

# Hands and face exposure for vitamin D production

<b>Submission date</b> 10/12/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 10/12/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 24/05/2021	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Vitamin D is essential for good health, because it helps our bodies to absorb calcium from the diet. There is a lot of evidence that having enough vitamin D can help prevent against many diseases, such as heart disease, bone diseases and cancer. Although vitamins generally come from the diet, in the case of vitamin D, the majority of people actually get most of it from sunlight. National guidance on requirements for vitamin D assumes that casual exposure of limited areas of skin to summer sunlight is sufficient to avoid vitamin D deficiency. Previous studies have shown that a six week course of exposures to simulated summer sunlight while casually dressed (shorts and T-shirt) can produce adequate vitamin D levels in the majority of the UK white Caucasian population. The aim of this study is to determine if exposure of only hands and face can produce a sufficient rise in vitamin D levels to avoid deficiency.

### Who can participate?

Healthy white Caucasian adults aged between 20 and 60.

### What does the study involve?

All participants undergo a six week course of treatment, in which they are exposed to simulated sunlight (ultraviolet light) wearing clothes that expose only hands and face. Blood samples are taken at the start of the study, and then once a week so that the amount of vitamin D can be measured.

### What are the possible benefits and risks of participating?

Participants will not benefit directly from taking part in this study, however if they are found to have vitamin D deficiency, their GP will be informed in order to offer advice and/or treatment. No notable risks are anticipated, however there may be slight discomfort and bruising following the blood sample.

### Where is the study run from?

Salford Royal NHS Foundation Trust (UK)

### When is the study starting and how long is it expected to run for?

November 2015 to October 2016

Who is funding the study?  
The British Skin Foundation (UK)

Who is the main contact?  
1. Dr Mark Farrar (scientific)  
2. Mrs Joanne Osman (public)

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Mark Farrar

**ORCID ID**  
<http://orcid.org/0000-0001-8602-7279>

**Contact details**  
Photobiology Unit  
Salford Royal NHS Foundation Trust  
Hope Hospital  
Stott Lane  
Salford  
Manchester  
United Kingdom  
M13 9PL

**Type(s)**  
Public

**Contact name**  
Mrs Joanne Osman

**Contact details**  
Photobiology Unit  
Salford Royal NHS Foundation Trust  
Hope Hospital  
Stott Lane  
Salford  
Manchester  
United Kingdom  
M6 8HD

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

19889

## Study information

### Scientific Title

An experimental photodermatology study examining the impact of hands and face exposure on cutaneous vitamin D production

### Study objectives

The aim of this study is to examine the change in vitamin D levels of white Caucasian adults during a course of simulated summer sunlight exposures to the hands and face.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

University of Manchester Research Ethics Committee, 22/10/2015, ref: 15440

### Study design

Non-randomised; Interventional; Design type: Prevention, Treatment

### Primary study design

Interventional

### Secondary study design

Non randomised study

### Study setting(s)

Other

### 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

Topic: Dermatology; Subtopic: Skin (all Subtopics); Disease: Dermatology

### Interventions

All participants undergo the intervention involving solar-simulated ultraviolet radiation. A dose of 1.3 SED (standard erythema dose) is given three times a week for 6 weeks. Blood samples are taken at the start of each week, before the first exposure, and one 3 days after the final exposure. Total duration for treatment and follow-up is 6 weeks.

### Intervention Type

Other

**Primary outcome measure**

Serum 25-hydroxyvitamin D (25(OH)D) concentration is measured using liquid chromatography tandem mass spectrophotometry (LC-MS/MS) at baseline and then weekly for up to 6 weeks.

**Secondary outcome measures**

N/A

**Overall study start date**

20/04/2015

**Completion date**

25/10/2016

## Eligibility

**Key inclusion criteria**

1. Aged 20--60 years
2. Ambulant
3. Healthy
4. White Caucasian (sun-reactive skin type I--IV)
5. Willing and capable of participating to the extent and degree required by the protocol

**Participant type(s)**

Healthy volunteer

**Age group**

Adult

**Sex**

Both

**Target number of participants**

Planned Sample Size: 40; UK Sample Size: 40

**Total final enrolment**

44

**Key exclusion criteria**

1. Sunbathing or sunbed use in the last 3 months
2. Taking photoactive medication or bone active therapies
3. Taking vitamin D, fish oil or calcium supplements
4. History of skin cancer or photosensitivity disorder
5. Pregnancy or lactation

**Date of first enrolment**

23/11/2015

**Date of final enrolment**

31/03/2016

## Locations

### Countries of recruitment

England

United Kingdom

### Study participating centre

**Salford Royal NHS Foundation Trust**

Stott Lane

Salford

United Kingdom

M6 8HD

## Sponsor information

### Organisation

University of Manchester

### Sponsor details

Oxford Road

Manchester

England

United Kingdom

M13 9PL

### Sponsor type

University/education

### ROR

<https://ror.org/027m9bs27>

## Funder(s)

### Funder type

Charity

### Funder Name

British Skin Foundation

**Alternative Name(s)**

BSF

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United Kingdom

## **Results and Publications**

**Publication and dissemination plan**

Primary outcome data will be published once data have been validated and analysed.

**Intention to publish date**

31/12/2021

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Data sharing statement to be made available at a later date