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Randomized controlled trial of a repeat mammography intervention: Effect of adherence definitions on results

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Abstract

Background. As overall mammography rates approach national goals, mammography promotion efforts must increasingly focus on repeat adherence. This randomized controlled trial examined the effect of two interventions on repeat mammography utilization using various adherence definitions.

Methods. 1,558 women aged 40–63 receiving a mammogram through a federally funded screening program were randomized to three groups: mailed reminder (minimum group); mailed thank you card, newsletters, and reminder (maximum group); no mailings (control). The primary outcome (repeat mammogram) was assessed 13, 15, 18, and 24 months after the qualifying mammogram using administrative data.

Results. The proportions receiving a repeat mammogram within 13 months were 0.28, 0.30, and 0.32 for control, minimum, and maximum groups, respectively. The corresponding proportions were 0.38, 0.43, and 0.45 at 15 months; 0.43, 0.49, and 0.51 at 18 months; and 0.47, 0.52, and 0.54 at 24 months. There were no significant differences across study groups at 13 months. The differences between control and maximum subjects at 15, 18, and 24 months were statistically significant. The differences between control and minimum subjects were significant only at 18 months.

Conclusions. The two low-cost mailed interventions evaluated modestly increased repeat mammography utilization. However, effects were not visible until at least 15 months after the qualifying mammogram.
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Keywords: Health education; Mammography; Randomized controlled trial; Intervention studies

Introduction

Despite significant progress in overall mammography rates in this country, considerable room for improvement in repeat mammography use remains. Previous studies have estimated that less than half of eligible women have obtained annual mammograms at least 2 years in a row (Champion, 1994; Clark et al., 2003; Miller and Champion, 1996; Zapka et al., 1991), at most 16% have obtained annual mammograms over a period of three to 6 years (Blanchard et al., 2004; Howe, 1992; Lee and Vogel, 1995; Yood et al., 1999), and less than 10% have obtained annual mammograms over a period of 9–10 years (Blanchard et al., 2004; Michaelson et al., 2002). Since significant population reductions in breast cancer mortality depend on most women adhering to mammography guidelines for extended periods, intervention efforts must increasingly turn to promoting repeat mammography.

A number of randomized controlled trials have evaluated patient-directed interventions for repeat mammography (Andersen et al., 2000; Bodiya et al., 1999; Clark et al., 2002; Costanza et al., 2000; Crane et al., 1998; Davis et al., 1998; Duan et al., 2000; Lauver et al., 2003; Lerman et al., 1992; Lipkus et al., 2000; Mayer et al., 2000; Rakowski et al., 2003; Richardson et al., 1996). Most evaluated relatively

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intensive interventions designed to address attitude and belief barriers (Clark et al., 2002; Crane et al., 1998; Lipkus et al., 2000; Rakowski et al., 2003), but three evaluated mailed reminders and/or educational interventions (Lerman et al., 1992; Mayer et al., 2000; Richardson et al., 1996). The results from these trials are highly variable, ranging from modest to no significant effects (Andersen et al., 2000; Clark et al., 2002; Davis et al., 1998; Lauver et al., 2003; Lerman et al., 1992; Rakowski et al., 2003; Richardson et al., 1996), or significant effects only among certain screening history subgroups (Costanza et al., 2000; Crane et al., 1998; Duan et al., 2000; Lipkus et al., 2000), to pronounced overall differences around 20% (Bodiya et al., 1999; Mayer et al., 2000). Because the variation in effects does not correspond with the intensity of the interventions, some have speculated the variation may be due to methodological differences such as how screening adherence was defined and assessed (Clark et al., 2003).

To enhance comparability across studies, many have advocated for standardized mammography adherence definitions (Clark et al., 2003; Mandelblatt and Yabroff, 1999; Partin et al., 1998; Hiatt, 1997; Hiatt and Rimer, 1999; Legler et al., 2002; Meissner et al., 1998; Yabroff and Mandelblatt, 1999; Vernon et al., 1990). A standard definition classifying women having a mammogram within 15 months of their previous mammogram as adherent has been recommended (Partin et al., 1998), and several recent studies have employed it (Clark et al., 2002; Mayer et al., 2000; Rakowski et al., 2003; Halabi et al., 2000). However, most studies continue to use the "mammogram in the past year/12 months" definition argued to be overly conservative (Partin et al., 1998), and a few recent studies have used adherence measures based on 18-month or longer intervals (Castellano et al., 2001; Harris et al., 2003; Quinley et al., 2004; Reeves and Remington, 1999; Sarr et al., 1998). Differences in repeat mammography rates of up to 48% have been demonstrated in several prior studies examining different screening interval definitions (Clark et al., 2003; Partin et al., 1998; Jepson et al., 1997; Song and Fletcher, 1998). However, the impact of different adherence definitions on effect sizes observed in interventions studies has not been assessed (Vernon et al., 1990).

This study evaluated the effect of two low-cost mailed interventions on repeat mammography use within 13, 15, 18, and 24 months of the previous mammogram, providing the first documentation of how adherence definitions based on different time intervals can impact intervention study conclusions.

Methods

Protocol

Planned study population and setting

The study sample was drawn from the population of women enrolled in the Sage Screening Program in Minnesota, funded by the Centers for Disease Control and Prevention to increase breast and cervical cancer screening rates. The program provides free breast and cervical cancer screening to low-income women through a network of more than 340 hospitals and clinics throughout the state.

Inclusion/exclusion criteria

Women were eligible for the study if they received a mammogram through Sage between June and November 1998 and were aged 40–63 at the time of that mammogram. Women were excluded from the study if they were seen at clinics requesting we not contact their patients (only one clinic did so); had abnormal mammogram results; were diagnosed with breast cancer; or had long lags (>70 days) between when they had their study qualifying mammogram and when it was entered into Sage databases.

Conceptual framework and intervention

The study intervention was guided by the transtheoretical model (TTM) (Prochaska and DiClemente, 1983; Velicer et al., 1999), which posits distinct stages individuals pass through before adopting a desired health behavior (Prochaska and DiClemente, 1982, 1983): (1) *precontemplation* (no prior mammogram and no plan to have one in the next 1–2 years), (2) *contemplation* (no prior or recent mammogram, but an intention to have one in the next year), (3) *action* (one mammogram on schedule and an intention to have another in the next year), and (4) *maintenance* (at least two mammograms on schedule and an intention to have another in the next year). The theory also allows for relapse to previous stages.

Because, only women who had a recent mammogram were eligible for this study, by definition, the majority were in the action or maintenance stage of change at the time we selected our sample. Because previous research suggests interventions designed to reinforce, support, and prompt mammography use will be the most effective approaches to sustaining behavior among women thus predisposed (Prochaska et al., 1992; Rakowski et al., 1998, our intervention used a combination of positive reinforcements, social support, and behavioral prompts to encourage repeat mammography. Because our formative work identified lack of knowledge of the ongoing availability of Sage services as a barrier in the target population (Partin and Slater, 2003), efforts to address this barrier were also integrated into the intervention.

Table 1 provides a summary of the timing, format, content, and purpose of each component included in the interventions. The first mailing (a "thank you" card praising women for having a mammogram, thanking them for participating in Sage, and encouraging them to continue receiving annual mammograms) was sent to women within 1 month of their study qualifying mammogram. The thank you card was followed by three newsletters (mailed approximately 2, 5, and 8 months after the study qualifying mammogram) designed to provide ongoing reminders of the