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Comparison of Efficacy of Differing Partner-Assisted Skin Examination Interventions for Melanoma Patients:

A Randomized Clinical Trial

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Abstract

IMPORTANCE—Early detection of melanoma may improve survival. The present study continued research establishing that in-person training on skin self-examinations (SSEs) was significantly enhanced when delivered to patients with their partners present instead of to patients alone.

OBJECTIVE—To examine 3 alternative SSE training approaches that included partners compared with a treatment-as-usual control condition.

DESIGN, SETTING, AND PARTICIPANTS—A randomized clinical trial with 4- and 12-month follow-up visits was conducted at the clinical offices in the ambulatory care area of a hospital. The evaluable population included 494 patients with stage 0 to IIB melanoma and their skin check partners drawn from an electronic medical record melanoma registry and advertisements in large regional newspapers. The study was conducted from June 6, 2011, to April 14, 2014, and analysis was performed between December 4 and December 11, 2014.

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INTERVENTIONS—Pairs of patients and their partners were randomly assigned to (1) in-person intervention, (2) take-home booklet intervention, and (3) treatment-as-usual controls. An additional subgroup of patients received an electronic interactive tablet personal computer intervention. The MoleScore content was comparable across formats and consisted of demonstrations of the ABCDE (*assess border, color, diameter, and evolution of pigmented lesions*) rule and skills training.

MAIN OUTCOMES AND MEASURES—Outcomes were self-reported SSE of the total body as well as easy-to-see and difficult-to-see regions at baseline, 4 months, and 12 months.

RESULTS—No significant differences in SSEs were observed between the 3 intervention conditions on all of the body areas; results for all 3 intervention conditions were significantly higher than for controls at 4- and 12-month follow-ups (all $P < .05$). Mean (SD) body areas examined by control pairs ($n = 99$) at 4 months (0.98 [1.17]) and 12 months (1.82 [1.43]) were significantly less compared with examination by pairs participating in all interventions at 4 months (workbook [$n = 159$], 2.68 [1.19]; in-person [$n = 165$], 2.66 [1.11]; and tablet [$n = 71$], 2.53 [1.17]) and at 12 months (workbook, 2.53 [1.25]; in-person, 2.59 [1.30]; and tablet, 2.34 [1.37]) ($F_{6,674} = 15.60$; $P < .001$; $\eta^2 = 0.12$).

CONCLUSIONS AND RELEVANCE—The findings of the research support the sustainability and efficacy at 12 months of partner-assisted SSE interventions for early detection targeting individuals with a history of melanoma.

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Melanoma is the fifth and seventh most common cancer in the United States for men and women, respectively.¹ Approximately 76 100 individuals in the United States were estimated to have received a diagnosis of invasive melanoma in 2014, and approximately 9710 were expected to die from the disease.¹ During 2002–2011, the melanoma incidence increased at an average annual rate of 1.6% for men and 1.5% for women.² People with a history of melanoma have a 10 times greater risk of developing a second primary melanoma compared with the general population.^{3,4} Early detection with surgical excision at an earlier stage, when treatment is usually more effective, is essential for saving lives.⁵

McPherson et al⁶ found that melanomas detected during deliberate skin self-examinations (SSEs) by lay people were more likely to have more favorable outcomes than were melanomas discovered incidentally. Robinson et al⁷ noted that in-person SSE training during a routine office visit when delivered to patients with partners present rather than to patients alone resulted in significantly more SSEs reported at 4 months after the intervention. In another study, Robinson and colleagues⁸ observed that more SSEs occurred for couples who had low-quality relationships (eg, lack of social support, consensus, and expression of affection by the partners) but did their training together compared with individuals in high-quality relationships who trained alone. The latter demonstrated the benefits of SSE training coupled with partner assistance even under less-than-ideal circumstances.

To broaden patient reach, the next phase of the research adapted the SSE training into a platform that made dissemination easier and not entirely dependent on the time and teaching

skills of the nonphysician clinical office staff. This adaptation resulted in the development of a take-home workbook SSE training intervention. Pilot work⁹ on a small sample of patient-partner dyads (n = 21) perceived the workbook to be readable, useful, and beneficial in promoting SSE knowledge, skills, and behaviors compared with in-person SSE training (n = 19). Although these findings suggested the potential promise of an SSE workbook, warranting broad dissemination based on the findings was premature considering the pilot study had a relatively small sample size, a short follow-up period, and no control group. Thus, the present study extended prior research by conducting a randomized clinical trial in patients with melanoma and their partners to examine the efficacy of in-person vs workbook vs tablet personal computer (tablet) SSE training in promoting SSE behavior on a short-term (4-month) and long-term (12-month) basis. Furthermore, the study conducted a more rigorous test of efficacy by assessing the effects on SSEs of the total body, easy-to-see areas (eg, face, feet, and arms), and difficult-to-see areas (eg, scalp, back, and buttocks).¹⁰

Methods

Sample and Procedure

Patients with a history of melanoma were recruited from a large Midwestern region from June 6, 2011, to April 14, 2013, in 2 phases. First, letters were sent to potentially eligible patients identified by electronic medical records of the Northwestern Medicine health care system. Second, advertisements were placed for 12 weeks in the health sections of 2 regional newspapers with large circulations (together, >1 200 000 weekly). Inclusion criteria consisted of the patient and partner being aged 21 to 80 years, having a partner who was willing to participate, and having acceptable vision (ie, both the patient and partner were able to read a newspaper). Additional inclusion criteria were having a previous diagnosis of stage 0 to IIB melanoma and at least 6 weeks having elapsed since surgical treatment. The histopathologic report was reviewed by the research assistant and the dermatologist to ensure that the patient had a melanoma that met inclusion criteria. Exclusion criteria included being overburdened with other comorbid diseases, being unable to participate in conversation at a sixth-grade language level due to cognitive impairment, or having a history of stage III or greater melanoma. Patients and partners received \$20 to complete each assessment, and each provided written informed consent. The institutional review board of Northwestern University approved the study. The study protocol is available in the Supplement. Analysis was conducted between December 4 and December 11, 2014.

At the 4-month visit with the dermatologist, the pathologic report on the melanoma was reviewed and placed into the context of the history of the qualifying melanoma and its treatment by the dermatologist. If inconsistencies in the clinical presentation (history and physical examination) with the narrative description of the pathology of the tumor became apparent and the pathologic report was from a laboratory other than Northwestern Medicine, the patient provided a request for the slide to be sent for review by a Northwestern Medicine dermatopathologist. In 4 cases, the dermatopathologist requested the original block of tissue to perform additional studies. On review of the histopathologic specimens with fluorescence in situ hybridization, the diagnosis was changed to Spitz nevi and the patients were no longer eligible for the study.¹¹

A total of 494 patient-partner dyads were enrolled into the study. While recruitment was ongoing, technological advancements in small tablet personal computers (tablet) became so popular and widespread that we decided to take advantage of the opportunity to examine a tablet version of the intervention that was comparable in content to the in-person and take-home workbook interventions. The first 150 pairs were randomized to 1 of the 3 groups (workbook, in-person, or control), and the remaining 344 pairs were randomized to 1 of 4 groups (workbook, in-person, tablet, or control).¹² The participants were randomized to (1) workbook intervention (reading the workbook during the baseline visit and taking it home, 159 pairs), (2) in-person intervention (165 pairs), (3) tablet (71 pairs), and (4) controls (treatment as usual, 99 pairs) (**Figure**). The mean duration of the educational intervention was 45 minutes for the workbook and 30 minutes for the in-person and tablet interventions.¹²

Interventions

Treatment as usual consisted of the information (if any) provided by a physician regarding the likelihood of developing another melanoma plus any information about finding a melanoma that is widely available on the Internet. The MoleScore content was comparable across the different intervention formats (in-person, workbook, and tablet) and consisted of providing patients and their partners with information on the ABCDE rule (*assess border, color, diameter, and evolution of pigmented lesions*) to assess moles. Each aspect of the ABCDE rule was explained with color picture examples.¹³ All dyads were provided with a ruler and a lighted magnifying lens to assess the moles, a laminated card with the ABCDE rule that summarized scoring the 3 features (border, color, and diameter) and evaluating changes in the 3 features (evolution), a body map consisting of a line drawing of regions of the body, and scorecards to record the monthly scores on each of the features. Participants in the intervention arms were taught to assign a letter to a concerning mole and place the letter onto the body map to indicate the location of the mole. The letter was placed on the scorecard, and the border, color, and diameter received a score from 1 to 3, with 1 indicating normal; 2, not sure; and 3, abnormal. To ensure the interventions were conducted with fidelity, after participating in the intervention, the participating pairs were given a skill quiz consisting of life-size photographs of 5 pigmented lesions printed in color with questions. The pair was asked to discuss and come to agreement on their response. Quiz scores were uniformly high (>95% correct), and no significant differences were observed across conditions ($P > .05$).

During each 4-month visit, the dermatologist performed a total body skin examination and responded to questions about scoring the lesions. At the first 4-month visit, the dermatologist selected 1 or 2 moles to demonstrate border irregularity and/or color variation to the pair of participants.

Skin Self-examinations

Skin self-examinations, which were reported independently by the patient and the partner, were assessed at baseline, 4 months, and 12 months. For total body assessment, patients were asked to report how often they had checked 17 different skin areas (eg, face, lower legs, and back of neck) with their partner during the past 4 months.^{7,8} Response options

were on a 5-point Likert scale that ranged from “0 times” to “4 or more times.” The mean of the 17 items was determined to give a score of skin examinations ($\alpha = 0.96-0.98$).

In addition, the 17 items were split into 2 categories: areas that are difficult and areas that are easy to be examined by the patient.¹⁰ The difficult-to-see areas included 6 skin regions (scalp, buttocks, and back of ears, neck, shoulders, and thighs); the mean score was then determined ($\alpha = 0.88-0.95$). Easy-to-see areas included the remaining 7 regions (face, front torso and neck, and both hands, arms, legs, and feet); the mean score was then determined ($\alpha = 0.95-0.98$).

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 our 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 η squares (ie, proportion of explained variance) in the range of 2% or smaller. Then, based on the response of the initial 80 individuals, 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 test the efficacy of the intervention at the short-term (4 months) and long-term (12 months) assessments, 3 different 4 (condition) $\times$ 3 (time) mixed measures analysis of variance tests were performed on SSEs across the entire body and on difficult-to-see and easy-to-see areas of the body. When omnibus significant effects were observed, post hoc pairwise comparisons using the Tukey test were then used to compare means across the groups as recommended by Jaccard.¹⁴

Results

Population

Of the 1481 individuals identified as having stage 0 to IIB melanoma by medical record search, 856 met the eligibility criteria. Of those failing to meet eligibility criteria, 511 patients did not have a partner (Figure). Fifty of the 494 participants were recruited from newspaper advertisements.

Demographics

Demographics of the 4 study groups are presented in **Table 1**. Examination of the demographics revealed no significant differences between the patients at baseline in the different arms of the study on age ($\chi^2_{15} = 23.39$; $P = .07$), sex ($\chi^2_{15} = 5.71$; $P = .13$), and educational level ($\chi^2_{15} = 13.60$; $P = .56$); however, there was a significant difference in the time since diagnosis, with more participants receiving the tablet intervention within 1 year of diagnosis than the other 3 arms ($\chi^2_{15} = 46.28$; $P < .001$). At the 4-month follow-up of overall performance of SSE, 410 pairs (83.1%) self-reported SSE performance and, at the 12-month follow-up, 342 pairs (69.2%) reported performing SSEs. Comparison tests between participants who were recruited from newspaper advertisements and participants

recruited within Northwestern Medicine indicated only one significant difference: time since diagnosis. Participants recruited from the advertisements had a smaller percentage of individuals who had melanoma less than 1 year (advertisements, 8.0%; Northwestern Medicine, 31.5%) ($\chi^2_{15} = 14.96$; $P < .01$). However, when time since diagnosis was added as a covariate in the analyses, it neither predicted any outcome nor changed the nature or significance of the initial analyses. Owing to the large sample size and number of variables compared (eg, ethnicity, race, age, attitudes and beliefs about SSE, and melanoma risk), we adopted a criterion of an effect size of 0.02 when comparing differences between participants who completed both follow-up assessments and those who did and did not complete follow-up assessments (4- and 12-month assessments). Using this criterion, no meaningful differences were observed for differential attrition by condition, demographics, or orientation toward SSE or melanoma.

Examination of SSEs Across the Entire Body

A 4 (condition) $\times$ 3 (time) mixed measures analysis of variance was performed to assess how the interventions affected total body SSEs (**Table 2**). Analyses showed a significant interaction of time $\times$ group ($F_{6,674} = 15.60$; $P < .001$; $\eta^2 = 0.12$). Post hoc pairwise comparisons using the Tukey test and comparing means across the groups at each time were performed as recommended by Jaccard.¹⁴ First, the analyses revealed that no significant differences were observed between any of the groups before the interventions were implemented at baseline. These findings provided evidence that the randomization to condition was effective at having equivalent groups at baseline and that the tablet condition was no different than the other groups despite being created after the randomization. Second, post hoc follow-up tests 4 months after the intervention revealed no significant differences in SSEs between the different treatment arms; however, all the treatment groups had significantly higher rates of SSEs compared with controls. Third, post hoc follow-up tests 12 months after the intervention revealed the same pattern: no significant differences in the rates of SSEs between the different treatment arms and significantly higher SSEs for all the treatment groups compared with controls. These findings, taken together, provide evidence that all interventions were efficacious in influencing patients and their partners to conduct more total body SSEs and that there is no evidence of decay of the effects of the interventions at a 12-month follow-up.

Examination of SSEs in Difficult-to-See and Easy-to-See Areas of the Body

Mixed analyses of variance were also conducted on SSEs performed on both difficult-to-see and easy-to-see areas on the body. These findings mirrored the results of the SSEs for total body ($F_{6,674} = 15.33$; $P < .001$; $\eta^2 = 0.12$; and $F_{6,674} = 14.14$; $P < .001$; $\eta^2 = 0.11$, for difficult-to see and easy-to see areas, respectively). Post hoc comparisons revealed (1) no significant differences at baseline in rates of SSEs across conditions in difficult-to-see and easy-to-see areas of the body, (2) no significant differences between the treatment arms at 4 and 12 months, and (3) significant differences between each of the treatment groups and the control group at both 4 and 12 months (**Table 3**).

Discussion

Findings from the present study demonstrate that different approaches of intervention delivery are as beneficial as training people in-person. Past research⁷ has provided evidence that SSE training is most optimal when partners were involved compared with patients alone, but the studies were mostly limited to a single training method. When considering which approach should be adopted (in-person vs workbook vs tablet), each was equally effective at increasing SSEs compared with treatment-as-usual controls. The present study also addressed whether the benefits of the SSE training would decay and whether the decay might be a result of a specific training method. The findings provide evidence that the benefits from the intervention were not short-lived (extending to 12 months after training) and that long-term effects were consistent across training methods. Rather than decay of SSE in 1 year, the research found improved SSE at 1 year. This improvement may be attributed to the scoring system providing a way to monitor lesions for change over time and placing emphasis on deliberate practice. Reinforcement occurred as the total body skin examination was performed by the dermatologist, who responded to questions about how to score moles. Finally, the study examined whether the effect of the different training methods limited SSE to specific sections of the body. The findings provided evidence that the intervention was beneficial when both easy-to-see areas (eg, face, arms) and difficult-to-see areas (eg, back of the neck or sexually sensitive regions) were examined, and this was consistent across training methods.

The present study also provides additional evidence that SSE training, specifically with partners, enables people to perform SSEs. Research has found that SSEs are associated with the patients being female, 59 years or younger, and having a perceived risk of melanoma or cancer¹⁵⁻¹⁹; however, perhaps the strongest predictor of SSE by a patient with a history of a skin cancer is confidence in SSE performance.^{8,16} Past research⁷⁻⁹ has also demonstrated that having partners assist in the process significantly increased SSE behaviors, even in difficult-to-see and sometimes sexually sensitive areas.⁹ Partners not only assisted with viewing locations that are difficult for the patient to see (eg, scalp, back, and ears), they provided a source of encouragement, knowledge, and reinforcement of SSE procedures for the patient.¹⁰

Finally, despite the consistency of observing higher numbers of SSEs across the different methods, the examinations were not equivalent in terms of ease of implementation or reach. Staff need to be trained to perform the in-person instruction of patients and their partners, which is time consuming and costly. Supervision of staff to ensure the quality of the training requires extensive time and expertise, which is also very costly.²⁰ The in-person approach has a narrow reach because there are limits to how many training sessions can be conducted in a given day, week, or month because of staffing concerns. Even if the staffing issues can be resolved, there are difficulties with being able to schedule patients and partners at the same time. When consideration is given to these concerns, the in-person delivery is less likely to be feasible in environments that do not have large and deep resources and infrastructure. In contrast, both the take-home workbook and tablet approaches are relatively easy to disseminate. They require little staff training or expertise and because of this they do not necessitate supervision costs. Both approaches can also have a large reach because they

can be delivered to thousands of individuals via the Internet, and patients and partners can perform the SSE training at their own pace without having to schedule a clinic visit. The findings of the present study strongly suggest that the take-home workbook and tablet SSE training methods can increase the use of SSEs.

The study is not without limitations. First, the research relies on self-reports. Having separate reports by patients and partners that confirm each other provides some validity of the self-reports of SSEs, and past work¹⁸ has shown that individuals are, for the most part, reliable reporters of their skin-related preventive behaviors. Second, our research and clinical staff, as well as the patients and partners, were blinded to condition, but patients and partners were aware by virtue of informed consent procedures that they were involved in a study examining SSEs. Finally, the enrolled population had a higher level of education than that found in the general population, which may limit generalizability. Further research is needed to examine the efficacy of the different methods under real-world conditions. Research examining use of SSEs in real-world conditions can be used to address the question of whether patients and partners will make the time and effort to use the SSE training approaches if they are not receiving incentives to complete regular and large surveys.

Conclusions

The present study provides evidence that patients and partners successfully learned how to conduct SSEs with work-book and tablet training, which have the ability to reach large populations. Patients engaged in sustained SSE behaviors for up to 12 months following training with their partners. These findings support the notion that systematic SSE training with partners is an empirically supported and sustainable approach to improve early detection of melanomas among high-risk individuals.

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Figure.
CONSORT Diagram

The CONSORT diagram presents the enrollment, randomization, and retention information about the pairs.

Table 1

Baseline Demographics

Characteristic	No. (%)			
	Control (n = 99)	Workbook (n = 159)	In-Person (n = 165)	Tablet (n = 71)
Sex				
Male	39 (39.4)	78 (49.1)	90 (54.5)	34 (47.9)
Female	60 (60.6)	81 (50.9)	75 (45.5)	37 (52.1)
Age, y				
18-29	7 (7.1)	5 (3.1)	4 (2.4)	7 (9.9)
30-39	7 (7.1)	21 (13.2)	14 (8.5)	5 (7.0)
40-49	20 (20.2)	25 (15.7)	23 (13.9)	13 (18.3)
50-59	19 (19.2)	40 (25.2)	51 (30.9)	13 (18.3)
60-69	24 (24.2)	43 (27.0)	48 (29.1)	25 (35.2)
70	22 (22.2)	25 (15.7)	25 (15.2)	8 (11.3)
Educational level				
Did not attend high school	0	0	1 (0.6)	0
Some high school	1 (1.0)	2 (1.3)	1 (0.6)	0
High school graduate	8 (8.1)	4 (2.5)	9 (5.4)	3 (4.2)
Some post-high school education	14 (14.1)	19 (11.9)	26 (15.8)	8 (11.3)
College graduate	35 (35.4)	73 (45.9)	62 (37.6)	24 (33.8)
Postgraduate degree	41 (41.4)	59 (37.1)	64 (38.8)	36 (50.7)
No response	0	2 (1.3)	2 (1.2)	0
Time since diagnosis, y				
<1	17 (17.2)	42 (26.4)	45 (27.3)	40 (56.3) ^a
Between 1-3	27 (27.3)	60 (37.7)	43 (26.0)	10 (14.1)
Between 4-5	16 (16.2)	18 (11.3)	27 (16.4)	8 (11.3)
>5	34 (34.3)	37 (23.3)	47 (28.5)	12 (16.9)
No response	5 (5.0)	2 (1.3)	3 (1.8)	1 (1.4)

^a χ^2 Difference test, $\chi^2_{12} = 46.28$; $P < .001$.

Table 2

Total Body Skin Self-examination Interventions

Condition	Body Areas Examined, Mean (SD)^a		
	Baseline	4 mo	12 mo
Control	0.30 (0.51)*	0.98 (1.17)†	1.82 (1.43)‡
Workbook	0.39 (0.86)*	2.68 (1.19)§	2.53 (1.25)§
In-person	0.32 (0.68)*	2.66 (1.11)§	2.59 (1.30)§
Tablet	0.27 (0.44)*	2.53 (1.17)§	2.34 (1.37)§

^aFootnote symbols that are different from the others in the same row indicate significant differences at $P < .05$.

Table 3

Difficult-to-See and Easy-to-See Skin Self-examination Interventions

Condition	Body Areas Examined, Mean (SD)^a		
	Baseline	4 mo	12 mo
Difficult-to-See Skin Areas			
Control	0.38 (0.65)*	1.08 (1.25)†	1.83 (1.40)‡
Workbook	0.41 (0.84)*	2.56 (1.18)§	2.58 (1.23)§
In-person	0.39 (0.74)*	2.57 (1.16)§	2.60 (1.31)§
Tablet	0.32 (0.57)*	2.57 (1.16)§	2.52 (1.22)§
Easy-to-See Skin Areas			
Control	0.26 (0.53)	0.96 (1.19)¶	1.81 (1.46)#
Workbook	0.35 (0.87)	2.70 (1.20)**	2.52 (1.29)**
In-person	0.29 (0.73)	2.69 (1.15)**	2.59 (1.32)**
Tablet	0.21 (0.44)	2.53 (1.17)**	2.32 (1.40)**

^aFootnote symbols that are different from the others in the same row indicate significant differences at $P < .05$.