

# UV-protection in outdoor workers: a controlled intervention study

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To assess the effectiveness of an intervention aiming at increase of sunscreens use in outdoor workers. Furthermore, to assess external UV-exposure and prevalence of NMSC including actinic keratosis (AK).

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Epidermal and dermal conditions
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON49345

### Source

ToetsingOnline

### Brief title

UV-protection in outdoor workers

### Condition

- Epidermal and dermal conditions

### Synonym

actinic keratosis, non melanoma skin cancer, skin cancer

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Outdoor workers, Sunscreen, Ultraviolet radiation

## Outcome measures

### Primary outcome

Self-reported frequency of sunscreen use. Frequency of sunscreen use averaged per person and day derived from electronic monitoring.

### Secondary outcome

Investigate prevalence of NMSC including AK in outdoor workers

Investigate external and internal occupational UV-exposure in outdoor workers

## Study description

### Background summary

Skin cancer is an increasing public health burden and its incidence is increasing in many countries with predominantly fair-skinned populations. Non-melanoma skin cancer (NMSC) incidence is increasing, annually 2-3 million people worldwide are diagnosed with NMSC. Occupational solar exposure contributes greatly to the overall lifetime UV dose. Outdoor workers experience far higher exposure levels compared to the general population. This is reflected in an excess risk of NMSC showing up to threefold increase in outdoor workers. This can be avoided if the appropriate measures to reduce UVR-exposure are taken e.g. working in the shadow, use of sunscreens or UV-protective clothing. However, sun-safety behaviour in outdoor workers is poor.

### Study objective

To assess the effectiveness of an intervention aiming at increase of sunscreens use in outdoor workers. Furthermore, to assess external UV-exposure and prevalence of NMSC including actinic keratosis (AK).

### Study design

Controlled intervention study in outdoor workers. A single-centre study.

## **Intervention**

Provision of dispensers with sunscreens (SPF 50+) and regular feedback on their use achieved by continuous electronic monitoring. Workers will wear personal UV-sensors on their wrist providing continuous information on external UV-exposure during the work-shift. Stratum corneum (SC) samples will be collected at the beginning, half-way and at the end of the study, for measuring biomarkers of the internal UV-dose. Questionnaires on sun-protecting behaviour will be taken at the beginning and end of the study. A skin examination of body parts exposed to the sun will be performed at the end of the study.

## **Study burden and risks**

The burden and health risk associated with participation is negligible. The outdoor workers will visit the researchers at the study sites three times, once at the beginning of the study (intake and baseline), after six weeks and at the end of the study (3 months). Each visit will take approximately 15 minutes needed for the collection of the SC samples and, at the beginning and end of the study, for the questionnaire. Collection of the SC will be performed by using adhesive tapes, a minimally invasive and painless procedure, which has often been applied in own studies and elsewhere. The provided sunscreen is classified as cosmetics and can be obtained without prescription at the pharmacy or drugstore.

## **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

Working outdoors

Aged 18 years or older

Individual who has read, understood, and signed an informed consent

Willingness to comply to the study protocol

### Exclusion criteria

Participation in, or being in the waiting period for another study

## Study design

### Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Prevention

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-05-2021
Enrollment:	200

Type:

Anticipated

## Ethics review

Approved WMO

Date:

29-04-2020

Application type:

First submission

Review commission:

METC Amsterdam UMC

## 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

NL72818.018.20