

Protocol Title: A Comparison of Interventions to Teach Melanoma Patients Skin Self-examination

Northwestern University Institutional Review Board: STU17005

Study Type: Interventional

Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Single Blind (Investigator)
Primary Purpose: Screening for melanoma

Primary Outcome Measures:

- Self-Efficacy in Performing SSE [Time Frame: 24 months]
To compare the self-efficacy of the in-person training vs. workbook vs tablet for patients and partners by self-report on a survey at 4-month intervals over 24 months.

Secondary Outcome Measures:

- Accuracy [Time Frame: 24 months] [
Accurate identification of concerning lesions (melanoma) by participants performing SSE in comparison with the dermatologist's assessment.
Estimated enrollment: 1000 (500 pairs of patient with melanoma and the skin check partner)

Specific Aims of the Study:

1. To compare the efficacy of the in-person training vs. workbook vs tablet for patients and partners relative to an assessment only control group that receive standard of care for patient education on SSE knowledge/skills, SSE performance, and accuracy on a short and long term basis.
2. To examine whether partner-patient relationship-qualities moderate the relationship between the training approaches and SSEs knowledge/skill acquisition and retention, and SSE performance and accuracy.

Background

Population based registries document that survival from melanoma, a growing public health problem with approximately 70,000 new melanoma cases and an estimated 8,600 deaths in 2010, is dependent on the thickness of the melanoma. By facilitating seeking medical care, skin self-examinations (SSEs) by individuals with a prior history of melanoma, who are at risk to develop subsequent melanomas, may lead to the early detection and treatment of melanoma when it is usually more effective. Thus, further

research that enhances early detection is warranted and our application directly tests novel methods of training high-risk melanoma patients and their partners on how to conduct SSEs to promote early detection. Our proposed research builds upon the strengths of the R21 that: a) established that in-person training to conduct SSE with a partner significantly enhanced SSE performance 4 months after the intervention, and b) developed and pilot tested a manualized take-home workbook training approach (WORKBOOK). Our pilot work on the WORKBOOK with partners suggests that patient-partner dyads (n = 21) perceived it to be readable, useful, and in the short term 4 month follow-up, empirically equivalent in promoting SSE knowledge, skills, and behaviors compared with patient-partner dyads in the in-person partner training condition (n = 19). Our proposed research builds on our NCI funded studies by conducting a formal examination with 500 pairs (1000 subjects) randomized to either the in-person, workbook or tablet training computer-based program (tablet) vs. an assessment only control group that receives standard of care over a 2 year longitudinal study with 4 month interval evaluations.

Our proposed research directly tests novel methods of training Stage 0 through IIB melanoma patients, who have a 5 year survival of 80-90%, and their partners, on how to conduct SSEs. We will compare the efficacy of the in-person training, workbook, and tablet for patients and partners vs. controls on SSE knowledge/skill acquisition and retention, and SSE performance and accuracy on a short (4 post baseline) and long term basis (12, 16, 20, and 24 months post baseline) and examine whether partner-patient relationship-qualities moderate the relationship between the training approaches and SSEs knowledge/skill acquisition and retention, and SSE performance and accuracy.

Establishing health promotion partnerships is important to those at risk to develop melanoma because SSE is difficult to successfully perform as an individual. It is expected that the workbook and tablet interventions will promote SSE at least as well as and perhaps better than in-person training and become an easily disseminated SSE training approach that is not dependent on the time and teaching skills of the non-MD clinical office staff.

Eligibility

Ages Eligible for Study: 18 Years to 80 Years

Genders Eligible for Study: Both

Inclusion Criteria:

1. Melanoma patient with Stage 0 through IIB melanoma as documented by a pathology report

2. At least 6 weeks post-surgical treatment of Stage 0 through IIA melanoma
3. Age 18-80 years old
4. Have sufficient vision to read a newspaper in order to visually detect changes on skin
5. Able to read English
6. Have a partner willing to participate in skin checks

Exclusion Criteria:

1. Subjects overburdened with other co- morbid diseases, medical treatments (e.g. chemotherapy), unable to participate in a conversation at a sixth grade language level due to cognitive impairment (e.g. by a stroke), or prior participation in SSE research.
2. Skin check partner not available
3. Unable to keep follow-up appointments at 4 month intervals over 2 years.
4. Unable to see to read a newspaper

Recruitment Methods

Letters will be sent to eligible patients identified by a search of the electronic medical records of the Northwestern Medicine health care system. After receipt of recruitment letters, the eligible patients will be called on the telephone to assess their willingness to participate. Advertisements in regional newspapers with large circulations will be placed weekly over 4-8 months.

Procedures

Baseline visit

After providing written consent and each member of the pair separately completing self-report surveys regarding their relationship with each other, their attitudes about the importance of melanoma and performing SSE, confidence in performing SSE and current performance of SSE at the baseline visit, subjects will be randomized to one of 4 groups. Those randomized to receive skills training together with one of three interventions will take a skills quiz together and receive a SSE enabling kit consisting of a body map, scorecard, laminated card with the ABCDE rule, ruler, and lighted magnifying lens. The body maps consist of line drawings of distinct body regions. The ABCDE rule is presented as **A**ssess moles for **B**order, **C**olor, **D**iameter and **E**volution and each aspect of the ABCDE rule is explained with color picture examples. Pairs randomized to the interventions and to the control group will be given an appointment to return in 4 months to complete the same surveys and be examined by the study dermatologist. Each person will receive \$20 for each visit.

Pairs randomized to the interventions will be advised to perform monthly total body SSE and to select 5-10 pigmented lesions (PLs) that may be of concern and to locate the lesions on the body map and to score the B,C and D features of each lesion. Pairs randomized to the interventions will be asked to bring the body map to each 4-month interval visit so they could review their chosen PLs with the doctor.

Four month interval visit

At each 4-month interval visit, the patient will be asked if they have seen a physician since the last study visit. If so, the patient will be asked the name of the doctor, if the doctor is a dermatologist, and if a skin biopsy was performed. If a skin biopsy was performed a copy of the pathology report will be requested.

The patient and the skin check partner will separately complete the self-report surveys. Then, the 4-month visual examination will be performed by the study dermatologist to assess whether the patient has concerning PLs that should be monitored for change or biopsied. During the total body skin examination, the doctor, who is blinded to the condition of the pair and to the pairs' assessment of PLs, will identify and score PLs using the body map and scorecard in the same manner as pairs are instructed to do in the SSE program. A research assistant will record each of the dermatologist's evaluations onto a blank body map. After recording the data from the dermatologist's examination, the research assistant will review the pairs' SSE body map and scorecard and compare the results to the dermatologist's scorecard to determine whether each pair's identified PLs is scored during the dermatologist's examination. If the research assistant is unsure if a specific PL identified during SSE matched the dermatologist's PL, both the dermatologist and the research assistant returned to the pair to determine if the spot identified during dermatologist's examination is the one the pair selected.

Measures

Body map scorecard. Pairs will use the scorecard during their SSE to record the body location of each PL and provide a rating on the border, color and diameter based on the criteria described in the program (rating options were 1 = *normal*, 2 = *not sure*, and 3 = *abnormal*). Following the first SSE, pairs will rate whether each PL met the **E**volution criterion in any of the **BCD** criteria, defined as a change from a prior score of *normal* to a score of *abnormal*. Pairs will also provide an evaluation of 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 three criteria or met the Evolution criterion). Pairs are instructed that PLs judged to be *serious* should be examined by a doctor within 2 weeks. The scoring (i.e., 1, 2, 3 ratings) was similarly used by the study dermatologist.

Patient characteristics. Select patient characteristic variables will be measured in a baseline assessment. Demographic characteristics included patients' gender, age, education, and time since melanoma diagnosis. Phenotypic variables included patients' tendency to freckle easily as a child (response option = *no, somewhat, yes*) and skin type as assessed by skin sunburn tendency of untanned skin (response options = *never sunburn, rarely, sometimes, usually, always*).

Patient SSE Self-efficacy Patient self-efficacy in performing SSE was measured with 16 items that assessed confidence in checking different skin areas, (e.g. *I am very confident I can carefully examine the skin on my FACE*); confidence in being able to have their partner's assistance, [e.g. *I am very confident that I can have my partner help check the places that I cannot see myself (such as my back)*] and the correct way to perform a SSE (e.g.. *I am very confident that I know how to examine a mole for an irregular border.*) Response options were on a 5-point Likert scale that ranged from -2 (strongly disagree) to +2 (strongly agree). Items were summed for a composite score of self-efficacy ($\alpha = 0.90$).

Partner Motivation The Spouse Treatment Mediation Inventory was adapted to measure various aspects of partner support. Partners reported on two items were used to assess motivation in the program: "*I am highly motivated to make changes through participating in this skin exam program,*" and "*I believe that participating in this skin exam program will help me.*" Partners responded on a 5-point Likert scale that ranged from -2 (strongly disagree) to +2 (strongly agree). The two items were summed to create a single index of motivation. The two items were significantly correlated ($r = 0.68$, $p < 0.01$).

Relationship Quality The Dyadic Adjustment Scale was adapted for use to assess the quality of the relationship between the patients and partners. Three aspects of the patient-partner relationship were assessed: agreeability between the patient and partner, activities spent together, and happiness in the relationship. Agreeability was measured using 14 items that asked participants how often they agree on various topics, such as handling financial matters, amount of time spent together, and career decisions, using a 5-point scale (-2 never agree to +2 always agree). The 14 items were measured for a single index of agreeability and the items had good reliability ($\alpha = 0.91$). Participants were asked to report using a 5-point scale ranging from -2 (never) to +2 (always) on the frequency they do 4 activities with their partner (e.g. *Have a stimulating exchange of ideas*). These 4 items were summed for a composite score of activities ($\alpha = 0.78$). Happiness was assessed by the question, "*I am happy in my relationship with my partner.*" Participants were asked to respond using a 5-point Likert scale that ranged from -2 (strongly disagree) to +2 (strongly agree).

Data Management

A study number will be assigned to each participant, and data will be stored in a password-protected customized database. Data will be analyzed by the study biostatisticians using SPSS.

Data Analyses

Efficacy of intervention according to relationship quality

Moderated regression modeling described in Jaccard and Turrissi will be used to examine patient SSE self-efficacy. Patient SSE self-efficacy was the outcome measure with three independent variables in the regression model that included: a) intervention variable (control, training intervention), b) the mean centered moderator variable (e.g., partner motivation or relationship quality), and c) the product term of the moderator variable x the intervention variable. These product terms, or interaction effects were computed using mean centered moderator variables (partner motivation, or relationship quality consisting of agreeability between the patient and partner, activities spent together, and happiness). The regression coefficient for the product term provides an estimate of the magnitude of the moderator effect. Significance was determined by observing a t-value associated with the regression coefficient >2). Post hoc analyses were conducted to understand the nature of moderator effects that were found to be significant. These analyses involved comparing the treatment and control group on self-efficacy at three different levels of the moderator using Tukey tests (e.g. at below average of agreeability, average agreeability, and above average agreeability).

Withdrawal of Subjects

This study involves minimal risk and we do not anticipate many circumstances under which subjects will be withdrawn from the research without their consent. However, one potential scenario is marked distress from learning and focusing on melanoma. If a subject or partner has increased anxiety attributable to the study, then counseling will be provided. The subject may be withdrawn from the study. Withdrawn participants will no longer provide data. Data from withdrawn participants will be kept for potential subset analyses.

Potential Benefits to Subjects

Not all study participants will benefit directly from the study. However, all subjects will receive education about early detection of melanoma, which has the potential to be beneficial to participants on an individual basis.