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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
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Contact information

Type(s)
Scientific

Contact name
Dr Mark Farrar

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)

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).

Key secondary outcome(s))
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)

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

Healthy volunteers allowed
No

Age group
Senior

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Charity

Funder Name
Dunhill Medical Trust

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes