GENERAL INFORMATION

Evaluation of a Letter Intervention Among At-risk Adults Promoting a Plant-based Diet Using a Combination of Provider Testimonials, the Forks Over Knives Documentary, and Commitment- or Prevention-focused Behavioral Nudges

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OBJECTIVES

Our mission is to promote healthier eating behavior and to reduce costs associated with healthcare. The purpose of this study is to evaluate the effects of mailing randomly selected participants a letter promoting a plant-based diet. Depending on the experimental condition, participants may additionally receive a free documentary, Forks Over Knives, and they may also get letters which use commitment- or prevention-focused messages to encourage watching the documentary and changing their eating behavior. We hypothesize that receiving the documentary will be associated with lower insurance claims and improved health outcomes one and two years later. We also hypothesize that using either commitment- or prevention-focused messages will also contribute to lower insurance claims and improved health outcomes compared to experimental conditions where materials did not include these messages.

BACKGROUND AND RATIONALE

Heart disease and diabetes are the first and seventh leading causes of death in the United States, respectively (Xu J, Murphy SL, Kochanek KD, 2016). Further, these medical conditions put a large strain on the economy. In 2016, treating cardiovascular disease in the United States costed $555 billion, while in 2017, diabetes contributed to $327 billion in medical costs and reduced productivity (American Diabetes Association, 2018; American Heart Association, 2017).

To address these problems in a cost-effective way, multiple randomized control trials have provided evidence that interventions that change people's lifestyles can reduce the risk of heart disease and diabetes (for reviews, see Artinian et al., 2010; Dunkley et al., 2014; Wing et al., 2001). Many of these interventions involved structured programs such as diet and exercise schedules, group sessions, and individual counseling. These programs are still costly in terms of time and personnel commitment and may be difficult to scale up to a larger population. We aim to test whether simply sending people a letter and some materials promoting a healthy diet can by itself promote behavior change and improved health outcomes.

The current study draws inspiration from unpublished research from a health insurance actuary in Omaha, Nebraska, which found that being given information about a plant-based diet can

reduce insurance claims (Beckmann, n.d.). Specifically, policy holders were mailed the documentary Forks Over Knives (Fulkerson, 2011), which promotes a plant-based diet. Prior research suggests that this particular diet can prevent or reverse the effects of heart disease (e.g., Campbell & Campbell, 2005; Esselstyn, Ellis, Medendorp, & Crowe, 1995). Those who received the documentary were also invited to order a book that provided more information about the diet, along with a number of recipes. People who ordered the book showed as much as 17% in reduced insurance claims in the next year. While this finding is promising, the sample was small and not randomly selected.

The current study aims to rigorously test whether receiving the Forks Over Knives documentary and ordering the associated book reduces healthcare costs and improves health outcomes by using a well-powered, randomly-selected sample. This study will not be able to test the effect of the plant-based diet itself, as the documentary does not detail a specific plan, and participants are not required to take any specific action. Rather, we plan to assess whether people's healthcare costs and health outcomes change as a function of being sent materials promoting a plant-based diet. We aim to compare groups of participants who received the documentary against groups who were not contacted, as well as groups who only received a letter promoting a plant-based diet with a personal testimonial.

In addition, the current study aims to test whether subtle design choices in the delivery of the study materials can nudge people towards watching the documentary and making healthy lifestyle changes (i.e., behavioral nudges; Loewenstein, Brennan, & Volpp, 2007; Thaler & Sunstein, 2008). Specifically, we plan to test two behavioral nudges. The commitment nudge involves asking people to write their intentions to implement the behavior of watching the documentary (Milkman, Beshears, Choi, Laibson, & Madrian, 2011). The prevention nudge involves presenting people with the health risk associated with not taking any action. Framing inaction as costly could encourage people to watch the documentary and change their lifestyle to prevent future health complications (Tversky & Kahneman, 1981).

Overall, the current study tests the effectiveness of a relatively low-cost intervention – a documentary promoting a plant-based diet – to reduce healthcare costs and improve health outcomes. This study will also test whether the use of commitment and prevention nudges can encourage more participants to watch the documentary and make lifestyle changes. The findings from this study will help researchers, hospital administrators, and health insurance companies design economical, evidence-supported programs that can improve people's health.

PROCEDURES

Research Design

We will use an experimental study with a factorial design (14 groups: 1 control, 1 letter only, 3 methods of documentary distribution x 4 behavioral nudges; see Detailed Study Procedures). We will also gather outcome data from five years before the intervention to two years after the intervention in order to allow pre-intervention and post-intervention analysis (which includes a primary analysis to be conducted one year after the intervention and a follow-up analysis the following year).

Study Population

Target Population and Inclusion/Exclusion Criteria. We will include Geisinger Health Plan (GHP) policy holders who are aged 18 and older. Participants should meet the following criteria:

- Has two out of the three following medical conditions:
  - Body mass index over 30
  - Diagnosis of type 2 diabetes (specifically, with at least one medication)
  - Diagnosis of cardiovascular disease
- Has health insurance through Geisinger Health Plan (is an active member with a full 12-month enrollment in the previous year) under one of the following categories:
  - Medicare with required primary care provider
  - Medicaid
  - Individual policy under the Affordable Care Act
- Has visited their primary care provider in the past 12 months
- Is not institutionalized
- Does not have cancer, cirrhosis, renal failure, dementia, or active psychosis
- Is not in the same household (spouse or adult child sharing the same address) as another selected participant

Participant Enrollment. There will be two steps in selecting participants for enrollment. For the first step, as many as 15,000 participants will be randomly selected. These are all participants who fulfill the inclusion criteria (based on an estimate from Geisinger Health Plan actuaries). Of this set, 8,800 will be mailed the intervention materials and the remainder (as many as 6,200, based on estimates from the GHP) will be in a control group that will not be contacted or sent any materials. For the second step, all household members (i.e., spouses or adult children sharing the same address) who are also GHP members regardless of inclusion criteria will be included in the data analysis. We need to expand the participant enrollment to these people since we expect that any materials sent to one person may be viewed and discussed by other people in the household. In effect, we are selecting 15,000 households (i.e., households that have eligible participants) and examining the claims and health data of all adult GHP members of that household. To account for these additional participants, we multiplied the number of households by 5, assuming a spouse and as many as three adult children per household, for a maximum sample size of 75,000 participants. Note that this is a generous upper limit to prevent having to stop data collection due to accidentally exceeding a smaller sample size limit. To simplify the discussion of recruitment and experimental groups, we will discuss our proposed plans at the household level, where most of the work will be conducted. For example, the random selection and assignment into experimental groups is done at the level of the household (i.e., 15,000 households selected) and only one set of materials will be sent to each household (as opposed to sending materials to each household member).

Recruitment and Screening Procedures. Geisinger Health Plan actuaries will have access to insurance and medical information necessary to identify eligible participants (see attached document, Proposal to Receive Data from GHP). They will then randomly select 15,000

households (see Participant Enrollment) to be enrolled in the study and randomly assign them to the 14 experimental groups. They will then give mailing information (names and addresses) to the Geisinger mailroom, who will address and mail the study materials. No recruitment or advertisement materials will be used. Our first contact with any households assigned to receive the intervention will be through the mailed study materials. If a household has multiple members, any materials will be addressed to all members of the household.

Detailed Study Procedures. Households will be randomly assigned to one of 14 experimental groups:

- Control group (1): 6,200 households will not be contacted, but their insurance and health data will be examined. This number is an estimate of the remainder of eligible participants who were not selected for other experimental groups. We plan to analyze the data of all remaining participants, as this increases statistical power for analysis without any additional cost in sending materials.
- Letter group (2): 2,200 households will receive a letter promoting a plant-based diet. This letter will feature a personal testimonial about the benefits of this diet (see attached document, Letter Versions).
- Groups 3-14 (550 households each) will receive a letter promoting a plant-based diet and the Forks Over Knives documentary. All of these households will be given a form and online link where they may choose to order a book that has more information on plant-based diets as well as a number of recipes. The groups will vary based on the method of delivering the documentary and the presence or absence of behavioral nudges in the letter. All possible combinations total to 12 groups.
    - Method of delivering the documentary
        - Online link
        - DVD
        - Online link and DVD
    - Behavioral nudge in the letter (see attached document, Letter Versions)
        - No nudge: There are no behavioral nudges included in the letter.
        - Commitment nudge: At the end of the letter promoting a plant-based diet, participants will be asked to write dates and personal signatures committing to watching the documentary. They will be asked to mail back this written commitment.
        - Prevention nudge: As part of the letter promoting a plant-based diet, one paragraph will describe the risks of not taking action. This phrasing reframes the status quo as contributing to future loss (e.g., costs of medication and operations).

We will record which households ordered the book and mail them the book. We will also record which participants mailed back written commitments.

To compare pre-intervention and post-intervention insurance and health data, we will use the following data (see data management and confidentiality section for more details on personnel with access to identifiable data):

- Geisinger Health Plan (GHP) actuaries will provide the initial participant list. This data includes identifiable data (name, date of birth, address, medical record number), but it will be processed by GHP actuaries who already have access to this information as part of their normal job responsibilities.
- Analysts from Business Intelligence Advanced Analytics (BIAA) will provide insurance claims data (amount of claims, number of specialty/primary care physician visits, number of prescriptions) and health data (body mass index, blood pressure, hemoglobin a1c, patient health questionnaire-2). This data is identifiable (name, date of birth, address, medical record number), but it will be processed by members of the BIAA and their colleagues, all of whom already have access to this information as part of their normal job responsibilities.
- The data broker (Henri Carlo Santos) will only have access to the identifiable data (name, date of birth, address, medical record number) in order to link these files. The other investigators will only have access to coded datasets (i.e., data stripped of identifiers).

The steps for dealing with identifiable data are detailed below:

- GHP actuaries will create a spreadsheet of all eligible participants, using inclusion and exclusion criteria (see Target Population and Inclusion/Exclusion Criteria).
- The data broker (Henri Carlo Santos) will receive this spreadsheet and will randomly assign participants to experimental groups. He will generate a spreadsheet of participant names, and addresses, information on which participants are part of the same household, and codes indicating experimental group the household is in.
- The spreadsheet will be given to the Geisinger mailroom, whose members generates address labels, and place different materials in the envelopes depending on the experimental group. The members of the mailroom will have access to names and addresses as part of their normal job responsibilities. They will not have any way of knowing what other information the names and addresses are linked to. Additionally, they will be only informed of the what materials to place in the envelopes for a given experimental group and will not know any details of the research study.
- Depending on the experimental group, some households will be invited to either mail back response forms or respond on an online link. Henri Carlo Santos will have access to the online link, and all mailed forms will be sent to him. He will record these responses.
- Henri Carlo Santos will forward any orders for a book to the Geisinger mailroom, which will address and mail a package with the book.
- One year after the intervention begins, BIAA analysts will provide outcome variables to Henri Carlo Santos.
- Once the outcome data from the BIAA analysts arrive, Henri Carlo Santos will merge the datasets using medical record numbers. He will remove all identifiable information from the dataset and share the coded dataset with other investigators. This will be used for the primary analysis that will be used to evaluate the effects of the intervention and its reception by Geisinger members. The primary data analysis is set for one year to match Beckman's (n.d.) Omaha study and to report on the results of the study in a timely manner to GHP.
- Two years after intervention begins, BIAA analysts will provide outcome variables to Henri Carlo Santos. This will be for a secondary analysis, which examines participants

two years later and aims to test for any longer-lasting effects of the intervention. Henri Carlo Santos will merge the datasets using names and addresses. He will remove names and addresses from the dataset and share the coded dataset with other investigators. Afterwards, the dataset with identifiable information will be deleted.

Participant Compensation. There will be no compensation for any of the participants. Those in the groups receiving the documentary will receive a free documentary (either via online link or DVD) and the option to order a free book as part of the study. They will be provided with stamped and addressed envelopes for sending commitment and/or request forms.

Participant Withdrawal. Participants are free to engage with the mailed materials to any degree that they choose. They may even choose not to open or read the materials. Regardless of how they respond other materials, their insurance and health data will still be analyzed, as with the participants in the control group.

STUDY DATA DETAILS

Data Management Procedures and Confidentiality. Paper data will be in the form of mailed commitment and book order forms. They will be handled by the Geisinger mailroom and Henri Carlo Santos. This includes identifiable information (names and addresses) and will be stored in locked file drawers in the Geisinger mailroom, the Autism and Developmental Medicine Institute, and Geisinger Office Building 1. After study completion, these files will be moved to a locked file drawer in Geisinger Office Building 1 and will be stored for 3 years.

All other data will be electronic and stored in password-protected spreadsheets on the investigators' password-protected computers. Datasets with identifying information will only be store on password-protected computers of the data broker (Henri Carlo Santos) for the purpose of linking datasets from different sources. These data will be stored in Geisinger's Virtual Desktop Infrastructure, which will have its own backup system. After all data have been linked in a de-identified, coded file, the datasets with identifiable information and any codes needed to link the identifiable information will be deleted. After the de-identified data have been fully analyzed, the de-identified dataset will be shared along with other publications from this study. The deidentified data will not be destroyed or removed after any period of time has elapsed. We intend to permanently and securely archive the deidentified dataset in order to be consistent with the best practices for open and reproducible science, as well as our obligation to the public as researchers.

Access to identifiable and protected health information will be limited to the following departments and people:

- Names and addresses only
    - Geisinger Mailroom
- Names, addresses, and electronic health records
    - GHP actuaries
- Names, medical record numbers, and electronic health records
    - BIAA analysts

- Names, addresses, medical record numbers, and electronic health records
    - Henri Carlo Santos (data broker)

The GHP, Geisinger mailroom, and BIAA analysts already have access to this kind of information as part of their normal job responsibilities. In addition to the names mentioned above, the investigators Amir Goren, Christopher F. Chabris, and Michelle N. Meyer will have access to the de-identified, coded data during data analysis.

Confidentiality will be maintained by taking the steps described above and by only sharing the deidentified dataset through a gated repository.

Data Analysis/Statistical Considerations. Preliminary power analysis for the reported effect in the unpublished study that inspired the current study (Beckman, n.d.) suggested a minimum sample size of 400 households. This computation was performed on G*Power and was based on the effect of people who requested (vs. did not request) a book on insurance claims. We increased this number to 550 households per group to have increased power. We allowed the control group to have a large number – the number of eligible participants who were not selected – as this is little cost in getting this sample, and it increases the statistical power of our analyses. The extent of the increase was guided by our overall budget and our preliminary estimates of costs. Across all experimental groups, this will yield a total of 15,000 households (see Participant Enrollment). This sample size is very large in the field of psychology and provides adequate statistical power for all confirmatory and exploratory statistical analyses.

We will analyze the data using standard survey research analyses methods, including computing bivariate correlations, using general linear models, using non-parametric models for non-normally distributed insurance data, and entering variables as independent predictors in regression models to attempt to predict desired outcomes. The primary analysis will focus on data one year after the intervention begins. Follow-up analysis will be conducted two years after the intervention begins. The analysis will conduct separate analyses of the selected participant (i.e., the individual who met the eligibility criteria) and other members of that participant's household. This will test whether there are any spillover effects of the intervention to other people in the household.

EXPECTED RISKS/BENEFITS

Risks. This study poses no more than minimal risk for participants. The letter participants will receive only mentions a vegetarian diet, with no specific plan recommended for participants (see attached document, Letter Versions). Although the topic of health may cause some stress for people, the letter would be similar to an everyday conversation about health and nutrition. In addition, Forks Over Knives is a PG-rated documentary that is already available on common media outlets like Netflix. Still any potential risks are noted below.

- Participants may attempt to make medicinal changes without professional guidance. We try to reduce this possibility by clearly stating in the letter that the materials are not professional medical advice and that they should consult with a doctor before making any changes to their medication.

- There is little risk for loss of confidentiality. Only a few people have access to identifiable data and most of them only have access to names and addresses. Only GHP actuaries, BIAA analysts (both as part of their occupation) and Henri Carlo Santos will have access to protected health information, and both are within the Geisinger Health System.
- There are no known political, economic, or social burdens that participants might face as part of this research.
- There may be some suspicion of goals of the investigators and of the Geisinger Health Plan if people figure out that only certain people are targeted. For this reason, only individual (and not group) plans were included to prevent discussions among people who share the same plan.

Benefits. Participants who receive any level of the intervention will potentially learn beneficial information about the importance of lifestyle to health and specifically, about plant-based diets. However, as we do not prescribe or enforce a specific action, there is a wide range of possible benefits. Regardless, participants are given educational materials in the form of a documentary and a book with more information and recipes (if they choose to request the book). Even without specifically following the recommendations of the documentary or book, participants may become motivated to take better care of their health by setting goals, consulting with medical professionals, or making other lifestyle changes. Any of these behaviors can result in increased knowledge about personal health, improved health outcomes, and reduced spending on healthcare.

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