Title: Optimizing an mHealth Intervention to Change Food Purchasing Behaviors for Cancer Prevention
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Study Design

This study is a National Cancer Institute (NCI)-funded pilot, randomized controlled trial (R21CA252933) utilizing a factorial design to test the effect of four different intervention components on dietary intake and grocery store purchases. The four factors yield 16 different combinations of intervention components (Table 1). An equal number of participants were randomized to receive vs. not receive each of the four experimental intervention components. For example, half of participants have their food purchasing data monitored by a coach and half do not have this feature as part of their intervention. As another example, half of participants were randomly assigned to have household member involvement included in their intervention package, but this randomization was done independently of that for coach monitoring (i.e., the four experimental intervention components were not "bundled" together). Baseline covariates used for randomization included biological sex, body mass index (BMI), age, household size, and dietary adherence score.

Ethics Approval

This study was approved by the Drexel University Institutional Review Board (Study ID #2003007695) on March 13, 2021.

Participants, Eligibility, and Recruitment

The study enrolled 62 index participants, as well as 31 household members who are serving in a support role. Participants were recruited from the Philadelphia area in two cohorts via targeted mailings, social media outreach, and Craigslist listings, and was supported in part by community recruitment resources from Thomas Jefferson University's Sidney Kimmel Cancer Center. Specifically, Jefferson's Regional Liaison Office employed their "honest broker" system which aided in identifying and contacting potential participants using internal communication resources, community contacts, and other available resources (e.g., participants within the Jefferson community who matched eligibility criteria were emailed about their interest in participating). Interested individuals completed a screening survey and, if deemed preliminarily eligible, attended an information session via videoconferencing. After the session, those interested in participating attended a baseline assessment, in which their final eligibility was determined.

Index participants were required to be age 18 or older and fluent in English. In addition, participants were required to be the primary grocery shopper in their household and report shopping at stores that could passively stream item-level data from a store loyalty card to the project portal (Walmart, Target, ShopRite, or Wegmans). Inclusion criteria also included having a smartphone with an iOS or Android operating system that was compatible with the program app and living in a household with another adult who indicated willingness to participate in a support role. Exclusion criteria were as follows: medical condition or psychiatric condition (e.g., active substance abuse, eating disorder) that would be a poor match with program content or limit ability to comply with program dietary recommendations; plans to enroll in another lifestyle modification program within 6 months of program start; bariatric surgery history; pregnant or breastfeeding or plans to become pregnant in the next 6 months. All index participants provided written informed consent for participation, as did the 31 household members of index participants randomized to HH.

Intervention

Uniform components

All index participants attend a nutrition education workshop (three sessions, 90 minutes each, all delivered via videoconferencing software) focused on eating a diet consistent with WCRF/AICR guidelines. Content is organized around the key WCRF/AICR dietary recommendations: 1) eat a diet rich in whole grains, vegetables, and fruit; 2) limit consumption of highly processed foods; 3) limit consumption of red and processed meat; 4) eliminate consumption of sugar-sweetened beverages. Sessions consist of psychoeducation about these nutrition recommendations, group discussions on health behavior change (e.g., common triggers for eating behavior), didactics on behavioral skills (e.g., stimulus control, functional analysis, problem solving), and hands-on practice (e.g., reading a nutrition label). Each workshop concludes with goal setting and meal planning, where participants identify concrete guideline-related goals for the coming week, create a weekly meal plan, and begin constructing a grocery list for relevant items. They are encouraged to finish their meal plan and grocery list independently after each session. Workshop sessions consist of 10-15 participants each. Coaches are experienced in delivering lifestyle modification and have an MS or Ph.D. in psychology, nutrition, or a related field. Each participant has continuity working with the same coach for all workshop sessions and, if applicable, any additional condition-specific contacts (i.e., extra workshop sessions, coaching calls, and coach messages).

All index participants also download an app that was created for this program (Figure 2). A key feature of the app is a display of graphs that reflect how well the participant's grocery shopping purchases align with each of the program recommendations across the previous 4 weeks. Participants are encouraged to utilize these graphs to track their progress and improvement towards recommendations over time. The grocery shopping data displayed in the graphs is passively collected from participant's store loyalty accounts, as described below. During the 20-week intervention period, all participants also receive once-weekly educational messages in the app that remind them of program dietary recommendations and behavioral strategies that can promote adherence (e.g., planning, self-monitoring, goal setting). Message content includes tips for meeting program guidelines such as swapping out processed snacks for healthier alternatives, or recipe ideas to incorporate fruits and vegetables (e.g., "Replacing high-calorie, processed foods with fruits, vegetables, whole grains, beans, and legumes can help you feel fuller longer, have more energy, and better manage cravings and appetite, all of which can help you manage your weight. Identify one thing you could do this week to continue to make progress on the goal of replacing processed foods with healthier items"). These messages are standardized, such that the content in any given week's message is the same for all participants.

Experimental intervention components and contact time

As described next, the four experimental intervention components are each provided to 50% of participants, in addition to the three workshop sessions and standard weekly messages that all participants receive. The study was designed such that program contact time varies by condition, in order to evaluate the benefit of added contact time. The total number of workshop sessions ranges from 3 to 5, with 26% of participants assigned to 3 sessions (i.e., no extra workshop sessions), 48% assigned to 4 sessions (i.e., one extra workshop session),

and 26% assigned to 5 sessions (i.e., two extra workshop sessions). The total number of coach calls ranges from 0 to 9, with 18% of participants assigned to 0 calls, 29% assigned to 3 calls, 39% assigned to 6 calls, and 14% assigned to 9 calls.

As described in detail next, all participants receive one message from the app each week that includes standardized educational content, and half of participants have benefits of change content appended to the message. For half of participants, delivery of the educational app message is location-triggered. Half of participants (i.e., those who receive coach monitoring) also receive a second message in the app each week, which is written by their coach. Half of participants have a message sent to their household member each week.

Location-triggered messages

Participants randomized to receive this component receive their weekly educational message in the program app when their smartphone is within a 50-meter geofence around designated grocery stores. At baseline, participants provided information about venues where they regularly grocery shop, for geofence programming. If the system does not detect the designated location in a given week (e.g., the participant does not go to the grocery store), the app message is delivered at the end of the week. The message is only delivered once per week, even if the participant is at a grocery shopping location more than once.

Participants who are not assigned to location-triggered message delivery receive their weekly educational messages at a fixed time (i.e., Sundays at 10am), regardless of location. The content of the messages does not differ according to whether location-triggered messaging is provided or not.

Reflections on benefits of change

Participants randomized to receive the benefits of change component receive one extra 60-minute workshop session, to reflect on the anticipated benefits of purchasing healthy foods. They also attend three brief, individual coaching calls (20 minutes each) to further discuss personally meaningful benefits of change (at weeks 9, 13, and 17). Personalized content on their anticipated benefits is also added to each educational app message delivered after week 5. During the benefits of change workshop session, participants individually complete an exercise identifying short- and long-term benefits of healthy eating that are important to them, and message content is programmed according to the responses they record. (Example: "Making healthy choices today will pay off in the long run because [I will be modeling these choices for my children, and they will benefit from healthier eating as well]," where bracketed input was generated by the participant.)

Participants who do not receive the benefits of change component do not attend the additional workshop or these three coach calls focused on benefits of change, and do not receive additional message content.

Coach monitoring

For participants assigned to receive coach monitoring, the coach accesses a web-based portal where they view the participant's food purchasing data, which is passively collected from the point of purchase using store loyalty accounts. The coach sends the participant a personalized message each week in the app, sharing feedback and observations from the food purchasing data. The participant also completes three calls with the coach (20 minutes each, held in

weeks 4, 10, and 15) designed to further enhance supportive accountability for program goals. The coach messages and calls provide reinforcement for purchases consistent with program goals (particularly those that represent a change from baseline) and express concern for areas in which adherence is low.

If a participant is not assigned to receive coach monitoring, the coach has no objective information about food purchasing and the participant does not receive any personalized coach messages in the app or phone calls focused on coach monitoring.

Household support

Participants assigned to receive household support as part of the intervention select one adult in their household to serve in the support role. This household member receives weekly text messages (Example: "Your household member is likely trying to keep up new healthy habits for meal planning and grocery shopping. Identify one thing you can do to support their efforts with these changes this week. For instance, communicating in advance about meal and snack preferences, showing appreciation, or offering to look for healthy recipes to try."). Additionally, the index participant and household member jointly participate in one extra 60-minute workshop session and three 20-minute coaching calls focused on household support (held in weeks 7, 11, and 16). (The household member does not attend any other workshop sessions or coaching calls). The content of the workshops and calls is designed to elicit support for changing the home food environment and enhance supportive accountability by making household members aware of the index participant's commitment to improving dietary intake.

For index participants who are not assigned to receive this intervention component, household members have no program involvement.

Measures

Feasibility and acceptability

Feasibility and acceptability data are being collected and will be compared to pre-established benchmarks. Recruitment feasibility will be operationalized with a benchmark of >5 participants enrolled per month of recruitment and <30% of those otherwise interested/eligible refusing participation. Retention feasibility will be operationalized with a benchmark of >70% of participants completing each follow-up assessment. Feasibility and acceptability of food purchasing data will be operationalized with a benchmark of >90% of participants having food purchase digital data successfully captured. Feasibility for message delivery will be assessed by location-triggered messaging delivery, with successful receipt of messages measured by <5% of delivery encountering technological problems. User-rated acceptability will be measured by the benchmark of a mean rating >28 on the Treatment Acceptability Questionnaire (adapted, 8-items; 7-point Likert scale; given at 10 and 20 weeks). Qualitative information about acceptability will be collected via post-intervention focus groups. Focus groups will be audio recorded, transcribed, with responses coded for themes and patterns, and used to further refine the intervention for future testing.

Dietary intake

All participants complete dietary intake questionnaires at 0 and 20 weeks. Cohort 1 participants completed three days of food recalls at each time point, administered by the Automated Self-

Administered 24-hour Dietary Recall (ASA24), an NCI-designed software tool [86]. ASA24 is based on the well-validated automated multiple pass method, which has been shown to be as or more accurate than nutritionist-administered 24-hour food recall when using doubly labeled water as the criterion.

After baseline administration of the ASA24, many Cohort 1 participants reported that they perceived this measure to be excessively burdensome. Due to the low acceptability, we replaced the ASA24 with the Diet History Questionnaire (DHQ-III) for Cohort 2 participants, due to its streamlined format and reduced completion time. The DHQ-III is a food frequency questionnaire developed by the NCI. The nutrient and food group database for DHQ-III is based on a compilation of national 24-hour dietary recall data from the National Health and Nutrition Examination Surveys. Cohort 2 participants completed the DHQ-III at baseline and will complete it again at 20 weeks. Given the different measures of dietary intake, differences in dietary intake variables across waves will be assessed and analyses on dietary intake will be conducted separately for each wave.

Both the ASA24 and DHQ-III provide item-level nutritional information for all food/drinks consumed as well as daily totals of various nutrient variables. For the NCI recommendation specific to highly processed food, food items will be flagged and included in this category based on those defined as highly processed based on the widely used NOVA classification system. Items in the processed food category include salty snacks, frozen and prepared meals, baked goods, dessert, fried potatoes, candy, packaged bread and buns, refined grains, breakfast cereal, processed cheese, etc. Relevant items that fall into this category are pulled from the ASA24 items-level output based on their Food and Nutrient Database for Dietary Studies (FNDDS) food code and from the DHQ-III items-level output based on their coding in the NCI's associated nutrient database and included in nutrient total calculations for processed foods. Similarly, sugar-sweetened drinks are identified in the ASA24 (based on their FNDDS food code) and DHQ-III (based on nutrient database) and used to calculate adherence to the relevant guideline. Sugar-sweetened drinks include non-diet sodas, non-diet fruit drinks, energy drinks, and sugary coffee drinks.

Average daily intake of the following items relevant to NCI dietary recommendations will be calculated from the ASA24 and DHQ-III:
1. Fiber: grams of fiber
2. Fruit and vegetables: cups of all fruit (intact whole or cut fruit not including fruit juices) and vegetables (all vegetables excluding starches)
3. Added sugar from processed food: grams of added sugar consumed from items flagged as highly processed (as described above)
4. Saturated fat from processed food: grams of saturated fat consumed from items flagged as highly processed (as described above)
5. Sodium from processed food: milligrams of sodium consumed from items flagged as highly processed (as described above)
6. Red meat: ounces of beef, veal, pork, lamb, and game meat
7. Processed meat: grams of frankfurters, sausages, corned beef, and luncheon meat made from beef, pork or poultry
8. Sugar-sweetened drinks: ounces of sugar-sweetened beverages (as defined above)

Given that NCI dietary recommendations for red and processed meat are on the week (vs. daily) level, average daily intake of red and processed meat are prorated to reflect intake over 7 total days.

Scores for adherence in each domain of the NCI dietary recommendations are calculated based on the 0, 0.5, 1 cutoff values established previously, where 1 reflects fully meeting the recommended level of intake, 0.5 indicates partially meeting recommended levels, and 0 reflects failure to meet the recommendation. When guidelines include multiple sub-categories (e.g., fiber and fruits/vegetables), the guideline score was calculated as the average of adherence on sub-categories. Two overall adherence scores were calculated: 1) the sum of adherence on the four guidelines (range 0-4) and 2) average adherence on the four guidelines (range 0-1). The subscores are: a) average of adherence scores for fiber and fruits/vegetables, b) average of adherence scores for added sugar, saturated fat, and sodium in processed foods, c) average of adherence scores for red and processed meats, and d) adherence score for sugar-sweetened drinks.

As a secondary outcome for dietary intake, an adapted, 13-item Food Frequency Questionnaire is administered at baseline and 20 weeks. Each item pertains to one of the four dietary guidelines (e.g., "Whole grain products or high fiber starches", "Red meats such as beef, pork, lamb", "Non-diet sweet drinks"), and participants are instructed to report the frequency with which they ate the foods in the past month with a 6-point Likert-type scale (ranging from 0 - "never" to 5 - "twice or more per day"). Total guideline scores will be calculated as the average of responses to all items pertaining to that guideline (e.g., guideline 1 as the average of 0-5 response for fiber and 0-5 response for fruits/vegetables).

Mediators

Consistent with the study's conceptual model, three potential mediators are measured. An adapted Goal Salience Questionnaire is administered at each time point (baseline, 10, and 20 weeks) to measure dietary goal salience, i.e., the extent to which participants think about dietary recommendations when grocery shopping. Motivation for dietary adherence is measured with items adapted from the Treatment Self-Regulation Questionnaire [98] at each time point. Two measures of household social factors are administered at baseline, 10 weeks, and 20 weeks, where items were adapted to apply to one's household rather than social network more broadly: Supportive Accountability Questionnaire and Sallis Social Support for Diet.

Moderators

Several potential moderators were measured at baseline. Participants completed a self-report demographics questionnaire that gathered information about sex, race, ethnicity, age, education level, household size, and grocery shopping frequency. To measure the quality of the relationship between the index participant and their household member, an adapted version of the Relationship Assessment Scale [103] was administered. Weight, height, and weight history were measured using an investigator-developed weight history questionnaire. Uncontrolled eating, cognitive restraint, and emotional eating were measured with a 21-item

version of the Three Factor Eating Questionnaire-R21 (TFEQ-21-item version) at baseline. The TFEQ will be completed at 10 and 20 weeks as well.

Household Member Information

Participating household members are administered the following questionnaires, which will be examined in exploratory analyses: an investigator-developed household demographics and goals questionnaire (at baseline only), the adapted Food Frequency Questionnaire (same instrument administered to index participants, at baseline and 20 weeks), and the Treatment Acceptability Questionnaire (same instrument administered to index participants, at 20 weeks).

Grocery store purchases

Beginning four weeks before intervention start date and continuing until four weeks after intervention end date, study software, utilizing an application programming interface (API), will continuously collect each participant's item-level food purchases to objectively measure how grocery shopping changes over time. Participants provided store account credentials for loyalty programs at one or more of the four designated stores (Wegmans, ShopRite, Target, and/or Walmart) to the study team at baseline. The API links item-level food purchases with nutrition databases (e.g., FNDDS) to create summary nutrition variables, including added sugar, sodium, and saturated fat from processed foods for each item in a grocery trip. Change in purchase amounts in each nutrition category of interest related to NCI guidelines (e.g., ounces of sugar sweetened beverages purchased per week) will be calculated. This will be an exploratory outcome because this method of data capture and categorization of grocery purchases is novel, and feasibility has not yet been tested.