



Breast Self-Examination for Disabled Women

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Abbreviated Abstract

A body of peer reviewed studies confirm that the MammaCare program is an effective protocol for learning to perform proficient manual breast examinations. The MammaCare Learning Systems advance tactile skills enabling clinicians and women to detect small simulated lesions in tactually accurate breast models and to transfer that skill to breast tissue. Approximately 10 million blind and visually impaired women and deaf and hard-of-hearing women cannot access the requisite visual or auditory training components of standard MammaCare Learning Systems. During the Phase I grant, a series of adaptive prototype systems were constructed and tested experimentally. The results indicated that the prototypes significantly improve breast self-examination proficiency. The Phase II proposal investigates home use of the adaptive prototypes by over 500 women in 37 states with these disabilities. The results establish whether the level of proficiency achieved by the participants using the adaptive versions are sufficient to disseminate the technology. If affirmed, the benefits of this potentially life-saving technology will become available to a substantial population of women with disabilities.

Primary Investigator

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MK Goldstein, Ph.D. is a research scientist who earned graduate degrees from Columbia and Cornell Universities. Dr. Goldstein and his colleagues began work on the problem of early detection of breast cancer in 1974, when he was invited by NCI to attend a special breast cancer conference for physicians and scientists in San Antonio, TX. At that conference, invitees addressed the problem of early detection of breast lesions. NCI recognized, and the data reveal, that initial detections are most frequently made by women themselves and that the lesions detected are quite large, averaging >3 cm. Goldstein and his colleagues reasoned that if women were to present far smaller and more treatable lesions, a method of self-examination based on valid, scientific measurement would have to be created and tested. Goldstein and colleagues at the University of Florida formed a research group of nationally recognized biomedical scientists, biomaterials engineers, experimental psychologists, and physicians to develop the first tactually accurate simulations of breast tissue to investigate the limits of human tactile thresholds in breast tissue. The first of many published studies by that group and others determined that subjects could, after training, regularly detect simulated lesions more than ten times smaller than the NCI average in lifelike simulated breast tissue. Subsequent studies suggested that the technology

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could be adapted to improve the nation's breast screening programs through proficient clinical breast examinations (CBE's). MammaCare Clinical training programs have become the recognized standard for CBE certification and are now taught at leading medical centers including OHSU, The Mayo Clinic, UF, Alexian Bros. Medical Centers. NCI supported the adaptation of MammaCare for women with disabilities resulting in proficient breast examinations for blind women and deaf women. A body of independent, published clinical research has replicated and validated the original work now regarded as the standard of training for clinical breast examination and breast self-examination. In 1982, at the suggestion of NCI directors, Goldstein and several distinguished colleagues co-founded MammaCare in Gainesville, FL, to disseminate the technology. Goldstein and MammaCare have received several U.S. and international patents on tactually accurate polymer breast models for teaching manual examination and for advanced tactile training platforms. Goldstein was elected and served as commissioner and mayor, City of Gainesville, FL (1978-84).

Research Team & Affiliations

MK Goldstein, Ph.D., HS Pennypacker, Ph.D., MA Mehn, Ph.D. MammaCare and the University of Florida, Center for Ambulatory Studies

Total Budget

\$585,169

Research Objectives

Aim 1: Adapt the MammaCare Learning System's tactile, visual and auditory instructional formats for two groups of women with sensory disabilities: (a) blind or visually impaired women and (b) deaf or hard-of-hearing women.

Aim 2: construct, test, and validate adaptive learning systems screening and interview items for remote (from the home) data acquisition.

Aim 3: Investigate whether the adaptive systems can be completed at home by women with sensory disabilities and determine their proficiency levels.

Theory/Hypothesis

MammaCare can be adapted into formats that will enable women with disabilities to perform proficient breast examinations equivalent to established standards for examination proficiency.

Experimental Design

To test the effect of the adaptive systems on proficiency of breast examination, we distributed the experimentally adapted and validated MammaCare Learning System Kits to over 500 women with disabilities in 37 states. The participants provided data about the number and location of simulated lesions (hidden lumps) they found, the thoroughness of their examinations in terms of breast tissue coverage, their confidence in performing a breast self examination before and after training. Results are compared with the same proficiency measured from women without disabilities.



Final Sample Size & Study Demographics

Over 500 blind or visually impaired women or deaf or hard-of-hearing enrolled through an accessible communications network that included dedicated toll-free voice and delete (TTY) telephone lines, project interactive web sites and e-mail and Braille mail. Participants are women between the ages 18 and 85 from 37 different states in the US.

Data Collection Methods

Pre and post training telephone interviews with blind participants, mail questionnaires, Braille instructions, TTY and email interviews with deaf participants. Online, email and mail interactions, questionnaires and telephone interviews to confirm breast model detections and thoroughness of breast tissue coverage by reporting the number of vertical strips palpated,.

Outcome Measures

Compliance with the protocols measured by knowledge of specific elements; Number of simulated lesions (lumps) detected measured by identifying lump location, size and hardness; Thoroughness of coverage measured by number of vertical palpation strips reported vs. expected by bra cup size; Self reported confidence in performing the examination before and after training on a Likert Scale.

Evaluation Methods

Univariate analyses: Described the data set collected. Established the viability of statistical assumptions for further multivariate approaches to the data. The SAS software package was used to perform all statistical analyses. Researchers computed and modeled the relationship between the observed and actual number of lumps in the breast models to gauge the internal validity of the reports of lump detection, search skills, and reported confidence data from the first 334 women to complete the study. Two data sets were analyzed: one for the women who were trained with the audiotape ("AUDIO" data set, n = 249) and the other for the women who were trained using the videotape ("VIDEO" data set, N = 85). The following relationships were analyzed:

- 1) between breast tissue coverage (vertical strip measurements corrected for bra cup size) and the number of lumps found on the full side of the model.
- 2) between the number of "signal/code" words or sounds recalled and the number of lumps found.
- 3) between the number of lumps found and any other potential predictors.
- 4) between the pre-training confidence level and ability to find lumps.
- 5) between the post training confidence level and the ability to find lumps.
- 6) between the change in confidence level and any predictors of it.

Analysis of the mean difference in expected vs. obtained result for:

1. Number of lumps (simulated lesions) detected in breast models
2. Completeness of breast self-examination coverage (# vertical strips)
3. Pre/Post difference in "confidence" performing the breast examination

Research Results

There were 5 lumps present, in the breast models. The expected mean number of lumps detected by untrained examiners is <2. After training the expected mean number is ~4. The mean number of lumps



found by these participants after training in the home was 4.1. This result is equal to (not significantly different from) the post-training detection skills of non-disabled examiners. The mean number of vertical strips examined after training was also equal to the expected number based on participant's bra cup size. The post-training mean confidence in performing the examination increased significantly (2.5 pre to 3.9 post) $p < .001$. .

Barriers & Solutions

Cost is a barrier for women with disabilities. Their income is below national averages for non-disabled women. To make the systems more available MammaCare has subsidized the retail price and provided substantial discounts where requested or needed. Some local libraries make the learning systems available and women's organizations whose membership is made up of persons with disabilities have distributed them to members. Knowledge of the availability of the product is difficult to promulgate. MammaCare has a popular website and amplifies the site using special services of Google and Yahoo to disseminate information and draw potential users to www.mammacare.com where the adaptive products are featured.

Product(s) Developed from This Research

Adaptive MammaCare - Tactually accurate, adaptive breast model kits with simulated lesions and special instructional content in Braille and large print, audiocassette, video with audio description for blind and visually impaired and video with open captions for deaf and hard-of-hearing women.