

**Clinical skin examination outcomes following a video-based behavioral intervention: analysis from a randomized controlled trial**

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## ABSTRACT

**Importance:** Older men are at risk of dying from melanoma.

**Objective:** To assess uptake of clinical skin examination (CSE) and clinical outcomes of CSEs.

**Design:** Behavioral randomized-controlled trial.

**Setting:** Video-based intervention in men 50 years or older.

**Participants:** Between June and August 2008, men 50 years or older were randomized to receive either a video-based intervention (n=469), or brochures only (n=461, response rate=37%), and were interviewed seven months later (n=870, 94% retention).

**Intervention:** video on skin self-examination and skin awareness and written information materials; Control: written information materials only.

**Main Outcome Measures:** 1) Participants who reported a CSE were asked for type of CSE (skin spot, part body or whole body), who initiated it, whether the doctor noted any suspicious lesions, and if yes, how it was managed; 2) doctors completed a case report form that included: type of CSE; who initiated it; number of suspicious lesions detected; how the lesion(s) was managed (excision, monitoring, referral); and 3) pathology reports for excised/biopsied lesion(s).

**Results:** Overall, 540/870 men who self-reported a CSE since receiving intervention materials, 321/540 (59%) consented for their doctor to provide medical information (received for n=266/321, 83%). Uptake of any CSE was similar between groups (246/436, 56% intervention; 229/434, 53% control group participants), but the intervention group were more likely to self-report a whole-body CSE (145/436, 35% intervention vs. 112/434, 27% control, p=0.01). Two melanomas, 29 squamous cell carcinomas, and 38 basal cell carcinomas were diagnosed, with higher proportion of malignancies in the intervention (60%) compared to control (40%; p=0.03).

Attitudes, behaviors, and skin cancer history were associated with higher odds of CSE and skin cancer diagnosis.

**Conclusions and Relevance:** A video-based intervention may increase whole-body CSE and skin cancer diagnosis in older men.

**Trial Registration:** Australian New Zealand Clinical Trials Registry N12608000384358

**Key words:** clinical skin examination, malignant melanoma, skin cancer, video intervention, males, prevention

## INTRODUCTION

Melanoma is a common malignancy of the skin. In Australia in 2008, the age-standardised rate was 65/100,000,<sup>1,2</sup> compared to 21/100,000<sup>3,4</sup> in the USA. While a stabilisation of incidence rates in younger birth cohorts has been observed,<sup>5,6</sup> incidence in older age groups is continuing to increase in the USA, Australia and Europe.<sup>7,8</sup> In the USA, death rates from melanoma have decreased in women whereas they have increased in men.<sup>9</sup>

Removing melanomas when they are thin (< 1mm) is associated with lower morbidity and mortality.<sup>10-12</sup> Early detection is an important strategy to reduce the burden of melanoma,<sup>13</sup> and can be achieved through visual inspection by a lay person (skin self examination (SSE)) or by a clinician (clinical skin examination (CSE)). In 1996, a population-based case-control study suggested that SSE was associated with a survival benefit.<sup>14</sup> A case-control study in Queensland (QLD) showed that melanomas detected during deliberate examinations (by a lay person or a doctor) were thinner.<sup>15</sup> Having one whole-body CSE within the past three years can reduce the risk of being diagnosed with a thick melanoma by 14%.<sup>16</sup> This may improve ten-year survival rates among screened (92.6%) versus unscreened (90.4%) melanoma survivors<sup>16</sup> although lead time bias needs to be considered. CSEs have also been shown in other studies to detect thin melanoma and reduce incidence of thick melanomas.<sup>15, 17, 18,19,20</sup> A skin cancer screening project in Germany reported a reduction in mortality from melanoma in one state offering screening by CSE, compared to states not offering.<sup>21</sup>

Approximately 30% of people attend a doctor for a CSE at least every three years,<sup>22</sup> but older men are less likely than other populations to do so.<sup>16,21</sup> In addition, others have found that men compared to females have worse survival even after controlling for tumour thickness, suggesting that sex-specific biological factors may play a role in survival. Older men are also more likely to be diagnosed with thick melanomas and their melanoma is more likely to be fatal.<sup>23</sup> A cost-analysis estimated that providing CSEs to men 50+ years would incur similar healthcare costs to

other early detection programs such as mammography for breast cancer, or faecal occult blood testing for colorectal cancer.<sup>24</sup> Despite this, melanoma screening is currently not recommended in most countries<sup>25</sup> due to lack of randomized trial evidence for mortality benefit (although one trial is of one currently ongoing).<sup>21,22</sup>

The present study forms part of a randomized controlled trial of a video-based intervention aiming to improve SSE, skin awareness and CSE behaviors in men 50+ years. Previous reports from this trial have focussed on methodology and SSE outcomes.<sup>26,27</sup> This analysis focussed on the pre-specified secondary aim of the trial to assess CSE uptake and outcomes. It aims to assess whether the intervention increased the proportion of men who presented to a doctor for a CSE, who received a whole-body CSE, and who were diagnosed with skin cancer. A further aim was to determine factors other than the intervention or control condition associated with having a CSE or skin cancer diagnosis during the trial.

## METHODS

Ethics approval was received from The Queensland University of Technology's ethics committee (approval number QUT 0600000645). Between June and August 2008, 930 men aged 50+ years were recruited through random selection from the QLD electoral roll (response rate 37%) (Figure 1). Eligibility criteria included proficiency in English, access to a DVD player and no previous history of melanoma. Participants were enrolled into a randomized controlled trial, the Skin Awareness Study (Australian New Zealand Clinical Trials Registry N12608000384358).

*Intervention and control conditions:* Intervention participants received video-based plus written skin awareness educational materials, and control group participants received the same written educational material only.<sup>27</sup> The intervention was underpinned by the health belief model (HBM).<sup>28</sup> The video highlighted the seriousness of a melanoma diagnosis (perceived seriousness according the HMB) risk factors for melanoma and the increased risk of men older than 50 (perceived susceptibility), modelled a whole-body SSE (self-efficacy), presented a melanoma surgeon who encouraged SSE (cues to action) and presentation to a doctor for a whole-body CSE, and showed a CSE being performed (overcome barriers). A national sports personality along with melanoma survivors encouraged men to become skin aware (benefit).

*Main outcome measures:* Outcomes were the prevalence and frequency of having had any type or whole-body CSEs since baseline, as well as clinical and histopathological outcomes of skin lesions treated during the past 6 months. Overall, 469 men were randomized to the intervention group, and 461 to the control group. Baseline telephone survey results were available for 929 participants.<sup>27,26</sup> At baseline, 81% of men reported that a doctor had ever checked any part of their skin for early signs of skin cancer, and 39% had had a whole body CSE within the past 12 months.<sup>26</sup>

For the present analysis, we used data from a telephone interview administered seven months after baseline, along with information from participants' doctors. Participants were asked if they had undergone CSE within the past six months. The validity of CSE self-report was previously established (concordance between self-report and doctor report 94% for CSE within the past 3 years), with some evidence for telescoping when the time interval assessed was shorter (concordance 74% for CSE within past 12 months).<sup>29</sup> If participants reported having had a CSE, we asked about the type of CSE (skin spot, part body or whole body), who initiated it (the participants themselves or their doctor during a consultation for another reason), whether the doctor noted any suspicious lesions, and if yes, how it was managed. With participant consent we asked the doctor to complete a case report form that included: type of CSE; who initiated it; number of suspicious lesions detected; how the lesion(s) was managed (non-surgical treatment, surgical treatment (excision/biopsy), monitoring, referral); and we obtained pathology reports for excised/biopsied lesion(s). Analysis was restricted to CSEs completed after the study starting date, 1<sup>st</sup> October 2008, and before the seven months interview.

### **Statistical analysis**

Analyses were performed using SAS 9.2 and SAS 9.3 software. Descriptive analyses were conducted, and Chi-square tests and Wilcoxon tests were used to assess differences in self-reported outcomes between intervention and control groups. Chi-square tests were also used to compare the distribution of doctors' responses to each question in the case-report forms and diagnostic outcomes between treatment arms. Agreement between patient reported and doctor reported data was assessed using Cohen's kappa.

Bivariate logistic regression analyses of demographic and clinical factors, phenotypic characteristics, SSE behaviors, attitudes and social supports associated with having at least one part or whole-body self-reported CSE during the study period were initially conducted.

Multivariable logistic regression was then used to assess which of these characteristics were

independently associated with self-reported CSE after adjustment for other variables (**key demographic, skin cancer risk factors, sun protection behaviours, and attitudes and beliefs a described previously**<sup>26</sup>), including randomization to intervention or control groups. Factors with a p-value of  $<0.2$  were initially included in the multivariable logistic regression, removed one by one then re-entered while observing changes in the likelihood ratio to derive the most parsimonious model. Terms were retained if  $p\text{-value} < 0.05$  within the multivariable model. Similarly baseline factors independently associated with being diagnosed with a skin malignancy (melanoma, squamous cell carcinoma (SCC) or basal cell carcinoma (BCC)) were established.

## RESULTS

Once baseline interviews were complete (Table 1 presents baseline characteristics), participants were randomized by computer-generated random number list generated separately from other study procedures by the study statistician (PB) into the intervention or control groups stratified by area of residence (south east corner of QLD versus rest of QLD). Due to the nature of the intervention it was not possible to mask participants for their group assignment; however telephone interviewers were working for a professional telephone survey company independent from the research team and blinded to participants' allocation. Seven months follow-up telephone interviews were completed by 870/930 men (94% of those enrolled); Figure 1 summarises participant flow. Demographic characteristics at baseline have been described previously.<sup>26</sup>

*Self-reported outcomes:* Overall at the 7-month interview, 475/870 men (55%) self-reported that a doctor had deliberately checked any part of their skin during the past 6 months, and this did not differ between intervention (246/436, 56%) and control group (229/434, 53%;  $p=0.28$ ). There was also no difference in the number of participants who reported that the doctor looked at a skin spot during a consultation for another reason (intervention 114/436, control 112/434). However, participants in the intervention group (154/436, 35%) were significantly more likely compared to controls (118/434, 27%;  $p=0.01$ ) to report a whole-body CSE during the past six months.

Among participants who reported either a dedicated CSE or skin spot check during another consultation, Table 1 compares the distribution of participants' self-reported outcomes of these consultations. Men in the intervention group were more likely to have been asked by their doctor to return for a follow-up exam ( $p<0.01$ ), but there was no difference between intervention or control groups in relation to self-reported skin lesion treatment (Table 2).

In the multivariable model, baseline factors positively associated with a self-reported CSE within the first six months of the trial included: have a regular GP (OR= 1.49; 95% CI 1.15-1.92); having had a spot or mole removed in the past (OR=1.45; 95% CI 1.24-1.71); currently concerned about a spot or mole (OR=1.31; 95% CI 1.10-1.56); checked own skin in the past 6 months (OR=1.15; 95% CI 1.00-1.33); a history of CSE in the previous 12 months (OR=1.47; 95% CI 1.26-1.70), and sometimes/usually wearing a hat (OR=1.34; 95% CI 1.01-1.78). Within men in the intervention group who reported at least any CSE, those who watched the DVD more than once were more likely to report a whole-body CSE (62%) than those that watched the DVD once (55%) or did not watch it (50%), however, this difference was not statistically significant ( $p=0.34$ ).

Of men who reported a CSE in the previous six months, 321/540 (59%, 159 intervention, 162 control) gave consent for their doctor to be contacted by the study team for further details about the CSE. Men who had black hair colour, no previous history of skin excision or treatment, and no CSE within the 12 months prior to baseline were less likely to consent for their doctor to be contacted (all  $p<0.05$ ). Men who did not provide consent to contact their doctor were less likely to self-report that at least one or more skin lesions were found during the CSE (84/216; 39%) compared to men who gave permission (165/321; 51%)  $p=0.004$ ; and the distribution of their self-reported number of lesions requiring treatment was also lower (median =2; range =1-15) than in men who consented to doctor contact (median = 2; range =1-28);  $p <0.001$ .

In total, medical case report forms and pathology reports (where applicable) were obtained from the doctor for 266 of the 321 (83%) men who consented. Of these case report forms, 211/266 (79%) were for CSEs conducted within the study period and were used in this analysis (104 intervention, 107 control).

*Doctor-reported outcomes:* Based on the case reports received from doctors, men in the intervention group were more likely to receive a whole-body CSE, than those in the control

group (75% vs 61%,  $p=0.05$ ), however men in both groups were equally likely perceived by the doctor to have initiated the CSE (65% vs 58%,  $p=0.31$ ). Following the CSE, doctors treated, monitored or referred one or more lesions in 76% of participants (76% intervention, 77% control). Of those, 49% (104/211) of participants had non-surgical management of one or more lesions (50/104, 48% intervention, 54/107, 51% control). Many of those participants (86/211) were treated by cryotherapy. Overall, 34% (72/211) had surgical excision or biopsy of one or more lesions (41% intervention, 27% control;  $p=0.03$ ), with median number of two lesions found (Table 3). Concordance between self-reported and doctor reported CSE was moderate for whole-body CSE (Cohen's Kappa = 0.53) and for whether any lesions were managed (Cohen's Kappa = 0.43).

Pathology reports were obtained for 130 lesions that were excised or biopsied (85 intervention, 45 control). Overall, two melanomas, 29 squamous cell carcinomas, 38 basal cell carcinomas, 17 solar keratoses, three dysplastic naevi, nine benign nevi, and 32 other pigmented/non-pigmented lesions were diagnosed. The two melanomas were diagnosed in intervention participants. Thus the study obtained a melanoma detection rate of 2/469 (426 per 100,000). In addition, 21 SCCs and 28 BCCs were detected in intervention participants ( $n=104$ ), and eight SCCs and 10 BCCs in control participants ( $n=107$ ). Significantly more skin cancers were detected in the intervention group than the control group (60% and 40%, respectively,  $p=0.03$ ) (Table 3).

Factors positively associated with being diagnosed with a skin cancer during the trial included: being an intervention participant (OR=1.45; 95% CI 1.20-2.08); conducted SSE in the past six months (OR=1.60; 95% CI 1.04-2.48); past history of treatment for a spot or mole (OR=1.78; 95% CI 1.19-2.67); and self-reported CSE in the past 12 months (OR=2.52; 95% CI 1.21-5.23). Men who rarely or never stayed in the shade and men who tanned without burning were more likely to be diagnosed with a skin cancer (OR=1.63; 95% CI 1.10-2.43 and OR=3.24; 95% CI 1.42-7.38, respectively) (Table 4).

## DISCUSSION

While screening for melanoma by CSE for men 50+ years may be cost-effective<sup>30</sup> it is often not recommended due to the absence of evidence of a mortality benefit from randomized clinical trials. However, data from observational studies on the value of CSE for the reduction of melanoma thickness and mortality is accumulating, highlighting benefit for men 50+ years.<sup>16 31</sup> This study found that a video-based intervention designed to increase skin awareness, SSE, and presentation to a doctor with suspicious skin lesions for men 50+ years resulted in a higher prevalence of self-and doctor-reported whole-body CSE than the provision of written materials alone in men who attended for any type of CSE. Among men who had a CSE, 34% had at least one lesion excised or biopsied, consistent with high levels of clinical suspicion for these lesions and highlighting the potential value of facilitating CSEs in this group of older men in Australia.

Compared to the control group, men receiving the video intervention were more likely to self-report a whole body CSE. Also noted by the doctors, a larger proportion of CSEs in intervention participants (75%) were whole body exams –whole body exams were recommended in the video intervention to make certain that lesions located on difficult to see body areas were also assessed.<sup>6,32,33</sup> Our analysis shows that men were more likely to self-reported CSEs if they who had a regular doctor, previous SSEs and/or CSEs, previous treatment of skin lesions or moles, or were current concern about a skin lesion, largely similar to previous findings.<sup>34,35</sup> The complementary nature of SSE and CSE has been noted previously in an investigation of skin cancer early detection behavior among melanoma survivors.<sup>36</sup>

A previous trial of a video-based intervention (the Check-it-out trial),<sup>37,38</sup> compared SSE and CSE outcomes among 1356 men and women (median age 52 years). The intervention included

educational materials provided in paper-based and video format plus individual behavioural counselling (one face-to-face, one telephone session). Control participants received the same attention, but were counselled about healthy diet. Participants randomized to the SSE group were significantly more likely to have skin surgery during the first six months after the intervention (8%), compared to 4% in the diet group. The number of malignancies found was small compared to our study (one melanoma, ten BCCs and three SCCs), most likely due to the younger age group involved and the lower skin cancer risk in the USA than Australia.<sup>8,38</sup> Another trial focusing on improving early detection of skin cancers in men 50+years,<sup>39</sup> randomized men to receive or not to receive photographs of their skin to help detect any changes in lesions. During the two year follow-up period, 34% had a skin excision, similar to the 34% observed in our study. The proportion of malignancies from the excised lesions (58% intervention, 42% control) was also similar to those observed in our study. These authors discussed whether the difference between intervention and control participants in overall excised lesions may have reflected missed lesions in the absence of photographs, or treatment of lesions by cryotherapy in the control participants.<sup>39</sup> However, in our study, the proportion of participants treated with cryotherapy was similar between the two groups. Our findings indicate that in 76% of men who had a CSE reported by their doctor, skin lesions were discovered that required some form of management, **of which 40% and 60% were skin cancers upon pathology report in the control and intervention groups, respectively.** This may suggest that a targeted educational programme such as ours may lead to early detection of melanoma or other skin cancers. While the overall level of excisions may seem high, we previously reported that Australian general practitioners are excellent at diagnosing skin cancer, needing to excise just two skin lesions on average to find one skin cancer.<sup>40</sup> Furthermore, Fransen et al reported that: “..83% of NMSC treatments were administered in people aged 55 years and over, and nearly two-thirds of NMSC treatments were administered in people aged 65 years and over.”<sup>41</sup>

Strengths of this study include its focus on men aged 50+ years, a group most at risk of dying from melanoma. Limitations include that those men who agreed to participate in the trial were already relatively skin aware at baseline (39% self-reported whole-body CSE 12 months before enrolment, with no difference between intervention and control groups). Our results could therefore underestimate the true effect of our intervention program, if less health-aware men are assumed to be more likely to carry unidentified skin cancers. A relatively low proportion of men gave consent for us to contact their doctors (321/540; 59%), mostly out of concern to create work for their doctor, although the response rate from doctors was good (266/321; 83%). This meant that CSE outcomes were available for 266/540 (49%) participants self-reporting a CSE. It is therefore likely that additional malignancies were diagnosed but not captured during the study. Men with fair phenotypes and previous skin excisions were more likely to consent to the doctor being contacted. Compared to men who consented to physician follow-up, men who did not consent self-reported fewer lesions being found during CSEs. Our results may thus overestimate somewhat the number of skin cancers that could be diagnosed if men who did not give consent were at lower risk of skin cancer. As previously highlighted<sup>28</sup>, Skin Awareness Study participants may have been more health conscious than men from general population, and 81% reported at baseline that they had ever had any type of skin examination by a doctor in the past. Our results may therefore overestimate what could be achieved in less health conscious men.

In summary, this trial shows that men 50+ years responded favorably to video-based education, increasing their skin awareness and uptake of whole-body CSE during seven months of follow up. CSEs in men in both groups resulted in a large number of malignancies being diagnosed and treated. We acknowledge that routine use of CSE as a screening tool will place a burden on the healthcare system, and could lead to the detection of skin cancers that are relatively indolent and may never cause death or significant morbidity.<sup>22,25</sup> However, with increasing evidence from observational studies supporting the impact of CSE on the incidence of thick melanomas and

mortality from melanoma,<sup>16, 31, 42</sup> and evidence for potential cost-benefit<sup>24</sup>, these results support implementing behavioral interventions that encourage skin awareness for men 50+ years.

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**Legends:**

Figure 1: Participant flow through study and clinical skin examination outcomes

CSE: Clinical skin examination, SCC: Squamous cell carcinoma, BCC: Basal cell carcinoma

Table 1: Participants' baseline demographic and health characteristics

	Intervention group		Control group	
	n=469	(%)	n=460	(%)
<b>Area of Queensland</b>				
Urban	234	(49.9)	221	(48.0)
Rural	235	(50.1)	239	(52.0)
<b>Age group</b>				
50-60 years	186	(39.7)	206	(44.8)
61-70 years	170	(36.2)	161	(35.0)
71-90 years	113	(24.1)	93	(20.2)
<b>Highest level of education completed<sup>a</sup></b>				
Less than junior high school	45	(9.6)	39	(8.5)
Completed junior high school	109	(23.3)	131	(28.7)
Completed senior high school	91	(19.4)	76	(16.6)
Trade or technical certificate or diploma	107	(22.8)	120	(25.8)
University or college degree	117	(24.9)	93	(20.4)
<b>Employment status</b>				
Employed full-time	189	(40.3)	199	(43.3)
Employed part-time or casual	48	(10.2)	58	(12.6)
Permanently ill/unable to work/looking for work	19	(4.0)	21	(4.6)
Retired	213	(45.4)	182	(39.6)
<b>Household income (yearly, before tax)</b>				
Less than \$20,000	64	(13.6)	56	(12.2)
\$20,001 to \$40,000	131	(27.9)	111	(24.1)
\$40,001 to \$60,000	81	(17.3)	84	(18.3)
\$60,001 to \$80,000	65	(13.9)	47	(10.2)
>\$80,001	105	(22.4)	127	(27.6)
Refused	23	(4.9)	35	(7.6)
<b>Country of birth</b>				
Australia	363	(77.4)	360	(78.3)
Other	106	(22.6)	100	(21.7)
<b>Has a doctor <u>ever</u> deliberately checked any <u>part of your skin</u> for early signs of skin cancer?</b>				
Yes	379	(80.8)	380	(82.6)
No	90	(19.2)	80	(17.4)
<b>In the past 12 months has a doctor deliberately checked the skin on your <u>whole body</u>?</b>				
Yes	182	(38.8)	180	(39.1)
No	287	(61.2)	280	(60.9)
<b>Ever had a skin cancer, mole, or other spot/s removed or treated</b>				
Yes	333	(71.0)	327	(71.1)
No	136	(29.0)	133	(28.9)

<sup>a</sup>Data missing for 1 participant.

**Table 2.** Self-reported outcomes of clinical skin examinations

	<b>Intervention (n=276)</b>	<b>Control (n=264)</b>	<b>P-value (from <math>\chi^2</math> or Wilcoxon test)</b>
Asked by Dr to return for follow-up exam in the future?	n (%)	n (%)	
Yes	136 (49)	94 (36)	<0.01
% of patients with $\geq 1$ lesions found during CSE	131 (47)	118 (45)	0.52
Number of lesions where at least 1 found: median (range)	2 (1-28)	2 (1-20)	0.85
% of patients with $\geq 1$ lesions treated during CSE	116 (42)	101 (38)	0.37
Course of treatment within those with at least 1 lesion treated:			
Excise	59/116 (51)	43/101 (43)	0.22
Other treatment	57/116 (49)	58/101 (57)	

Abbreviations: Dr: doctor; CSE: clinical skin examination

Table 3: Details from clinical skin examinations reported by doctors

	Control (n=107)		Intervention (N=104)*		P-value from regression
	n(%)	OR (95% CI)	n(%)	OR (95% CI)	
<b>Exam initiated by:</b>					
Participant	59 (58%)	1 (Ref)	66 (65%)	1.34 (0.76-2.35)	0.31
Usual or another doctor	43 (42%)	-	36 (35%)	-	
<b>Type of skin exam:</b>					
Whole body	62 (61%)	1 (Ref)	76 (75%)	1.84 (1.01-3.36)	0.05
Part of body or specific lesion	39 (39%)	-	26 (25%)	-	
As a result of CSE, patient received treatment/monitoring/referral	82 (77%)	1 (Ref)	79 (76%)	1.00 (0.53-1.90)	0.99
Number of pts who had lesions non-surgically managed	54 (51%)	1 (Ref)	50 (48%)	0.91 (0.53-1.57)	0.73
Number of lesions non-surgically managed: median (range)	9 (1-30)		3.5 (1-100)		
Cryotherapy	47 (44%)		39 (38%)		
Cream/monitoring/other	7 (7%)		11 (11%)		
Number of pts who had surgical management for lesions (excision or biopsy)	29 (27%)	1 (Ref)	43 (41%)	1.90 (1.06-3.38)	0.03
Number of lesions excised or biopsied: median (range)	1 (1-5)		1 (1-8)		

Table 3 continued:

	Control (n=107)	Intervention (N=104)*	
			<b>P-value</b>
<b>Diagnoses (total lesions n):</b>			
Melanoma	0	2	0.03**
Squamous cell carcinoma	8	21	
Basal cell carcinoma	10	28	
Proportion malignant of total	40%	60%	
Solar keratosis	2	15	
Dysplastic naevus	1	2	
Benign naevus	7	2	
Other pigmented lesions	8	6	
Other non-pigmented lesions	9	9	
<i>Total</i>	45	85	

Abbreviations: CSE: clinical skin examination; pts: patients. \*Denominators vary slightly due to missing data; \*\* p-value from Chi-Square test

**Table 4.** Multivariable model factors associated with being diagnosed with a skin malignancy during the trial (malignant melanoma, SCC or BCC) (N=929, 40/929 diagnosed with malignancy)

		<b>Odds of diagnosis with skin malignancy</b>	<b>Lower CI limit</b>	<b>Upper CI limit</b>	<b>P-value</b>
Treatment arm					
	Intervention	1.45	1.20	2.08	0.05
	Control	1.00	-	-	-
Checked own skin in past 6 months at baseline:					
	Yes	1.60	1.04	2.48	0.03
	No/Unsure	1.00	-	-	-
During last skin check, did the doctor treat any particular spots or skin lesions?					
	Yes	1.78	1.19	2.67	<0.01
	No	1.00	-	-	-
In past 12 months, has a doctor deliberately checked any part of pt's skin for early signs of skin cancer?					
	Yes	2.52	1.21	5.23	0.01
	No/Don't know	1.00	-	-	-
Stays in the shade:					
	Rarely/Never	1.63	1.10	2.43	0.02
	Sometimes/Usually/Always	1.00	-	-	-
On exposure to strong sun for 30 minutes:					0.04
	Burn and not tan	0.89	0.43	1.81	0.74
	Burn then tan	1.16	0.65	2.06	0.62
	Tan slightly without burning	1.00	-	-	-
	Tan a lot without burning	3.24	1.42	7.38	<0.01

Abbreviations: SCC: squamous cell carcinoma; BCC: basal cell carcinoma; CI: confidence interval