



The Skin Cancer Screening Education Study

Thank you for your time and interest in the Skin Cancer Screening Education Study (SCSES). This research project is being conducted by the Association of Dermatological Prevention (ADP) in cooperation with Dr. Lynne Robertson from the University of Calgary, and with Dr. Gordon Searles from the University of Alberta. The work is being funded by the LEO-Foundation with an unrestricted grant. Ethics approval for the SCSES has been obtained from the Research Ethics Committees of the University of Calgary and of the University of Alberta. This document describes the background, the rationale, and the objectives of the study, and it provides information on what will be required if you agree to participate.

Background

Skin cancer, particular nonmelanoma skin cancer is the most frequently diagnosed cancer worldwide in the white population (Geller *et al.*, 2010). Incidence rates have more than tripled in recent decades (Erdmann *et al.*, 2012) and in most affected countries melanoma mortality rates have not declined. Melanoma and nonmelanoma skin cancer have recognizable early and preliminary stages; if clinicians can identify and treat skin cancer in their patients early, before the patient is aware of any abnormality, lives might be saved, morbidity and costs reduced, and quality of life increased. Although skin cancer is amenable to early detection and screening, hardly any systematic skin cancer screening (SCS) programs exist. Germany is the only country worldwide with a standardized nationwide screening program for melanoma, basal cell carcinoma, and squamous cell carcinoma. Residents who are covered by the statutory health insurance and aged 35 years and above are eligible for a standardized screening examination every 2 years. Since its implementation in 2008, an estimated 20 million of 44 million eligible residents have participated in the program. The SCS examination can be carried out by dermatologists and family physicians, i.e. the SCS examination can be linked to a general health check for individuals aged 35 years and above. The screening procedure is designed as a two-step intervention: if a family physician diagnoses a suspect lesion, the patient is referred to a dermatologist for a second screening examination. If the dermatologist also states a presumptive clinical diagnosis, a skin biopsy is taken for histopathological verification by a dermatopathologist. Alternatively, patients have the option to visit a dermatologist for the initial screening (Choudhury *et al.*, 2012).

The decision of the Joint Federal Committee (the supreme decision-making body of the health care system in Germany) to implement a SCS program was based on the outcomes of a pilot study with more than 360,000 screenees. This pilot study was planned and conducted by the ADP in 2003/4 and it is the largest skin cancer screening study to date. The results show that population-based skin cancer screening was feasible and that screening had an effect on skin cancer epidemiology, i.e. more tumors were detected (increase in incidence) and favorable changes in tumor stage distribution were observed (Breitbart *et al.*, 2012; Waldmann *et al.*, 2012). Furthermore, the results strongly indicate that a standardized SCS program can reduce mortality - within five years of the beginning of the pilot project the melanoma mortality declined approximately 50% in the federal state of Schleswig-Holstein where screenings took place, whereas in the adjacent regions (the rest of Germany and Denmark) no change in mortality was seen. Schleswig-Holstein used to have one of the highest melanoma mortality rates in Germany – now it has the lowest rate (Katalinic *et al.*, 2012).

The key component of the pilot project as well as the nationwide screening program is the mandatory training course for physicians. The training was originally developed for the pilot study and with only few modifications this curriculum is being used for the nationwide SCS program. In order to take part in the

screening program, family physicians and dermatologists must complete the training program. In Germany participation in the training course has a cost (this is not the case in Canada) and successful candidates are awarded the credits for continuing medical education. The content of the curriculum includes, among other topics, an overview of the medical and epidemiological aspects of skin cancer, the skin cancer screening test, and communicative aspects to address potential screenees. Since the start of the program, an estimated 77% of eligible physicians have taken part in this training course.

Rationale for the SCSES

Breitbart *et al.* (2012) hypothesize that the combination of physicians' training and public awareness activities during the pilot study (Anders *et al.*, 2014) lead to the observed *early* decline of mortality in Schleswig-Holstein. The training course has never been thoroughly evaluated, i.e. its effects on screening outcomes have not been examined yet. Preferably this should be done by comparing screening outcomes of a group of trained physicians with non-trained physicians (control group). Due to the nationwide introduction of the SCS program as well as the training course in Germany, a control group or control region where physicians' training has not been implemented is no longer available, i.e. it is not possible anymore to carry out such a study in Germany. For this reason study sites outside Germany were searched for. Of all Canadian provinces Alberta has been chosen as the optimal study location for following reasons: (i) it is an English-speaking province in which the English version of the training program can be used, (ii) there is a single health authority for the whole province, (iii) the skin cancer incidence is quite high, (iv) both, melanoma and nonmelanoma skin cancers are registered by the Alberta Cancer Registry, (v) there are a sufficient number of dermatologists, and (vi) there is currently no skin cancer screening curriculum available.

Objectives of the SCSES

The overall objective of the study is to determine whether the SCS training of family physicians and dermatologists leads to improved screening outcomes.

This will be assessed by achieving a set of primary objectives, i.e. it will be determined whether

- there is an increase of knowledge about skin cancer screening among family physicians and dermatologists that have completed the training program
- immediate clinical screening outcomes are more favorable in the group of trained physicians compared to untrained physicians (no of presumptive diagnoses, no of verified diagnoses based on histopathological reports, no of excisions, no of false-positives tests)
- skin cancer screenings are associated with psychosocial harms (patient-rated well-being)
- this population-based screening study has an effect on the overall incidence of melanoma and nonmelanoma skin cancer, and whether it leads to a stage shift toward early-stage melanoma.

Study design of the SCSES

In order to carefully evaluate the impact of the SCS training program on educational, clinical, and epidemiological outcomes as well as on patient-rated well-being, a *nonrandomized interventional study with a control group* will be carried out. Family physicians and dermatologists in Calgary will be trained in conducting skin cancer screenings (intervention region), while physicians in Edmonton (control region) will not receive training until after the completion of the study. These two metropolitan regions were selected because they have comparable demographic populations, physician resources and are within the same provincial healthcare system.

Screening takes place in both regions and outcomes of both regions will be compared.

What taking part involves

1. We are aiming to recruit 100 family physicians and dermatologists per region (max 200 physicians). Eligible physicians should be registered in Alberta, administer health care either in Calgary or in Edmonton, and have access to the internet in their office.
2. Recruited physicians in Calgary will be required to participate in the SCS training (face-to-face 5.5 hour course), while physicians in Edmonton will complete several podcasts which will take about 1 hour. Knowledge of physicians regarding skin cancer and cancer screenings in general will be assessed pre- and post-training/podcasts.
3. Following completion of the SCS training or podcasts, physicians will start recruiting screenees from their own pool of patients. Screenees should be English-speaking residents of Alberta aged 20+.
4. Trained physicians will carry out skin cancer screenings according to instructions they received in the training course which will take not more than 5 minutes, whereas non trained physicians will conduct screenings as it is standard medical practice. Screenings can be embedded into other clinical examinations such that, the study should not interfere with the daily clinical routine (e.g. into regular physical examinations). Each physician has 17-20 months for screening (screening phase); with a recommended rate of 1 screening examination per business day, max 400 screening examinations per physician are anticipated. This equates to max 40,000 screening examinations per region.
5. The SCSES includes a referral pathway similar to the SCS program in Germany. If a family physician detects a suspicious skin lesion or if the screenee is a high-risk person, a referral to a participating dermatologist for a second screening examination should be done. Subsequent procedures such as biopsy taking, histopathological examination of specimen, and treatment will follow standard medical practice in the intervention region and control region.
6. *After* the screening examination, each screenee should be given the 'patient questionnaire'. This can be done by the nurse/medical assistance or the physician. The screenee should complete the questionnaire while he/she is still in the doctor's office.
7. For each screenee a standardized web-based case report form has to be filled out and submitted to the study team. This will take approximately 2-3 minutes per patient.

What variables will be measured?

In order to evaluate the impact of the training program, physicians' knowledge tests, case report forms, and patient questionnaires of the intervention and control region will be analyzed.

The knowledge tests include items (multiple choice questions) about screening in general, skin cancer, primary prevention counseling, and the screening test. In addition, the diagnostic accuracy and self-assessed confidence-levels in counseling and in making a presumptive skin cancer diagnosis will be analyzed.

Following information will be collected from case report forms: number of screenees, number of clinical examinations, number of referrals, number of tentative diagnoses, number of biopsies, type of biopsies that were performed, number of confirmed diagnoses, tumor thickness, staging. Based on these variables, the number needed to screen (NNS) to detect one skin tumor, the number needed to excise (NNE) to detect one skin tumor, and the number of false-positive test results will be calculated.



The patient questionnaire will be used to evaluate 'patient-rated well-being' during the screening examination, i.e. the perceived burden of screening, the quality of primary preventive counselling, and informed decision-making will be assessed.

Data confidentiality

All information about your participation in this study will be transferred to the study team in Germany, and it will be kept confidential. Data collected on your individual performance and practice will never be exposed. Results of the knowledge tests, case report forms, and patient questionnaires will be published only in aggregate form stratified by region and/or specialty, i.e. identifying information will be removed and no individual, be it patient or physician can ever be identified from research findings.

A description of this clinical trial will be available on www.clinicaltrials.gov. This Web site will not include information that can identify participants. At most, the Web site will include a summary of the results.

Benefits of participation

Participation in the training course and the provision of training material is free of charge. At completion of the course, family physicians will be awarded with 5.5 MainPro-C credits from the College of Family Physicians, and dermatologists will receive 5.5 MOC credits, section 3 from the Royal College of Physicians and Surgeons. *The training course will be offered to physicians in Edmonton after completion of the screening phase.*

Participating physicians will gain confidence in detecting suspicious skin lesions through the immediate feedback from referring physicians and the study team over the 20 months long screening phase. In addition, this study will foster interdisciplinary networking of family physicians, dermatologist, and dermatopathologists, and these established networks could be beneficial for physicians and their clinical practice in the future.

Importance of the SCSES

The results that this 2.5 year-long study will produce are crucial for determining and improving the accuracy of the screening test. This is necessary to achieve the greatest benefit from a screening program. The results of the SCSES are also important for the continuation of the training program in Germany. The German training program has only been evaluated regarding educational outcomes; its impact on clinical and epidemiological screening outcomes and on patient-rated well-being has not been assessed yet.

Key gaps in physician education can also be identified and conclusions can be drawn on potential harms of a SCS program such as number of excisions, number of false-positive tests etc. Only few studies have examined potential harms and risks of skin cancer screenings and existing evidence is rather weak. For this reason organizations like the U.S. Preventive Services Task Force and the Australian Cancer Council do not recommend for or against routine skin cancer screenings. Organizations worldwide could benefit from positive and negative results that the SCSES will generate as it will help them to make clear recommendations in the future.

Furthermore, implementing the SCSES will reveal whether population-based skin cancer screening is feasible in the existing primary care setting in Alberta. The results could provide new insights in skin cancer prevention and could have a significant impact on patient care in Alberta, and the findings are therefore important for stakeholders such as Alberta Health, Alberta Health Services, physician's organizations, and patient groups.

Withdrawal

You may withdraw at any time; just inform our study coordinator that you do not want to participate anymore. All data that you have collected (case report forms and patient questionnaires) should then be submitted and send to the study team. Pending results from histopathological examinations should also be submitted to the study team. You are requested to retain patients' consents and case report forms (source documents) for at least 5 years after the project is closed. We hope that you will still let us contact you for any clarifications that we might need on the data that you have collected.

Thanks again for your interest in our research project. For further information on participation or if you have questions, please visit our website: www.scses-alberta.org or call the study coordinator at (403) 891-7961. If you agree to participate and after verification of the inclusion/exclusion criteria by the study team, you will be requested to sign a 'Consent for Participation' form which repeats exactly all items and information of the study synopsis.

References:

Geller AC, Greinert R, Sinclair C, Weinstock MA, Aitken J, Boniol M, Capellaro M, Doré JF, Elwood M, Fletcher SW, Gallagher R, Gandini S, Halpern AC, Katalinic A, Lucas R, Marghoob AA, Nolte S, Schüz J, Tucker MA, Volkmer B, Breitbart E. *A nationwide population-based skin cancer screening in Germany: proceedings of the first meeting of the International Task Force on Skin Cancer Screening and Prevention (September 24 and 25, 2009)*. *Cancer Epidemiol*. 2010 Jun;34(3):355-8

Erdmann F, Lortet-Tieulent J, Schüz J, Zeeb H, Greinert R, Breitbart EW, Bray F. *International trends in the incidence of malignant melanoma 1953-2008--are recent generations at higher or lower risk?* *Int J Cancer*. 2013 Jan 15;132(2):385-400.

Choudhury K, Volkmer B, Greinert R, Christophers E, Breitbart EW. *Effectiveness of skin cancer screening programmes*. *Br J Dermatol*. 2012 Aug;167 Suppl 2:94-8

Breitbart EW, Waldmann A, Nolte S, Capellaro M, Greinert R, Volkmer B, Katalinic A. *Systematic skin cancer screening in Northern Germany*. *J Am Acad Dermatol*. 2012 Feb;66(2):201-11.

Katalinic A, Waldmann A, Weinstock MA, Geller AC, Eisemann N, Greinert R, Volkmer B, Breitbart E. *Does skin cancer screening save lives?: an observational study comparing trends in melanoma mortality in regions with and without screening*. *Cancer*. 2012 Nov 1;118(21):5395-402.

Waldmann A, Nolte S, Weinstock MA, Breitbart EW, Eisemann N, Geller AC, Greinert R, Volkmer B, Katalinic A. *Skin cancer screening participation and impact on melanoma incidence in Germany--an observational study on incidence trends in regions with and without population-based screening*. *Br J Cancer*. 2012 Feb 28;106(5):970-4.

Waldmann A, Nolte S, Geller AC, Katalinic A, Weinstock MA, Volkmer B, Greinert R, Breitbart EW. *Frequency of excisions and yields of malignant skin tumors in a population-based screening intervention of 360,288 whole-body examinations*. *Arch Dermatol*. 2012 Aug;148(8):903-10.

Anders MP, Nolte S, Waldmann A, Capellaro M, Volkmer B, Greinert R, Breitbart EW. *The German SCREEN project – design and evaluation of the communication strategy*. *Eur J Public Health*. 2014 May [Epub ahead of print].