The impact of a SmartPhone applicatiOn for skin cancer risk assessmenT on the healthcare system (SPOT-study): A randomized controlled trial.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24380

Source
NTR

Brief title
The SPOT Study

Health condition

Premalignant skin lesions, skin malignancies (including: melanomas, basal cell carcinomas, cutaneous squamous cell carcinomas and rare skin cancers) and benign skin tumors.

Sponsors and support

Primary sponsor: Department of Dermatology, Erasmus MC Cancer Institute Dr. Molewaterplein 40, 3015 GD Rotterdam, the Netherlands
Source(s) of monetary or material Support: This study is initiated by the Erasmus MC University Medical Center Department of Dermatology and is supported by an unrestricted research grant from SkinVision and DSW

Intervention

Outcome measures

Primary outcome

The primary outcome of this study is the difference in skin tumor related care between the intervention group and the control group during 12 months, which is assessed by comparison of:
- The incidence of malignant skin tumors in Palga (national pathology database).
- The incidence of claims for benign skin tumors.
- The incidence of claims for (pre)malignant skin tumors.

Secondary outcome

The secondary outcomes have been defined as:
- The cost-effectiveness of the SVA, which will be measured by the costs per detected skin cancer.
- The impact of SVA usage on primary care, which will be measures by surgical claims in primary care, although rather general coding will be a limiting factor.
- Comparison of the proportion of dermatological care received between the intervention group and the control group: Dermatological care will be specified for new dermatology consultations, follow-up visits, performed biopsies and excisions.
- The proportion of false negative melanomas within 2 years after using the SVA based on linkage with Palga.

Study description

Background summary

Background: Recently, deep learning algorithms have been integrated into smartphone applications that allow risk assessments of skin lesions to be performed at home by people in the general population. The SkinVision app (SVA) is a CE marked class 1 medical device that uses a machine learning algorithm to classify a skin lesion as low or high risk. Based on this classification, users can be advised to visit a doctor when the lesion is at high risk of skin cancer. The SVA is reimbursed by multiple healthcare insurances in Europe, including the Netherlands. Although previous studies have tested the accuracy of the SVA, the impact of smartphone-based skin cancer risk assessments on health care systems is unknown.

Objective: In this prospective randomized study, we will study the effects of the SVA on healthcare consumption in the Netherlands on a population-wide level.

Methods: In this randomized controlled trial, all customers (+/-200.000) of DSW aged >18 years will be invited to participate. After randomization, the intervention group will be offered to use the SVA at no extra costs for the duration of one year. After this year the control group will receive access to the SVA for the period of one year. Both groups will enter a passive

follow-up for 2 years after the use of the SVA. Data will be collected on the incidence of (pre)malignant and benign skin lesions through Palga and on the incidence of claims from the DSW database.

Study objective

Our hypothesis is that the incidence of skin cancer and (pre)malignant diagnosis and related healthcare claims will be higher in the intervention group compared to the control group, while the incidence for benign tumor related claims will be lower in the intervention group compared to the control group.

Study design

The first year of the study will be an active comparison phase in which the intervention group will have access to the SVA and the control group will receive the current standard of healthcare. One year after the start of the study the control group will also get access to the SVA for a year. Both groups will enter a passive follow-up phase after one year of using the SVA. In this period, data will be collected on the incidence of skin malignancies, benign skin lesions and pre-malignancies through Palga. Additionally data on claims will be collected from the database of DSW.

Intervention

The intervention group will be offered to use the SkinVision app for free, for a duration of one year. After this year the control group will receive access to the SVA for the period of one year. Both groups will enter a passive follow-up for 2 years after the use of the SVA.

Contacts

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Eligibility criteria

Inclusion criteria

To be eligible to participate in this study, a subject must meet all of the following inclusion criteria:
- Ability to give informed consent for this study.
- ≥ 18 years old.
- Receive health care insurance from DSW.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Persons without an email address.
- Persons without a (compatible) smartphone.
- Persons without an internet connection.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	09-07-2021
Enrollment:	200000
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description

N/A

Ethics review

Positive opinion
Date: 01-07-2021
Application type: First submission

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
NTR-new	NL9586
Other	Medisch Ethische Toetsings Commissie Erasmus MC, Rotterdam : MEC-2021-0180

Study results

Summary results
N/A