Evaluation of Mailers Promoting Mammogram Screening
(NCT04555902)

Study Protocol with Statistical Analysis Plan

June 11, 2021

Study Protocol

Purpose

The purpose of this study is to evaluate, prospectively, the potential impact of different mailer conditions (standard content including a free gift, content designed with behavior science, content designed with behavior science including a free gift) on mammogram screening.

Introduction

Mammogram screening for women, starting at age 50, can significantly reduce the risk of complications due to breast cancer. As part of an existing outreach campaign, the health system mails a postcard and small gift (pink socks) to women on the month of their 50th and 64th birthdays to promote annual mammogram screening.

The researchers are evaluating two new versions of the mailers against a standard mailer to see which version leads to greater uptake in mammograms. The new mailers had content that applied behavioral nudge theory - specifically, loss frames and fear appeals - to encourage taking action. One of the two new versions did not include the small gift, to test whether its inclusion or exclusion has any effect on mammogram screening.

Methods

Sample

Female Geisinger Health Plan members turning age 50 and 64 in that month were included in the study. Although the intervention began in October, women with birthdays as early as June 2020 were included. These additional participants were included because the mailer program was paused from June to October 2020 due to the COVID-19 pandemic; the October mailing was meant to contact all the eligible women who were not contacted since June.

Experimental conditions

All participants received a two-sided, 9x6 postcard that had a picture and attention-grabbing slogan in the front. The back of the postcard included a brief, persuasive message, with a toll-free number that could be used for scheduling a mammogram. Participants were randomly assigned to receive one of the three versions of mailers detailed below.

Standard Version with Socks (V1): The picture in front showed a woman posing against a pink background. The slogan in front said, “It’s time to think pink” and the back of the postcard mentioned that staying healthy benefited the recipient and their loved ones. It encouraged recipients to get their annual mammogram and show they are “part of the fight against breast cancer” by putting on some cute pink socks. This postcard and a pair of pink socks were sent together in a larger envelope.

Enhanced Version without Socks (V2): The picture in front showed two women with pink- and grey-colored clothing jogging together. The slogan in front said, "To do: Lower my risk of breast cancer." The back of the postcard framed an annual mammogram as the best way to find and beat breast cancer, with late detection leading to more costs, less effective treatments, and lower chances of recovery. Like the standard version, it mentioned that staying healthy benefited the recipient and their loved ones. This version was not accompanied by socks and was not sent in an envelope.

Enhanced Version with Socks (V3): This postcard was identical to V2, with the exception of an additional message at end, which asked recipients to accept the socks as a small gift and reminder to take care of their health. This postcard and a pair of pink socks were sent together in a larger envelope.

Outcome measures

The primary outcome measure was mammogram completion (yes/no) 6 months from the intervention date.

The secondary outcome measures were mammogram completion at 12 months (yes/no), primary care provider (PCP) visits (count) at 6 and 12 months, Obstetrician-Gynecologist (OB-GYN) visits (count) at 6 and 12 months, breast cancer diagnosis (lab notes) at 6 and 12 months, and emergency department visits (count) at 6 and 12 months.

Exploratory outcome measures were mammogram completion, primary care provider visits, breast cancer diagnosis, and emergency department visits in 2019.

The preregistered plan was to randomly assign participants to different groups through April 2021 (6 months from the start of the intervention; April mailers were sent on April 6, 2021). However, data have not yet been viewed or analyzed as of the uploading of this document. Therefore, random assignment continued past April 2021 and will continue until results inform a decision regarding which version should be sent to all participants. Data until April 2021 will be pulled and examined for the primary analysis. Data past April 2021 may be examined in exploratory analyses.

Statistical Analysis Plan

As of the writing of this plan, all mailers have been sent and the data have not yet been examined.

Primary Research Question: Which mailer version leads to more mammograms?

H1a: Compared to V1, V2 will lead to more mammograms at 6 months.
H1b: Compared to V1, V3 will lead to more mammograms at 6 months.

The researchers do not have a hypothesis on whether sending enhanced versions with or without socks (V2 and V3) would lead to more mammograms.

For these analyses, a logistic regression will be used, using the following model: Outcome ~ Condition. In the model, V2 and V3 will be entered as predictors with V1 as the reference group. For all tests, two-tailed p-values < 0.05 were used to determine statistical significance.

Secondary Research Question 1: Which mailer version leads to greater improvements in health-related outcomes?

H2a: Compared to V1, V2 will lead to more PCP visits, OB-GYN visits (both as proxies for engagement with the health system), and less emergency department visits (less acute issues) at 6 months.
H2b: Compared to V1, V3 will lead to more PCP visits, OB-GYN visits (both as proxies for engagement with the health system), and less emergency department visits (less acute issues) at 6 months.

The researchers do not have a hypothesis on whether sending enhanced versions with or without socks (V2 and V3) would lead to better health-related outcomes.

For these outcomes, regression models with a log-link function and negative binomial distribution will be used (accounting for positively skewed count or count-related data). If the negative binomial models fail to converge or fit appropriately, a Poisson distribution or another model appropriate for the outcome data will be used instead.

The following basic model will be used for the above analyses: Outcome ~ Condition. For each outcome, V2 and V3 will be entered as predictors with V1 as the reference group. For all tests, two-tailed p-values < 0.05 were used to determine statistical significance.

Secondary Research Question 2: Which mailer version leads to more mammograms and greater improvements in health-related outcomes in the long term (12 months)?

H3a: Compared to V1, V2 will lead to more mammograms, PCP visits, OB-GYN visits (both as proxies for engagement with the health system), and less emergency department visits (less acute issues) at 12 months.
H3b: Compared to V1, V3 will lead to more mammograms, PCP visits, OB-GYN visits (both as proxies for engagement with the health system), and less emergency department visits (less acute issues) at 12 months.

The researchers do not have a hypothesis on whether sending enhanced versions with or without socks (V2 and V3) would lead to better health-related outcomes.

For the mammograms, a logistic regression will be used. For the PCP visits, OB-GYN visits, and emergency department visits, regression models with a log-link function and negative binomial distribution will be used (accounting for positively skewed count or count-related data). If the negative binomial models fail to converge or fit appropriately, a Poisson distribution or another model appropriate for the outcome data will be used instead.

The following basic model will be used for the above analyses: Outcome ~ Condition. For each outcome, V2 and V3 will be entered as predictors with V1 as the reference group. For all tests, two-tailed p-values < 0.05 were used to determine statistical significance.

Exploratory Research Question: Which mailer version leads to greater improvements in health-related outcomes over time?

H4a: Compared to V1, V2 will lead to a greater increase over time of PCP visits, OB-GYN visits (both as proxies for engagement with the health system), and decrease over time emergency department visits (less acute issues) in the 12 months after the intervention date compared to 12 months before the intervention date.
H4b: Compared to V1, V3 will lead to a greater increase over time of PCP visits, OB-GYN visits (both as proxies for engagement with the health system), and decrease over time emergency department visits (less acute issues) in the 12 months after the intervention date compared to 12 months before the intervention date.

The researchers do not have a hypothesis on whether sending enhanced versions with or without socks (V2 and V3) would lead to better health-related outcomes.

While the number of mammograms 12 months before the intervention was included as an outcome in the Clinical Trials record, this will no longer be analyzed, as having mammograms in this time period was part of the exclusion criteria. The preregistration of this outcome at this particular time period was done in error.

For the PCP visits, OB-GYN visits, and emergency department visits, mixed-effects regression models with a log-link function and negative binomial distribution will be used (accounting for positively skewed count or count-related data). If the negative binomial models fail to converge or fit appropriately, a Poisson distribution or another model appropriate for the outcome data will be used instead.

The following random intercepts model will be used for the above analyses: Outcome ~ Condition + (1| Participant). For each outcome, V2 and V3 will be entered as predictors with V1 as the reference group. For all tests, two-tailed p-values < 0.05 will be used to determine statistical significance.

Examination of Additional Outcomes

Only descriptive statistics will be reported for breast cancer diagnoses at 6 and 12 months. These will be used to illustrate how many people detected breast cancer due to the program and to estimate the costs to the hospital system.