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Behavioral mediators of colorectal cancer screening in a randomized controlled intervention trial

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Abstract

Background—Understanding mediators for behavioral change is important for the optimization of intervention strategies. This report examines mediators of change in the context of a randomized controlled intervention trial (Los Angeles, 2004–2009) that successfully increased colorectal cancer (CRC) screening among Filipino Americans.

Methods—The intervention, based on the Health Behavior Framework, targeted knowledge/awareness of CRC screening, communication with health care provider, health beliefs, social support and barriers to CRC screening. Health Behavior Framework variables were assessed at baseline and 6 month follow-up (N=432). Variables targeted for change were tested as potential mediators of the primary outcome, self-reported receipt of CRC screening during the follow-up period, which was previously found to have increased significantly among intervention participants.

Results—Consistent with the Health Behavior Framework, knowledge/awareness of CRC screening and patient-provider communication mediated receipt of screening. Increase in knowledge/awareness of CRC screening accounted for 13% (95% confidence interval 2%–24%) of the total intervention effect size while patient-provider communication accounted for 20% (5%–36%). Combined, these two variables accounted for 28% (10%–46%) of the total effect size.

Conclusion—Examining the roles of potential mediators in intervention trials may help identify constructs to target in order to enhance the effectiveness of interventions to increase screening.

Keywords

colorectal cancer; cancer screening; immigrants; intervention trial; mediation

Introduction

Numerous factors influence health behaviors and a comprehensive theoretical model can provide a roadmap for systematically addressing determinants of health behavior in an intervention trial (Bastani et al. 2010). In turn, a controlled trial of a theory-based intervention can inform the underlying theory by shedding light on pathways by which behavioral change was achieved (Rothman 2004; Anderson et al. 2010). Understanding mediators for behavioral change can help us to optimize intervention strategies by focusing

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Conflict of interest statement

The authors declare that there are no conflicts of interest.

on the factors that are most important in achieving behavior change (MacKinnon and Luecken 2008; Mackinnon and Fairchild 2009). Many theory-based interventions to increase cancer screening have been reported in the literature (Wardle et al. 2003; Lipkus et al. 2005; Marcus et al. 2005; Tu et al. 2006), but to our knowledge this is one of the first analyses that examines the pathways through which change was achieved..

Our prior work demonstrated the effectiveness of an intervention in increasing colorectal cancer (CRC) screening among Filipino Americans in a randomized trial. Participants randomized to either of the two intervention arms were significantly more likely to report screening at follow-up than participants assigned to the control group (odds ratios 4.9 and 3.7 compared with control, both $p < .001$ (Maxwell et al. 2010). In this report, we assess the impact of this intervention on behavioral constructs, including awareness of CRC screening, patient-provider communication about CRC screening, health beliefs and barriers to FOBT and sigmoidoscopy/colonoscopy. We examine these variables as mediators of the desired change in CRC screening behavior. Identifying the underlying mechanisms through which behavior change is enacted is important for adaptation of evidence-based interventions for wide dissemination and for informing the development of future cancer screening behavioral interventions.

Methods

Randomized Trial to Increase CRC Screening among Filipino Americans

In collaboration with 45 Filipino American community-based organizations and churches in Los Angeles County, we recruited 548 Filipino Americans 50 to 70 years of age who were non-adherent to CRC screening guidelines: no fecal occult blood test (FOBT) during the past 12 months, no colonoscopy during the past 10 years and no sigmoidoscopy during the past 5 years. Following a baseline interview, participants were organized into small groups of 6–10 subjects in a manner that capitalized on existing bonds between members of the same organization and each group was randomized into one of three arms: a control arm consisting of a small-group education session promoting physical activity and 2 intervention arms consisting of a small-group CRC education session, print take-home materials, a letter reminding subjects to get screened 3 months after the session, and a letter to subjects' providers urging them to offer CRC screening to their patients. The only difference between the two intervention arms was that participants in one arm additionally received free FOBT kits. A total of 103 small-group sessions were conducted at community organizations and churches in English or in Filipino, each 60 to 90 minute long and lead by trained Filipino health professionals, mostly nurses. Follow-up telephone interviews were conducted 6 months after the session. The study was approved by the Institutional Review Board of the University of California, Los Angeles, and all participants provided informed consent. The trial was registered at ClinicalTrials.gov (NCT00742729). More details regarding recruitment, eligibility criteria and randomization are reported elsewhere (Maxwell et al. 2010).

Theoretical Framework

The intervention was based on the theoretical perspective of the Health Behavior Framework (Bastani et al. 2001; Bastani et al. 2010), see Figure 1. This Framework incorporates constructs from many of the common theoretical formulations in health behavior research including Social Cognitive Theory (Bandura 1989; Bandura 2004), the Health Belief Model (Becker and Maiman 1974), the Theory of Planned Behavior (Fishbein and Ajzen 1975; Ajzen and Madden 1986), and Social Influence Theory (Greer 1988; Lomas and Haynes 1988; Mittman et al. 1992). The Health Behavior Framework assumes that individual variables and provider and health care system variables influence intentions,

which in turn influence health behavior. Barriers and supports at the individual, system or societal level can influence whether or not intentions translate into behavior. In addition, the model considers the context within which the desired behavior and behavior change are enacted, including characteristics of the provider and the health care setting as well as larger community and societal influences. While some variables of the model are not mutable (e.g., demographic characteristics), mutable variables represent potential targets for intervention.

Our intervention focused mainly on the individual variables from the framework fundamental to health behaviors. (For more details on the intervention, please see (Maxwell et al. 2010). For example, we attempted to increase knowledge and awareness of CRC screening guidelines by discussing CRC screening tests in small-group sessions and by providing print materials. To increase communication with providers, group leaders urged participants to ask their provider about CRC screening. We attempted to influence several health beliefs. For example, we explained FOBT to increase participants' belief that a stool blood test can detect CRC in its early stages (perceived efficacy of FOBT). We showed the relatively high mortality of CRC compared to other cancers graphically to increase *perceived susceptibility*. We held small-group discussion sessions at community venues and invited friends and relatives to the same session to increase *social support* for CRC screening and to take advantage of existing bonds between participants. *Barriers* to CRC screening such as cost, not knowing that the test is needed, concern about finding cancer, and absence of symptoms were discussed in the small-group session. FOBT kits were provided free of charge to one of the intervention arms because lack of access to screening tests is a common barrier to CRC screening. Participants without health insurance were instructed to mail their completed FOBT kits to a clinic that charged processing of the kits to the study. In addition, participants received a letter three months after the session reminding them to complete the FOBT kits or to ask their provider for screening. In an attempt to influence provider and health care system variables, the intervention included a letter to providers, informing them that their patient is participating in a study promoting CRC screening and urging them to recommend CRC screening to their patients. The Health Behavior Framework also acknowledges the influence of individual variables that cannot be changed in the context of an intervention, including demographic characteristics, medical history and health insurance status as well as prior CRC screening. These variables were assessed at baseline.

Mediators

Health Behavior Framework variables were assessed at baseline and 6 month follow-up in a 20 minute survey that was administered either face-to-face (baseline) or by telephone (follow-up) in English or Filipino. Many of the constructs were assessed with single items to reduce respondent burden. Response options for most items were yes/no or 3 point Likert scales. We assessed the following potential mediators that were targeted by our intervention (see specific items for each construct in Table 2):

- Knowledge/awareness of CRC screening (a summary score ranging from 0 to 6 was constructed as the number of correct responses);
- Communication with provider
- Health beliefs, including perceived efficacy of FOBT, self-efficacy for requesting FOBT, efficacy of early detection, perceived susceptibility, fatalism, cultural beliefs
- Barriers to doing FOBT and for undergoing sigmoidoscopy or colonoscopy.

Because we assessed intentions to get screened only at baseline, we were not able to examine if this construct was a mediator.

Primary Outcome

Receipt of CRC screening tests was assessed as part of the 6 month follow-up survey. The primary outcome was self-reported receipt of any CRC screening (FOBT, sigmoidoscopy or colonoscopy) during the follow-up period. We also validated self-reported CRC screening in a subsample (data not shown).

Data Analysis

Analyses for this report include only participants who completed both baseline and follow-up surveys (N=432/548, 79% of all subjects enrolled in the trial). Completers are more likely to be college educated (72% versus 56% among non-completers, $p<.001$), have an annual income of \$50,000 or more (36% vs 24%, $p<.02$), and have completed the baseline interview in English (63% versus 51%, $p<.01$). Completers are also more likely than non-completers to report receipt of a doctor's recommendation to obtain FOBT or an endoscopy at baseline (29% versus 19%, $p<.03$ and 32% versus 22%, $p<.03$). Participants in the two intervention arms were not significantly different from each other with respect to baseline demographic characteristics, acculturation, health and access to health care and history of colorectal cancer screening, and the only difference between the two intervention arms was the distribution of free FOBT kits in one of the arms. Of the intervention participants who reported CRC screening during the follow-up period, 73% (N=77) received an FOBT only, 17% (N=18) received an FOBT plus an endoscopy, and 10% (N=11) received an endoscopy only, with no significant differences between the two intervention arms. Of the control group participants who reported CRC screening during follow-up, 64% (N=9) received an FOBT only, 14% (N=2) received an FOBT plus endoscopy, and 21% (N=3) received an endoscopy only (Maxwell et al. 2010). Because the two intervention arms had similar rates of FOBT and endoscopy and similar estimated mediated effects in separate-arm analyses, the two intervention arms were combined to increase power.

We conducted analyses to test whether the intervention changed individual variables of the Health Behavior Framework including knowledge/awareness of CRC screening, communication about CRC screening with health care providers, health beliefs and barriers to CRC screening. For this analysis, we dichotomized items that were assessed with a three point Likert scale as indicated in Table 2. The analysis approach used accounted for the multisite, session-randomized design. For dichotomous variables, analyses were conducted using mixed-effects logistic regression with random intercepts for organization and session. For knowledge/awareness summary scores, mixed-effects linear regression was used. We tested for change from baseline to follow-up within group (intervention and control groups separately) and for differences in change over time between the intervention and control groups using linear hypothesis tests.

The Health Behavior Framework variables that were targeted for change by the intervention and for which change from baseline to follow-up was significantly associated with intervention group assignment were tested for mediation. We tested for mediation using the method of decomposing a total effect in a logit model into direct and indirect effects described by Erikson and colleagues and Buis (Erikson et al. 2005; Buis 2010). This method estimates the total effect size of the intervention on the outcome as the difference between the average predicted probability of the outcome in the intervention group and in the control group, after transforming the probabilities to log odds. The indirect (mediated) effect size is estimated by reference to a counterfactual scenario in which the intervention had no effect on the potential mediator, i.e., the distribution of the potential mediating variable in the intervention group is equal to its distribution in the control group. The average predicted probability of the outcome for the intervention group under this counterfactual scenario is obtained, and the indirect effect size is estimated as the difference between the actual

predicted probabilities in the intervention and counterfactual groups, after transforming the probabilities to log odds. The direct effect size is the difference between the average predicted probabilities in the counterfactual and control groups, after log odds transformation. These analyses were conducted using the *ldecomp* package in Stata. Standard errors were obtained using 500 bootstrap replications. All tests controlled for ever had an FOBT in the past (yes/no) due to baseline differences in the intervention (combined) and control groups on this variable.

We have determined that the intervention was broadly effective for various subgroups (e.g., low and high income, insured and uninsured, various levels of acculturation; manuscript in preparation, data not shown). Therefore, modifiers of the intervention were not further studied for this report.

Results

Study Participant Characteristics

The mean age of the sample was 59 years, average years lived in the United States was 19 years, and 67% of the sample was female (Table 1). More than two-thirds were married and had a college education and slightly less than two-thirds had an annual income less than \$50,000. Most considered themselves more Filipino than American (61%) or equally Filipino and American (35%) and only 18% spoke mainly Filipino with their friends. Although most had health insurance (72%) and a regular doctor (82%), only 24% had received any CRC screening test in the past, and none were current on screening per guidelines (which was an eligibility criteria). Subjects in the intervention group were more likely to have had an FOBT in the past than those in the control group (22% versus 12%, $p<0.03$). No other significant differences between intervention and control subjects were found.

Health Behavior Framework Variables

At baseline, participants had relatively low awareness of CRC screening tests (average score 2.4 out of 6). More than 70% had heard of colonoscopy and more than half had heard of sigmoidoscopy, but few knew how often these tests were recommended. Only one third of participants knew that FOBT should begin at age 50, and about half knew that FOBT should be done yearly. The mean CRC screening test knowledge/awareness summary score increased significantly from 2.45 to 2.90 in the intervention group but not in the control group and the change in knowledge/awareness from baseline to follow-up was significantly higher in the intervention group than in the control group (see last column in Table 2).

Communication with providers about CRC screening was reported by only 16–18% of participants at baseline. At follow-up, communication with providers increased 2½ times from 16 to 40% ($p<.001$) in the intervention group but not in the control group, and the increase in patient-provider communication about CRC screening was significantly higher in the intervention group than in the control group.

Several health beliefs changed significantly from baseline to follow-up in the intervention group but not in the control group. The belief that an FOBT can find CRC in its early stages (perceived efficacy of FOBT) and perceived susceptibility to CRC increased and fatalism decreased. However, only the increase in perceived efficacy of FOBT was significantly higher in the intervention group than in the control group. Several health beliefs did not change over time in either group. At both time points, the majority of participants in both groups believed that they would be able to request an FOBT from their provider (self-efficacy for requesting FOBT) and believed in the efficacy of early detection. The majority of respondents did not believe that CRC is a punishment for something done wrong.

The majority of respondents expressed no barriers for doing FOBT and was not concerned about being embarrassed when undergoing an endoscopy, and these *barriers* also did not change over time. At baseline, about two-thirds of respondents in both groups voiced concern about pain and discomfort during endoscopy, and 75% of respondents in both groups voiced this concern at follow-up. The change over time was statistically significant in the intervention group only, which is probably due to the larger sample size in this group. The extent of the change was not significantly different between the two groups ($p < .71$).

Based on their significant difference in change scores (from baseline to follow-up) between the intervention and control groups, we identified knowledge/awareness summary score, communication with provider and perceived efficacy of FOBT as candidates to test as mediating variables. Knowledge/awareness summary score and patient-provider communication emerged as mediators (Figure 2); a mediating effect was not found for perceived efficacy of FOBT ($p = .10$). Figure 2 presents the estimated total, indirect and direct effect sizes on the log odds ratio scale, on which total effect = indirect + direct effect. On this scale, increase in knowledge/awareness of CRC screening tests accounted for 13% of the total intervention effect size (95% confidence interval 2%–24%), while patient-provider communication accounted for 20% (95% confidence interval 5%–36%). When tested for their combined effect, these two variables accounted for 28% of the total intervention effect size (95% confidence interval 10%–46%).

Discussion

After having demonstrated the effectiveness of an intervention in increasing CRC screening among Filipino Americans, this report examines behavioral mediators of change in screening behavior. The most important mediator that emerged in our analysis was patient-provider communication about CRC testing. Many studies have demonstrated that patient-provider communication and specifically a provider recommendation is strongly associated with cancer screening (Maxwell et al. 1997; Taylor et al. 2003; Beydoun and Beydoun 2008; Nguyen et al. 2008; Jandorf et al. 2009). Therefore, the intervention used several strategies to encourage study participants to discuss CRC screening with their provider: health educators strongly urged participants to ask their providers for CRC screening; some intervention subjects received a free FOBT kit, all received a handout on “how to request CRC screening from your provider”; and *providers* received a letter reminding them to recommend screening to their patients.

Since few participants had discussed CRC screening with a doctor or nurse at baseline, there was substantial room for improvement. Indeed, communication with provider about CRC screening was the variable from the Health Behavior Framework that changed most dramatically from baseline to follow-up among intervention subjects. This increase in the intervention group but not in the control group explains why it emerged as the most important mediator in our analyses. Information on how many patients versus *providers* initiated these interactions was not collected, but the increased communication can likely be attributed to both strategies that targeted patients and providers. This finding confirms the importance of promoting patient-provider communication about CRC screening for increasing screening utilization.

The second mediator that emerged was the only continuous variable that was tested, a summary score for knowledge of screening guidelines and awareness of CRC screening tests. CRC knowledge/awareness increased moderately but statistically significantly in intervention but not in control subjects and the difference in change between intervention and control group was statistically significant. This finding confirms that knowledge is an important Health Behavior Framework variable. Changes in knowledge may be more

important when baseline levels are relatively low and it may not emerge as a mediator in populations with higher knowledge levels at baseline. These two mediators were not independent; the combined mediated effect explained 28% of the total effect size, which was less than the sum of the two mediated effects when evaluated singly (13% for knowledge/awareness and 20% for patient-provider communication). Increased knowledge/awareness of CRC screening may have increased patient-provider communication and vice-versa. Similar to our findings, other health promotion studies have also found that only small proportions of their effect sizes were mediated by the variables that they examined (MacKinnon et al. 1991; Barrera et al. 2006; Anderson et al. 2010). Reasons for this may include poor predictive ability of theoretical models, the fact that important mediators are not being measured or that measures that are being used are not sensitive to change or that interventions fail to influence potential mediators.

When conducting mediation analysis, it is also important to examine the variables of the theoretical framework that were not significant mediators. Although beliefs regarding perceived efficacy of FOBT and perceived susceptibility for CRC cancer increased significantly in the intervention group and beliefs in fatalism decreased significantly, the magnitude of these changes were not as big as the increase in patient-provider communication. This may be due to the fact that at baseline many respondents already believed that FOBT was efficacious in finding CRC, that they felt somewhat susceptible for getting CRC and most respondent did not hold fatalistic beliefs. Although these variables did not emerge as mediators in this analysis, the changes in the intervention group are in the expected direction based on the Health Behavior Framework.

Another set of variables from the Health Behavior Framework did not change at all from baseline to follow-up: Most respondents believed that they would be able to request an FOBT from their provider, that early detection increases survival, and most did not view CRC as a punishment for something done wrong. In addition, most respondents had no strong barriers to FOBT or sigmoidoscopy/colonoscopy. The fact that we observed no changes in these variables may be due to baseline values that are already supportive of CRC screening and/or due to the intervention that failed to influence these individual variables.

Limitations

Potential mediators were only assessed twice, at baseline and at 6 month follow-up. The behavioral outcome, CRC screening, was self-reported for the time period between baseline and 6 month follow-up. Although we assume that individual variables changed prior to CRC screening, it is possible that they changed as a result of CRC screening. Future studies should include and analyze repeat measures of the hypothesized mediators to facilitate a more conclusive analysis of mediation. Because few respondents received an endoscopy, we were not able to examine mediators separately for FOBT and endoscopy. Most measures consisted of single items to keep surveys short. More refined scales may be needed to capture the impact of the intervention on potential mediators. However, items were identical or similar to those used in prior cancer control studies and many had produced relationships in the expected direction. They were extensively pretested in several populations, including Filipino Americans.

Conclusions

Consistent with the Health Behavior Framework, awareness of CRC screening and patient-provider communication about CRC screening mediated increased screening in this randomized trial in the Filipino American community. Examining the roles of these and other constructs as potential mediators in different intervention trials in different settings and

populations may help in the identification of constructs that need to be targeted to optimize interventions to increase screening.

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Figure 1.
Health Behavior Framework

* Variable was specifically targeted by the multi-component intervention to promote colorectal cancer screening

Figure 2.
Mediators of the effect of the intervention on receipt of colorectal screening

TABLE 1

Baseline characteristics of intervention and control subjects who completed the 6 month follow-up survey (Filipino Health Study, Los Angeles, CA, 2004–2009)

	Intervention (n = 302)	Control (n = 130)		Total (n = 432)	p-value		
General Demographics							
Age, Mean (SD)	59.5 (6.0)	59.1 (6.6)	59.4 (6.2)	0.53			
Years living in the U.S., Mean (SD)	18.3 (12.7)	20.0 (12.3)	18.7 (2.5)	0.27			
	n	%	n	%			
Female	204	68	86	66	67	0.78	
Married	217	72	86	66	300	70	0.22
Education							
Less than college	87	29	35	27	122	28	0.69
College or more	215	71	95	73	310	72	
Annual income less than \$50,000	188	66	73	59	261	64	0.24
Acculturation							
Baseline interview in English	183	61	89	69	272	63	0.12
Consider self							
More Filipino than American	180	61	75	62	255	61	0.93
Equally Filipino and American	106	36	41	34	147	35	
More American than Filipino	9	3	6	5	15	4	
Language used with friends							
Mainly Tagalog	57	19	21	16	78	18	0.07
Half Tagalog, half English	231	77	95	74	326	76	
Mainly English	13	4.3	13	10	26	6	
Health and Access to Health Care							
Has any health problem	245	81	98	75	343	79	0.18
Has family history of cancer	109	36	37	29	146	34	0.12
Has health insurance	214	71	97	75	311	72	0.43
Has regular doctor	247	82	105	81	352	82	0.80

	Intervention (n = 302)		Control (n = 130)		Total (n = 432)	p-value
Colorectal Cancer Screening						
Provider recommended any CRC screening	138	46	55	42	193	45
Ever had any CRC screening	80	27	24	19	104	24
Ever had FOBT	64	22	16	12	80	19
Ever had endoscopy	12	4	7	5	19	4
						0.52
						0.07
						0.03
						0.52

Some numbers do not sum to 548 due to missing values.

P-values based on analysis of variance and chi-square tests.

FOBT = fecal occult blood test

Endoscopy = sigmoidoscopy + colonoscopy

TABLE 2
Health Behavior Framework Variables (Filipino Health Study, Los Angeles, CA, 2004–2009)

Items	Intervention (n = 302)		Control (n = 130)	Inter- vention versus control *** p
	Baseline	Follow-up	Baseline	Follow-up
Knowledge/Awareness of CRC screening tests				
Summary Score, Mean (SD)	2.45 (1.33)	2.90 (1.29)	2.42 (1.19)	2.52 (1.06)
Individual knowledge items (% yes or % correct)	%	%	%	%
(1) Heard of colonoscopy	71	82	76	77
(2) Heard of sigmoidoscopy	57	66	53	62
(3) Age people should start FOBT	33	41	34	30
(4) How often should people do FOBT	54	58	56	62
(5) How often should people do sigmoidoscopy	24	35	20	19
(6) How often should people do colonoscopy	6	9	2	2
Communication with provider: Have you discussed CRC screening with a doctor in the past 6 months?	16	40	18	22
Health beliefs				
Perceived efficacy of FOBT: Do you believe that a stool blood test can detect CRC in its early stages?	87	94	82	85
Self-efficacy for requesting FOBT from provider: Would you be able to request a stool blood test from your doctor?	95	95	90	91
Efficacy of early detection: Assuming a person gets CRC, how likely do you think early detection increases this person's chance of survival?				
Very likely	82	82	79	80
Somewhat likely*	15	14	14	18
Not likely*	3	4	7	2
Perceived susceptibility: Compared to other people your age, how likely do you think it is that you could				

Items	Intervention (n = 302)		p **	Control (n = 130)		Inter- vention versus control *** p
	Baseline	Follow-up		Baseline	Follow-up	
<i>get CRC?</i>						
<i>Much more likely</i>	19	33	<0.001	24	32	0.12
<i>No difference*</i>	49	42		51	42	
<i>Much less likely*</i>	32	25		25	26	
Fatalism: <i>Some people say they either get CRC cancer or they don't. There is nothing that can be done about it.</i>						
<i>Strongly agree*</i>	22	8	0.006	20	15	0.46
<i>Somewhat agree*</i>	18	22		19	20	
<i>Not agree with this</i>	60	70		61	65	
Cultural belief: <i>Some people say that a person gets CRC as punishment for something they have done wrong</i>						
<i>Strongly agree*</i>	8	6	0.91	10	10	0.20
<i>Somewhat agree*</i>	10	13		6	9	
<i>Not agree with this</i>	82	81		84	81	
Barriers to FOBT						
Unpleasant to collect stool						
<i>Very unpleasant</i>	12	10	0.47	12	9	0.45
<i>Somewhat unpleasant*</i>	28	27		29	29	
<i>Not unpleasant</i>	60	63		59	62	
Inconvenient to avoid certain food						
<i>Very inconvenient*</i>	6	7	0.42	4	7	0.21
<i>Somewhat inconvenient*</i>	20	20		17	16	
<i>Not inconvenient</i>	74	73		79	77	
Barriers to Sigmoidoscopy/Colonoscopy						

Items	Intervention (n = 302)		*** p	Control (n = 130)		*** p	Inter- vention versus control *** p
	Baseline	Follow-up		Baseline	Follow-up		
Pain and discomfort							
<i>Very concerned*</i>	24	31	<i>0.01</i>	33	39	0.20	0.71
<i>Somewhat concerned*</i>	43	44		35	36		
<i>Not concerned</i>	33	25		32	25		
Embarrassment							
<i>Very embarrassed*</i>	9	8	0.36	5	12	0.51	0.29
<i>Somewhat embarrassed*</i>	31	29		29	26		
<i>Not embarrassed</i>	60	63		66	62		

* These categories were combined for statistical tests.

** p-values for the corresponding differences between baseline and follow-up were obtained using mixed-effects logistic regression.

*** p-values for the corresponding differences in change over time between intervention and control groups were obtained using mixed-effects logistic regression.