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Testing Messages to Encourage Discussion of Clinical Trials among Cancer Survivors and Their Physicians: Examining Monitoring Style and Message Detail

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Abstract

Encouraging cancer survivors to discuss clinical trials with their physicians may increase enrollment in clinical trials. Health messages offer one method for encouraging such discussions. We hypothesized that matching messages to an individual's preference for detailed or non-detailed information (i.e., monitoring style) would result in more discussions. Participants ($N = 538$) were cancer survivors, who phoned the National Cancer Institute's Cancer Information Service (CIS). Participants were classified as higher or lower monitors and then randomized to receive detailed or non-detailed messages in the mail one and four weeks following their baseline CIS call. At 12-weeks there was a significant interaction between monitoring style and message detail. Follow-up analyses were non-significant but suggested a theoretically consistent pattern in which non-detailed messages were more effective among lower-monitors. These findings imply that providing extremely detailed information may be excessive, even to individuals engaged in information seeking behavior.

Keywords

clinical trials; cancer survivor; health messages; monitoring style

There are approximately 11.7 million cancer survivors in the United States [1]. A person is considered a cancer survivor from the time of diagnosis through the rest of his or her lifetime [2]. The five-year relative survival rates for cancer have been increasing over the past two decades, but cancer remains the second leading cause of death in the U.S. [1]. New treatments are central to improving the prognosis and quality of life for cancer survivors, but advances in cancer treatments depend upon their scientific merit shown in clinical trials. Clinical trials are the primary research vehicles for identifying the relative efficacy of cancer therapies. Each year only 3% of survivors with new cancer cases enroll in clinical trials [3].

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This low rate of accrual delays the development and dissemination of new and innovative treatments.

One barrier limiting participant accrual is the failure of patients and physicians to discuss clinical trials as a treatment option [4]. Accordingly, one method to increase participation is to encourage physicians to introduce the topic of clinical trials to their patients; however, the likelihood of physicians presenting this information often hinges on their attitudes toward clinical trials more than their patients' well-being [4–6]. Alternatively, patients can be encouraged to broach the topic of clinical trials with their physicians, which empowers survivors to be active partners in treatment decisions [7, 8]. The experiment reported here tested different methods for promoting this patient-empowering approach.

Print materials can enhance survivors' understanding of clinical trials [9, 10] and may be useful for encouraging them to discuss clinical trials with their physicians. One challenge in delivering treatment information is determining the amount of detail patients need in the message [11, 12]. Although many survivors seek information about their diagnosis, treatment, side effects, and the implications of cancer and treatment for their quality of life [13], others experience information overload [14]. Thus, both leaving patients under-informed with minimal details and overwhelming patients with explicit details are concerns when providing cancer-related information [15]. One strategy for determining the appropriate level of detail may be to consider individual differences in the tendency to attend to or avoid threatening information.

Two ways of coping with information have been identified: monitoring and blunting [16, 17]. Individuals who are more likely to seek out information are referred to as *monitors*. Individuals who tend to distract themselves from information in order to blunt its psychological impact are referred to as *blunters*. Compared to blunters, monitors desire more thorough information about cancer prevention and detection behaviors [18], are more concerned and distressed about cancer risks, are more knowledgeable about their medical situations, and tend to be more adherent to medical recommendations [19]. Additionally, monitors tend to have lengthier visits with their physicians compared to blunters [20]. Based on these findings, it seems that monitors would prefer more detailed health information, whereas blunters would prefer shorter, more general, and less threatening information.

Monitoring and blunting are not simply opposite ends of one dimension, but rather they differentially predict behavior under different circumstances [21]. Indeed, some researchers have considered coping in terms of high- versus low-monitoring, high- versus low-blunting, or both [22–24]. In the current study, we consider coping from the perspective of high- versus low- monitoring. We chose to focus on monitoring exclusively because the participants were callers seeking information from the National Cancer Institute's toll-free telephone hotline – the Cancer Information Service – thus, were actively engaged in monitoring behavior. Additionally, even cancer survivors who do not use this service are unlikely to blunt all cancer information given that their treatment decisions require them to attend to treatment-related information. The purpose of this study was to compare the effectiveness of detailed and non-detailed messages encouraging cancer survivors, who differed in their tendency toward monitoring, to ask their physicians about clinical trials. We predicted that higher monitors who received detailed messages and lower monitors who received non-detailed messages would be more likely than not to initiate a discussion about clinical trials with a physician and that higher monitors receiving non-detailed messages and lower monitors receiving detailed messages would be equally likely to discuss clinical trials with their physician than not to discuss them.

Method

Design

A quasi-experimental, 2 (monitoring style: higher, lower) $\times$ 2 (message type: detailed, non-detailed) design was used. In this between-subjects design, participants who were classified as higher or lower monitors were randomly assigned to read a message (detailed or non-detailed) and complete evaluations of the message.

Participants

Participants were recruited at the end of their call to the NCI's toll-free telephone hotline - the Cancer Information Service (CIS). The CIS is the NCI's link to the American public (e.g., cancer patients and their family and friends), interpreting and explaining research findings in a clear understandable manner, and providing personalized responses to specific questions about cancer [25].

Figure 1 describes the flow of participants through the trial. Five hundred and thirty-eight cancer survivors were randomized to either the detailed ($n = 267$, 178 women) or the non-detailed ($n = 271$, 191 women) message condition. Callers were excluded if they: (a) did not consent to screening questions, (b) were not cancer survivors, (c) would not have an appointment to speak with their cancer doctor within the next 3 months, (d) were participating in another CIS clinical trials campaign, (e) were awaiting a possible cancer diagnosis, (f) were in remission (completed treatment or had surgery without follow-up adjuvant therapy), (g) were in hospice care, (h) had already participated in the study, (i) were under 18 years of age, (j) requested information about clinical trials during the call or had already received information about clinical trials from the CIS, (l) had already discussed clinical trials with their doctor as a treatment option for their current cancer diagnosis, (m) were determined by the CIS specialists to be significantly distressed, (n) were an international caller or did not speak English, or (o) hung up. Participants varied in cancer stage and were awaiting or receiving treatment. Our aim was to recruit participants who would be considering options related to their primary cancer treatment.

Message development

We created two types of messages (detailed and non-detailed) for this study. The messages took the form of letters that were mailed to participants in two installments; the first was sent one day after the baseline call and the second was sent 4 weeks later. Message content was adapted from the NCI booklet "Taking Part in Clinical Trials: What Cancer Patients Need to Know." The letters were designed to highlight important information from the NCI booklet and in the case of the detailed messages, elaborate on them. The detailed messages included more information and focused on evidence related to clinical trials while non-detailed messages were shorter and offered less evidence. The letter included general information about talking to a physician about clinical trials including the reasons to talk about clinical trials and points to consider in these discussions. The non-detailed letter was approximately 600 words and two pages long while the detailed letter was 1500 words and four pages long. The literacy and numeracy levels as well as general formatting and style were kept constant across conditions. Participants also received stickers, pens, and notepads with messages matched to condition such as "Remember to ask your doctor about clinical trials" for individuals in the non-detailed condition, and "Feel sure you know all of your options—remember to ask your doctor about clinical trials" for participants in the detailed condition.

At Week 4, participants received a second letter which reinforced the information from the initial mailing and provided a list of questions the survivor might ask about clinical trials. In

the non-detailed condition, one suggested question was, “Do you think a clinical trial would be an option for me?” In the detailed condition, the suggestion was, “I have heard that clinical trials provide quality cancer treatment and, in some cases, are the best treatment option for certain cancer patients. Do you think a clinical trial would be an option for me?” In the Week 4 mailing, the non-detailed letter was 400 words and one and a half pages long while the detailed letter was 600 words and two pages long. At this time, participants also received a wallet card matched to message condition which listed questions to ask their doctor that they could take with them to a doctor’s appointment. The top of this card included a message (i.e., “Consider your treatment options,” and “Feel confident about your decision, consider all of your treatment options,” for individuals in the non-detailed and detailed conditions, respectively).

Procedure

The Yale University Institutional Review Board approved the research protocol. Trained CIS Information Specialists screened potential participants for eligibility after addressing their initial reason for calling. Eligible callers were asked if they were interested in participating in the research. Those callers willing to take part answered a 7-minute telephone survey that included assessments of monitoring style and potential determinants of participants’ likelihood of talking to their physician about clinical trials (i.e., intentions and understanding).

Participants were sent one mailing the day after the baseline call and another mailing 4 weeks later. Participants were assigned randomly to receive either detailed or non-detailed information in both mailings. In the first mailing, participants received a letter, sticker, pen, and notepad along with the standard NCI booklet. Health messaging interventions may have a greater impact if the participant is exposed to multiple message doses [26–28]; thus, to ensure repeated exposure to the messages, the mailings included gift items (i.e., the sticker, pen, etc.) with detailed or non-detailed messages printed on them. The Week 4 mailing included a follow-up survey that assessed whether or not they discussed clinical trials with their physician (i.e., behavior). Participants returned completed questionnaires in pre-stamped, pre-addressed envelopes.

Twelve weeks after the initial phone call, research assistants blind to participant condition contacted each participant for a brief follow-up phone survey that assessed the amount of material read, use of the gift items, and behavior. Participants not reached on the first attempt were called a maximum of 15 times over 4 weeks. Participants not reached after 15 calls received a pre-addressed, stamped postcard questionnaire assessing behavior. To ensure confidentiality, the postcards displayed an identification number, rather than the participant’s name. Participants received \$10 for completing each follow-up survey.

Measures

Demographics—We collected information about participants’ gender, ethnicity, race, education, income, and cancer site during the baseline interview.

Theoretical determinants of behavior—At baseline, participants indicated their *intentions* to ask their physician about clinical trials from 1 (*definitely not*) to 5 (*definitely yes*), and their *understanding* of clinical trials from 1 (*very unclear*) to 4 (*very clear*). Because CIS restrictions limited the length of the telephone call to 7 minutes, each determinant was measured using a single item.

Monitoring style—At baseline we assessed monitoring style using the 16-item monitoring subscale of the Monitoring-Blunting Style Scale (MBSS) [21]. Although the MBSS has

separate scales for monitoring and blunting, there is research precedence for using only the monitoring subscale [22–24]. Four stressful scenarios were presented (e.g., being on a turbulent airplane ride). For each scenario, participants listened to four coping strategies (e.g., “I’d carefully read the information provided about safety features in the plane”) which reflected the degree to which they would seek as much information as possible and indicated whether or not each statement described how they would act in the given situation (yes, no). Responses to the 16 items were summed to calculate the monitoring style score which ranged from 0 to 16 with higher scores indicating more monitoring. Consistent with previous research [22], we described participants scoring above the median as “higher monitors” and those below the median as “lower monitors.”

Intervention implementation—During the Week 12 follow-up call, we assessed the degree to which the intervention was implemented as intended. Participants indicated how much of the materials they had read from 1 (*none*) to 5 (*all*). Participants reported how useful they found the supplemental materials by answering (0 = *no*, 1 = *yes*) whether they (a) placed the reminder sticker on their calendar, (b) referred to the pocket card during a discussion of clinical trials, and (c) used the notepad to take notes about clinical trials. The participants also indicated how many days in the past week they used the pen.

Behavior—We assessed behavior at weeks 4 and 12. At Week 4, participants indicated if they had discussed the clinical trials information with their physician (0 = *no*, 1 = *yes*). At Week 12, we assessed behavior with two questions. We provided the participants with the date they enrolled in the study and asked them to indicate whether they had an appointment to speak with their physician since then (0 = *no*, 1 = *yes*). Those who had an appointment were asked if they had discussed the clinical trials information with their physician (0 = *no*, 1 = *yes*). Those who had not had an appointment were excluded from the study.

Analysis Plan

Randomization and intervention implementation—We conducted analyses of variance (ANOVAs) for continuous data, and chi-square tests for categorical data to examine differences in baseline sample characteristics between experimental groups and between study completers and dropouts. Intervention implementation was compared across message types and monitoring styles using ANOVA and chi-square tests. Analyses included only participants with complete data.

Hypothesis testing—We conducted a binary logistic regression analysis to examine the effects of message condition on the likelihood that individuals had talked to their physician about clinical trials at week 12. Covariates, including baseline intentions and understanding, cancer type, and stage of cancer treatment were entered in the first step. The main effects for message type and monitoring style were entered next, followed by the interaction term (message type $\times$ monitoring style). Message type and monitoring style were dummy-coded (non-detailed message/lower-monitoring style = 0, detailed message/higher-monitoring style = 1). To follow up a significant interaction we used binomial tests to determine if, within each group, the proportion of people who discussed clinical trials with their physician was significantly different than the proportion of people who did not. Specifically, we tested whether the proportion of people who discussed clinical trials with their physician was greater than the proportion of people who did not among higher monitors who received detailed messages and lower monitors who received non-detailed messages.

We applied intention-to-treat principles for these analyses. Participants were carried forward if they either indicated talking to their doctor at Week 4 or having a doctor’s appointment at Week 4.

Results

Participant Description

No differences were observed between participants randomized to the detailed ($n = 267$) and non-detailed ($n = 271$) conditions on monitoring style or demographic variables, indicating that randomization was successful. Data were available from 244 participants at the 12-week follow-up ($n = 120$ in the detailed condition and $n = 124$ in the non-detailed condition). Attrition was due primarily to participant dropout (e.g., lack of interest) and inability to reach participants for follow up (Figure 1). Compared to those participants who dropped out or could not be reached, the participants who were retained at follow up were more likely to have achieved higher levels of education ($\chi^2[5] = 17.67, p = .003$). Women were more likely to drop out than men ($\chi^2[1] = 4.88, p = .03$). Participants who dropped out were not different from those who were retained with respect to education, race, and monitoring style ($ps > .05$).

The frequency statistics for gender, Hispanic ethnicity, race, education, income, cancer site, and phase of cancer treatment are presented in Table 1, separately for participants who received non-detailed and detailed messages. Table 2 shows the mean scores (by group) for intentions to discuss clinical trials with a physician, understanding of clinical trials, and monitoring (all measured at baseline). For the collective sample, the mean monitoring style score was 12.16 ($SD = 2.36$) and the median was 13.00 indicating that overall, participants in this sample were relatively high monitors. The mean monitoring style scores were 10.10 ($SD = 1.67$) for lower monitors (classified by a median split) and 14.00 ($SD = .93$) for higher monitors.

Intervention Implementation

The majority of retained participants (94.5%) reported reading ‘most’ or ‘all’ of the materials mailed at Week 12. In the ANOVAs testing group differences in the amount of materials read at week 12, neither the effects for message condition or monitoring style, nor their interaction were significant ($p = .21$) indicating that amount of material read was consistent across message conditions and monitoring styles. Approximately a quarter of the participants reported using the gifts: 22.5% of the participants reported placing the sticker on their calendar, 26.2% reported referring to the pocket card, and 25.8% reported using the notepad. Participants reported using the pen on 2.26 days in the past week ($SD = 2.73$). Chi-squared tests indicated no difference in usage patterns as a function of experimental group or monitoring style ($ps > .05$) with one exception; 50% of the lower monitors and only 29% of the higher monitors reported using the sticker ($p = .01$).

Behavior

Overall, 42.6% (104/244) of participants contacted at follow-up talked to their physicians about clinical trials. The pattern of results was consistent with our hypothesis. The percentage of survivors who reported discussing clinical trials with their physician was 68.1% for lower monitors who received non-detailed messages, 58.3% for lower monitors who received detailed messages, 51.8% for higher monitors who received non-detailed messages, and 57.1% for higher monitors who received detailed messages. Based on these frequency statistics, lower monitors were more likely to discuss clinical trials when the message was non-detailed and higher monitors were more likely to discuss clinical trials when the message was detailed. The binary logistic regression analysis predicting whether participants spoke to their physician about clinical trials indicated that there were no main effects for message type or monitoring style; however, the message type $\times$ monitoring style interaction was significant, $OR = 1.21$, 95% CI: 1.04–1.41, Wald = 6.98, $p = .008$. Follow-up binomial tests indicated that among lower monitors who received non-detailed messages, the

proportion of people who discussed clinical trials with their physician was significantly greater than the proportion of those who did not ($p = .02$). Binomial tests were not significant for the other groups (see Figure 2).

Discussion

The purpose of this study was to determine whether detailed and non-detailed messages encouraging cancer survivors to talk to their physicians about clinical trials were differentially effective among higher as compared to lower monitors. The omnibus test of the message type $\times$ monitoring style interaction was significant. Follow-up tests indicated that among lower-monitors who received non-detailed messages, the proportion of people who spoke to their physician about clinical trials was greater than the proportion of people who did not. The pattern of findings was consistent with our prediction and with previous research suggesting that matching the level of detail in a message to an individual's monitoring style can help to motivate behavior [29], particularly among lower monitors. The substantial dropout of participants in this study and the use of a dichotomous outcome variable limited our ability to detect statistically significant group differences in follow-up analyses. The findings suggest that the impact of matching messages to monitoring style is worthy of further investigation.

To understand why messages matched to monitoring style tend to be more effective, it would be helpful to examine potential mediators such as the regulation of stress or anxiety. Researchers have demonstrated that high monitors amplify threatening cues in health information [19], ruminate over threatening information, and experience greater concern, distress, and anxiety about threatening information and the risk for disease [30–32]. As such, in order to motivate high monitors, health information should be detailed and should include actionable steps to reduce anxiety [19]. In the experiment reported here, the detailed messages provided the survivors with both thorough information and actionable steps (i.e., a list of questions to ask) and thus, may have reduced anxiety levels of the higher monitors. Because low monitors tend to have less anxiety related to health risks and tend to be less sensitive to ambiguous or threatening health information [19], it is logical that they would be more motivated by non-detailed information. Indeed, tailoring health information to an individual's coping style can have advantageous effects on physiological arousal [18]. In the current study, anxiety was not assessed; but future studies should examine anxiety as a mediator of the impact of messages matched to coping style.

There are a few notable limitations to this study. First, our findings suggest that matching the level of detail in a health message to monitoring style mattered most for individuals who were relatively low in monitoring; however, our sample was comprised of survivors who called the CIS and thus, it is unlikely that any of our participants were truly low monitors. This may help to explain the finding that more of the lower monitors reported using the sticker. Perhaps the effects of matching message detail to monitoring style would be stronger in the general survivor population in which there is likely to be a broader range of monitoring styles. Second, our sample was also somewhat homogeneous with respect to gender (69% female) and ethnicity (75% white), which limits the ability to generalize findings to other populations. Because ethnic minority populations bear a substantial and disproportionate cancer burden in the U.S. [33], interventions aimed at encouraging survivors to discuss all of the potential treatment options with their doctors are particularly important for ethnic minorities. Third, there was substantial attrition from baseline to the 4- and 12-week follow-up assessments. Although the analyses indicated few differences between study adherers and dropouts at baseline, participant dropout may have eroded intervention effects and reduced statistical power. Finally, the study design did not include a no-message control group. Thus, we were not able to determine whether receiving any type

of message is more effective than receiving no message. Because information about clinical trials is frequently presented during CIS calls (i.e., most callers are exposed to at least some information about clinical trials), we determined that it would not be practically relevant to include a no-message control condition.

The findings suggest directions for future research and practice. From a research perspective, because so few participants reported talking to their doctors about clinical trials (42.6%), we suggest that health messaging may not be sufficient as a stand-alone intervention for encouraging survivors to discuss clinical trials with their physicians. Researchers should determine if pairing messaging with another strategy would result in more survivors discussing clinical trials with their physicians. From a practical perspective, although participants did read most or all of the print information mailed to them, most did not report using tailored gifts (stickers, pens, notepads, etc.). It seems that providing messages via letters and brochures may be a more cost-effective message delivery modality than providing tailored gifts.

The findings from this study raise issues that should be considered in efforts to motivate cancer survivors to seek information from their physicians about potential treatment options. Because monitors are sensitive to threatening or negative health information, practitioners may be inclined to withhold details that could be perceived as ambiguous or distressing [19]. The findings suggest the opposite approach would be more effective. Matching the amount of detail provided in health information to an individual's monitoring style may be an effective means of enhancing survivors' motivation to seek treatment information, and in particular, information about clinical trials. We do not mean to imply that health information should be withheld from low monitors but rather that information may be delivered in a manner that would better resonate with them. Specifically, our findings demonstrate that lower monitors may respond best to clear and direct statements free from superfluous detail that may be perceived as distracting. With respect to implications for services such as the CIS, our findings suggest that we should not assume a caller is seeking extensive amounts of information. Although that may be the case, information specialists and other practitioners should be conscious of how much information survivors want and can manage, and balance these preferences and needs with the provision of sufficient information to make informed decisions.

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Figure 1.
Flow Diagram of Participants through the Study.

Figure 2.

Proportion of participants who spoke to their physician about clinical trials

* Binomial tests indicated that the proportion of participants who spoke to their physician about clinical trials was significantly greater than the proportion of participants who did not ($p < .05$).

Table 1**Demographic Characteristics of Participants by Condition**

	Non-detailed <i>n</i> (%)	Detailed <i>n</i> (%)
Gender		
Male	80 (29.52)	89 (33.33)
Female	191 (70.48)	175 (65.54)
Hispanic		
Yes	13 (4.80)	7 (2.62)
No	253 (93.36)	252 (94.38)
Race		
American Indian or Alaska Native	18 (6.64)	14 (5.24)
Asian	4 (1.48)	2 (0.75)
Black or African American	48 (17.71)	39 (14.61)
Native Hawaiian or Other Pacific Islander	1 (0.37)	2 (0.75)
White	202 (74.54)	200 (74.91)
Education		
Grade school	6 (2.21)	4 (1.50)
Some high school	22 (8.12)	27 (10.11)
High school	82 (30.26)	75 (28.09)
Some college	73 (26.94)	80 (29.96)
College	57 (21.03)	38 (14.23)
Post-graduate	29 (10.70)	37 (13.86)
Income		
< \$20,000	83 (30.63)	72 (26.97)
\$20,000 – \$39,000	69 (25.46)	78 (29.21)
\$40,000 – \$59,000	43 (15.87)	38 (14.23)
\$60,000 – \$79,000	29 (10.70)	23 (8.61)
> \$80,000	28 (10.33)	33 (12.36)
Cancer site		
Breast	31 (25.00)	28 (23.30)
Gastro-intestinal	15 (12.10)	14 (11.80)
Hematologic (leukemia/lymphoma)	11 (8.90)	11 (9.20)
Female reproductive or urinary tract	14 (11.30)	5 (4.20)
Male reproductive or urinary tract	17 (13.70)	24 (20.00)
Melanoma	7 (5.60)	3 (2.50)
Lung	9 (7.3)	6 (5.00)
Other	20 (16.10)	29 (24.20)
Phase of primary cancer treatment		
Treatment has not begun	16 (12.90)	12 (10.00)
Less than half way through treatment	25 (20.20)	19 (15.80)
Half way through treatment	20 (16.10)	20 (16.70)
More than half way through	17 (13.70)	26 (21.70)

	Non-detailed <i>n</i> (%)	Detailed <i>n</i> (%)
Treatment is complete	31 (25.00)	23 (19.20)

Table 2

Descriptive Statistics for Intentions, Understanding, and Monitoring by Condition

	Non-detailed <i>M</i> (<i>SD</i>)	Detailed <i>M</i> (<i>SD</i>)
Intentions	4.05 (.91)	4.03 (1.05)
Understanding	2.44 (1.09)	2.36 (1.02)
Monitoring	12.13 (2.25)	12.18 (2.48)