and capable of participating to the extent and degree required by the protocol

### Participant type(s)
Patient

### Age group
Senior

### Sex
Both

### Target number of participants
Planned Sample Size: 125; UK Sample Size: 125

### Key exclusion criteria
1. Taking medication influencing vitamin D, or that is bone-active or photoactive
2. History of sunbathing/sunbed use within 3 months
3. History of skin cancer or photosensitivity
4. Taking any vitamin D, fish oil or calcium supplements (intervention study only)

### Date of first enrolment
01/06/2016

### Date of final enrolment
01/09/2017

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
### Salford Royal Hospital
Photobiology Unit
Stott Lane
Salford
United Kingdom
M6 8HD

## Sponsor information

### Organisation
University of Manchester

### Sponsor details
FBMH Research Office
3.53 Simon Building
Oxford Road
Manchester
England
United Kingdom
M13 9PL

### Sponsor type

Hospital/treatment centre

**ROR**
https://ror.org/027m9bs27

# Funder(s)

**Funder type**
Charity

**Funder Name**
Dunhill Medical Trust

# Results and Publications

**Publication and dissemination plan**
Outcomes will be communicated to the research community through publication in high-impact open access general and specialist journals within one year of the study end-date. Findings will be communicated to wider audiences via relevant charities and societies promoting research and public education, including the Dunhill Medical Trust (funder). Communication of findings to UK government bodies formulating health policy and guidance relating to vitamin D acquisition will be expedited through the investigatory team's several active roles on relevant public health and medical committees.

**Intention to publish date**
31/12/2021

**Individual participant data (IPD) sharing plan**
The datasets generated during and/or analysed during the current study are/will be available upon request from the Principal Investigator Prof Lesley Rhodes (Lesley.e.rhodes@manchester.ac.uk)

**IPD sharing plan summary**
Available on request

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |