Effect of SSE education delivered during the mammography experience.

PROTOCOL TITLE:

Effect of skin self-examination education delivered during the mammography experience.

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1.0 Purpose of the Study

The proposed study is the second phase of a project assessing the feasibility and effectiveness of enhancing the early detection of melanomas among women, who are engaging in health promotion by having mammograms. The initial phase of the project framed risk messages, developed posters and brochures with the input provided by women undergoing screening mammograms, and assessed the feasibility of delivering the program during the mammogram visit at the Lynn Sage Comprehensive Breast Center of Northwestern Medicine/ Prentice Women's Hospital. Now, we seek to evaluate performance of skin self-examination (SSE) by women, who receive information during their mammogram appointment, and follow-up with dermatology for a melanoma screening examination.

In the second phase, a more intensive intervention in which women will not only receive information about SSE, but will also receive a reminder to perform SSE one week after the screening mammogram and information on how to schedule an appointment with dermatology will be provided. The number of women who perform SSE at home and find a concerning mole (lesion), number who see a dermatologist, and number who have a concerning lesion biopsied will be compared in two arms of the study 1) women who receive the intensive intervention 2) women who receive the informational brochure about SSE alone.

Our hypothesis is that women who receive more the intensive educational intervention will be more likely to perform SSE at home and schedule a follow-up dermatologist appointment as compared to those who receive the information brochure alone. This project builds upon Robinson's successful SSE training program for melanoma patients that resulted in patients' accurate evaluations of suspicious lesions relative to dermatologists' skin examinations.[4]

***The study aims are as follows*:**

1. Assess whether SSE education introduced during routine screening mammography encourages women to implement SSE at home, find concerning lesions, and seek follow-up with a dermatologist.
2. Assess the effectiveness of additional reminders to perform SSE and providing information on how to schedule follow-up with a dermatologist on participant performance of SSE with identification of a concerning lesion or scheduling a screening examination with a dermatologist without performing SSE.

2.0 Background / Literature Review / Rationale for the study

1. Significance

Invasive melanoma, a lethal form of skin cancer, is the seventh most common cancer in women. The vast majority of melanomas are curable if the cancer is caught early, yet over 10,000 people in the United States are estimated to have died of melanoma in 2017.[1] New opportunities to decrease mortality from this deadly cancer, which is visible on the skin surface, are warranted.

Melanoma incidence increased 3% per year for the last two decades in part due to indoor tanning by young women. In 1994, Dr. Robinson's group found that 24% of teen women in Illinois tanned indoors.[2] Since 1994, indoor tanning has increased from 24% to 40% among women between the ages of 18 and 30 years old.[3] Currently, about 30 million people, most of whom are women, indoor tan every year. Indoor tanning for 10 or more sessions prior to age 30 is linked with a 6-fold increase in the risk

of developing melanoma. The Food and Drug Administration recently recognized the need for screening and recommending regular skin exams among women who have tanned indoors. Reaching the vast numbers of at-risk women requires access to large numbers of women, preferably in a supportive health care environment. Because women have screening mammograms every 1-2 years starting at age 40, many at-risk women could become aware of their risk of developing melanoma during their mammogram experience.

Inclusion and exclusion criteria

3.1 Inclusion Criteria for Patient

Women 18 years of age and older, who are waiting to have a mammogram

Women agree to complete informed consent and registration forms allowing follow-up reminders and access to their EMR record limited to the visit with a dermatologist or primary care physician regarding a concerning skin lesion and the results of the biopsy of the lesion.

3.2 Exclusion Criteria for Patient

Women who are unable to see to read a newspaper, unable to read English, and who have cognitive impairment causing problems with functioning at a sixth grade reading level or inability to speak.

3.3 Special populations

Special populations will not be invited to participate in this research.

3.0 Procedures Involved

3.1 Study Design

Phase 1: *Delivery of educational SSE program*.
Each of the eight changing rooms of the Lynn Sage Comprehensive Breast of Northwestern Memorial Hospital will be equipped with a poster, brochures (Fig 1 and Fig 2) and cards with information about obtaining an appointment with a dermatologist for concerning skin lesions.

A woman research assistant will obtain consent to participate in the research and review of medical information, collect contact information and if the woman owns an iPhone X, 8+ or 8, and ensure receipt of an informational brochure. Women will be asked if they own an iPhone X, 8+ or 8 to assess the prevalence of these specific phones in the population of interest. These iPhones models are of particular interest to the research team as they offer superior image quality compared to older models. If a woman has this type of phone, she will be asked about her experience using it to take close-up pictures.The woman will be asked her preference for being contacted by email, telephone, or text message. The two arms of the study will be delivered on different weeks. During weeks 1,3,5 and 7 of the study period 400 women will be given brochures and a card with information on scheduling dermatology follow-up prior to check-out (Group 1), (Fig 3). During weeks 2, 4, 6 and 8 of the study period, 400 women will be given brochures to perform SSE at home and proceed to check-out of the mammogram area (Group 2). The women in Group 1 will also receive a reminder about performing a SSE one week after their mammogram visit via phone call,

email or text message. One month after the mammogram visit both groups will be called and surveyed to see if they checked their skin and/or made an appointment to see a dermatologist. Three months after the mammogram, both groups will be asked to participate in a complete survey (either via REDCap or telephone), including whether the women followed up in dermatology and if any concerning lesions were biopsied.

Fig 1. SSE Poster

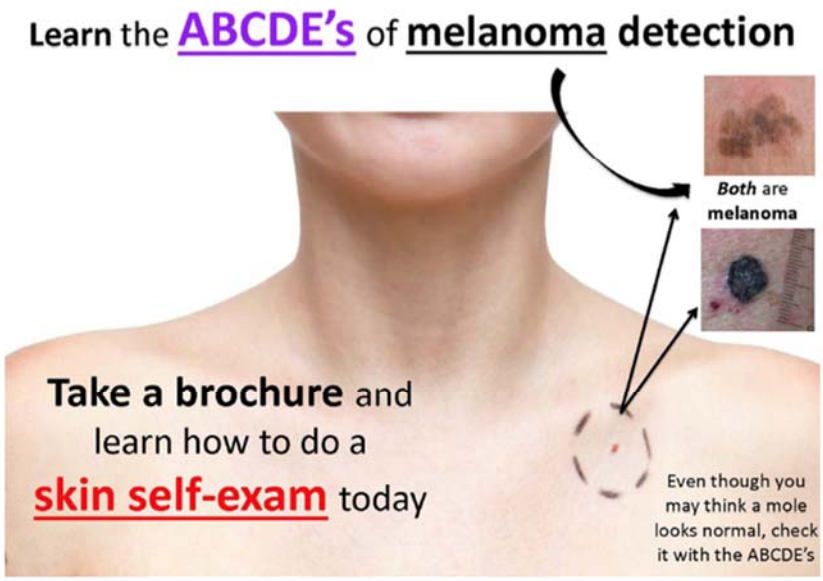
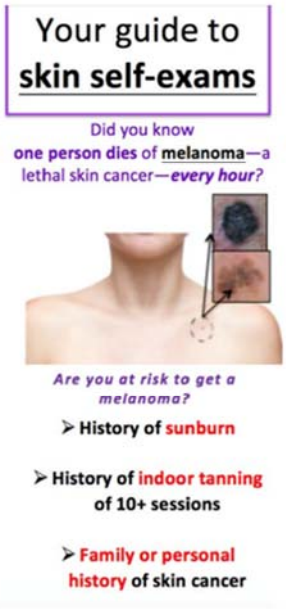


Fig 2. Cover of SSE

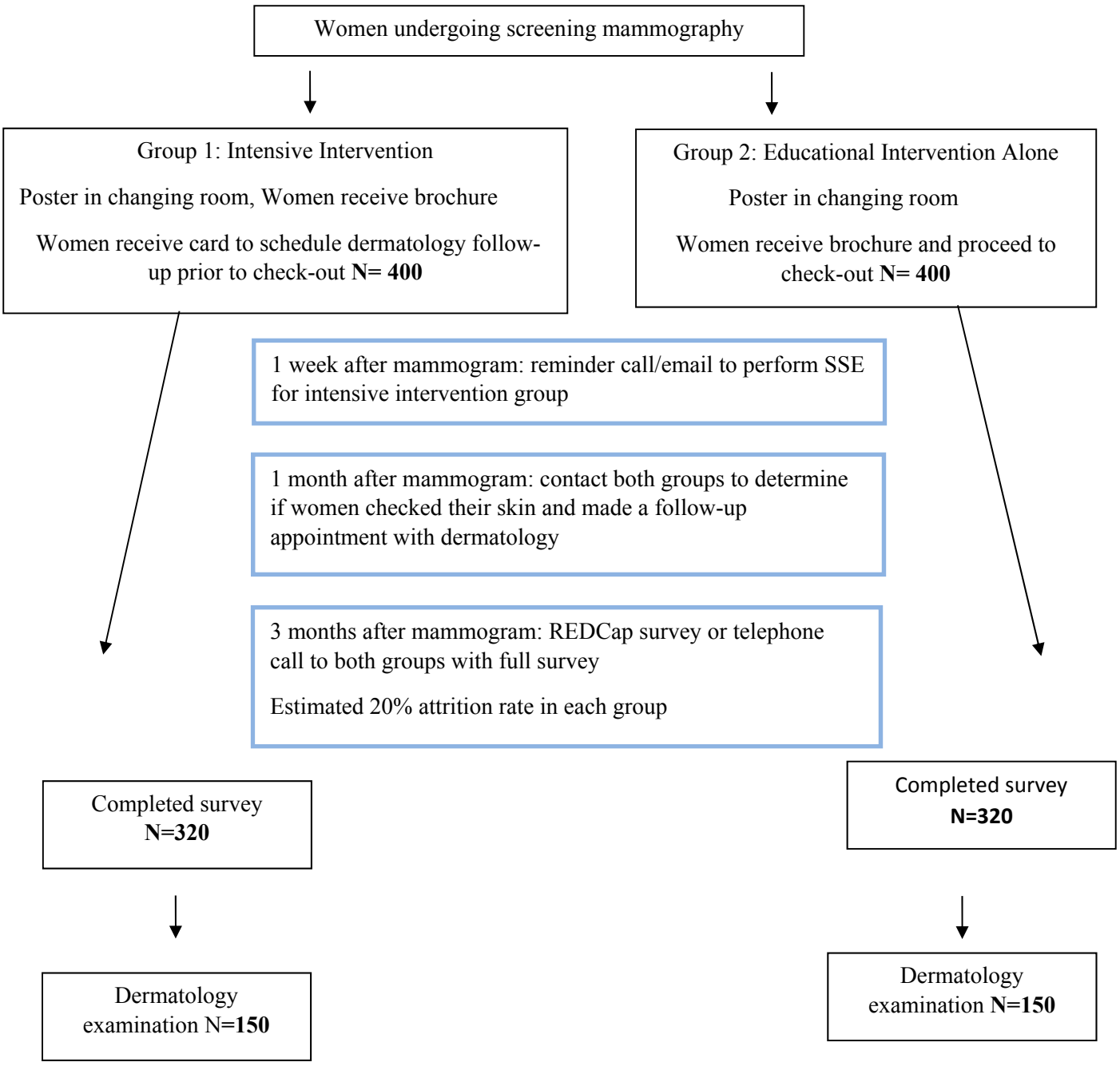


Phase 2: *Assessment of SEE Implementation*

A research assistant will be present at the mammography center to collect consent, telephone numbers, iPhone model information, and email addresses to have women sign onto REDCap to complete a survey. A telephone survey will be administered to each woman enrolled in the study in both groups (N=800) one month after the mammogram asking if she performed a SSE at home and whether a follow-up with dermatology was made. An anonymous REDCap survey may be used in place of the telephone call, depending on participant's preferred method of contact preference. Then, three months after the screening mammogram, an anonymous <2 minute REDCap survey will be sent via email to each woman enrolled in both groups to ascertain the number of women who identified that they were at increased risk for melanoma (history of sunburn, history of indoor tanning >10+sessions, family or personal history of skin cancer), performed a SSE at home, found a concerning lesion, made a follow-up appointment with a dermatologist, and had any concerning lesions biopsied. If participants do not complete the REDCap survey in 2 weeks, they will be called and surveyed via telephone. We anticipate a 20% attrition rate (Fig 3). Participants will be offered a $10 Amazon gift card in appreciation of completing the one month survey and an additional $10 for completing of a second REDCap survey three months after the mammogram visit.

Effect of SSE education delivered during the mammography experience.

Fig 3. CONSORT diagram for two arms of study



Effect of SSE education delivered during the mammography experience.

3.2 *Informed Consent, Participant Surveys, and Educational Intervention*

As patients wait to have the mammogram, they will be screened for eligibility. Following completion of the mammogram, patients will return to the changing room and put on their clothing. After exiting the changing room in the Lynn Sage Comprehensive Breast Center of Northwestern Medicine/Prentice Women's Hospital and as they are preparing to leave, a research assistant (RA) will interview potential participants to acquire a randomly selected convenience sample of eligible participants (n=800). Participants will be invited to complete a survey that will assess will assess knowledge of melanoma and the risk of developing a melanoma. They will be provided with a consent form and the research study will be discussed, questions will be invited and then they will be asked to sign a consent form and to fill out a registration form containing contact information. (see attached)

The complete survey includes general demographic items such as age, education, household income, race and ethnicity. The survey questions are as follows:

1. During your visit for mammography, did you notice any information about checking your skin for melanoma?

   ___Yes __ No

2. Did you think this applied to you?

   ___Yes __ No

3. If no, why not? (open ended)
4. If yes, why? (open ended)
5. Did you check your skin? (If no, please proceed to question #7)

   ___Yes __ No

6. If yes, did you notice any concerning moles?

   ___Yes __ No

7. If no, will you consider checking your skin in the future?

   ___Yes __ No

8. If you found any concerning moles, did you make an appointment to see a dermatologist?

   ___Yes __ No

The RA will record the responses.

3.3 Research procedures and activities

Follow-Up

1 week after the mammogram, RA will contact participants in group 1 via their preferred method to remind them to perform SSE and schedule a dermatologist appointment if they find a concerning mole. (see attached telephone script)

1 month after the mammogram, the RA will call participants in group 1 and administer a survey to see if they checked their skin and/or made an appointment with a dermatologist.

Effect of SSE education delivered during the mammography experience.

(see attached telephone script) An anonymous REDCap survey may be used in place of the telephone call, depending on participant's preferred method of contact preference.

The survey questions are as follows:

1. Did you read the brochure?

   ___Yes __ No

2. Did you check your skin? (If no, please proceed to question #4)

   ___Yes __ No

3. If yes, did you notice any concerning moles?

   ___Yes __ No

4. If no, will you consider checking your skin in the future?

   ___Yes __ No

5. If you found any concerning moles, did you make an appointment to see a dermatologist?

   ___Yes __ No

   If no, do you intend to do so in the near future?

6. Did you share the brochure with anyone else?
   ___Yes __ No

7. If yes, who did you share it with:
   a) A relative: son, daughter, father, mother, sister, brother
   b) A friend : woman, man
   c) Someone I work with: woman, man

REDCap Survey

3 months after the mammogram, an anonymous REDCap survey will be emailed to each woman enrolled in both groups. If participants do not complete the REDCap survey in 2 weeks, they will be called and surveyed via telephone. The following items with relevance to the research:

1. Do you have a history of sunburn? Yes/No
2. Do you have a history of more than 10 indoor tanning sessions? Yes/No
3. Do you have a personal or family history of melanoma? Yes/No
4. Have you ever performed a skin self-examination prior to your most recent mammogram? Yes/No

Effect of SSE education delivered during the mammography experience.

5. Did you perform a skin self-examination after your most recent mammogram? Yes/No
   If no, then go to item 8.
6. Did you find a concerning mole? Yes/No
7. If you found a concerning mole, did you make an appointment to see a dermatologist? Yes/No
8. If you did not perform a skin self-examination, did you still make a follow-up appointment to see a dermatologist for a skin examination? Yes/No
9. Have you had an appointment with a dermatologist yet? Yes/No
10. If you found a concerning mole and saw a dermatologist, was the concerning mole biopsied? Yes/No
    a. If yes, was the biopsy done at Northwestern? Yes/No
    b. If No, were you told by your dermatologist that the skin biopsy was melanoma? Yes/No
11. If you saw a dermatologist, were any other concerning moles biopsied? Yes/No

EMR review

If a woman responds yes to item 9 indicating that they made an appointment with a dermatologist, then the EMR will be checked to ascertain the findings of the dermatologist. The pathology report of biopsied mole(s) will be reviewed and added to the deidentified database.

3.4 Measures

The number of women with risk factors for melanoma, who performed SSE after the screening mammogram, who found a concerning mole, who saw dermatology, who had a concerning lesion biopsied in each group will be analyzed by descriptive statistics. The difference in proportions of women who 1) performed SSE 2) saw a dermatologist in the educational intervention group from the intensive intervention group will be compared using a $\chi 2$ test. If the woman responded "yes" to follow-up in dermatology, a chart review of the electronic medical record will be performed to assess whether any lesions were biopsied and pathology of the concerning lesions. The accuracy of the woman's selection of a concerning lesion will be assessed by examining the correspondence rate between the woman's assessment during SSE and the dermatologist. The overall correspondence rate will be calculated with a random intercept-only mixed logistic regression model. The statistical analysis will be performed by Namita Jain, MD, MPH.

Online data
REDCap survey (see page 8 above)

Approvals required

Effect of SSE education delivered during the mammography experience.

Dr. Friedewald obtained permission for this research to be conducted in the Lynn Sage Comprehensive Breast Center of Northwestern Medicine/Prentice Women's Hospital

4.7 Vulnerable populations

No vulnerable populations will take part in this study.

4.0 Multiple sites

4.1 Northwestern University will serve as the study site solely responsible for contacting participants and conducting study procedures.

6.0 Incomplete Disclosure or Deception

6.1 N/A. This research will not use incomplete disclosure or deception.

5.0 Recruitment

7.1 Recruitment of Patients

A woman research assistant will perform in-person interviews with participants to ascertain if women is eligible for the study and interested to participant. Women who sign written consent and fill out a registration form will be entered into the study. (n=800) (see attached forms)

8.0 Consent Process

8.1 Written consent will be obtained at the following location: Lynn Sage Breast Center of Prentice Hospital/Northwestern Medicine. (see attached consent document)
8.2. N/A. Non-English speaking participants will not be enrolled in this research.
8.3. Participants who are not yet adults (infants, children, teenagers) will not be enrolled in this research. Participants in structured interviews, who are the age of 18 years or older, will be enrolled in this research. Assent will be required from all participants. The RA will obtain verbal assent from each participant and will be documented. The RA will read the assent script to the participant and will then document the participant's response.
8.4 Cognitively Impaired Adults: Participants will be screened for preexisting conditions that would prohibit their participation due to being over burdened by co-morbid diseases, unable to participate in a conversation at a sixth grade language level due to cognitive impairment (e.g., by a stroke), and unable to speak and read English, inability to see to read a newspaper. Subjects having conditions that contraindicate participation will not be enrolled in this research.
8.5. Adults Unable to Consent: Please see above rationale for excluding Cognitively Impaired Adults.

9.0 Process to Document Consent

9.1. Written consent will be obtained in the changing area of the Lynn Sage Comprehensive Breast Center. (See attached consent document)

10.0 Risks to Participants

10.1. The potential risks to participants are expected to be minimal, if they occur. Subjects will be participating in an educational intervention that may enhance their awareness of their risk of developing skin cancer. All study participants will be provided with an email address

and phone number to contact study staff in the event they have concerns. If a subject becomes concerned that they have a suspicious lesion, the control subject will be instructed to make an appointment with their own dermatologist for an examination. The research assistant will communicate other concerns to the PI. In such circumstances, Dr. Robinson will consult with the patient's own dermatologist and an appropriate referral will be made.

Because of the potential for the educational intervention to help the subject identify melanoma at a stage of development with the best prognosis, we feel that the potential benefits, in reduced morbidity and mortality, to the subject outweigh the risk of potential enhanced anxiety in discovering a suspicious mole. Should subjects report high levels of anxiety a referral for psychological support will be made.

10.2. We do not believe that subjects in this study will be exposed to any risk of physical or psychological harm as a result of either the intervention or research processes. Our measures do not assess individuals at risk of immediately harming themselves (e.g. suicide); therefore we will not have to screen the data to potentially intervene with individuals who may be a risk to themselves.

10.3. N/A. There are no anticipated risks to others who are not participants.

11.0 Potential Benefits to Participants

Because of the potential for the educational intervention to help the subject improve their ability to detect melanomas in the early and potentially curable phase, they will reduce their risk of death from melanoma. We feel that the potential benefits in reduced morbidity and mortality to the subject outweigh the risk of potential enhanced anxiety in discovering that they are at risk to develop another melanoma. Should subjects report high levels of anxiety, a referral for psychological support will be made.

The knowledge to be gained by the proposed study is key to the evaluation of the long-term benefit of skin self-examination. By evaluating means of encouraging and facilitating regular skin self-examination, the applicants believe that it will be possible to determine if the educational intervention that can be used in mammogram facilities, which would be beneficial if brought into widespread use.

12.0 Financial Compensation

12.1 N/A. Participants will receive a $10 Amazon gift card for participation in the second survey (telephone call/REDCap one month after mammogram visit) and an additional $10 Amazon gift card for completing a third survey (REDCap) three months after the mammogram.

13.0 Provisions to Protect the Privacy Interests of Participants

13.1. This research includes provisions for protecting the privacy of participants. Study interactions will take place in person. The research team will make every effort to address the questions and concerns of potential and current participants.

Steps will be taken to ensure that the participants feel at ease. To reduce the sense of intrusiveness a subject may experience in response to survey questions, subjects will be informed that they may decline to provide any information they do not wish to disclose. The

information being collected is limited to only the minimum amount of data necessary to accomplish the research purposes.

13.2. The research team will be permitted to access study-related, subject-reported information and the EMR of subjects who have a visit with the dermatologist for a concerning mole. The database will have deidentified data.

14.0 Data Analysis

14.1. This convenience sample of women undergoing screening mammograpy will all receive education either as a brochure and a 1-week reminder or as only the brochure. Demographic characteristics of the two groups will be examined using means and standard deviations (age) and counts and percentages for all categorical variables. Primary outcomes of SSE performance, biopsy, and diagnoses will be compared using Chi-square tests of association or Fisher's exact tests where sample sizes were restrictive. Due to the skewed nature of the anxiety scale, a Wilcoxon rank sum test will be used to compare anxiety, the secondary outcome, in the two groups. Descriptive statistics will be performed for the tertiary outcome of dissemination.

15.0 Confidentiality and Data Management:

1. There are no biological specimens. All of the following data is collected in person consent and responses to structured interviews and focus groups.
2. Our systems are guarded against outside entry by Northwestern's own firewall supporting 128-bit encryption. This level of encryption provides the highest level of protection against hackers, computer break-ins, etc. All data is deidentified. Experienced research assistants will be employed and will receive training that includes emphasis upon the importance of confidentiality of information, and all personnel on the project will complete the required NIH training in the protection of human research participants.
3. Data will be retained in separate locked file cabinets and on computers with restricted and password protected access, without links to the master code list. All data based on the research will be reported in aggregate form. No individual respondents will be identified. Electronic data will be maintained in a study specific database on the server of the Department of Dermatology at the Feinberg School of Medicine. Paper- based files will be kept in a locked cabinet in a locked room within the Northwestern University Department of Dermatology research offices. Identifiable data will be kept separate from the case report forms and source documents. Data gathered as a result of this study are available to inspection on request by Food and Drug Administration or other government regulatory agency auditors, and the Northwestern University Institutional Review Board (IRB).
4. Only approved research personnel will have access to the stored data. The PI is ultimately responsible for receipt and transmission of the data. As per Department of Dermatology protocol, data will retained indefinitely after the completion of the study.
5. All data and other information in this study will be maintained confidentially. In order to protect against risks posed by a potential loss of confidentiality, we will take the following steps: First, subjects will be assured they are free to refrain from answering any questions they do not wish to answer. Secondly, all data will be identified only by a unique subject

number. All data is recorded by a study number, which preserves the confidentiality of the information.

6. Please refer to Section 15.0 for the data analysis plan, which includes statistical procedures.

15.1 Data Monitoring Plan to Ensure the Safety of Participants:

As previously described, all participants are encouraged to contact the PI, Dr. Robinson at Northwestern, to report complaints or adverse events. A telephone number and email address will be given to patients to contact Dr. Robinson if they have any concerns or increased anxiety, or if they become worried about developing skin cancer. Instructions for reporting adverse events and complaints, as well as for contacting the Investigators, are included in the consent documents and on all contact information provided to participants through the course of the study. Any significant adverse events will be reported to NIH in addition to the local IRB, in compliance with federal regulations.

Our measures do not assess individuals at risk of immediately harming themselves (e.g., suicide); therefore, we will not have to screen the data to potentially intervene with individuals who may be a risk to themselves.

Dr. Robinson has been a board certified physician for over three decades and has conducted a NCI funded R01 of a similar nature. We will notify the Northwestern University IRB, our project officers, and NCI within 24-48 hours of any serious adverse event. We will provide an annual report to the NCI Project Officer summarizing all adverse events, should any arise.

16.0 Data and if applicable, Specimen Banking Not applicable.

17.0 Qualifications to Conduct Research and Resources Available

17. 1. All members of the research team have completed and maintained current Human Subjects Protection Training, such as CITI and the Department of Dermatology compliance modules. The PI has over 30 years of clinical research experience, including multiple NIH-funded studies and studies involving the educational training of physicians.

17.2 The PI's office is located within the clinical research office in the Clinical Research offices of the Department of Dermatology of Northwestern University. Dr. Robinson's skin cancer control group occupies 500 sq. ft. with 4 offices and a small conference room. All standard office equipment is available for use including PC, fax, color printer, locked filing cabinets, etc.

Northwestern provides web-based submission of IRB protocols and financial management.

There are no anticipated adverse consequences associated with the research. However, should a participant request medical or psychological resources, the PI and Co-Is are available for debriefing and will arrange referrals as necessary.

The PI will ensure that the RAs are thoroughly trained on the protocol, the research procedures, and their respective duties and functions. The RAs will be readily available to participants for questions and technical troubleshooting. The PI and RAs will personally

meet on a weekly basis to discuss study progress and review duties and functions as applicable. A continual, open dialogue among the PIs and RAs will be encouraged.

18.0 References

1. American Cancer Society. Cancer Facts & Figures 2016 (2016). http://www.cancer.org/research/cancerfactsstatistics/cancerfactsfigures2016/
2. Robinson JK, Rademaker AW, Sylvester J, Cook B. Summer sun exposure: knowledge, attitudes, and behaviors of Midwest adolescents. *Prev Med* 1997;26:364-72.
3. Schneider S, Kramer H. Who uses sunbeds? A systematic literature review of risk groups in developed countries. *J Eur Acad Dermatol and Venereol*. 2010;24(6):639-48
4. Robinson JK, Wayne JD, Martini MC, Hultgren BA, Mallett KA, Turrisi R. 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. *JAMA Dermatol* 2016;152(9):979-985.

Effect of SSE education delivered during the mammography experience.