Original Investigation

Early Detection of New Melanomas by Patients With Melanoma and Their Partners Using a Structured Skin Self-examination Skills Training Intervention
A Randomized Clinical Trial

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IMPORTANCE More than 1 million patients with melanoma in the United States are at risk to develop a second primary melanoma. Early detection of melanoma improves survival. Patients with melanoma may be able to self-manage care with their skin-check partners ("partners") and alert the physician when a concerning lesion is identified, thus providing an important adjunct to yearly skin examinations by a physician.

OBJECTIVE To evaluate the effect of a structured skin self-examination (SSE) intervention for patients with melanoma and their partners ("dyads") on SSE performance and the detection of new melanomas by the dyad or the physician.

DESIGN, SETTING, AND PARTICIPANTS Randomized clinical trial with 24-month follow-up assessments. Patients with stage 0 to IIB melanoma and their skin-check partners participated from June 6, 2011, to April 24, 2015.

INTERVENTIONS Dyads of patients and their partners were randomly assigned to receive the skills training intervention or customary care (control group).

MAIN OUTCOMES AND MEASURES The main outcome was frequency of SSE performance. The secondary outcome was detection of a new or recurrent melanoma by the dyad or physician. The tertiary outcome was the number of unscheduled physician appointments for concerning lesions.

RESULTS The study cohort comprised 494 participants. The patient population was 51.2% (253 of 494) female and had a mean (SD) age of 55 (10) years. Patients in the intervention arms had significantly increased SSEs with their partners at 4, 12, and 24 months ($P < .001$ for all) compared with the control group (mean differences, 1.57 [95% CI, 1.29-1.85], 0.72 [95% CI, 0.39-1.06], and 0.94 [95% CI, 0.58-1.30], respectively). Patients in the intervention arms identified new melanomas more than those in the control group ($\chi^2_1 = 28.77$, $P < .01$ [n = 51 melanomas in situ] and $\chi^2_1 = 6.43$, $P < .05$ [n = 18 invasive melanomas]) and did not increase physician visits.

CONCLUSIONS AND RELEVANCE Patients with melanoma and their partners reliably performed SSE after participating in a structured skills training program lasting approximately 30 minutes, with reinforcement every 4 months by the study dermatologist. Accurate SSE by those at risk to develop melanoma may enhance early detection and relieve some of the burden on health services to provide continuing follow-up to a growing population of eligible patients.

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More than 1 million patients with melanoma in the United States are at risk to develop a second primary melanoma.[1] The risk of a second melanoma is elevated for up to 20 years and is 10 times greater than the risk of a first melanoma in the general population.[2-4] In populations with genetic mutations, 12.7% developed a second primary melanoma within 2 years of the initial diagnosis and 19.1% by 5 years after diagnosis.[5,6] Under current practice guidelines, in the third year after treatment, skin examinations of patients with early melanoma usually decrease to annual examination by a dermatologist and continue for 5 years.[7] After 5 years, skin examination may be performed annually as clinically indicated for the remainder of the life of the patient.

Patients with melanoma and their skin-check partners ("partners") may self-manage early detection of new or recurrent melanoma with skin self-examination (SSE). If a concerning lesion is identified, the patient has an appointment with the physician. The median depth of invasion of melanoma ranges from 0.12 to 0.5 mm or more per month.[8] During the period between annual physician examinations, a melanoma could invade several millimeters deeper. The depth of invasion of melanoma, and subsequent staging, greatly influences patient survival. Patients treated at stage IB (1.01-2.0 mm in depth without ulceration) have a 92% 5-year survival rate, whereas those treated at stage IIC (>4.0 mm with ulceration) only have a 35% 5-year survival rate.[9] It is important to determine if patients with melanoma and their partners who are provided with a structured program to learn SSE will consistently perform SSE and can detect new primary melanomas.

In a randomized clinical trial, this study evaluated the effect of a structured educational intervention for patients with melanoma and their partners ("dyads") on performance of SSE over 2 years. The secondary outcome was identification of new melanomas by dyads. Last, potential overuse of medical services by unnecessary visits to the physician was assessed.

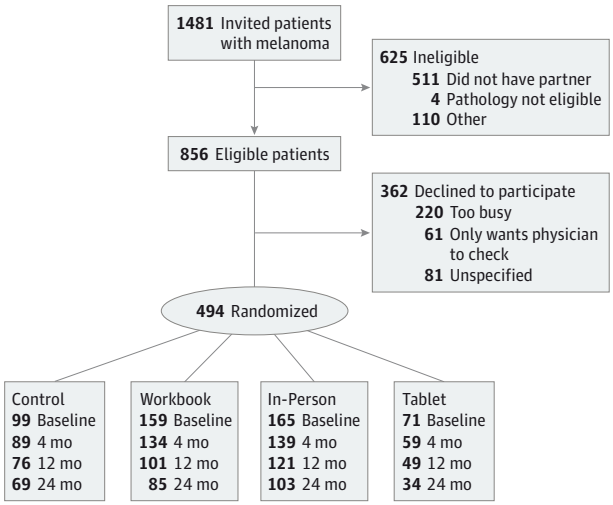
Key Points

Question Can at-risk patients with melanoma and their skin-check partners be trained to perform skin self-examination and detect new melanomas?

Findings In this randomized clinical trial trained dyads of patients and their partners increased skin self-examination and identified new melanomas more than those in the control group. Physician visits were not increased by the trained dyads.

Meaning Accurate skin self-examination by those at risk to develop melanoma may enhance early detection and relieve some of the burden on health services to provide continuing follow-up to a growing population of eligible patients.

Figure 1. CONSORT Study Flow Diagram



CONSORT indicates Consolidated Standards of Reporting Trials.

Methods

Study Design

Patients with a history of melanoma and their partners were recruited from a Midwestern region through April 14, 2013. Recruitment methods and additional details about the study design are available in previously published work.[10] The Institutional Review Board of Northwestern University approved the study. The full study protocol can be found in Supplement 1. Patients and partners provided written informed consent, and each received $20 to complete each assessment. At each data collection point, the patients and partners were separated from each other in different rooms to complete the self-reported survey.

Participants

Patients with melanoma and their partners were eligible if both were 21 to 80 years old and had acceptable vision (ie, were able to read a newspaper). Additional inclusion criteria were that patients had a diagnosis of stage 0 to IIB melanoma, with the pathology report confirming the diagnosis, and that at least 6 weeks had elapsed since surgical treatment of the patients. Exclusion criteria were being overburdened with other comorbid diseases, having a history of stage III or greater melanoma, or being unable to commit to having skin examinations by the study dermatologist (J.K.R.) every 4 months for 2 years. Patients were encouraged to continue with regularly scheduled follow-up visits with their customary dermatologist. If a partner died during the 2 years of follow-up, the patient remained in the study.

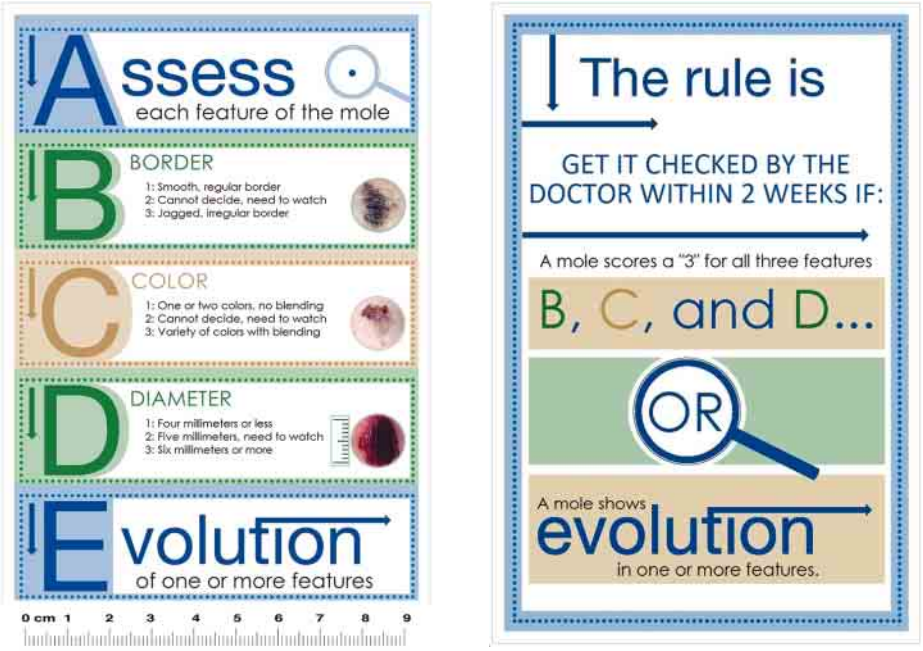
Randomization

A random number sequence was generated for 1 of the following 3 groups: in-person intervention in the office, intervention with a workbook read in the office and taken home, and controls (who received customary education). Technology advancements in small tablet personal computers ("tablets") allowed the potential benefit of education with tablets to be explored. After the initial 150 pairs, the remaining pairs were randomized among the following 4 groups (**Figure 1**): 3 intervention groups (in-person, workbook, and tablet in the office) and controls.[10]

Figure 2. Laminated Card Given to Each Dyad

A Summary of the skin self-examination visual inspection scoring of features

B Guidance for management decisions



The recruiting personnel and participants were masked to the randomization until after the baseline surveys were completed. If participants were randomized to receive the in-person intervention, then the recruiting research assistant provided the standardized educational intervention. At subsequent follow-up visits, a different research assistant interacted with the participants and the dermatologist, who were both masked as to the intervention to which the participants were randomized. At the follow-up visit, the research assistant and dermatologist were informed if the participants were randomized to the control arm to prevent discussion of aspects of the intervention with participants during the skin examination by the dermatologist.

Intervention

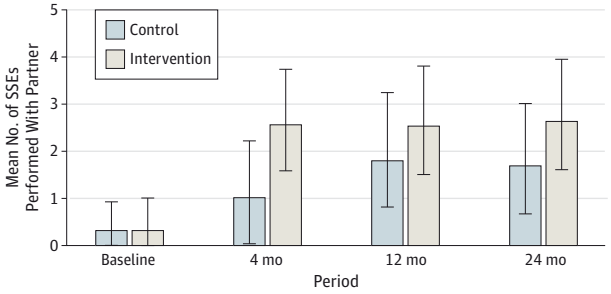
The training given at baseline was the same in all 3 forms of the intervention. Monthly SSE was recommended. The skills were reinforced in all those randomized to any intervention at 4-month intervals during skin examinations by the dermatologist.[11] Recognition of change in the border, color, and diameter of nevi requires comparison of lesions over 6 months to 1 year. To assist the dyad in making these comparisons, a scoring system provided instruction in categorizing the border, color, and diameter as 1 if normal, 2 if not sure, and 3 if abnormal (**Figure 2**). The border was normal if it was smooth (score of 1), if not sure (score of 2), and abnormal or irregular if it contained jagged pointed projections extending from the pigmented lesion (PL) into the surrounding skin (score of 3). Similarly, the color was normal if 1 or 2 colors were uniformly distributed over the surface of the PL (score of 1), not sure (score of 2) if many shades of brown and black and the distribution of color was uniform, and abnormal if more than 3 colors (brown, black, blue, pink, white, and gray) with nonuniform color distribution (score of 3). Last, the diameter was measured across the widest part of the PL and given a score of 1 if it measured 1 to 4 mm, score of 2 for 5 mm, and score of 3 for 6 mm or more.[12] Because 30% of melanomas have a diameter less than 6 mm, a diameter of 5 mm was chosen to initiate monitoring the PL for change.[13] In addition, in the series of melanomas of Breslow,[14] none of the melanomas with a diameter less than 5 mm recurred or metastasized. To assist the dyads in making management decisions, they were told to monitor features scored as 2 (not sure) for change (evolution) at the next SSE. Pairs were also asked to evaluate each PL as either benign (if the PL had normal scores on all 3 criteria), watch (for change during subsequent SSE if the PL had a score other than normal on any of the criteria), or serious (if the PL had a score of abnormal on all 3 criteria or met the evolution criterion).

The following aids were provided: (1) a laminated card stating the adapted ABCDE rule[15] (assess border irregularity, color variety, diameter, and evolution) (Figure 2), (2) a diary to record the scores, (3) a set of maps of the regions of the body to label the site of the mole, (4) a ruler in millimeters, and (5) a lighted magnifying lens. The training intervention included quizzes requiring the participants to score features in color pictures of PLs and gave feedback about their responses.[12]

Follow-up

At each visit at 4-month intervals, the dyad completed a self-report survey with responses about performing SSE and assistance by the partner. The dyad also provided their diary of

Figure 3. Mean Number of SSEs Performed With a Partner in the Prior 4 Months



SSEs indicates skin self-examinations.

SSE performance. The dyad reported if the patient had visited a physician since the last study visit, indicated if a skin biopsy was performed, and gave authorization to obtain the results of the skin biopsy. If a biopsy was performed or recommended, the pair was asked to select who found the lesion that was biopsied (eg, the patient, the partner, or the physician). The dermatologist performed a complete cutaneous skin examination, compared scars from recent skin biopsies with the sites indicated on pathology reports, and made recommendations to the dyad regarding the need to have lesions biopsied, continuing, or ceasing to follow lesions for change. Biopsy specimens interpreted as melanoma or dysplastic nevus were independently reviewed by 2 dermatopathologists. If the dermatopathologists did not concur on the diagnosis of melanoma, then the lesion was not entered into the database as a melanoma.

Study Outcomes

The primary outcome was SSE frequency as recorded on the self-reported survey. The extent of SSE was obtained by the self-reported survey of each member of the pair. Patient-reported measures of SSE were used in the analysis because the patient and partner reports were so highly correlated ($r > 0.77$ for all). The secondary outcome was detection of a new or recurrent melanoma by the dyad or the physician. The tertiary outcome was the number of unscheduled physician appointments for concerning lesions.

Measures

All measures were drawn from previous SSE literature.[16,17] Patients with melanoma were asked to indicate the number of times in the last 4 months that they examined 17 body areas. Response options were on a 5-point Likert-type scale that ranged from "0 times" to "4 or more times." Patients with melanoma used the same list of body areas to indicate the number of times the region was closely examined with their partner in the last 4 months. For these analyses, SSEs performed alone and with the partner were examined at 4, 12, and 24 months. A mean score for SSE performed alone at each time point was created by taking the average of all 17 skin locations the patient reported checking alone. Similarly, a mean score for partner-assisted SSE at each time point was created by taking the average of all 17 skin locations the patient reported checking with his or her partner.

Skin self-examination frequency was also examined for the following 3 types of skin site locations: skin areas that were easy to see by the patient and not in a sexually sensitive area, skin areas that were hard to see by the patient and not in a sexually sensitive area, and skin areas in a sexually sensitive location.[16] Areas not in a sexually sensitive area included the face, front of neck, chest (for men only), abdomen, arms, hands, front of thighs, lower legs, and the top of the feet. Areas hard to see by the patient and not in a sexually sensitive area included the scalp, ears, back of neck, back and shoulders, back of thighs, and the soles of the feet. Sexually sensitive areas included the chest (for women only), the groin, and the buttocks.

Statistical Analysis

The sample size of 430 patients and their partners (100 controls and 165 in-person and 165 workbook participants) were chosen based on an estimated 20% attrition over the duration of the study. For comparisons of the 3 groups (2 SSE training approaches and the control group), it was determined that we would be able to detect effect sizes that correspond to small eta squares (ie, proportion of explained variance) in the range of 2% (or smaller). Then, based on the response of the initial 80 participants, the sample of the tablet group was calculated to require 71 participants. The sample sizes were expected to yield power of greater than 0.90 for the contrasts of interest. To assess the randomization of the patients, χ^2 analyses were conducted to test for baseline differences in demographics between the study arms. To test for effects of attrition, participants were coded as "1" for completing the 24-month follow-up assessment and as "0" for not completing the 24-month follow-up assessment. χ^2 Analyses were conducted to test for statistically significant differences between patients who did and who did not complete the 24-month assessment in regard to demographics, original melanoma diagnosis, and time since diagnosis.

SSE Frequency

Preliminary analyses showed no differences between the 3 intervention groups (in-person, workbook, and tablet) in regard to patient SSE and partner-assisted SSE. Therefore, *t* tests were conducted to compare the control group and participants in all the intervention groups on the mean levels of partner-assisted SSE and SSEs performed by the patient alone at 4, 12, and 24 months. Patient SSE concordance with partner-assisted SSE was examined by conducting *t* tests comparing frequency of SSE performed alone with frequency of SSE when assisted with a partner. Last, *t* tests were performed to examine differences between the treatment and control groups on frequency of SSE of skin areas that were easy to see by the patient and not in a sexually sensitive area, skin areas that were hard to see by the patient and not in a sexually sensitive area, and skin areas in a sexually sensitive location. To reduce the increased probability of a type I error, *t* test effects were considered to be significant if they were at least $P < .01$.

Table 1. Skin Surface Examined by Patient and With Partner Assistance

Skin Locations	Mean (SD)[a] Intervention	Control	t Statistic (95% CI)[b]
4 mo			
Easy to see	1.06 (1.30)	1.05 (1.30)	−11.07 (1.35 to 1.93)
Hard to see	2.49 (1.18)	1.01 (1.18)	−10.45 (1.20 to 1.76)
Sexually sensitive	2.45 (1.28)	0.91 (1.24)	−10.17 (1.25 to 1.85)
12 mo			
Easy to see	2.58 (1.33)	1.86 (1.46)	−4.11 (0.38 to 1.07)
Hard to see	2.50 (1.29)	1.79 (1.40)	−4.19 (0.38 to 1.05)
Sexually sensitive	2.41 (1.68)	1.68 (1.52)	−4.01 (0.37 to 1.08)
24 mo			
Easy to see	2.67 (1.37)	1.71 (1.39)	−5.16 (0.61 to 1.35)
Hard to see	2.63 (1.34)	1.73 (1.34)	−4.87 (0.54 to 1.26)
Sexually sensitive	2.47 (1.38)	1.57 (1.34)	−4.87 (0.54 to 1.27)

[a] The number of times an area was examined in the last 4 months.

[b] $P < .001$ for all.

Identification of Melanoma

χ^2 Analyses were performed to compare the intervention and control groups on the number of melanomas that were found by the dyad vs those found by the physician. Separate analyses were done for melanomas that were stage 0 and melanomas that were greater than stage 0.

Results

Study Patients and Partners

Of the 1481 individuals identified as having stage 0 to IIB melanoma by medical record search, 856 met the eligibility criteria (Figure 1). Based on an estimated 20% attrition over the duration of the study, a minimum sample size of 430 patients and their partners was chosen.[10] A total of 494 participants were enrolled in the study.

At baseline, χ^2 analyses revealed no statistically significant differences in the demographic characteristics of the 494 patients between the intervention and control groups ($P > .05$ for all). The patient population was 51.2% (253 of 494) female and had a mean (SD) age of 55 (10) years. Partners were also a mean (SD) of 55 (10) years old, and 56.7% (280 of 494) were female (eTable 1 in Supplement 2 lists the 24-month demographic information). At 12 months, 347 of 494 (70.2%) patients with melanoma and their partners were retained. At 24 months, 291 of 494 (58.9%) were retained (eTable 2 in Supplement 2 lists the attrition rates). There were no statistically significant differences between those who completed the 24-month assessment and those who were lost to attrition in regard to demographics, original melanoma diagnosis, or time since diagnosis. There was a statistically significant difference between the study arms in the number of patients lost to attrition at 24 months ($\chi^2_3 = 11.12$, $P = .01$) (n = 494). The control group and in-person intervention group had larger proportions (69.7% [69 of 99] and 62.4% [103 of 165], respectively) of patients who completed the 24-month assessment than the workbook and tablet intervention groups (53.5% [85 of 159] and 47.9% [34 of 71], respectively). Pairs (n = 47) reported the following reasons for failing to keep follow-up appointments: not learning anything new (n = 24), no change in PL (n = 13), and too far to travel (n = 10).

SSE Performance

SSE Frequency

Patients receiving the intervention had significantly increased SSEs with their partner at 4 months compared with the control group ($t = 11.02$, $P < .001$; mean difference, 1.57 [95% CI, 1.29-1.85]), 12 months ($t = 4.22$, $P < .001$; mean difference, 0.72 [95% CI, 0.39-1.06]), and 24 months ($t = 5.13$, $P < .001$; mean difference, 0.94 [95% CI, 0.58-1.30]). The combination of consistency across 2 years and the reliability and magnitude effects makes these highly clinically significant as well. Patients in the intervention group did not have statistically significant differences from the control group on SSEs performed alone at baseline, 4 months, 12 months, or 24 months (**Figure 3**).

SSE Alone and With a Partner

Patients reported higher average SSE rates alone than SSE performed with their partner at baseline ($t = 28.55$, $P < .001$; mean difference, 1.42), 12 months ($t = 2.80$, $P < .01$; mean difference, 0.21), and 24 months ($t = 5.00$, $P < .001$; mean difference, 0.37). The intervention groups had significantly higher frequencies of SSEs for all body areas at all time points (**Table 1**).

Identification of Melanoma

Among the 494 patients, 69 melanomas were identified. Three patients developed in-transit metastasis, and 66 developed new melanomas; therefore, 13.4% (66 of 494) of patients developed a new melanoma. Among the dyads receiving the intervention (n = 395), dyads identified 43 melanomas, and physicians identified 10 melanomas on different patients. Three of the 10 melanomas identified by physicians occurred in patients receiving the intervention whose partner died after entering the study. The melanomas occurred in locations that the patient could not see without assistance.

In comparison, none of the dyads in the control group (n = 99) identified melanoma, and physicians identified melanoma in 16 different patients. Dyads receiving the

Table 2. Melanoma Found by Patient, Partner, or Physician

Person Identifying Melanoma	Stage 0 (n = 51)	Stage 1A (n = 15)	Stage 3B (n = 3)
Intervention (n = 395)			
Patient	14	3	1
Partner	19	5	1
Physician	6	3	1
Control (n = 99)			
Patient	0	0	0
Partner	0	0	0
Physician	12	4	0

intervention found a significant number of stage 0 melanomas (n = 33), whereas dyads in the control group did not find any melanomas ($\chi^2_1 = 28.77$, $P < .01$ [n = 51 melanomas in situ]). A total of 18 invasive melanomas were found by dyads who received the educational intervention ($\chi^2_1 = 6.43$, $P = .02$ [n = 18 invasive melanomas]) (**Table 2**).

Unscheduled Physician Visits for Concerning Lesions

Among the 2868 total visits with the study physicians, there were 30 unscheduled visits (1.0%) requested because lesions were thought to be of concern by the dyad (2 in the control group and 28 in the intervention group). The unscheduled visits in the control group resulted in 1 biopsy of a benign nevus. The unscheduled visits in the intervention group resulted in biopsies revealing 2 melanomas and 2 nonmelanoma skin cancers, as well as 8 additional lesions that were biopsied and showed dysplastic nevi, which clinically resembled early-stage melanomas.

Discussion

This prospective randomized clinical trial demonstrated increased SSE performance and increased detection of melanoma among dyads receiving the intervention compared with controls. The self-reported frequency of SSE was approximately once every 2 months. Previously, our group demonstrated that the pairs accurately identified concerning lesions.[16] In this study, pairs trained to perform SSE with a structured skills training program reliably identified melanoma in situ and melanoma without unnecessary visits to the dermatologist.

Lack of sufficient evidence of the efficacy of SSE counseling prevented the US Preventive Services Task Force from supporting routine SSE.[18,19] While others have used the ABCDE criteria[20,21] to teach simple visual inspection techniques for early detection of melanoma, none used a rigorous skills training program supporting assessment of change or performed a prospective randomized clinical trial with evidence of the accuracy of SSE. Other SSE programs demonstrated increase in SSE knowledge and attitudes in patients with melanoma, ability to identify features of melanoma on training evaluations, and increased SSE but have not prospectively demonstrated identification of new melanomas by those performing SSE.[22-30] Including an SSE partner during training[17] helped the partner to identify, track, and detect changes in PLs and enhanced the efficacy of the SSE program.[10,11,17]

Static visual inspection of the ABCD features did not support monitoring lesions for change over time; therefore, the scoring system was created to assist with monitoring PLs.[12,15] Recording the scores required dyads to assess the features and make a decision about change in the features. Using the scoring system, pairs found early melanomas (stages 0 and 1A). Patients who perform SSE have significantly earlier-stage melanomas (thinner) compared with those who do not,[28] and melanomas identified during SSE are thinner than those found incidentally.[29,30] In retrospective studies,[30-33] there is evidence of decreased tumor thickness among patients who perform SSE.

The study has some limitations. First, the research relies on self-reported responses to surveys. Submission of the scorecard provides some validity of the SSE self-reports. Second, pairs were aware by virtue of informed consent procedures that they were involved in a study examining SSE. Adherence to SSE performance may have been prompted by the quarterly visits with the study dermatologist. Third, unscheduled visits may have been prevented by having a standing quarterly appointment with the study dermatologist. Fourth, the pairs had a higher level of education than that found in the general population. Generalizability of SSE training to patients with melanoma will be limited by their willingness to learn and perform SSE, as well as having a partner.

Conclusions

Patients with melanoma and their partners reliably performed SSE after participating in a structured skills training program lasting approximately 30 minutes, with reinforcement every 4 months by the study dermatologist. Future research will determine if a skills training program delivered via the web without reinforcement by the dermatologist will yield reliable sustained performance of SSE by those at risk to develop another melanoma.

ARTICLE INFORMATION

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Study concept and design: Robinson, Turrisi.
Acquisition, analysis, or interpretation of data: Robinson.
Drafting of the manuscript: Robinson.
Critical revision of the manuscript for important intellectual content: All authors.
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