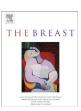


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Original article

A relaxation response training for women undergoing breast biopsy: Exploring integrated care



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ABSTRACT

Background: Recent changes in clinical guideline recommendations for age of breast cancer screening initiation highlighted the potential psychological ramifications associated with screening. This study examined the feasibility, acceptability, and preliminary efficacy of a brief Relaxation Response training (RRT) to decrease distress among women undergoing breast biopsy.

Methods: Women scheduled for percutaneous core-needle biopsy were recruited into a single-arm RRT trial, including 3 individual sessions. Psychosocial assessments were completed pre- and postintervention.

Results: Forty women were enrolled between 6/1/10 and 8/31/11. Among enrollees, 75% completed all 3 RRT sessions, and 75% completed the post-assessment. Participants showed significant reductions in acute distress following each RRT session. Qualitative feedback indicated a positive impact of RRT on clinic care experiences.

Conclusions: RRT is a portable intervention that was feasible to implement, acceptable to patients and associated with significant decreases in acute emotional distress during the period of diagnostic uncertainty related to percutaneous breast biopsy.

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Introduction

Early screening and detection have been shown to decrease breast cancer mortality.^{1,2} In 2009, the U.S. Preventive Services Task Force (USPSTF) revised breast cancer screening guidelines, changing recommendations from annual screenings, beginning age 40, to biannual screenings, beginning age 50.³ A critical part of the risk/benefit debate on age of breast cancer screening initiation are the potential adverse psychological ramifications of screening younger women who have a lower age-specific breast cancer incidence. Past research has shown that breast cancer screening procedures generate stress and anxiety.^{4–6} Thus, the psychological burden associated with early screening may be more harmful than beneficial.³

Approximately 10% of diagnostic mammograms have findings which are deemed suspicious or suggestive of breast malignancy and referred for biopsy.⁷ Anxiety and uncertainty while awaiting

breast biopsy results have been associated with dysregulation in immune and endocrine functioning. 4,8,9 Unattended psychological distress during the biopsy period can also have negative implications on women's cognitive functioning 10 and coping behaviors. 11,12 Most women with screening results that are suspicious for breast cancer will have benign breast disease, as only approximately 30% of breast biopsies are positive for malignancy.⁷ However, while malignant findings are more distressing than benign ones, 13 even women with benign disease may continue to experience elevated distress after receiving biopsy results. 4,14,15 These findings are congruent with other cancer screening research showing that ambiguity about one's health can have a substantial and persistent psychological impact on patients. 10–12,16 Thus, the diagnostic testing period (e.g. waiting for results), is a critical period and could be a critical time to teach strategies designed to reduce the deleterious effects of anxiety and stress.

A few studies have examined how to intervene to assist women undergoing breast biopsy. Two studies have demonstrated that single-session hypnosis, delivered either immediately before or during the breast biopsy procedure, decreased women's levels of

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distress. ^{17,18} However, while women's distress levels may increase during breast biopsy and receipt of results, their distress begins prior to undergoing this procedure. ¹⁹ Women scheduled to undergo biopsy report significant increases in both anxiety and mood disturbances, ^{4,9} which could adversely influence women's biopsy experiences and subsequent treatment decisions. Yet, to our knowledge, no intervention trials have been targeted to assist women during this early vulnerable period of diagnostic uncertainty. Therefore, the current study emphasized relaxation training and skill building integrated throughout the entire diagnostic testing period, from the time of biopsy procedure notification through the time period immediately following the procedure.

Relaxation exercises have been associated with reduction of psychological distress and perceived stress. ²⁰ These techniques have been hypothesized to evoke the Relaxation Response (RR), the physiological and psychological state counter to the stress response. ^{21,22} Thus, we conducted a single-arm pilot trial to test a brief Relaxation Response Training (RRT) intervention to reduce distress among women during the period from pre-biopsy through receipt of biopsy results. Our primary aim was to assess intervention feasibility (screening, recruitment, and enrollment; study retention, and intervention adherence) and acceptability. We also evaluated effect sizes for changes in acute distress following guided relaxation sessions, and changes in perceived stress and global distress during the study period, to inform future trials. Secondarily, we evaluated relationships of demographic and clinical factors with the proposed study outcomes, to identify potential covariates.

Methods

Study design

This study was a single-arm pilot trial of a RRT intervention for women undergoing breast biopsy at the Massachusetts General Hospital (MGH) Avon Foundation Comprehensive Breast Evaluation Center in Boston, Massachusetts. All study procedures were approved by the MGH/Partners HealthCare Institutional Review Board.

Participants

Women who were 18 years of age or older, fluent in English, and referred for stereotactic or ultrasound-guided percutaneous breast biopsy at the Avon Center from June 2010 to August 2011 were eligible to participate. Exclusion criteria included biopsy scheduled within 24 h after biopsy referral, breast cyst aspirations, and unable to participate (i.e., cognitive impairment such as inability to complete eligibility screening and consent process). Initially, the study excluded women who were already regularly eliciting the RR (e.g., deep breathing, yoga) at least once per week. However, this exclusion criterion was eliminated three months after initiating

recruitment, once it was evident that women with regular relaxation practice were interested in learning about RRT.

Enrollment and assessments

During the study period, the Avon Center nurse practitioner introduced the study to patients during initial consultation for biopsy scheduling and gave out a study flyer to all potentially interested patients. A research assistant then called potentially interested patients to confirm eligibility and verbal consent. The research assistant informed participants that study participation included two assessments and several relaxation sessions but did not include any additional clinic visits or medication. Participants were informed that relaxation training sessions would take place over the phone and in-person at the Avon Center, at the day of their biopsy. At enrollment and approximately 1–2 weeks after participants had received their breast biopsy results, the research assistant conducted assessments over the telephone.

Intervention

The RRT intervention consisted of three half-hour sessions delivered by a licensed psychologist from the MGH Benson-Henry Institute for Mind Body Medicine (AW, LT). The integration of the intervention is shown in Fig. 1. The first session was conducted via phone, at least one day prior to the scheduled biopsy. The psychologist provided psycho-education about the RR, guided the participant through a 15-20-min deep breathing and body scan exercise, and introduced brief 'mini' relaxation exercises. The second session was conducted approximately one hour prior to biopsy, in a semi-private waiting area within the breast evaluation center. The psychologist guided the participant through a second practice of the relaxation exercise and provided the participant with a CD recording of the exercise for home practice. The final session was conducted via phone, within a week after the scheduled biopsy date but prior to receipt of results and included a third relaxation practice. During the second and third sessions, the psychologist worked with the patient to identify stress warning signals (e.g., back pain exacerbation or trouble concentrating); discussed experiences of eliciting the relaxation response; and explored barriers to relaxation practice during the biopsy waiting period.

Measures

Feasibility and acceptability

Study staff recorded rates of study eligibility (percent of all patients who were eligible), recruitment (percent of eligible patients who expressed interest in the protocol), enrollment (percent of interested patients who consented to enroll), retention (percent of enrolled participants who completed the follow-up), and intervention adherence (number of RRT sessions attended). At the

	Week 1			Week 2		Week 3
CLINIC FLOW	Scheduled for biopsy	Waiting period	Biopsy day	Waiting period	Receive biopsy results	Post-results period
STUDY FLOW	Introduce study	• Pre-intervention assessment • Session 1 (phone)	Session 2 (at clinic)	Session 3 (phone)		Post-intervention assessment

Fig. 1. Integration of study flow into breast evaluation timeline.

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