# **BMJ Open** Anxiety, locus of control and sociodemographic factors associated with adherence to an annual clinical skin monitoring: a cross-sectional survey among 1000 high-risk French patients involved in a pilot-targeted screening programme for melanoma

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#### **ABSTRACT**

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Objective The aim of the study was to assess whether adherence to annual clinical skin monitoring is dependent on patient sociodemographic characteristics or personality traits.

Design The study was a questionnaire survey.

Setting and participants Data were collected between February and April 2013 in a sample of 1000 patients at high risk of melanoma who participated in a pilot-targeted screening programme in western France.

Outcome measures Sociodemographic data, overall anxiety level (State-Trait Anxiety Inventory questionnaire), locus of control (Multidimensional Health Locus of Control scale) and levels of anxiety specifically associated with screening and melanoma were collected. Actual participation in the skin monitoring examination was reported by 78 general practitioner investigators.

Statistical analysis Statistical analysis was performed using R statistical software. Factors associated with nonadherence were identified by multivariate analysis. Results Our analysis included 687 responses (526 adherent patients and 161 non-adherent patients). Non-adherence was higher in younger patients and in men (OR=0.63 (0.41-0.99)). Viewing health status as dependent on external persons (OR=0.90, 95% CI 0.83 to 0.97) or determined by chance (OR=0.89, 95% CI 0.80 to 0.98) and overall anxiety (OR=0.98, 95% CI 0.97 to 0.99) were also factors associated with non-adherence. In contrast, there was no link between anxiety specifically associated with the screening performed or melanoma and patient adherence to monitoring. Adherence was higher in married patients (OR=1.68 95% CI 1.08 to 2.60). Conclusions The results of this study suggest that sociodemographic and psychological characteristics should be considered when including patients at elevated risk of melanoma in a targeted screening programme.

Trial registration number NCT01610531; Post-results.

#### Strengths and limitations of this study

- Participation in this questionnaire survey was higher than 70%.
- Our findings are based on actual adherence after several months of follow-up (and not on intention to participate).
- We used validated tools to assess anxiety and locus of control
- We also used Likert scales that were created for our study but were not validated.

#### INTRODUCTION

In the last 20 years, the incidence of melanoma has increased more than that of any other cancer worldwide, reaching 10.9 per 100000 in France, 21.9 in the USA and 55.4 in Australia.<sup>12</sup> The 5-year survival rate of melanoma patients in the localised stage is 98.5% versus 19.9% in the metastatic stage.<sup>12</sup> Although these statistics should lead to increased melanoma screening, decreased mortality with routine screening has not yet been proven,<sup>3 4</sup> and screening the general population would be expensive.<sup>56</sup> One issue is the development of targeted screenings. Recent reviews have reported that melanoma screening is beneficial with regard to melanoma thickness, promoting screening in high-risk populations.<sup>3–7</sup> In addition, our team has experimented with a targeted screening programme using Self-Assessment of Melanoma Risk Score,<sup>7 8</sup> and the results were encouraging because many lesions were identified at an early stage.<sup>910</sup>

As with all cancer screening strategies, the low adherence of patients included in a melanoma screening programme is a concern.<sup>8 9 11 12</sup> In cognitive theories focusing on screening behaviours, motivations, perceived benefits and barriers and the social environment are reportedly key factors related to patient adherence.<sup>13 14</sup> Our team has published two papers focused on the weighting of these factors at various steps of the melanoma targeted screening programme.<sup>15 16</sup> In one, we reported that physician recommendation is a strong predictor of adherence to melanoma screening,<sup>15</sup> and in the second, we found that non-adherence is also linked to logistical barriers such as waiting time for an appointment or conflicting activities (eg, work, family obligations).<sup>16</sup> These findings are consistent with the results of other authors.<sup>11 17 18</sup> A limitation of previous corresponding studies is that they have focused on external factors but neglected potential variations between individuals. Indeed, various cognitive theories state that 'personality' or 'psychological factors' might have a major impact on patient screening behaviour.<sup>13</sup> <sup>14</sup> <sup>19</sup> When informing patients that they are at elevated risk of melanoma, a remaining question is how general practitioners (GPs) should take into account sociodemographic factors or personality traits.

The impact of personality traits on adherence to cancer screening has been poorly studied to date. One potential reason is the complexity of interactions between psychological traits, unconscious thoughts and logistical constraints; another is the lack of appropriate measures for assessing the corresponding concepts. In the Health Belief Model, Rosenstock initially refers to the 'perceived threat' or 'fear of the disease' as the combination of perceived severity of the disease and perceived susceptibility<sup>19</sup> and also refers to 'self-efficacy' (corresponding to a person's beliefs about his/her ability to have an impact on his/her own health). However, Rosenstock did not provide any score or scale to measure these concepts. Other authors have developed theoretical frameworks emphasising the main role of anxiety (rather than 'fear') and locus of control (rather than 'self-efficacy').<sup>20 21</sup> Recent publications refer to these concepts, either within theoretical frameworks<sup>13</sup> or in publications in which these concepts are measured using validated tools.<sup>21-23</sup>

The Fear Arousing Communications Theory<sup>24</sup> suggests that an elevated level of anxiety may be positively associated with healthcare behaviours, whereas too little or too much anxiety may result in denial or avoidance behaviours and thus be negatively associated with screening practice adherence. Rotter's theory is based on the concept 'locus of control'.<sup>20</sup> Distinct from 'self-efficacy',<sup>19</sup> which involves a patient's belief in his/her own abilities, 'locus of control' refers to a patient's beliefs about the power he/she has over his/her life. Locus of control can be classified into three components depending on the tendency to attribute his/her health (1) to destiny or fate ('chance locus') or (2) to external elements ('external locus') or (3) to believe that individuals themselves may improve their health by their own behaviours and choices ('internal locus').  $^{13\ 20}$ 

In this study, we performed a survey involving individuals who had been informed that they were at high risk of melanoma. The aim of this study was to assess whether adherence to the recommended annual skin examination is associated with patient sociodemographic characteristics or the following personality/psychological traits: anxiety, locus of control and anxiety related to melanoma screening.

#### **METHODS**

#### **Design and setting**

A questionnaire survey was conducted between February and April 2013 with patients at high risk of melanoma living in rural and urban areas in western France. Ethical approval was obtained from the Ethics Committee of Tours University Hospital.

#### **Participants**

Participants were patients at elevated risk of melanoma who had been enrolled in a targeted screening programme. The original cohort of patients who participated in the melanoma screening programme was initially formed between April and October 2011 through the involvement of 78 volunteer general practitioners (GPs).<sup>9</sup> The patients had been asked to complete a Self-Assessment of Melanoma Risk Score (SAMScore) questionnaire to determine whether they were at high risk of melanoma (regardless of the reason for the initial consultation with the GP).<sup>89</sup> The SAMScore questionnaire was based on patient responses to seven questions: photo type, freckling tendency, number of moles, residence in a country with strong sunshine, severe sunburn during infancy, personal history of melanoma and family history of melanoma (figure 1). For these patients at elevated melanoma risk, the relative risk of developing a melanoma was estimated to be 11 times higher than that of the general population.<sup>89</sup> When patients were identified as being at high risk according to SAMScore, they were informed about this status by the GP and about the proposed monitoring and provided informed consent. The GP then performed a complete skin examination (CSE), and the patients were referred to a dermatologist when a suspicious lesion was identified during the CSE. One year after their inclusion, the patients were contacted by mail to repeat a CSE with the GP.

For this survey conducted in 2013, a sample of 1000 eligible participants was randomly drawn from the existing cohort database (3976 patients), so that we addressed both representativeness requirements and practical constraints. Two patients who had developed a melanoma since their inclusion were excluded from the survey because specialised monitoring—not monitoring in a general medicine setting—was needed and because measurable anxiety may have been induced by the diagnosis of malignant melanoma (which was not the subject

#### Answer each question by checking the corresponding square

1. What type of skin do you have?

. Skin-type I: very fair skin, blond or red hair, light eyes (blue or green), never tan and always sunburn after sun exposure

. Skin-type II: fair skin, blond or light-brown hair, light eyes (blue or green), usually sunburned

- . Skin-type III: deep skin, brown hair, light to medium eye color
- . Skin-type IV: olive skin, dark-brown hair, brown eyes
- . Skin-type V: brown skin, black hair, black eyes
- . Skin-type VI: black skin, black hair, black eyes
- 2. Do you have freckles? Yes / No
- 3. How many moles do you approximately have on both arms? More than 20 / Fewer than 20
- 4. Have you had one or more episodes of severe blistering sunburn during your childhood or teenage years? Yes / No
- 5. Did you live more than one year in a country where sunshine is high (Africa, French West Indies, southern United States, Australia...)? Yes / No
- 6. Have you been diagnosed with melanoma in the past (it is a skin cancer, arising in melanocytes, skin cells that make skin pigment)? Yes / No
- Have any of your first-degree relatives (parents, children, brother or sister) ever had melanoma? Yes / No / don't know

## According to SAMScore, a patient is considered at elevated risk for melanoma if at least one of these three criteria is verified:

. First criterion: Presence of at least three risk factors among the seven following risk factors: phototype I or II, freckling tendency, number of melanocytic nevi >20 on both arms, severe sunburn during childhood or teenage years, life in a country at low latitude, a history of previous melanoma, a history of melanoma in a first-degree relative

- . Second criterion: A subject under 60 years of age and a number of melanocytic nevi >20 on both arms
- . Third criterion: A subject 60 years old or older with a freckling tendency

Figure 1 Questionnaire used for Self-Assessment of the Melanoma Risk Score (Figure 5).<sup>8</sup>

of the survey). Six other patients who had withdrawn their consent between inclusion and the time of the survey were also excluded. In addition, the addresses of 18 patients had changed. The questionnaire was sent by postal mail to 974 patients. Of the 763 responses received (78.3%), 76 had three or more missing data points and were excluded from the analysis. In total, 687 surveys were included in the statistical analyses.

#### Measures

The questionnaire was developed based on a literature review, followed by unstructured personal face-to-face exploratory interviews with eight high-risk patients who participated in the pilot targeted screening programme for melanoma. The final version of the questionnaire was three pages long.

#### Sociodemographic characteristics

The first page of the questionnaire was used to collect the following sociodemographic data: age, gender, place of residence, education level, socioprofessional category, marital status and number of children.

#### **Overall anxiety**

The anxious nature of each individual was assessed using revised version Y of the State-Trait Anxiety Inventory (STAI) questionnaire,<sup>25 26</sup> a reference tool that has very good internal consistency (Cronbach  $\alpha$ =0.86–0.95)

and good reliability ( $\alpha$ =0.73–0.86).<sup>25</sup> <sup>26</sup> Moreover, the French translation has been validated.<sup>27</sup> This questionnaire includes two parts with 20 questions each and four possible responses per question. Score-based standards for the classification of the assessed subjects have been described.<sup>28</sup>

#### Locus of control

Locus of control was assessed using the Multidimensional Health Locus of Control (MHLC) scale.<sup>29</sup> For a given patient, the scale assesses three independent dimensions: internality, externality/chance and externality/other powerful factors.<sup>29 30</sup> According to this model, an individual is more likely to execute to a behaviour related to health if he/she has a strong internal locus of control. Other individuals have an external locus of control and believe that their health mainly depends on external factors: chance or other powerful factors (or both). The tool has been validated, and it has good internal consistency (Cronbach  $\alpha$ =0.65–0.75) and very good reliability ( $\alpha$ =0.70–0.80).<sup>29</sup> MHLC includes 18 questions, each with four possible responses. A French version is available.<sup>31</sup>

#### Induced and specific anxiety

As no validated tool is currently available for evaluating these aspects, induced and specific anxiety related to (1) the melanoma screening monitoring, (2) being at high risk of melanoma and (3) the fear of melanoma were assessed using three different Likert scales. Participants were provided Likert scales ranging from 0 to 10, with 0 corresponding to 'no anxiety' and 10 to 'maximum anxiety'. Participants were then asked to circle the number corresponding to their assessment of 'the anxiety related to the melanoma screening procedure', 'the anxiety related to being at high risk of melanoma' and 'the fear of melanoma'.

#### Patient adherence to the annual complete skin examination

Patient adherence to the annual clinical skin examination was obtained from the cohort monitoring database, as based on information provided by GPs 6 months after mailing the invitation to participate. Patients who consulted a physician for an annual skin examination after receiving the reminder were considered adherent (regardless of whether they consulted a GP or a dermatologist).<sup>9</sup> Between June and December 2013, all patients for whom no data were available were recontacted by phone to determine whether they had consulted a GP or a dermatologist. All patient data collected during these phone calls were then confirmed or invalidated based on the data obtained from the physician (GP or dermatologist).

#### **Statistical analysis**

All analyses were performed using R V.3.2.3 software (The R archive network). The responses to the questionnaires (strongly agree/agree/disagree/strongly disagree and almost always/often/sometimes/almostnever) were quantitatively coded (1–4 points). Descriptive statistics are presented as means and SD or as distribution frequencies. Factors for which there were too many missing data or data too far from the significance threshold were not included in the analyses. Univariate analysis was used to compare adherent and non-adherent patients using the  $\chi^2$  test or Student's t-test. All variables with a p value <0.20 in univariate analyses and those reported to be linked with melanoma screening behaviours in previous publications (gender, having children) were included in a multiple logistic regression.<sup>32</sup> The selection of variables was based on the Akaike information criterion. Results were reported as ORs and their 95% CI. OR higher than 1 indicated a higher adherence and OR lower than 1 a lower adherence.

#### RESULTS

#### Patient demographic characteristics (table 1)

The survey sample included 687 participants. Among them, 526 performed the annual skin examination, whereas 161 were non-adherent. Mean patient age was 44.8 years. The survey included 170 men (24.75%); 62.45% of the participants were married and 82% had children (table 1). There were large variations in occupation and level of education (table 1).

## Overall anxiety level, locus of control and induced anxiety (table 2)

The mean STAI score was 41.48 and was higher in non-adherent than in adherent patients (43.19 vs 40.95, p=0.012).

The mean score of the 'external persons' dimension of the external locus of control was higher in non-adherent patients than in adherent patients (13.70 vs 13.27, p=0.063), and the mean score of the 'chance' dimension was higher in non-adherent patients than in adherent patients (14.93 vs 14.33, p=0.0020). The mean internal locus of control score was assessed at 13.79, with no significant difference between the groups.

The mean score of the anxiety induced by subsequent melanoma screening monitoring was 2.22/10, and those induced by the awareness of the risk of melanoma and by the fear of melanoma itself were 3.07/10. and 4.61/10, respectively. There were no significant differences between groups for these three variables.

### Factors associated with adherence to annual clinical skin monitoring (table 3)

Multivariate analysis identified eight factors that were significantly associated with adherence to annual clinical skin monitoring. Being older or married was associated with greater adherence. Conversely, factors associated with lower adherence were male gender, having children, overall anxiety level and considering health status to be mainly dependent on external persons or chance (table 3). Values for other parameters were not significantly different between the groups.

Table 1 Demographic characteristics of the participants								
	Total n=687		Adherent patients n=526		Non-adherent patients n=161		Р	
	n; %	mean, SD	n; %	mean; SD	n; %	mean; SD		
Age		44.82; 14.16		46.08; 14.46		40.71; 12.28	<10 <sup>-5</sup>	
Male gender	170; 24.75		127; 24.14		43; 26.71		0.58	
Marital status								
Married	429; 62.45		341; 64.83		88; 54.66		0.025	
Single	181; 26.3		129; 24.52		52; 32.30		0.036	
Divorced	45; 6.55		30; 5.70		15; 9.32		0.073	
Separated	8; 1.16		4; 0.76		4; 2.48		0.065	
Widowed	24; 3.49		22; 4.18		2; 1.24		0.19	
Having children	559; 81.37		428; 81.37		131; 81.37		1.00	
Occupation								
Farmer	13; 1;89		10; 1;90		3; 1.86		1.00	
Worker	51; 7.42		40; 7.60		11; 6.83		0.88	
Employee	316; 46.00		240; 45.63		76; 47.20		0.79	
Intermediate occupation	120; 17.47		89; 16.92		31; 19.25		0.57	
Business owner, manager	76; 11.06		54; 10.27		22; 13.66		0.10	
Other	111; 16.16		93; 17;68		18; 11.18		0.066	
Level of education								
Primary/elementary school	60; 8.73		53; 10.08		7; 4.35		0.056	
Secondary school	163; 23.73		125; 23.76		38; 23.60		1.00	
High school	113; 16.45		94; 17.87		19; 11.80		0.090	
Bachelor studies	167; 24.31		124; 23.57		43; 26.71		0.48	
Postgraduate studies	184; 26.78		130; 24.71		54; 33.54		0.035	

#### DISCUSSION

In our study, patient non-adherence to the annual clinical skin examination appeared to be dependent on personality/psychological traits, particularly external locus of control (considering one's health status as dependent on external persons or determined by chance) and overall anxiety. Our study also identified the following sociodemographic factors related to screening non-adherence: male gender, being single and having children. In contrast, being married and

	Total n=687 mean, SD	Adherent patients n=526 mean, SD	Non-adherent patients n=161 mean, SD	Р
Overall anxiety				
STAI	41.48; 9.49	40.95; 9.27	43.19; 9.99	0.012
Locus of control (multidimensional health locus of control)				
Internal	13.79; 2.16	13.84; 2.20	13.64; 2.02	0.30
External/Other powerful factors	13.37; 2.49	13.27; 6.47	13.70; 2.56	0.063
External/Chance	14.47; 1.97	14.33; 1.89	14.93; 2.17	0.0020
Induced and specific anxiety (Likert 0–10) related to				
Melanoma screening monitoring	2.22; 2.15	2.20; 2.11	2.31; 2.29	0.57
Being at high risk of melanoma	3.07; 2.31	3.04; 2.28	3.16; 2.40	0.60
Fear of melanoma	4.61; 2.82	4.61; 2.78	4.60; 2.98	0.97

STAI, State-Trait Anxiety Inventory questionnaire.

Table 3Factors related to adherence to an annual clinicalskin monitoring in patients at high risk of melanoma (logisticregression analysis)

	<b>OR</b> <sup>*</sup>	95% CI	Р
Age			
Age<30	Ref		
30 <age <40<="" td=""><td>1.73</td><td>0.91 to 3.31</td><td>0.095</td></age>	1.73	0.91 to 3.31	0.095
40 <age <50<="" td=""><td>2.27</td><td>1.16 to 4.52</td><td>0.018</td></age>	2.27	1.16 to 4.52	0.018
50 <age <60<="" td=""><td>1.70</td><td>0.82 to 3.55</td><td>0.16</td></age>	1.70	0.82 to 3.55	0.16
60 <age <70<="" td=""><td>8.73</td><td>3.4 to 24.97</td><td>&lt;10<sup>-4</sup></td></age>	8.73	3.4 to 24.97	<10 <sup>-4</sup>
Age>70	6.85	1.99 to 32.26	0.0053
Being married	1.68	1.08 to 2.60	0.020
Male gender	0.63	0.41 to 0.99	0.042
Having children	0.44	0.23 to 0.80	0.0085
Overall anxiety (STAI)	0.98	0.96 to 1.00	0.029
External/Other powerful factors (MHLC)	0.90	0.83 to 0.97	0.0092
External locus/Chance (MHLC)	0.89	0.80 to 0.98	0.016

\*OR lower than one for factors related to lower adherence; OR higher than one for factors related to higher adherence. MHLC, Multidimensional Health Locus of Control; STAI, State-Trait Anxiety Inventory guestionnaire.

older age were associated with greater adherence to the CSE.

In accordance with theoretical frameworks derived from the Health Belief Model,<sup>13</sup> <sup>14</sup> <sup>20</sup> <sup>21</sup> this study assessed whether patient health behaviours are modified by personality traits and sociodemographic factors. Our findings might help GPs in personalising prevention messages when facing a patient at elevated risk of melanoma. Previous publications related to melanoma screening have focused on factors accessible to clinicians and policy-makers, allowing the development of undifferentiated actions to improve patient healthcare routes. The findings of our study provide insight into the impact of patient characteristics and personality and emphasise the need to personalise communication. Figure 2 provides an adapted version of the Health Belief Model, as based on our findings.

Overall, this study demonstrates a statistical link between STAI or HLOC score and adherence with an annual clinical skin examination. On the one hand, the clinical significance of such statistical links is difficult to determine; on the other hand, we assume that these ORs should be considered as important. The STAI or HLOC score was analysed as a continuous measure, such that a one-point increase in the score would lead to multiplication of adherence by the corresponding OR. (In contrast, other variables were considered dichotomous variables.) The importance of the locus of control in adherence with melanoma screening is consistent with the findings of other authors for other cancer sites.<sup>21 33</sup> The study by Hallal is one of the first to use health locus of control as a predictor of behaviour in cancer screening.<sup>34</sup> In contrast, our findings focusing on links between overall anxiety and adherence with screening do not support previous results for breast, colon and prostate cancers,<sup>21 23 33-36</sup> for which the most anxious patients participate more in screening.<sup>21 23 33-36</sup> However, our results are consistent with those of studies on pilot screening for ovarian cancer, in which the most anxious patients appeared to be less adherent.<sup>37-40</sup> It might be assumed that screenings for melanoma or ovarian cancer are still experimental and focus on lesser known locations. Screenings for breast, colon



Figure 2 Factors leading to adherence to annual clinical skin examination (adapted from the Health Belief Model).

<u>6</u>

and prostate cancers are, in contrast, very common and are the subject of public health campaigns. Assessment of obstacles and benefits for anxious patients may lead to lower adherence for screenings that are still experimental. Taken together, providing a clear picture of how anxiety might influence behaviour remains a challenge. One hypothesis is that anxiety might have a different impact depending on the situation (patient, type of cancer). Indeed, anxiety would have a negative impact on adherence in a patient convinced that cancer evolution depends largely on fate, whereas anxiety would lead to greater adherence in patients convinced that cancer evolution depends on early diagnosis (figure 2).<sup>21</sup>

Finally, our study demonstrates a relationship between adherence and various sociodemographic factors, in accordance with previous publications.<sup>35–38</sup> Men and younger patients are less adherent to prevention approaches.<sup>35 36</sup> Being in a relationship has also been reported by several authors to be a factor associated with better adherence to melanoma screening.<sup>37 38</sup> In our study, we did not find any influence of education level on adherence, whereas other authors have reported lower adherence in populations with lower education levels.<sup>8 39 40</sup>

This study has many strengths. Participation in the survey was high (more than 70%), and the proportions of adherent and non-adherent patients among the patients who completed the questionnaires were consistent with the figures published as part of the general monitoring of the entire cohort<sup>9 10</sup>; therefore, our results should be representative. In addition, we used validated tools to assess anxiety and locus of control. Finally, we did not examine the intention to participate; rather, we analysed the data by integrating information about actual adherence or non-adherence to annual clinical skin monitoring after several months of follow-up.

Nonetheless, this study has some limitations. First, the psychology of the individuals was only explored in relation to overall anxiety (STAI), locus of control (MHLC) and induced anxiety (Likert scales). Indeed, we intentionally limited the number of tools so that the questionnaire was not too long. Because the scores used to assess the psychological characteristics of individuals included numerous items, we therefore had to limit the explored fields to avoid discouraging some participants. Second, we used simple Likert scales for exploring induced anxiety. We opted for these scales because no adapted tool has yet been published. Although the use of Likert scales is common in many publications, the scale created for our study was not validated. Third, the design of our study did not allow for assessing the impact of various modalities used by GPs to reveal a high-risk status to a patient (though the approach could influence the patient's anxiety level). Fourth, the study was performed with a French population, and there might be cultural specificities related to psychological factors. Fifth, the potential for selection bias remains: the study was based

on people who signed up for screening in 2011, the results tell us about secondary failure in patients who were screened already and not about any wider population (and nothing about people who would never get screened at all).

Overall, this study allowed for analysis of factors associated with adherence to annual clinical skin examination in a targeted screening of melanoma conducted in primary care. This is a major issue because participation can be disappointing, even for programme implemented for several years, such as screening programme for breast or colorectal cancer. Associations between poor adherence and younger age or male gender are repeatedly identified, and physicians should be aware of these factors. Our study confirms that being married is a factor related to adherence to melanoma screening. Finally, our work highlights the fact that GPs should consider the psychology of each patient: in our study, patients with a strong external locus of control-who were likely more fatalistic-as well as anxious patients were less adherent.

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**Contributors** CR conceived of the study, participated in its design and supervision and was responsible for the GP network and for drafting the manuscript. SH was responsible for data management, performed the statistical analysis and participated in drafting the manuscript. AG participated in data management and the statistical analysis and helped to draft the manuscript. AK and BD participated in the design and provided administrative and technical support. ABA participated in the study design and helped to develop the survey questionnaire. JMN participated in the design of the study, was responsible for the statistical analysis, helped to draft the manuscript, and obtained the grant for the pilot targeted melanoma screening program. All authors read and approved the final manuscript.

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