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Effectivity of using a low-dose UVB lighting solution to maintain healthy vitamin D levels

Submission date
03/12/2021

Recruitment status
No longer recruiting

Registration date
03/12/2021

Overall study status
Completed

Last Edited
20/09/2023

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The key objective of this study is to test the effectiveness of a home office lighting solution using low-dose ultraviolet light (UVB) exposure to sustain vitamin D levels of office workers during the winter months. The secondary objective is to explore the correlations between changes in serum vitamin D and indicators of sleep timing, sleep quality, and general levels of fatigue.

Who can participate?
Desk-based office workers, working from home (during COVID-19 restrictions)

What does the study involve?
The study was conducted in the home office of participants. Participants will be allocated to one of two groups, with an equal chance of being in either group (like tossing a coin) where possible. One group will have a desk lamp installed to provide exposure to very low-intensity ultraviolet light spread over 8 hours a day for 8 weeks and the other group will not be provided with additional ultraviolet light exposure. Vitamin D levels will be measured via blood sampling at the start of the study, at 4 weeks, and at 8 weeks. Participants will be asked to complete questionnaires about sleep timing, quality, and fatigue at the same times as the blood samples. Daily questionnaires will also be used to record time spent outside, sunlight exposure duration, and the surface exposed to sunlight.

What are the possible benefits and risks of participating?
There are no specific benefits nor any risks of participating.

Where is the study run from?
Signify (Netherlands).

When is the study starting and how long is it expected to run for?
From October 2020 to March 2021

Who is funding the study?
Signify (Netherlands)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
W20.113

Study information

Scientific Title
Using a Low-dose UVB Lighting Solution During Working Hours: An Explorative Investigation Towards the Effectivity in Maintaining Healthy Vitamin D Levels

Study objectives
We hypothesize that the participants exposed to ultra-low doses of UVB during office hours will demonstrate a less rapid decline in 25(OH)D levels during the eight-week study period (January to March) than the control group without UVB supplementation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/10/2020, Máxima Medisch Centrum, Veldhoven (METC Máxima MC, Postbus 7777. 5500 MB Veldhoven, De Run 4600, 5504 DB Veldhoven, The Netherlands; +31408889528; metc@mmc.nl), ref: W20.113

Study design
Partly-randomized controlled study

Primary study design
Interventional

Secondary study design
Partly randomised

Study setting(s)
Home

Study type(s)
Prevention

Participant information sheet
See additional file (In Dutch)

Health condition(s) or problem(s) studied
Vitamin D deficiency

Interventions
Participants were allocated randomly to the two study conditions as much as possible. This was, however, not possible for several participants as they either changed in their work location or amount of working hours at home before or during the study, or because they did not have grounded electricity outlets in their houses needed for the installation of the lamp. To this end, 9 participants were allocated to the control group before randomization. All participants were

recruited by an independent recruitment organization to ensure independence of the research team.

The study was performed in participants' home offices as COVID-19 regulations asked people to work from home during the study period (January 2021 to March 2021 in The Netherlands). For participants in the intervention group, a lamp was installed at the home office before the start of the study. In the visual wavelength range, the lamp provided an illuminance of about 1100 lx (~ 3700 K) at 20 cm distance and about 100 lx at 80 cm distance. Additionally, the lamp emitted a continuous ultra-low and safe artificial actinic UV irradiance of less than 3.0 mW/m² at 20 cm distance and 0.77 mW/m² at 80 cm distance. This resulted in an estimated maximal received dose of ~0.3 SED (UVI = 0.04) per 8 h workday when seated at the desk. Participants in the intervention group and members of their household were advised to respect the indicated minimum application distance (80 cm). This distance keeps the actinic UV exposure within Risk Group Exempt limits, which allows for a continuous exposure of 30000 sec per day (8 h and 20 min) according to the IEC62471. The UVB irradiance stability was checked by a before and after actinic UVB measurement at the Lighting Test Center Europe, Eindhoven. The equipment used for these measurements consisted of a Cary 17d monochromator and a Keithley 2000 multimeter. The scanned spectral range was 200-800 nm and measurements were executed at 80 cm distance. The averaged actinic UV weighted UVB irradiance before and after were respectively 0.76 mWA/m² (SD = 0.04 mWA/m²) and 0.75 mWA/m² (SD = 0.07 mWA/m²). The stability was realized by an adjustment of the DALI settings at the end of Week 4 to correct for the slow decline in UV intensity due to the lifetime degradation of the used UVB LEDs. Participants in the control group did not receive a lamp in their home office and were therefore not exposed to extra UVB.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Standing lamp with a continuous ultra-low and safe artificial actinic UV irradiance of less than 3.0 mWA/m2 at 20 cm distance and 0.77 mWA/m2 at 80 cm distance.

Primary outcome measure
Serum 25(OH)D level measured using blood sampling and automated immunoassay at baseline, 4, and 8 weeks

Secondary outcome measures
Sleep duration, midsleep timing, sleep quality, and fatigue measured using participant questionnaire at baseline, 4, and 8 weeks

Overall study start date
26/10/2020

Completion date
12/03/2021

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Fitzpatrick skin type II or III
3. Living in/around Eindhoven
4. Medically fit to work the hours as contractually agreed
5. Desk presence (at the home office) of at least 2.5 days per week during the 8 weeks study
6. Finding it no problem to have blood drawn three times over a period of 8 weeks

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
28

Total final enrolment
28

Key exclusion criteria
1. Current pregnancy, breast feeding or a desire to become pregnant
2. Having children at home aged 10 years or younger
3. Having malignant skin conditions in the past or currently
4. Photosensitive medical conditions or photo-sensitising drugs
5. Users of medicines and/or crèmes mentioning in the prescription as side effect extra sensitivity to the sun/interaction with sun exposure
6. Planned use of sun beds, or sunbed use during the past 4 weeks
7. Currently taking or planning to take oral vitamin D3 supplements or have been taking D3 supplements during the past 4 weeks
8. High vitamin D levels at the start of the study (>375 nmol/l) which need medical attention

Date of first enrolment
23/11/2020

Date of final enrolment
18/12/2020

Locations

Countries of recruitment
Netherlands

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Sponsor information

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Signify (Netherlands)

Results and Publications

Publication and dissemination plan
Planned to publish the study in PLOS ONE.

Intention to publish date
31/03/2023

Individual participant data (IPD) sharing plan
Data cannot be shared publicly because of the informed consent form stating that data will only be available to others in an encrypted and password protected institutional online data repository. Data are available upon request via the OSF project page through which requests can be sent to the authors (https://osf.io/qnk26/) or via the institutional Ethics Committee (contact via ethicalreviewboardHTI@tue.nl).

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Dutch language version 3.0		03/12/2021	No	Yes
Protocol file		26/10/2020	03/12/2021	No	No
Results article		31/03/2023	03/04/2023	Yes	No