BMJ Open

A randomised, controlled trial of alternative messages to increase enrolment in a healthful food programme among individuals with diabetes

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2016-012009
Article Type:	Research
Date Submitted by the Author:	21-Mar-2016
Complete List of Authors:	Gopalan, Anjali; Corporal Michael J. Crescenz VA Medical Center; Kaiser Permanente Northern California, Division of Research Paramanund, Jithen; Discovery Vitality Shaw, Pamela; University of Pennsylvania Perelman School of Medicine, Department of Biostatistics and Epidemiology; University of Pennsylvania, LDI Center for Health Incentives and Behavioral Economics Patel, Deepak; Discovery Vitality Friedman, Joelle; University of Pennsylvania Perelman School of Medicine, Departments of Medicine and Medical Ethics and Health Policy; University of Pennsylvania, LDI Center for Health Incentives and Behavioral Economics Brophy, Christine; Vitality USA Buttenheim, AM; University of Pennsylvania School of Nursing, Department of Community and Family Health; University of Pennsylvania, LDI Center for Health Incentives and Behavioral Economics Troxel, Andrea; University of Pennsylvania Perelman School of Medicine, Department of Biostatistics and Epidemiology; University of Pennsylvania, LDI Center for Health Incentives and Behavioral Economics Asch, David; Corporal Michael J. Crescenz VA Medical Center; University of Pennsylvania, LDI Center for Health Incentives and Behavioral Economics Volpp, Kevin; Corporal Michael J. Crescenz VA Medical Center; University of Pennsylvania, LDI Center for Health Incentives and Behavioral Economics
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Diabetes and endocrinology, Public health
Keywords:	DIABETES & ENDOCRINOLOGY, health promotion, messaging, active choice, NUTRITION & DIETETICS

Title: A randomised, controlled trial of alternative messages to increase enrolment in a healthful food programme among individuals with diabetes

Corresponding Author:
Anjali Gopalan
2000 Broadway
Oakland, CA, USA, 94618
Anjali.Gopalan@kp.org

Authors: A Gopalan[1,2], J Paramanund[3], PA Shaw[4,5], D Patel[3], J Friedman[5,6], C Brophy[7], AM Buttenheim[8,5], AB Troxel[4,5], DA Asch[1,5,6,9], KG Volpp[1, 5, 6, 9]

Affiliations:

1. Corporal Michael J. Cresencz VA Medical Center, Philadelphia, PA, USA
2. Kaiser Permanente Northern California, Division of Research, Oakland, CA, USA
3. Discovery Vitality, Johannesburg, South Africa
4. Department of Biostatistics and Epidemiology, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, USA
5. LDI Center for Health Incentives and Behavioral Economics, University of Pennsylvania, Philadelphia, PA, USA
6. Departments of Medicine and Medical Ethics and Health Policy, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, USA
7. Vitality USA, New York, NY, USA
8. Department of Community and Family Health, University of Pennsylvania School of Nursing, Philadelphia, PA
9. Department of Health Care Management, Wharton School, University of Pennsylvania, Philadelphia, PA, USA

Running title: Uptake of a healthful food benefit in adults with diabetes

Key Words: diabetes, health promotion, messaging, active choice, diet

Word count:
Abstract: 367, Body: 1730

Abstract

Objectives: We compared the effectiveness of diabetes-focused messaging strategies at increasing enrolment in a healthful food programme among adults with diabetes.

Methods: The HealthyFood (HF) programme is designed to encourage healthier eating by providing cash back for healthful food purchases. We randomised adults with diabetes to one of five arms: 1) control, 2) a diabetes-specific message, 3) a message with a recommendation of HF written from the perspective of a HF member with diabetes, 4) a message containing a physician's recommendation of HF, or 5) the diabetes-specific message from Arm 2 paired with an "enhanced active choice"(EAC). In an EAC, readers are asked to make an immediate choice (in this case, to enroll or not enroll); the pros and cons associated with the preferred and non-preferred options are highlighted. HF enrolment was assessed one month following the first emailed message.

Results: Eligibility was determined at the start of the calendar year and 3906 members underwent randomisation. After excluding those who enrolled in HF or had departed from the Vitality program prior to the time of the first intervention email, 3665 (94%) were included in a modified intent-to-treat analysis. All four experimental arms had significantly higher rates of enrolment in HealthyFood compared to control ($p<0.0001$ for all comparisons). When comparing experimental arms, the diabetes-specific message with the EAC had a significantly higher enrolment rate (12.6%) than the diabetes-specific message alone (7.6%, $p=0.002$). There were no adverse events related to this completed study.

Conclusions: Messages focused on diabetes were effective at increasing enrolment in a healthful food programme. The addition of a framed active choice to a message significantly raised enrolment rates in this population. These findings suggest that simple, low-cost

interventions can enhance enrolment in health promoting programmes and can also be pragmatically tested within those programmes.

Trial Registration: NCT02462057; Testing Different Messaging Approaches to Increase Activation of a Healthy Food Benefit in Adults with Diabetes.

Strengths of this study

- In this randomised, controlled trial, we found that diabetes-specific messaging strategies were effective at increasing enrolment in a healthful food programme among adults with diabetes.
- The incorporation of a behavioural economics-based technique called “enhanced active choice” that prompted an immediate decision was the most effective at increasing programme enrolment.
- These findings speak to the potential of simple, low-cost interventions to promote engagement in programmes designed to encourage healthier behaviours in high-risk, high cost populations.

Limitations of this study

- Few demographic details were available on randomised participants, limiting conclusions regarding the generalisability of the findings to other populations.
- While large differences in programme enrolment were observed, this does not necessarily translate into programme utilization, diet, and health outcomes. Still, enrolment is a critical first step.

INTRODUCTION

Considerable evidence demonstrates reduced cardiovascular complication risk in adults with type 2 diabetes who consume a healthier diet.[1-4] Maintaining healthy diets, however, is a considerable challenge for many.

The HealthyFood (HF) benefit is a three-tiered incentive program designed by Vitality, an incentive-based wellness program that is part of the South Africa-based insurer Discovery Health, to encourage healthier eating by offering monthly cash back for healthful food purchases. Upon activation, members are eligible for 10% cash back monthly. By completing additional steps, members can increase their cash back amount to 25%. While available to all Vitality members as a free benefit, the participation rate among members with diabetes, in whom the benefits of healthy food might be particularly important, has been lower than desired.

Improved messaging about HF to increase its salience for individuals with diabetes could be a low-cost way to increase program enrolment. Past work demonstrates the importance of message framing on subsequent actions, ranging from organ donor registration to vaccine adherence.[5-7] Strategic messaging may also prompt more immediate action. Given the financial benefits of enrolling in HF, it is conceivable that some members intend to enrol but postpone the task. To combat procrastination, we tested an approach that asked participants to make an immediate “active choice.” This choice was further enhanced by highlighting the relative benefit of the preferred option.[8] Past work using “enhanced active choice” has shown success in increasing health-related behaviours ranging from influenza vaccination to automated pharmacy refill enrolment.[8]

In this study, we compared the effectiveness of diabetes-focused messaging strategies in increasing HF enrolment among Vitality members with diabetes. We hypothesised that

messages that are more personalised and relatable, as well as those that prompt immediate action, would increase the rate of enrolment.

METHODS

Study Design

The protocol was approved by the University of Pennsylvania Institutional Review Board and the University of Witswatersrand Ethics Committee. Study participants were all eligible Vitality members at the time of randomisation. Participants were assigned to one of the five study arms with equal chance, following a simple randomisation scheme. The study statistician generated a randomisation list and this was sent to Vitality who then linked this list to their eligible member database according to study ID. Automated email messages were generated and sent according to arm assignment. Participants were already enrolled at the time of randomisation and the analytic team had no contact with study participants. Because this study addressed alternative messages by study arm, participants were not blinded to the assigned intervention.

Study Population

Eligible participants lived in South Africa, were Vitality members 18 years old or older with a diagnosis of diabetes, were not yet enrolled in HF, and were registered on the Vitality website (reflecting internet access and an available email address).

Study Outcomes

The primary outcome was HF enrolment at one month, collected using Vitality internal, electronic tracking systems.

Member Involvement

Vitality members were not involved in the research design or in the selection of outcome measures.

Study Intervention

Eligible members were randomised to one of five study arms with equal chance: 1) control arm (no message), 2) a diabetes-specific message, 3) a message with a recommendation to participate in HF written from the perspective of a Vitality member with diabetes, 4) a message with a recommendation to participate in HF from a physician with diabetes expertise, or 5) the diabetes-specific message from Arm 2 paired with an "enhanced active choice". All tested messages were written by the study team, delivered via email, and contained common elements: a personalised subject line, a description of the HF benefit, mention of two potential health benefits for individuals with diabetes (better sugar control and weight management), and a link to initiate enrolment.

The diabetes-specific message contained only the elements described above. The diabetes-specific message with an "enhanced active choice" included the following choices, which were designed to make more salient the advantages/disadvantages of enrolling/not enrolling: *"Yes! I want to active the HealthyFood benefit and get up to 25% cash back on the healthy food I buy.*" or "*No, I'd prefer not to activate and continue paying full price for my healthy food purchases.*" The "Yes" checkbox took participants directly to the HF enrolment site. The "No" box linked to an internal website informing subjects that they could still enrol at a later time. The diabetes-specific messages with and without the "enhanced active choice" used in the study are included as a supplemental figure.

The intervention occurred in June and July 2015. We sent three email messages (an initial message plus two reminders) to participants in the experimental arms. All messages were separated by at least two days. Before the second and third messages, participant data was refreshed and only participants who had not signed up for HF were sent reminders.

Statistical Analysis

There were 5467 individuals determined to be initially eligible in January 2015. After excluding subjects due to enrolment in HF prior to the intervention and departures from the Vitality programme, we estimated that at least 3500 individuals would still meet eligibility criteria at the time of the study launch in June 2015. The initial sample was identified several months before the launch to allow study participants ample time to have learned about HF from other sources (e.g., Vitality website and marketing communications) and enrol if interested. The primary endpoint of interest was a binary indicator of enrolment; pairwise hypothesis tests of enrolment rates were planned across the five arms, for a total of ten possible comparisons. The anticipated sample size of 3500 provided 80% power to detect a 3% pairwise difference between the proportions of participants who enrolled in HF with significance testing conducted at the Bonferroni-corrected significance level of 0.005 (0.05/10) to account for the ten pairwise between-arm comparisons and pessimistically allowing for up to 10% further exclusions. The baseline monthly enrolment rate was estimated at approximately 1% per month. We compared the proportion enrolled between arms using a Fisher's exact test. All data analyses were performed using R software (version 3.2.1; R Development Core Team, Vienna, Austria).

RESULTS

Figure 1 shows the CONSORT diagram for the study. There were 3,906 randomised participants, and 3665 in the analysis cohort of current members not enrolled in HF at the time of intervention launch. Age and gender were similar between the arms (Table 1).

Figure 2 reports enrolment rates across arms. All interventions were superior to control at the Bonferroni-corrected significance level ($p<0.0001$ for all comparisons). The "enhanced active choice" arm revealed the largest difference compared to control (12.6% vs. 0.9%, $p<0.0001$). There were no significant differences in enrolment between those who received the diabetes-specific message and those receiving either the message written from another member's perspective or the message with the physician's recommendation. Compared to those who

received the message with the physician's recommendation of HF, those who received the message written from the perspective of another member with diabetes had higher enrolment rates (6.8% vs. 9.9%, p=0.04), but this difference was not significant at the Bonferroni-corrected level. Those in the "enhanced active choice" arm had a higher rate of enrolment than both those receiving the diabetes-specific message alone (12.6% vs. 7.6%, p=0.002) and those receiving the message with the physician's recommendation (12.6% vs. 6.8%, p<0.001). None of the other pairwise comparisons revealed statistically significant differences in enrolment rates. There were no adverse events reported during the study period.

DISCUSSION

In this randomised, controlled trial of adults with diabetes, we found that four diabetes-specific messaging strategies were more effective at increasing enrolment in a healthful food benefit than current practice.

The "enhanced active choice" arm had the highest rate of HF enrolment. This simple, no-cost messaging approach could be used more widely to help people take action to address their underlying risks. "Enhanced active choice" is well-suited to conditions where people must make an affirmative choice (because defaults are seen as too presumptuous), yet most people would see clear advantages of a particular path if those were highlighted. In the context of enrolment into an automatic pharmacy refill program, for example, default enrolment might be seen as too aggressive, because credit cards would be charged on prescription refills and some people would find that too invasive. But encouraging participants to actively select automatic referrals is a middle ground.[8] Moreover, encouraging an immediate choice (for example, by preventing people online from proceeding to the next page without accepting or declining) prevents procrastination. Note that we stopped short of actually requiring participants to make a decision; in many contexts such as in signing up for benefits it would be relatively easy to do that, but

here we took the less paternalistic approach of simply encouraging participants to make a decision and highlighting some of the relevant advantages and disadvantages.

The study design had several limitations. First, sparse available demographics limited assessments of generalisability to other populations. Second, the use of a non-active control did not allow for direct comparisons between the tested diabetes-specific messages and less targeted messages. However, available data from past Vitality HF marketing campaigns have noted enrolment rates of only 1-3%, well below the rates seen in all of the intervention arms. Third, this study was limited to those who had already established an online account with Vitality. These individuals may already be more motivated to participate and are easier to reach electronically, and others without established accounts might benefit even more from such interventions. Last, we measured enrolment in the program, and while we found large effects, it would be important to explore the downstream effects on program utilization, diet, and health outcomes. Still, HF enrolment is a critical first step towards dietary change; past work has demonstrated that HF participants make positive changes in their food choices, increasing healthy choices and decreasing unhealthy ones.[9 10]

This study also has strengths. In particular, it was conducted pragmatically, in the context of the very operational system in which it would be later implemented, and so the results have a high degree of external validity. Also, the design of this study reveals how real-time operational systems can become laboratories for health behaviour change.

While many interventions to improve health are operationally intensive and costly, some, like those tested here, are not. The results of this trial demonstrate that messaging targeted at individuals with a particular condition and offering concrete steps towards improved health can help nudge people with diabetes in the direction of better health.

Competing Interests and Disclosures: AG and JF have no financial disclosures to report. PAS, ABT, and KGV have received research funding from the Vitality Institute. JP and DP are employees of Discovery Vitality, and CB is an employee of Vitality USA. Given these relationships, these three individuals were not responsible for data analysis but provided only operational support and expertise. DAA and KGV are both principals at the behavioural economics consulting firm, VAL Health. KGV also has received consulting income from CVS Caremark and research funding from Humana, CVS Caremark, Discovery (South Africa), Hawaii Medical Services Association, and Merck, none of which are related to the work described in this manuscript. ABT serves on the scientific advisory board of VAL Health.

Authorship: All the listed authors meet the requirements for authorship. AG contributed to study conception, design, data analysis and interpretation, and manuscript construction. JP, DP, and CB contributed to study operations and provided feedback on the manuscript. PAS contributed to the statistical planning, data analysis and interpretation, and provided feedback on the manuscript. JF contributed to study conception, design, and provided feedback on the manuscript. ABT and DA contributed content expertise and to manuscript construction. KGV served as the principal investigator on the study. He contributed to study conception, design, and manuscript construction.

Contributors: All the listed authors meet the requirements for authorship. AG contributed to study conception, design, data analysis and interpretation, and manuscript construction. JP, DP, and CB contributed to study operations and provided feedback on the manuscript. PAS contributed to the statistical planning, data analysis and interpretation, and provided feedback on the manuscript. JF contributed to study conception, design, and provided feedback on the manuscript. ABT and DA contributed content expertise and to manuscript construction. KGV

served as the principal investigator on the study. He contributed to study conception, design, and manuscript construction.

Transparency Declaration: Dr. Anjali Gopalan, the lead author and guarantor, affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Human Subjects: Before any contact with participants we obtained protocol approval from both the University of Pennsylvania Institutional Review Board and the University of Witswatersrand Ethics Committee. Given the pre-existing language in the Vitality membership agreement regarding use of data for research purposes, including collaboration with outside research groups, we were granted a waiver of informed consent by both approving bodies.

Funding Source: The study was funded by an unconditional award from Vitality USA. The study topic, research question, and study design were at the discretion of the lead author and not the funder. Though several Vitality USA and Discovery Vitality employees were involved in helping to operationalise the study, these individuals were not involved in data analysis or interpretation and only provided general feedback on the manuscript (i.e. had no control over how findings were presented and interpreted).

Trial Registration: NCT02462057; Testing Different Messaging Approaches to Increase Activation of a Healthy Food Benefit in Adults with Diabetes.

Data Sharing: No additional data available

CONSORT Statement: This manuscript has been constructed following CONSORT guidelines. The completed CONSORT checklist is included as a supplementary document.

Figure legend

Figure 1: Participant enrolment, allocation, follow-up, and analysis

Figure 2. Enrolment in HealthyFood by study arm

Note: Vertical error bars depict 95% Clopper and Pearson confidence intervals

Supplemental Figures 1a and 1b: Diabetes-specific messages with and without "enhanced active choice"

S1a. Diabetes-specific message without "enhanced active choice"

S1b. Diabetes-specific message with embedded "enhanced active choice"

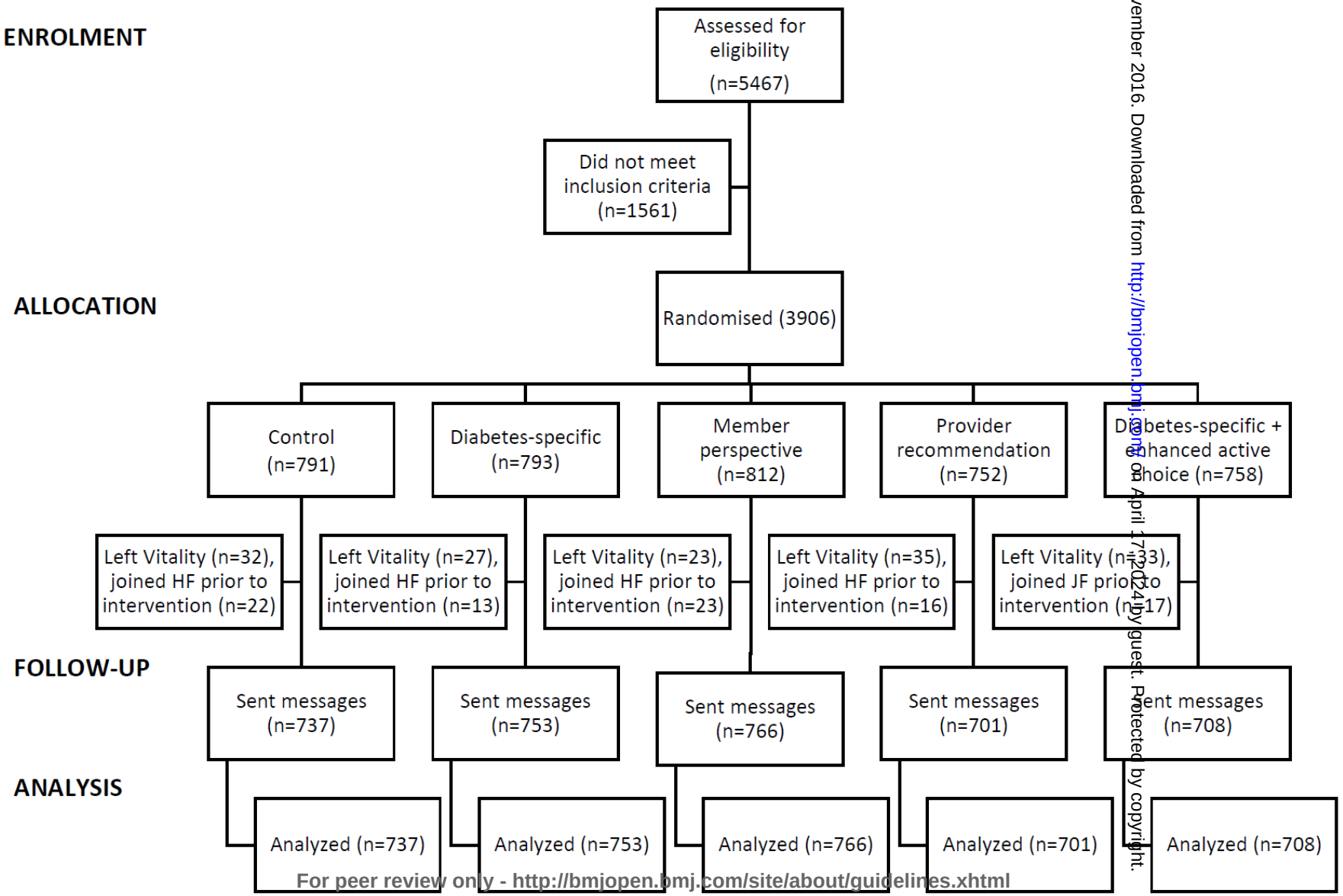
Table 1. Member characteristics

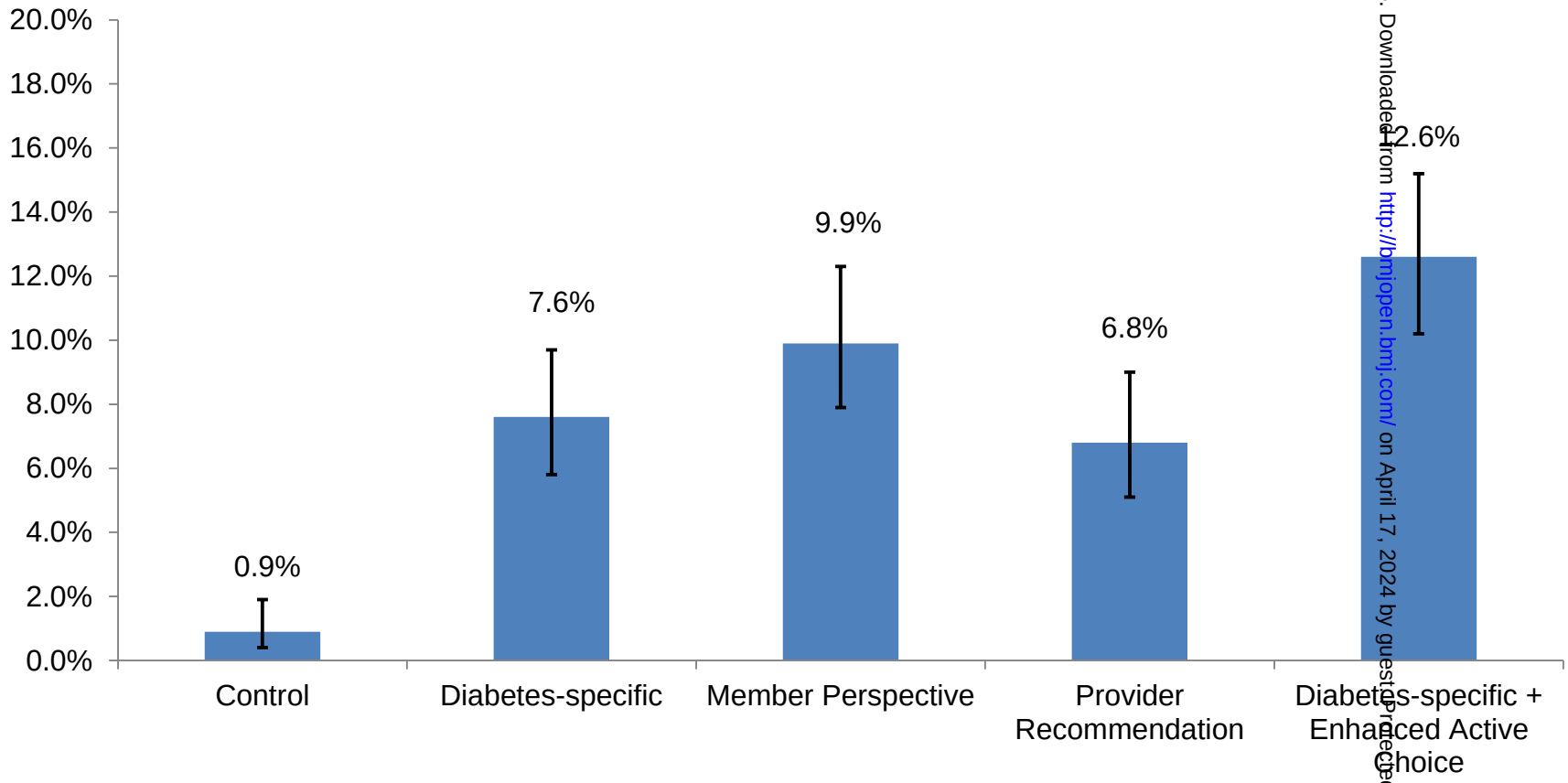
	Control	Diabetes-specific	Member perspective	Provider recommendation	Diabetes-specific + Enhanced Active Choice
(N=3665)	n=737	n=753	n=766	n=701	n=708
Female (%)*	145 (19.7)	152 (20.2)	152 (19.8)	134 (19.1)	146 (20.6)
Age, mean(SD)	55.9 (10.9)	55.2 (10.7)	55.0 (10.8)	55.4 (10.0)	56.0 (10.6)

*This is the gender of the primary Vitality member

References:

1. Foundations of Care: Education, Nutrition, Physical Activity, Smoking Cessation, Psychosocial Care, and Immunization. Diabetes Care 2015;**38**(Supplement 1):S20-S30.
2. Elmer PJ, Obarzanek E, Vollmer WM, et al. Effects of comprehensive lifestyle modification on diet, weight, physical fitness, and blood pressure control: 18-month results of a randomized trial. Annals of internal medicine 2006;**144**(7):485-95.
3. Gordon NF, Salmon RD, Franklin BA, et al. Effectiveness of therapeutic lifestyle changes in patients with hypertension, hyperlipidemia, and/or hyperglycemia. The American journal of cardiology 2004;**94**(12):1558-61.
4. Wing RR, Tate DF, Gorin AA, et al. A self-regulation program for maintenance of weight loss. The New England journal of medicine 2006;**355**(15):1563-71.
5. Kreuter MW, Wray RJ. Tailored and targeted health communication: strategies for enhancing information relevance. American journal of health behavior 2003;**27 Suppl 3**:S227-32.
6. Kreuter MW, Caburnay CA, Chen JJ, et al. Effectiveness of individually tailored calendars in promoting childhood immunization in urban public health centers. American journal of public health 2004;**94**(1):122-7.
7. The Behavioural Insights Team. Applying Behavioural Insights to Organ Donation 2013.
8. Keller PA, Harlam B, Loewenstein G, et al. Enhanced active choice: A new method to motivate behavior change. Journal of Consumer Psychology 2011;**21**:376-83.
9. Sturm R, An R, Segal D, et al. A cash-back rebate program for healthy food purchases in South Africa: results from scanner data. Am J Prev Med 2013;**44**(6):567-72.
10. An R, Patel D, Segal D, et al. Eating better for less: a national discount program for healthy food purchases in South Africa. American journal of health behavior 2013;**37**(1):56-61.





To: johndoe@xxx.com
From: Craig (craignossel@discovery.co.za)
Subject: <Preferred name>, why haven't you activated the Vitality HealthyFood benefit?

Dear <preferred name>

We noticed that you have not activated the Vitality HealthyFood benefit. With this benefit, you can get up to 25% cash back on your healthy food purchases from Pick n Pay or Woolworths each month!

A diet rich in vegetables, fat-free dairy, and whole grains is recommended for all people with diabetes. Eating these healthier foods can help with weight management and improving blood glucose levels.

All of these foods qualify for cash back when you activate the HealthyFood benefit!

Activating is easy. Just follow the steps below:

If you have registered on www.discovery.co.za, click here to log in.

Once you log in, you can start step one of your HealthyFood benefit activation

We hope you decide to activate. Your health is very important to us.

Regards

Dr. Craig Nossel
Discovery Vitality
Head of Vitality Wellness

To: johndoe@xxx.com
From: Craig (craig@discovery.co.za)
Subject: <Preferred name>, why haven't you activated the Vitality HealthyFood benefit?

Dear <preferred name>

We noticed that you have not activated the Vitality HealthyFood benefit. With this benefit you can get up to 25% cash back on the healthy foods you purchase each month!

A diet rich in vegetables, fat-free dairy, and whole grains is recommended for all people with diabetes. Eating these healthier foods can help with weight management and improving blood glucose levels.

All of these foods qualify for a cash back when you activate the HealthyFood benefit!

Please select one of the following choices:

☐ **Yes! I want to activate the HealthyFood benefit and get up to 25% cash back on** HealthyFood **I buy at Pick n Pay or Woolworths**

☐ **No, I'd prefer not to activate and continue paying full price for my healthy food purchases**

We hope you decide to activate. Your health is very important to us.

Regards

Dr. Craig Nossel
Discovery Vitality
Head of Vitality Wellness

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2-3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	4-5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5-6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	5
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	6-7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	5
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	5
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	5
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	5

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	6
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	7
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	7
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6-7
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figure 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Figure 2
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	8
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	8-9
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	8-9
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	8-9
Other information			
Registration	23	Registration number and name of trial registry	3
Protocol	24	Where the full trial protocol can be accessed, if available	N/A
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	11

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

A randomised, controlled trial of alternative messages to increase enrolment in a healthy food programme among individuals with diabetes

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2016-012009.R1
Article Type:	Research
Date Submitted by the Author:	10-Oct-2016
Complete List of Authors:	Gopalan, Anjali; Corporal Michael J. Crescenz VA Medical Center; Kaiser Permanente Northern California, Division of Research Paramanund, Jithen; Discovery Vitality Shaw, Pamela; University of Pennsylvania Perelman School of Medicine, Department of Biostatistics and Epidemiology; University of Pennsylvania, LDI Center for Health Incentives and Behavioral Economics Patel, Deepak; Discovery Vitality Friedman, Joelle; University of Pennsylvania Perelman School of Medicine, Departments of Medicine and Medical Ethics and Health Policy; University of Pennsylvania, LDI Center for Health Incentives and Behavioral Economics Brophy, Christine; Vitality USA Buttenheim, AM; University of Pennsylvania School of Nursing, Department of Community and Family Health; University of Pennsylvania, LDI Center for Health Incentives and Behavioral Economics Troxel, Andrea; University of Pennsylvania, LDI Center for Health Incentives and Behavioral Economics; NYU School of Medicine, Department of Population Health Asch, David; Corporal Michael J. Crescenz VA Medical Center; University of Pennsylvania, LDI Center for Health Incentives and Behavioral Economics Volpp, Kevin; Corporal Michael J. Crescenz VA Medical Center; University of Pennsylvania, LDI Center for Health Incentives and Behavioral Economics
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Diabetes and endocrinology, Public health
Keywords:	DIABETES & ENDOCRINOLOGY, health promotion, messaging, active choice, NUTRITION & DIETETICS

Title: A randomised, controlled trial of alternative messages to increase enrolment in a healthy food programme among individuals with diabetes

Corresponding Author:
Anjali Gopalan
2000 Broadway
Oakland, CA, USA, 94612
Anjali.Gopalan@kp.org

Authors: A Gopalan[1,2], J Paramanund[3], PA Shaw[4,5], D Patel[3], J Friedman[5,6], C Brophy[7], AM Buttenheim[5,8], AB Troxel[5,9], DA Asch[1,5,6,10], KG Volpp[1, 5, 6, 10]

Affiliations:

1. Corporal Michael J. Cresencz VA Medical Center, Philadelphia, PA, USA
2. Kaiser Permanente Northern California, Division of Research, Oakland, CA, USA
3. Discovery Vitality, Johannesburg, South Africa
4. Department of Biostatistics and Epidemiology, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, USA
5. LDI Center for Health Incentives and Behavioral Economics, University of Pennsylvania, Philadelphia, PA, USA
6. Departments of Medicine and Medical Ethics and Health Policy, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, USA
7. Vitality USA, New York, NY, USA
8. Department of Community and Family Health, University of Pennsylvania School of Nursing, Philadelphia, PA
9. Department of Population Health, NYU School of Medicine, New York, NY, USA
10. Department of Health Care Management, Wharton School, University of Pennsylvania, Philadelphia, PA, USA

Running title: Uptake of a healthy food benefit in adults with diabetes

Key Words: diabetes, health promotion, messaging, active choice, diet

Word count:
Abstract: 297, Body: 2574

Abstract

Objectives: We compared the effectiveness of diabetes-focused messaging strategies at increasing enrolment in a healthy food programme among adults with diabetes.

Methods: Vitality is a multi-faceted wellness benefit available to members of Discovery Health, a South Africa-based health insurer. One of the largest Vitality programmes is HealthyFood (HF), an incentive-based programme designed to encourage healthier diets by providing up to 25% cash-back on healthy food purchases. We randomised adults with type 2 diabetes to one of five arms: 1) control, 2) a diabetes-specific message, 3) a message with a recommendation of HF written from the perspective of a HF member with diabetes, 4) a message containing a physician's recommendation of HF, or 5) the diabetes-specific message from Arm 2 paired with an "enhanced active choice "(EAC). In an EAC, readers are asked to make an immediate choice (in this case, to enrol or not enrol); the pros and cons associated with the preferred and non-preferred options are highlighted. HF enrolment was assessed one month following the first emailed message.

Results: We randomized 3,906 members. After excluding those who enrolled in HF or departed from the Vitality programme before the first intervention email, 3,665 (94%) were included in a modified intent-to-treat analysis. All four experimental arms had significantly higher HF enrolment rates compared to control ($p<0.0001$ for all comparisons). When comparing experimental arms, the diabetes-specific message with the EAC had a significantly higher enrolment rate (12.6%) than the diabetes-specific message alone (7.6%, $p=0.0016$).

Conclusions: Messages focused on diabetes were effective at increasing enrolment in a healthy food programme. The addition of a framed active choice to a message significantly raised enrolment rates in this population. These findings suggest that simple, low-cost

interventions can enhance enrolment in health promoting programmes and can also be pragmatically tested within those programmes.

Trial Registration: NCT02462057; Testing Different Messaging Approaches to Increase Activation of a Healthy Food Benefit in Adults with Diabetes.

Strengths of this study

- In this randomised, controlled trial, we found that diabetes-specific messaging strategies were effective at increasing enrolment in a healthy food programme among adults with diabetes.
- The incorporation of a behavioural economics-based technique called “enhanced active choice” that prompted an immediate decision was the most effective at increasing programme enrolment.
- These findings speak to the potential of simple, low-cost interventions to promote engagement in programmes designed to encourage healthier behaviours in high-risk, high cost populations.

Limitations of this study

- Few demographic details were available on randomised participants, limiting conclusions regarding the generalisability of the findings to other populations.
- While large differences in programme enrolment were observed, this does not necessarily translate into programme utilization, diet, and health outcomes. Still, enrolment is a critical first step.

INTRODUCTION

Considerable evidence demonstrates reduced cardiovascular complication risk in adults with type 2 diabetes who consume a healthier diet.[1-4] Maintaining a healthy diet, however, is a considerable challenge for many. One barrier may be the cost of healthy foods.[5] Financial savings can promote healthier food purchases.[6-8] Randomised interventions have demonstrated that participants who receive monetary discounts on healthy food items purchase greater quantities of fruits and vegetables compared to those who receive no discounts or who only receive nutritional education.[7 8]

The HealthyFood (HF) programme offered by Discovery Health's Vitality wellness programme offers cashback rewards for healthy food purchases. Discovery Health is the largest commercial health insurer in South Africa, serving approximately 2.6 million of the 8 million South Africans with private health insurance (16% of the population is privately insured).[9] Available to all Discovery Health members is the Vitality wellness programme, an incentivized health promotion programme; membership is voluntary and costs only a small amount per year.[10] Included with Vitality are benefits ranging from gym subsidies to discounted Weight Watchers memberships. HealthyFood (HF), one of the largest Vitality initiatives, is a three-tiered incentive programme designed to encourage a healthier diet by offering monthly cash-back payments on healthy food purchases (examples of eligible foods are included in an appendix). Upon initial HF activation, members are eligible for 10% cash-back monthly. By completing an online health risk assessment and an in-person health screening, members can increase their monthly cash-back amount to 25%. While this benefit is available at no additional cost to all Vitality members, immaterial of age or health status, there is particular interest in increasing current engagement in HF among individuals with high-risk, diet-sensitive, health conditions, like diabetes. Currently less than half of Vitality's approximately 31,000 South African members with type 2 diabetes are enrolled in the HF programme.

Tackling barriers to HF enrolment is a necessary first step to increasing programme engagement and, hopefully, improving diets. Improved messaging about HF to increase its salience for individuals with diabetes could be a low-cost way to increase HF programme enrolment. Past work demonstrates the importance of message content and framing on promoting subsequent health behaviours, ranging from organ donor registration to vaccine adherence.[11-13] Targeted and tailored messages, for example those designed for and sent to individuals with a certain condition, are more effective at shifting behaviour than more generic messages.[11] The effectiveness of messages can also vary by whether a message is gain- or loss-framed (framed to emphasize the potential gains or losses relating to performing or not performing the targeted health behaviour).[14 15] While some messaging studies targeting low-risk behaviours like dietary changes or exercise suggest that gain-framed messages may be more effective than loss-framed messages[14], when financial losses are a highlighted consequence of not engaging in the targeted behaviour the reverse pattern has been observed.[16]

These types of message framing strategies may also prompt more immediate action. Given the financial benefits of enrolling in HF, some members may intend to enrol but postpone the task assuming the process is overly time consuming or complex. To combat this present bias (the natural tendency to overweight the upfront "costs" of something compared to the future or longterm benefits)[17], we tested a behavioural economics-based approach that asked participants to make an immediate "active choice." This choice was further "enhanced" by both gain- and loss-framing that highlighted the relative benefit of the preferred option (HF enrolment) and the losses of the non-preferred option (not enrolling).[18] Past work using "enhanced active choice" has shown success in increasing health-related behaviours ranging from influenza vaccination to automated pharmacy refill enrolment.[18]

In this study, we compared the effectiveness of diabetes-focused messaging strategies in increasing HF enrolment among Vitality members with type 2 diabetes. We hypothesised that

messages that are more personalised and relatable, as well as those that prompt immediate action, would increase the rate of enrolment.

METHODS

Study Design

The protocol was approved by the University of Pennsylvania Institutional Review Board and the University of Witwatersrand Ethics Committee. Eligible study participants were identified by the Vitality team. No formal consent process was required given existing language in the Vitality membership agreement. The study statistician generated a randomisation list that was sent to Vitality who then linked it with the eligible member database according to study ID. Using a simple randomization scheme, participants were assigned to one of the five study arms with equal chance. Automated email messages were generated and sent according to arm assignment. The analytic team had no contact with study participants. Because this study addressed alternative messages by study arm, participants were not blinded to the assigned intervention.

Study Population

Eligible participants lived in South Africa, were Vitality members 18 years old or older with a diagnosis of type 2 diabetes, were not yet enrolled in HF, and were registered on the Vitality website (reflecting internet access and an available email address). Vitality members with Type 2 diabetes were identified based on billing codes for diabetes along with any pharmacy codes for oral hypoglycemic medications (not prescribed to patients with type 1 diabetes).

Study Outcomes

The primary outcome was HF enrolment at one month, collected using Vitality internal, electronic tracking systems. An intended secondary outcome was participants' interaction with the messages, specifically undelivered emails, unread emails, clicks to the embedded link to the HF enrolment page, time spent on the Vitality website, and initiation of the enrolment process.

Unfortunately, technical issues within the electronic data collection system prevented these data from being captured.

Member Involvement

Vitality members were not involved in the research design or in the selection of outcome measures.

Study Intervention

Eligible members were randomised to one of five study arms with equal chance: 1) control arm (no message), 2) a diabetes-specific message, 3) a message with a recommendation to participate in HF written from the perspective of a Vitality member with diabetes, 4) a message with a recommendation to participate in HF from a physician with diabetes expertise, or 5) the diabetes-specific message from Arm 2 paired with an "enhanced active choice". All tested messages were written by the study team, delivered via email, and contained common elements: a personalised subject line, a description of the HF benefit, mention of two potential health benefits for individuals with diabetes (better sugar control and weight management), and a link to initiate enrolment.

The diabetes-specific message contained only the elements described above. The diabetes-specific message with an "enhanced active choice" included the following choices, which were designed to make more salient the advantages/disadvantages of enrolling/not enrolling: *"Yes! I want to activate the HealthyFood benefit and get up to 25% cash back on the healthy food I buy.*" or "*No, I'd prefer not to activate and continue paying full price for my healthy food purchases.*" The "Yes" checkbox took participants directly to the HF enrolment site. The "No" box linked to an internal website informing subjects that they could still enrol at a later time. The diabetes-specific messages with and without the "enhanced active choice" used in the study are included as supplemental figures.

The intervention occurred in June and July 2015. We sent three email messages (an initial message plus two reminders) to participants in the experimental arms. All messages were separated by at least two days. Before the second and third messages, participant data was refreshed and only participants who had not signed up for HF were sent reminders.

Statistical Analysis

There were 5,467 individuals determined to be initially eligible in January 2015 (Figure 1). After excluding subjects due to enrolment in HF prior to the intervention and departures from the Vitality programme, we estimated that at least 3,500 individuals would still meet eligibility criteria at the time of randomisation and study launch in June 2015. The initial sample was identified several months before the launch to allow study participants ample time to have learned about HF from other sources (e.g., Vitality website and marketing communications) and enrol if interested. The primary endpoint of interest was a binary indicator of enrolment; pairwise hypothesis tests of enrolment rates were planned across the five arms, for a total of ten possible comparisons. The anticipated sample size of 3,500 provided 80% power to detect a 3% pairwise difference between the proportions of participants who enrolled in HF with significance testing conducted at the Bonferroni-corrected significance level of 0.005 (0.05/10) to account for the ten pairwise between-arm comparisons and pessimistically allowing for up to 10% further exclusions. The baseline monthly enrolment rate was estimated at approximately 1% per month. We compared the proportion enrolled between arms using a Fisher's exact test. All data analyses were performed using R software (version 3.2.1; R Development Core Team, Vienna, Austria).

RESULTS

Figure 1 shows the CONSORT diagram for the study. There were 3,906 randomised participants, and 3,665 in the analysis cohort of current members not enrolled in HF at the time of intervention launch. Age and gender were similar between the arms (Table 1).

Figure 2 reports enrolment rates across arms. All interventions were superior to control at the Bonferroni-corrected significance level ($p<0.0001$ for all comparisons). The "enhanced active choice" arm revealed the largest difference compared to control (12.6% vs. 0.9%, $p<0.0001$). Those in the "enhanced active choice" arm had a higher rate of enrolment than both those receiving the diabetes-specific message alone (12.6% vs. 7.6%, $p=0.0016$) and those receiving the message with the physician's recommendation (12.6% vs. 6.8%, $p=0.0003$). Compared to those who received the message with the physician's recommendation of HF, those who received the message written from the perspective of another member with diabetes had higher enrolment rates (6.8% vs. 9.9%, $p=0.0386$), but this difference was not significant at the Bonferroni-corrected level. None of the other pairwise comparisons revealed statistically significant differences in enrolment rates.

DISCUSSION

In this randomised, controlled trial of adults with diabetes, we found that four diabetes-specific messaging strategies were more effective at increasing enrolment in a healthy food benefit than current practice.

The "enhanced active choice" arm had the highest rate of HF enrolment. This simple, no-cost messaging approach could be used more widely to help people take action to address their underlying risks. "Enhanced active choice" is well-suited to conditions where people must make an affirmative choice (because defaults are seen as too presumptuous), yet most people would see clear advantages of a particular path if those were highlighted. In the context of enrolment into an automatic pharmacy refill programme, for example, default enrolment might be seen as too aggressive, because credit cards would be charged on prescription refills and some people would find that too invasive. But encouraging participants to actively select automatic referrals is a middle ground.[18] Moreover, encouraging an immediate choice (for example, by preventing people online from proceeding to the next page without accepting or declining) prevents

potential procrastination. Note that we stopped short of actually requiring participants to make a decision; in many contexts such as in signing up for benefits it would be relatively easy to do that, but here we took the less paternalistic approach of simply encouraging participants to make a decision and highlighting some of the relevant advantages and disadvantages.

While an enrolment rate of 12.6% (the highest observed rate in the "enhanced active choice" arm) may seem to some a small step towards achieving 100% HF enrolment, the results must be viewed in context of past Vitality HF marketing campaigns and the cost of the tested interventions. Past Vitality HF marketing campaigns have resulted in enrolment rates of only 1-3%, well below the rates seen in all of the intervention arms. So while an "enhanced active choice" messaging strategy is unlikely to result in 100% enrolment among members with diabetes, it could be a first, resource-conserving step if 12.6% of the currently unenrolled population enrolled in HF without prompting from a paper mailer or a personal phone call. Given the "light touch" nature of the tested interventions, we focused only on differences in programme enrolment. Still, HF enrolment is a potential first step towards dietary change; past work (analyses of member surveys and grocery scanner data) have demonstrated that HF enrollees make positive changes in their food choices, increasing healthy choices and decreasing unhealthy ones.[19 20] It is important that future studies explore the downstream effects of HF enrolment, specifically programme utilization, dietary changes, and health outcomes.

The study design had several limitations. First, the generalisability of the study findings to other contexts was limited by the current uniqueness of Vitality and the Healthy Food programme, as well as the sparse demographic information available. We had limited information on member characteristics. For example, Table 1 presents the age and gender of the primary Vitality members, but we did not collect any information about who received the study emails or who regularly does the household grocery shopping. Second, the use of a non-active control did not allow for direct comparisons between the tested diabetes-specific messages and less targeted

messages. Third, we were not able to assess message opening or partial enrolment. Fourth, this study was limited to those who had already established an online account with Vitality, who may already be more motivated to participate and are easier to reach electronically. Vitality members without established accounts might benefit even more from such interventions but are harder to reach.

This study also has strengths. The design of this study reveals how real-time operational systems can become laboratories for health behaviour change; this study was conducted pragmatically, in the same setting in which it would be later implemented. This design lends the findings a high degree of external validity with regard to the ability to successfully incorporate these types of framed messaging strategies into Vitality's health promotion outreach efforts for similar populations.

While many interventions to improve health are operationally intensive and costly, some, like those tested here, are not. The results of this trial demonstrate that targeted, framed messages can help nudge individuals with diabetes to enrol in a healthy food programme. This step could be the first one towards healthier food choices, an essential contributor to ideal diabetes management and reduced cardiovascular risk.

Competing Interests and Disclosures: AG, AMB, and JF have no financial disclosures to report. PAS, ABT, and KGV have received research funding from the Vitality Institute. JP and DP are employees of Discovery Vitality, and CB is an employee of Vitality USA. Given these relationships, these three individuals were not involved in data analysis but provided only operational support and expertise. DAA and KGV are both principals at the behavioural economics consulting firm, VAL Health. KGV also has received consulting income from CVS Caremark and research funding from Humana, CVS Caremark, Discovery (South Africa), Hawaii Medical Services Association, and Merck, none of which are related to the work described in this manuscript. ABT serves on the scientific advisory board of VAL Health.

Author Contributions: All the listed authors have met the requirements for authorship. AG, the lead author, was responsible for overseeing study conception and design, communication between team members, data analysis and interpretation, manuscript construction, and manuscript revision. JP, DP, and CB, who are all affiliated with Vitality, were responsible for day-to-day study operations (e.g., sending of the email messages and abstracting enrolment data from internal Vitality tracking systems to send to Penn team). Given their affiliations with Vitality, the study's funder, JP, DP, and CB were not involved with data analysis and interpretation and only provided general feedback on the manuscript (i.e., they had no influence on how findings were presented and interpreted). PAS, the study's lead biostatistician, oversaw all statistical planning, data transfer from the Vitality team, data analysis and interpretation, and provided critical feedback on the manuscript. JF and AMB contributed to study conception and design, result interpretation, and provided detailed feedback on the manuscript. ABT and DA contributed content expertise in the areas of biostatistics and behavioural economics, respectively, and both were actively involved in manuscript preparation. KGV served as the principal investigator on the study. He contributed his significant expertise in behavioural

economics and randomised interventions to study conception and design, data interpretation, and manuscript construction. KG is the guarantor of this manuscript.

Acknowledgements: Elle Alexander for her assistance with initial study design and conception.

Transparency Declaration: Dr. Anjali Gopalan, the lead author and guarantor, affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Human Subjects: Before any contact with participants we obtained protocol approval from both the University of Pennsylvania Institutional Review Board and the University of Witwatersrand Ethics Committee. Given the pre-existing language in the Vitality membership agreement regarding use of data for research purposes, including collaboration with outside research groups, we were granted a waiver of informed consent by both approving bodies.

Funding Source: The study was funded by an unconditional award from Vitality USA. The study topic, research question, and study design were at the discretion of the lead author and not the funder. Though several Vitality USA and Discovery Vitality employees were involved in helping to operationalise the study, these individuals were not involved in data analysis or interpretation and only provided general feedback on the manuscript (i.e., had no control over how findings were presented and interpreted).

Trial Registration: NCT02462057; Testing Different Messaging Approaches to Increase Activation of a Healthy Food Benefit in Adults with Diabetes.

Data Sharing: No additional data available

CONSORT Statement: This manuscript has been constructed following CONSORT guidelines. The completed CONSORT checklist is included as a supplementary document.

Figure legend

Figure 1: Participant enrolment, allocation, follow-up, and analysis

Figure 2. Enrolment in HealthyFood by study arm

Note: Vertical error bars depict 95% Clopper and Pearson confidence intervals

Supplemental Figures 1a and 1b: Diabetes-specific messages with and without "enhanced active choice"

S1a. Diabetes-specific message without "enhanced active choice"

S1b. Diabetes-specific message with embedded "enhanced active choice"

Table 1. Member characteristics*					
	Control	Diabetes-specific	Member perspective	Provider recommendation	Diabetes-specific + Enhanced Active Choice
(N=3665)	n=737	n=753	n=766	n=701	n=708
Female (%)	145 (19.7)	152 (20.2)	152 (19.8)	134 (19.1)	146 (20.6)
Age, mean(SD)	55.9 (10.9)	55.2 (10.7)	55.0 (10.8)	55.4 (10.0)	56.0 (10.6)
*This is the age and gender distribution of the primary Vitality member (not necessarily the email reader or primary shopper)					

Appendix

Foods Eligible for HealthyFood Cash-Back Rewards	
Food Group	Description/Examples
Vegetables	All fresh vegetables and herbs, canned tomatoes, and several types of dried or frozen vegetables
Fruit	All fresh fruit, selected dehydrated and frozen fruit, and canned apples
Carbohydrates	Breads (e.g., wheat, rye, seeded), crackers (e.g., rye, rice), cereals (e.g., bran, low glycemic index muesli) , other starchy foods (e.g., whole wheat couscous), porridge (oats), rice (brown, wild), whole grains (e.g., barley, quinoa) , and whole wheat pastas
Proteins	Skinless chicken, eggs, fresh or frozen fish, fish canned in water, ostrich, other fresh raw seafood (e.g., shrimp, calamari), and uncooked, unflavored tofu
Dairy	Fat-free milk, fat-free unsweetened yogurt, fat-free cottage cheese, and unsweetened soy milk
Lentils and Legumes	All dried legumes and select canned legumes
Oils, Nuts, Seeds, and Spreads	Selected oils (e.g., olive, sunflower, avocado), unsalted, unseasoned raw nuts and seeds, canola spread, selected nut butters, and selected cooking sprays

References:

1. 4. Foundations of Care: Education, Nutrition, Physical Activity, Smoking Cessation, Psychosocial Care, and Immunization. Diabetes Care 2015;**38**(Supplement 1):S20-S30.

2. Elmer PJ, Obarzanek E, Vollmer WM, et al. Effects of comprehensive lifestyle modification on diet, weight, physical fitness, and blood pressure control: 18-month results of a randomized trial. Annals of Internal Medicine 2006;**144**(7):485-95.

3. Gordon NF, Salmon RD, Franklin BA, et al. Effectiveness of therapeutic lifestyle changes in patients with hypertension, hyperlipidemia, and/or hyperglycemia. The American Journal of Cardiology 2004;**94**(12):1558-61.

4. Wing RR, Tate DF, Gorin AA, et al. A self-regulation program for maintenance of weight loss. The New England Journal of Medicine 2006;**355**(15):1563-71.

5. Rao M, Afshin A, Singh G, et al. Do healthier foods and diet patterns cost more than less healthy options? A systematic review and meta-analysis. BMJ Open 2013;**3**(12):e004277.

6. An R. Effectiveness of subsidies in promoting healthy food purchases and consumption: a review of field experiments. Public Health Nutr 2013;**16**(7):1215-28.

7. Geliebter A, Ang IY, Bernales-Korins M, et al. Supermarket discounts of low-energy density foods: effects on purchasing, food intake, and body weight. Obesity (Silver Spring) 2013;**21**(12):E542-8.

8. Ball K, McNaughton SA, Le HN, et al. Influence of price discounts and skill-building strategies on purchase and consumption of healthy food and beverages: outcomes of the Supermarket Healthy Eating for Life randomized controlled trial. Am J Clin Nutr 2015;**101**(5):1055-64.

9. Mayosi BM, Benatar SR. Health and health care in South Africa--20 years after Mandela. The New England Journal of Medicine 2014;**371**(14):1344-53.

10. Patel DN, Nossel C, Alexander E, et al. Innovative business approaches for incenting health promotion in sub-Saharan Africa: progress and persisting challenges. Prog Cardiovasc Dis 2013;**56**(3):356-62.
11. Kreuter MW, Wray RJ. Tailored and targeted health communication: strategies for enhancing information relevance. American Journal of Health Behavior 2003;**27 Suppl 3**:S227-32.
12. Kreuter MW, Caburnay CA, Chen JJ, et al. Effectiveness of individually tailored calendars in promoting childhood immunization in urban public health centers. American Journal of Public Health 2004;**94**(1):122-7.
13. The Behavioral Insights Team. Applying Behavioural Insights to Organ Donation 2013.
14. Gallagher KM, Updegraff JA. Health message framing effects on attitudes, intentions, and behavior: a meta-analytic review. Ann Behav Med 2012;**43**(1):101-16.
15. Rothman AJ, Salovey P. Shaping perceptions to motivate healthy behavior: the role of message framing. Psychol Bull 1997;**121**(1):3-19.
16. Patel MS, Asch DA, Rosin R, et al. Framing Financial Incentives to Increase Physical Activity Among Overweight and Obese Adults: A Randomized, Controlled Trial. Annals of Internal Medicine 2016;**164**(6):385-94.
17. Glanz K, Rimer BK, Viswanath K. *Health behavior : theory, research, and practice*. Fifth edition. ed, 2015.
18. Keller PA, Harlam B, Loewenstein G, et al. Enhanced active choice: A new method to motivate behavior change. Journal of Consumer Psychology 2011;**21**:376-83.
19. Sturm R, An R, Segal D, et al. A cash-back rebate program for healthy food purchases in South Africa: results from scanner data. Am J Prev Med 2013;**44**(6):567-72.
20. An R, Patel D, Segal D, et al. Eating better for less: a national discount program for healthy food purchases in South Africa. American Journal of Health Behavior 2013;**37**(1):56-61.

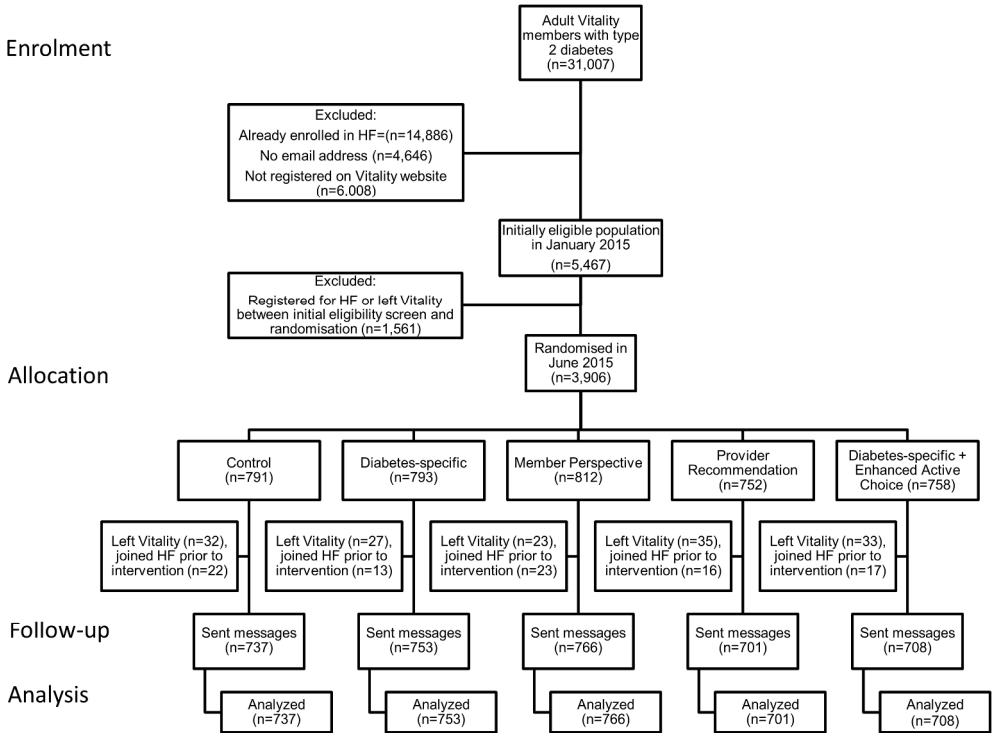


Figure 1. Participant enrolment, allocation, follow-up, and analysis

254x190mm (300 x 300 DPI)

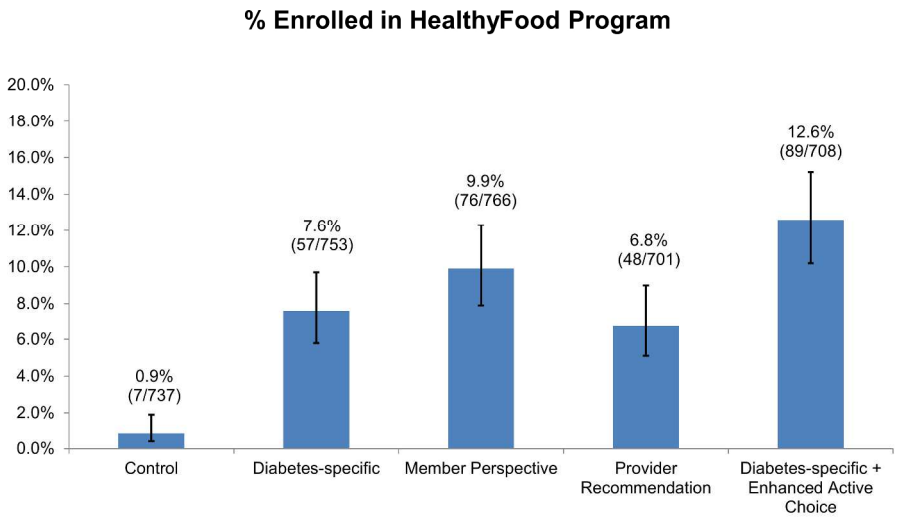


Figure 2. Enrolment in HealthyFood by study arm‼ ⟊
Note: Vertical error bars depict 95% Clopper and Pearson confidence intervals

254x190mm (300 x 300 DPI)

To: johndoe@xxx.com
From: Craig (craignossel@discovery.co.za)
Subject: <Preferred name>, why haven't you activated the Vitality HealthyFood benefit?

Discovery Vitality

Dear <preferred name>

We noticed that you have not activated the Vitality HealthyFood benefit. With this benefit, you can get up to 25% cash back on your healthy food purchases from Pick n Pay or Woolworths each month!

A diet rich in vegetables, fat-free dairy, and whole grains is recommended for all people with diabetes. Eating these healthier foods can help with weight management and improving blood glucose levels.

All of these foods qualify for cash back when you activate the HealthyFood benefit!

Activating is easy. Just follow the steps below:

If you have registered on www.discovery.co.za, click here to log in.

Once you log in, you can start step one of your HealthyFood benefit activation

We hope you decide to activate. Your health is very important to us.

Regards

Dr. Craig Nossel
Discovery Vitality
Head of Vitality Wellness

Supplemental Figure 1a. Diabetes-specific message without "enhanced active choice"

190x254mm (300 x 300 DPI)

To: johndoe@xxx.com
From: Craig (craig@discovery.co.za)
Subject: <Preferred name>, why haven't you activated the Vitality HealthyFood benefit?

Discovery Vitality

Dear <preferred name>

We noticed that you have not activated the Vitality HealthyFood benefit. With this benefit you can get up to 25% cash back on the healthy foods you purchase each month!

A diet rich in vegetables, fat-free dairy, and whole grains is recommended for all people with diabetes. Eating these healthier foods can help with weight management and improving blood glucose levels.

All of these foods qualify for a cash back when you activate the HealthyFood benefit!

Please select one of the following choices:

☐ **Yes! I want to activate the HealthyFood benefit and get up to 25% cash back on** HealthyFood **I buy at Pick n Pay or Woolworths**

☐ **No, I'd prefer not to activate and continue paying full price for my healthy food purchases**

We hope you decide to activate. Your health is very important to us.

Regards

Dr. Craig Nossel
Discovery Vitality
Head of Vitality Wellness

Supplemental Figure 1b. Diabetes-specific message with embedded "enhanced active choice"

190x254mm (300 x 300 DPI)

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2-3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4-5
	2b	Specific objectives or hypotheses	5-6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	4-6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6-7
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	6

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	7-8
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	8
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	8
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figure 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Figure 2
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	10-11
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	10
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	10-11
Other information			
Registration	23	Registration number and name of trial registry	3
Protocol	24	Where the full trial protocol can be accessed, if available	N/A
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	13

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.