Explorative investigation towards the effectivity of a special lighting solution in influencing 25(OH)D serum levels

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Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49492

Source
ToetsingOnline

Brief title
Vitamin D3 pilot

Condition

- Other condition

Synonym
VIT D insufficiency; fatigue and sleep

Health condition

VIT D insufficiency and general wellbeing by bringing the benefits of natural daylight inside (i.e. ultra small dose UV-B for VIT D)

Research involving
Human

Sponsors and support

Primary sponsor: Signify research (previously Philips Research)
Source(s) of monetary or material Support: signify

Intervention

Keyword: 25(OH)D, fatigue, lighting, sleep, UV-B, VIT D

Outcome measures

Primary outcome

The main study parameter is the difference in 25(OH)D serum levels.

Secondary outcome

self reported indicators of sleep timing, sleep quality and general levels of

fatigue.

Study description

Background summary

Vitamin D3 is essential for people*s general health. Sunlight, through its UVB irradiance, delivers the most efficient route to sufficient vitamin D3 levels. Unfortunately, the modern lifestyles in urban and often indoor environments lead to a lack of UV exposure in the natural way. Moreover, it is not possible to create sufficient vitamin D in the skin during the autumn and winter months, while vitamin D intake via food is not sufficient. Therefore, supplementation with artificial UVB light seems an unobtrusive solution. This study explores whether addition of artificial low and safe doses of UVB to LED lighting solutions is sufficient to maintain healthy vitamin D3 levels for office workers. 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 than the control group without UVB supplementation.

Study objective

The key objective of the pilot study is to test the effectiveness of a desk-based lighting intervention to sustain 25(OH)D levels of office workers during autumn/winter months. The secondary objective is to explore the correlations between changes in serum 25(OH)D and indicators of sleep timing,

sleep quality and general levels of fatigue.

Study design

This 8-week pilot study involves 28 office workers in which type of lighting is manipulated between subjects (low-dose UVB light exposure vs. no artificial UVB exposure). Randomization will be conducted in case of sufficient eligible participants. Vitamin D blood levels and participants* self-reports on fatigue and sleep timing and quality be conducted three times, with 4-week intervals, supplemented with extremely short daily diaries (i.e., desk presence, time spent outside and body exposure surface).

Intervention

The individual workspaces of 14 office workers will be equipped with the desk-based intervention light and subsequently be exposed to a low dose of artificial UVB during daytime hours with a maximum of 8 hours and 20 min (<0.5 SED, UVI =~0.06 under normal application conditions). The other 14 office workers will act as the control group.

Study burden and risks

The main burden for participation in the study will be the discomfort experienced during blood sampling and the time consumption associated with the blood sampling and completing the questionnaires on sleep timing and quality, and general fatigue (~ 10 min. per long questionnaire and less than 1 minute per daily diary probing desk presence and time spent outside). The frequency of the blood sampling and completing the long questionnaire is three times during eight weeks with an estimated time consumption of 10 minutes per questionnaire and 10 minutes for each blood sampling. Risk assessment in relation to the ultra-low doses UVB indicated that the potential risk associated with photobiological safety are mitigated to negligible/tolerable residual risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Age over 18 years old
* Fitzpatrick skin type II or III
* Desk presence of at least 2,5 days per week during the 8 weeks study period or at least 4 days present in the office.
* Medically fit to work the hours as contractually agreed

Exclusion criteria

* * Current pregnancy, breast feeding or a desire to become pregnant
* Office workers with malignant skin conditions in the past or currently
* Photosensitive medical conditions or photo-sensitising drugs
* Users of medicines and/or cremes mentioning in the prescription as side effect extra sensitivity to the sun
* Planned use of sun beds, or sunbed use during the past 4 weeks
* Currently taking or planning to take oral vitamin D3 supplements or have been taking D3 supplements during the past 4 weeks.
* High vitamin D levels at the start of the study (>375 nmol/L) which need medical attention

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	28
Type:	Anticipated

Ethics review

Not approved

Date:	21-07-2020
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL72938.015.20