Impact of a video-based intervention to improve the prevalence of skin-self examination (SSE) in men 50 years or older: the randomised Skin Awareness trial.

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Background: Men 50 years or older are at increased risk of being diagnosed with thick melanomas and of dying from melanoma.

Objectives: Randomised trial of a video-based intervention compared to control.

Methods: Nine-hundred-and-thirty men (consent rate 37%) from the Australian electoral roll were randomly assigned to receive the video-based intervention plus written materials plus two postcard reminders or control (written materials only (no reminders)). Telephone interviews were conducted at baseline, 7 and 13 months.

Results: Participants' mean age was 64 years, and most (84%) were married or living with a partner. We observed a significant time by group interaction for performing at least partial SSE ($p < 0.001$). By seven months, the proportion of men conducting partial SSE increased from 52% at baseline to 80% in the intervention group compared to the control group (56% at baseline, 69% at seven months, $p < 0.001$). However, by 13 months, both groups reported similar prevalence of partial SSE (83% vs 80%). In addition, at 7 months the intervention group was significantly more likely to examine at least one part of their back ($p < 0.001$) and examine a greater number of body sites ($p < 0.001$). Both groups increased similarly over time in whole-body SSE (increase from baseline to 13 months: intervention group 25%, control group 20%; $p = 0.85$).

Limitations: Relying on self-report for the main outcome measure may have introduced social desirability bias.

Conclusions: Men 50 years or older are responsive to appropriately targeted intervention materials to improve SSE behaviours, with the video-based approach leading to a more rapid uptake of, and greater adherence to, optimal SSE guidelines.

Introduction

In the USA, the incidence of melanoma in men 50 years or older has been steadily increasing over the last two decades to 90/100 000 in 2007, while remaining relatively stable in younger age groups (1). In Queensland, Australia, which has the highest rate of melanoma in the world (2), men aged 50 and over have a two-fold higher risk of melanoma compared to women (incidence rates 209 and 112/100 000, respectively) (2). Older men are also significantly more likely to be diagnosed with thick melanomas and to die from melanoma. Death rates in the USA continue to increase for men diagnosed with melanoma, while they are falling for women (3).

There is now increasing evidence that a visual inspection of the skin by a doctor (clinical skin examination, CSE) (4) or a lay person (skin self-examination, SSE) (5-7) may result in reduced thickness of melanoma at diagnosis and thus improve survival from melanoma. For example, in a Queensland case-control study, people who had received a whole-body CSE in the three years prior to their diagnosis had a 14% lower risk of being diagnosed with a thick melanoma than those who had not, resulting in an estimated 26% fewer melanoma deaths within 5 years in Queensland (4). Berwick and colleagues' landmark case-control study showed that people who had ever performed SSE had a 63% lower risk of being diagnosed with advanced disease (5). Recently Pollitt and colleagues showed that the thoroughness of the SSE was the best predictor of reduction of melanoma thickness (7).

As melanoma frequently occurs on the back in men, a check involving hard to see areas of the body is important (8). However the prevalence of such behaviour is low in the general population. A population-based telephone survey conducted in Queensland (9) found that 26% of all participants had self-examined the skin on their whole body at least once in the past year (only 20% of men aged 50 or older). A number of previous small trials have had success increasing SSE in at-risk populations (10-14), and one large, population-based trial has been conducted. This was called the 'Check-it-out' trial, and defined a thorough SSE as looking at all of seven body areas at least once within the past two months (15). It used a video-based intervention, face-to-face counselling session and a telephone call by a health educator and reported increasing the prevalence of thorough SSE from 18% to 55% (16). However, the Check-it-out trial recruited people attending doctors' practices who would presumably already be health conscious, did not specifically focus on men 50 years or older (mean age=53 years; SD=14.8; 42% male), and used a labour- and resource-intensive intervention (15). Given the successful Check-it-out trial, the importance of SSE in the absence of a routine population-based clinical screening program, and the increased risk of melanoma in men 50 years or older, we designed a randomised controlled trial to determine whether a video-based intervention

without face-to-face contact can increase SSE behaviours in men 50 years or older, selected from the general population.

Our primary aim was to examine the impact of a video-delivered intervention with two mailed reminder postcards compared to a written-materials- only control group on the prevalence of SSE in men aged 50 years or older. The primary hypothesis of this trial was that the prevalence of SSE in the video intervention group would increase by at least 10% more than in the control group. A secondary hypothesis was that the intervention would be more effective in men with lower baseline knowledge and awareness of melanoma.

Methods

Trial methods and baseline participant characteristics have previously been reported in detail (17). Ethical clearance was provided by the Queensland University of Technology ethics committee, and the trial was registered with the Australian New Zealand Clinical Trials Registry (ANZCTR N12608000384358).

Study population

In total, 5000 potential participants (men aged 50 or older) were randomly selected from the Australian electoral roll (enrolling to vote is compulsory in Australia). Names and addresses were manually cross-referenced with the telephone directory, and those whose telephone number could not be found were excluded, resulting in a final list of 2899 potential participants. These men were posted a study pack including a letter of invitation and a colored brochure featuring a well-known sports and TV personality. We sent one postal reminder and made up to two follow-up phone calls to non-respondents. Men were considered ineligible if they had a disconnected phone line, were too ill, could not speak English, or had previously had a melanoma. The overall consent rate was 37% (969 of 2610 eligible); however 39 men withdrew before the study began, leaving a final sample of 930 men who were randomised to the control or intervention condition (Figure 1). Randomisation was by computer-generated random number list, stratified by men's region of residence (metropolitan or other).

Intervention materials

All participants received a package of study materials via mail approximately two weeks following their enrolment in the study. Those in the intervention group received a 12-minute DVD, featuring the above-mentioned sport and TV personality as narrator. The DVD was developed following extensive pilot work as described in our previous publication, and was guided by the extended

Health Belief Model (18). The intervention group were also sent a body chart diagram (for men to note down moles they found, to facilitate self-monitoring and/or to aid recall when visiting a doctor) suitable to be mounted on a fridge, and a page of instructions on how to conduct a whole-body SSE, developed by the researchers, entitled '*The ten step guide to checking your own skin*'. Men also received a standard colour brochure issued by the Cancer Council Queensland entitled '*Take the time to spot the difference*' (19) showing benign and malignant lesions and identifying the features of each. Finally, two and four weeks following the initial mail-out, we sent the men a postcard reminding them to watch the DVD and to examine their own skin.

Men in the control group received the written materials only, but no video, body chart or reminder postcards.

Data collection

Computer Assisted Telephone Interviews (CATIs) were conducted by a professional survey company at baseline, and at 7 and 13 months after study materials were sent to participants. At baseline, information was collected about participants' skin type, skin cancer history, SSE and CSE history (these questions have been previously validated (20)), attitudes and beliefs about skin examination, self-efficacy, and social support. At each of the three time points we collected information about the main SSE outcome measures.

Main outcome measures

Past SSE was assessed with two questions: "In the past six months, have you or someone who is not a doctor, such as your spouse or partner, deliberately checked any part of your skin for early signs of skin cancer?"; and "*How often* in the past 6 months have you or someone who is not a doctor, such as your spouse or partner, checked your skin?". SSE thoroughness was measured by asking men to nominate which of thirteen body area(s) they had examined during their last SSE (including visible sites and the back, the back of the neck and the back of the legs), as well as if they had used a mirror/another person to help them examine difficult-to-see areas.

We computed three measures of SSE, increasing in thoroughness: *partial SSE*, *intermediate SSE*, and *whole body SSE (wbSSE)*. All men who indicated that they had deliberately checked part of their skin in the past six months were considered to have performed at least *partial SSE*. Men who also indicated that they had checked at least one part of their back during their last SSE (including upper/lower back, back of neck/scalp, or back of legs) were considered to have performed at least

intermediate SSE. Men were classified as having performed a thorough *wbSSE* if they indicated that during their last SSE, they had checked each of the thirteen body areas mentioned; **and** had either a) another person help them check their skin or b) used a full length mirror and another mirror to check their skin.

Other outcome measures reported included the frequency of at least partial SSE, and the number of body areas checked during the last SSE. For those in the intervention group, we also documented the number of times they watched the intervention DVD.

Statistical analysis

All statistical analysis was carried out using SPSS for Windows version 17.0 (21). We used descriptive statistics to summarise the intervention and control group participants' baseline demographic characteristics and SSE outcome measures (as described above) at baseline, 7-months and 13-months. Chi-squared and *t*-tests were used to assess differences in baseline variables between the two groups.

Binary logistic regression was used to assess the effect of the intervention on the main outcome measures at each time point. To assess the effect of the intervention on the outcomes over time, we used generalized estimating equations (GEE) with binary or ordinal regression frameworks. The control group at baseline was used as the referent group, against which we compared the intervention group at baseline, and the intervention and control groups at subsequent time points.

To test whether the intervention was more effective among men who had lower prior knowledge/awareness about melanoma, we stratified the analyses by whether or not men reported having had a CSE in the past 12 months, and by whether they had ever had a spot or mole excised (as measured at baseline).

Results

Participant characteristics

Demographic characteristics of participants were similar between the intervention and control groups as previously reported (18) and shown in Table 1. Overall, 716 (77%) men had previously had a prostate specific antigen (PSA) test, and 366 (39%) had had a faecal occult blood test (FOBT) (Table 1).

At 7 months, 93% of the intervention group and 94% of the control group completed their follow-up telephone interview. At 13-months, 90% of the original intervention group and 89% of the control

group participated (Figure 1). Men who did not complete the 7-month interview (n=60) and the 13-month interview (n=99) were similar in terms of age, income, education, skin type, and past SSE/CSE, compared to those who did. Those who did not complete the 7- and 13-month interviews were significantly less likely to have private health insurance compared to men who were surveyed at both these time points (30% vs 47%, $p = 0.024$).

SSE performance at baseline and throughout the intervention period

At least partial SSE

Baseline prevalence of at least partial SSE was similar in the intervention and control groups (52% vs 56%, $p=0.191$). At 7 months, a larger proportion of the intervention group reported at least partial SSE compared to the control group (80% vs 70%; $p < 0.001$) while at 13 months, the groups were similar (83% vs 80%, $p=0.249$). Compared to the control group at baseline, both groups had significantly higher odds of SSE at 7 months (intervention OR: 3.18, 95% CI: 2.36-4.29; control OR: 1.78, 95% CI: 1.41-2.26); increasing by 13 months (intervention OR: 3.94, 95% CI: 2.87-5.40; control OR: 3.15 95% CI: 2.41-4.11) ($p < 0.001$) (Figure 2a).

At least intermediate SSE

At baseline, 47% of both the intervention and control groups reported intermediate SSE (that is, they checked at least one area of their back during their last SSE). The groups were significantly different at 7 months (69% vs 57%, $p < 0.001$), while at 13 months, they were again similar (71% vs 68%, $p=0.325$) (Table 2). Compared to the control group at baseline, both groups had significantly higher odds of intermediate SSE at 7 months (intervention OR: 2.48, 95% CI: 1.88-3.25; control OR: 1.47, 95% CI: 1.18-1.84) and at 13 months (intervention OR: 2.72, 95% CI: 2.06-3.59; control OR: 2.30, 95% CI: 1.82, 2.90) ($p < 0.001$) (Figure 2b).

Whole-body SSE

At baseline a similar proportion of the intervention and control group performed a wbSSE during their last SSE (12% vs 10%, $p=0.531$). At 7 and 13 months more of the intervention group had performed wbSSE compared to the control group, but this was not statistically significant (7 months: 28% vs 23%, $p=0.114$; 13 months: 36% vs 31%, $p=0.083$) (Table 2). Compared to the control group at baseline, at 7 and 13 months the intervention group had around three (OR: 3.20, 95% CI: 2.22, 4.59) and five times higher odds (OR: 4.85; 95% CI: 3.40, 6.92) of performing a wbSSE. Similarly, compared

to baseline, the control group had higher odds of wbSSE at the 7-month time-point (OR: 2.52, 95% CI: 1.82-3.49) and at 13 months (OR: 3.74, 95% CI: 2.69-5.20) ($p = 0.85$) (Figure 2c).

Increase in the number of body areas examined and SSE frequency

Compared to the number of body areas checked by the control group at baseline, the odds of examining a greater number of areas were higher for both groups at 7 months (intervention group OR: 1.82, 95% CI 1.32-2.31; control OR: 1.24, 95% CI: 1.01-1.53); and at 13 months (intervention OR: 2.57, 95% CI 2.01-3.29; control OR: 2.19, 95% CI: 1.79-2.68) ($p=0.003$). With regards to frequency of examination, at baseline 23% of both groups had performed at least partial SSE three times or more over the past six months. At 7 months significantly more men in the intervention group had performed ≥ 3 SSEs (52%) compared to the control group (43%, $p=0.009$); while the groups were similar at 13 months (58% vs 55%, $p=0.325$). Compared to the control group at baseline, the odds of performing ≥ 3 SSEs increased in both groups over time ($p = 0.003$) (Table 2).

Moderators of intervention effect

Stratified analysis showed that the intervention had a larger effect in those men who had not had a skin excision in the past, and in those men who did not report a skin examination by a doctor in the past 12 months at baseline (Table 2).

Intervention dose-response effect

Within the intervention group we observed a significant dose-response effect of the DVD. Men who indicated that they had watched the DVD more than once in the past six months were significantly more likely to perform wbSSE at 7 and 13 months ($p < 0.001$) (Table 3).

Discussion

The Skin Awareness randomised trial was designed to specifically test whether a video-delivered intervention could increase the prevalence of SSE in men 50 years and older. Among all participants the prevalence of any SSE increased by around 30% and wbSSE increased by around 20% from baseline to 13 months. The increased prevalence of SSE occurred sooner in the intervention group than in the control group. The intervention was more effective among men who had not previously had a skin lesion excised, and among men who had not had a CSE in the twelve months prior to the trial. These results have important public health significance since increasing SSE by approximately 10% or more has been estimated to increase the likelihood of presenting to a doctor with a melanoma less than 1mm thick (7), and thus has the potential to increase survival following a diagnosis of melanoma among men 50 years or older (22).

It is interesting that even among those in the control group, and among those who had previous skin excisions or CSE history, rates of SSE rose significantly over the study period. This suggests that the increase was partly attributable to some factor/s apart from the video intervention and/or self-perceived risk of melanoma. We based our control group intervention on our previous study conducted in Queensland, which tested the impact of a glossy brochure when recruiting men to skin screening clinics (23). In that study, addition of the brochure showed little advantage over a standard letter (signed by a sports personality) for the recruitment of men to skin cancer clinics. The coloured brochure we used for recruitment in the Skin Awareness study featured a sports and media personality well-known by men 50 years or older. A recent Belgian study reported that endorsement by a prime-minister successfully attracted men aged 50 years or older to free melanoma screening clinics (24). Use of age- and gender-appropriate models has been recommended (24-25), and endorsement of our study by the TV and sports personality may have increased attention and commitment to skin cancer prevention even among men assigned to the control group. Another reason for increased skin cancer behaviour in our control group participants may have been that written materials on SSE were provided to men. However, in the Check-it-out trial, a similar increase in thorough SSE was observed among the control group (14%); despite the fact that this group received study materials related to diet only (15). The increase may be the result of participants' expectation of being asked about the behaviour at a subsequent time-point.

Those in the control group may also have over-reported SSE. In a recent trial which included an objective measure of adherence to sunscreen use, self-reported adherence was over-estimated by both groups; however, it was over-estimated by a greater percentage in the control group (26). It

was not possible to include an objective measure of SSE in our study, but a similar effect is likely to have occurred, resulting in a reduced difference between the control and intervention groups.

Assignment to the intervention group led to significantly earlier uptake of SSE. We observed a strong dose-response effect; showing that watching the DVD more often was associated with higher odds of performing a wbSSE. Further analysis will explore in more detail the characteristics of those men who chose to watch the DVD more than once, as well as mediators of intervention effects in general, to identify whether the design of the intervention material was more suitable for a particular subgroup of men.

As has been noted by Pollitt et al (7), different studies vary widely in their definition of SSE, and the methods used to assess the thoroughness of SSE. In this study we computed three different measures of SSE with increasing degree of thoroughness. Our definition of wbSSE meant that participants were required to be assisted by another person or to use two mirrors to view the back of the body. The video intervention provided a step-by-step demonstration of wbSSE, and men who received the DVD were more likely to check their back at the 7-month time point. Both groups received a written step-by-step guide to wbSSE. At the end of the study, the control and intervention group were three and four times more likely (respectively) to have performed a wbSSE using a person to help or two mirrors to aid checking the back, compared to the control group at baseline. While the proportion of participants who performed a wbSSE at the end of the study (36% of intervention group, 31% of control group) was lower compared to the 55% reported in the Check-it-out trial, Check-it-out trial participants were not required to use these aids to be assigned a thorough wbSSE completion score (15). Pollitt et al however (7) used a different definition of wbSSE, requiring participants to have used pictures of skin cancers to aid them with SSE.

Video-delivered interventions have many obvious advantages such as being appropriate to those with low literacy, able to transmit culturally-targeted clues, and being available for use at a time and location of the watcher's choice. While more intensive interventions or face-to-face interventions may be more successful in increasing the prevalence of wbSSE, they may be too resource intensive to be disseminated population-wide. In contrast, distribution of our intervention seems feasible and online distribution methods may further increase accessibility (25).

Limitations

Limitations of this study include reliance on self-report of SSE, which when combined with data collection by telephone interviews, may have introduced social desirability bias. The nature of SSE behaviour makes it impractical to measure by other methods such as direct observation. In addition, there is some indication that participants who agreed to participate in the Skin Awareness trial may have been more health conscious than men from general population. For example, a larger proportion of our participants reported they previously had either an FOBT or PSA test (39% and 77% respectively), compared to men in a previous cross-sectional telephone screening survey (16% and 52%) (28). However, our data was obtained 5 years later than those reported by Carriere et al (28), and prevalence of PAS and FOBT may have increased among the older population in Queensland. Finally, due to the nature of telephone assessment, participants were excluded if they had no publicly listed telephone number, which may have introduced selection bias.

Conclusion

In summary, the results of our trial show that SSE behaviour among men 50 years or older is amenable to a suitably age- and gender- tailored intervention. While significant increases in reported SSE prevalence were observed in both the control and intervention group, the intervention materials demonstrated some advantages including quicker uptake, inclusion of crucial areas of the back in SSE and greater increase in frequency of SSE compared to brochures-only. Given the large mortality gains that can potentially be achieved by earlier detection of melanomas, providing support to men 50 years or older through appropriately targeted intervention materials should be considered for population-wide dissemination, especially in high melanoma environments such as Queensland.

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Table 1: Demographic and health characteristics, skin self-examination and clinical skin examination behaviour

Characteristic	Intervention group		Control group	
	n=469	(%)	n=460	(%)
Area of Queensland				
South East Queensland	234	(49.9)	221	(48.0)
Other	235	(50.1)	239	(52.0)
Age group				
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)
Highest level of education completed ^a				
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)
Employment status				
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)
Household income (yearly, before tax)				
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)
Country of birth				
Australia	363	(77.4)	360	(78.3)
Other	106	(22.6)	100	(21.7)
Doctor suggested self-checking of skin	138	(36.4)	147	(39.0)
Doctor showed how to check skin	98	(25.9)	84	(22.3)
Has had a Prostate Specific Antigen (PSA) test	366	(79.6)	350	(74.6)
Has had a Faecal Occult Blood Test (FOBT)	191	(41.5)	175	(37.3)

^a Data missing for 1 participant.

Table 2: Odds (95% confidence intervals) of performing skin examination in the past six months in the intervention group (compared to control group at each time point)

Outcome*	Control		Intervention		p-value	p-value for group x time Interaction
	%	OR (95% CI)	%	OR (95% CI)		
<i>Performed partial SSE</i>						<0.001
Baseline	56.1	1.00	51.8	0.84 (0.65,1.09)	0.191	
7 months	69.5	1.00	80.0	1.76 (1.29,2.40)	<0.001	
13 months	80.2	1.00	83.3	1.23 (0.86,1.75)	0.249	
<i>Performed intermediate SSE</i>						<0.001
Baseline	47.4	1.00	47.3	1.00 (0.77,1.29)	0.231	
7 months	57.3	1.00	68.8	1.65 (1.25,2.17)	<0.001	
13 months	67.8	1.00	71.0	1.16 (0.86,1.56)	0.325	
<i>Performed whole-body SSE</i>						0.850
Baseline	10.4	1.00	11.4	1.14 (0.76,1.72)	0.531	
7 months	22.9	1.00	27.5	1.28 (0.94,1.74)	0.114	
13 months	30.7	1.00	36.4	1.29 (0.97, 1.72)	0.083	
<i>Performed partial SSE at least 3 times</i>						0.003
Baseline	22.8	1.00	23.2	1.02 (0.75,1.39)	0.881	
7 months	42.7	1.00	51.6	1.43 (1.09,1.87)	0.009	
13 months	54.6	1.00	58.1	1.15 (0.87,1.52)	0.315	
<i>Performed partial SSE: among men with no excision history (n=269)***</i>						<0.001
Baseline	42.9	1.00	36.8	0.78 (0.48,1.27)	0.308	
7 months	58.1	1.00	79.5	2.81 (1.60, 4.91)	<0.001	
13 months	69.5	1.00	81.8	1.98 (1.08, 3.62)	0.028	
<i>Performed partial SSE: among men with no CSE in past 12 months (n=395)</i>						<0.001
Baseline	44.3	1.00	39.9	0.84 (0.56, 1.25)	0.379	
7 months	61.7	1.00	80.9	2.63 (1.64, 4.21)	<0.001	
13 months	78.1	1.00	80.7	1.17 (0.69, 1.97)	0.554	

*Control group at each time point is referent category'

***Participants categorised as having 'excision history' if they had ever had a spot, mole, or other lesion removed

Table 3: Dose-response effect of watching the DVD once or more than once on *whole-body SSE (wbSSE)* within intervention group participants

DVD	7 months			13 months		
	Did wbSSE (n, %)	OR (95% CI)	p-value	Did wbSSE (n, %)	OR (95% CI)	p-value
Never watched	17 (15.6)	1		68 (28.3)	1	
Watched once in past 6 months	47 (22.9)	1.61 (0.87,2.97)	0.127	39 (38.6)	1.59 (0.976, 2.59)	0.063
Watched > than once in past 6 months	56 (46.3)	4.52 (2.45,8.61)	<0.001	46 (59.7)	3.53 (2.08,5.98)	<0.001

Fig. 1. Participant recruitment, randomization and follow-up schedule.

^aOne participant who could not be reached for baseline assessment provided data for the 7 and 13 months time points and is therefore included here.

^bThose who could not be contacted at 7 months were considered as still participating, therefore we attempted to recontact them at 13 months.

Figure 2a-c: Odds of performing SSE in the intervention group at baseline and control and intervention groups at subsequent time points, compared to the *control group at baseline* (referent group)*

*Bars represent 95% confidence intervals (CIs)

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