Intervention Mediators

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Birmingham, Wendy C.; Brumbach, Barbara H.; Boonyasiriwat, Watcharaporn; Walters, Scott; and Kinney, Anita Y., "Intervention Mediators" (2017). *Faculty Publications*. 6038. [https://scholarsarchive.byu.edu/facpub/6038](https://scholarsarchive.byu.edu/facpub/6038)

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Intervention Mediators in a Randomized Controlled Trial to Increase Colonoscopy Uptake Among Individuals at Increased Risk of Familial Colorectal Cancer

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Published online: 24 February 2017 © The Society of Behavioral Medicine 2017

Abstract

Background Understanding the pathways by which interventions achieve behavioral change is important for optimizing intervention strategies.

Purpose We examined mediators of behavior change in a tailored-risk communication intervention that increased guideline-based colorectal cancer screening among individuals at increased familial risk.

Methods Participants at increased familial risk for colorectal cancer (N = 481) were randomized to one of two arms: (1) a remote, tailored-risk communication intervention (Tele-Cancer Risk Assessment and Evaluation (TeleCARE)) or (2) a mailed educational brochure intervention.

Results Structural equation modeling showed that participants in TeleCARE were more likely to get a colonoscopy. The effect was partially mediated through perceived threat (β = 0.12, p < 0.05), efficacy beliefs (β = 0.12, p < 0.05), emotions (β = 0.22, p < 0.001), and behavioral intentions (β = 0.24, p < 0.001). Model fit was very good: comparative fit index = 0.95, root-mean-square error of approximation = 0.05, and standardized root-mean-square residual = 0.08.

Conclusion Evaluating mediating variables between an intervention (TeleCARE) and a primary outcome (colonoscopy) contributes to our understanding of underlying mechanisms that lead to health behavior change, thus leading to better informed and designed future interventions.

Trial Registration Number ClinicalTrials.gov, NCT01274143.

Keywords Colorectal cancer screening · Colonoscopy · Extended parallel process model · Implementation-intention strategies · Structural equation modeling

Introduction

In the USA, colorectal cancer is a leading cause of cancer-related death in both men and women [1]. Average lifetime risk for developing colorectal cancer is approximately 5% in the general population; risk increases twofold to fourfold or more if an individual has a first degree relative (FDR) with the disease [2–4]. Regular colorectal cancer screening with colonoscopy has the potential to reduce both incidence and mortality through early detection and removal of polyps before they become cancerous. At the time of the present study, the National Comprehensive Cancer Network guidelines [5] recommended that individuals with a moderately increased risk (i.e., colorectal cancer diagnosis in a FDR < age 60; two or more first-degree or second-degree
relatives with colorectal cancer; did not meet criteria for genetic testing for hereditary cancer syndrome) begin colorectal cancer screening at age 40 or 10 years before the youngest case age in the immediate family [5–7] and to repeat screenings every 3–5 years.

Although colorectal cancer incidence and mortality rates have been declining in the USA since the mid-1980s, screening rates among relatives of colorectal cancer patients remain disappointingly low [8–11]. It may be that these individuals do not adequately understand their personal family histories or fail to have discussions regarding their risk with their primary care provider [12, 13]. Patients may find it difficult to overcome logistical barriers (e.g., health insurance coverage [14], distance to testing center [15]) or emotional barriers (e.g., fears about screening procedures [16] associated with colorectal cancer screening). Other patients may not be fully aware of their colorectal cancer risk and, thus, lack motivation to pursue preventative measures (e.g., colonoscopy) [17]. The Family Colorectal Cancer Awareness and Risk Education (Family CARE) Project was a remote, tailored-risk communication intervention (Tele-Cancer Risk Assessment and Evaluation (TeleCARE)) aimed at individuals at familial risk for colorectal cancer who were not up-to-date with guideline-based screening. Specifically, Family CARE was designed to assess the degree to which barriers, risk perceptions, efficacy beliefs, emotions, knowledge, and intentions might be influenced by a phone-based genetic counseling session with a licensed genetic counselor and whether these mediating factors lead to increased health behaviors (i.e., colonoscopy). We compared the efficacy of TeleCARE to a mailed educational brochure for improving colonoscopy rates [18]. We previously reported that 34.5% of those in the TeleCARE arm and 15.7% of those in the educational brochure arm obtained a colonoscopy within 9 months of the intervention (OR = 2.83, 95% CI [1.87–4.28]) [18]. Additionally, TeleCARE increased colonoscopy uptake, even when cost was a reported barrier [19]. This finding was robust across subgroups where no effect modification was associated with income or rural status [18]. This study has significantly advanced knowledge in regard to designing an effective intervention to address low rates of colonoscopy screening adherence. Because of its success in changing behavior, it is crucial to examine the psychological mechanisms linking the intervention to behavioral change; the present study aims to do this.

Theoretical Framework

There is increasing evidence that tailored-risk communications are more effective than targeted interventions in informing individuals of their cancer risk and motivating behavior change [20–23]. Tailored-risk communications can be personalized to the individuals’ efficacy beliefs, personal risk factors, cancer knowledge, behavioral intention, or any combination thereof [23]. Therefore, combining constructs from both health communication and behavioral theories can address both affective and cognitive factors in risk communication. Further, there is an increasing need to evaluate the theoretical basis for behavioral mechanisms that underlie the beneficial effects of cancer risk communications to fully understand how and why a particular intervention may work better than another [20, 24]. Guided by theory, the TeleCARE intervention incorporated behavioral change theory and approaches [25], contributing unique, mediating constructs for intervention effects.

The study’s theoretical framework incorporated the extended parallel process model [26–28] and implementation-intention strategies [29–36] as guides to development and implementation of the TeleCARE intervention (see Fig. 1). Additionally, previous research suggests that increasing knowledge can contribute to decision-making [37]; thus, TeleCARE also aimed to increase colorectal cancer knowledge. While the intervention was not designed to be a strict test of these theories, major components of the extended parallel process model and implementation-intention strategies were used as a basis for the intervention. Therefore, the following study is not a pure test of extended parallel process model or implementation-intention strategies; rather, it is a test of constructs proposed by these theories as potential mediating factors connecting the intervention to positive behavior change.

Risk communication based on the extended parallel process model incorporates both affective and cognitive processes that can lead to behavior change. The extended parallel process model purports that affect, or emotions, specifically those relating to fear, play an important role in guiding behavior. In addition to fear, other associated negative emotions to consider include distress and worry. Cognitive processes identified in the extended parallel process model are threat and efficacy. Threat is characterized both in terms of perceived susceptibility (degree of applicability) and severity (level of magnitude). Together, perceived susceptibility, severity, and overall perceptions of risk comprise an individual’s global level of perceived threat. Efficacy is
composed of both response and self-efficacy. A sense of response efficacy is the degree to which someone believes in the effectiveness of a recommended response. Self-efficacy is the degree to which someone believes that they can carry out the recommended response. Barriers can be conceptualized as part of self-efficacy since barriers limit one’s ability to act. Perceived response efficacy, self-efficacy, and barriers comprise a global level of perceived efficacy. The extended parallel process model purports that levels of threat, efficacy, and emotions in combination can lead to positive or negative health behaviors. Fear is aroused when threat perceptions are high. An individual with high perceived threat might believe that they are at risk for colorectal cancer (perceived susceptibility) and consider it a life-threatening disease (perceived severity). To channel the fear in a positive direction, individuals need strong efficacy beliefs incorporating both response and self-efficacy. For example, someone with strong efficacy beliefs may believe that colonoscopy screening is effective in reducing their colorectal cancer risk (high response efficacy) and that they are capable of obtaining a colonoscopy (high self-efficacy). When threat perceptions are combined with high efficacy levels, fear is more likely to lead to adaptive, self-protective health behaviors [27]. TeleCARE was tailored to raise both threat and efficacy related to colorectal cancer screening in participants.

Implementation-intention strategies link specific situations (date and time, e.g., If I call to schedule colonoscopy next week, I will have one within a couple of months) or cues (e.g., being reminded by a postcard to get a colonoscopy) with goal-directed responses (e.g., getting a colonoscopy for screening and prevention). Moreover, research has shown that patients are more likely to carry out an intended action if they identify when, where, and how they will do so [29–33, 35, 36]. Specifically, it has been shown that implementation intention-based interventions help close the intent-to-behave gap and can increase colorectal cancer screening rates, even among underserved minority and low-income groups [38]. TeleCARE interventionists encouraged participants to create a specific action plan to get screened, trouble-shot logistical considerations (e.g., transportation, timing, social support, and insurance coverage), and provided participants with a reminder postcard as a cue to act.

In terms of the delivery style, the intervention used elements of motivational interviewing, an evidence-based communication strategy. Motivational interviewing is a participant-centered, directive style of interacting with a person to help explore and resolve ambivalence about change [39]. The contribution of motivational interviewing is to encourage the participant to engage and respond more positively to the risk information, rather than to view the participant as a passive recipient of information. There is evidence that motivational interviewing reduces defensive responses (message rejection, paralyzing fear, low response efficacy/fatalistic beliefs) after receiving fear-arousing cancer information and effectively motivates people to engage in preventive behavior [18, 25, 40–42]. Finally, it has been shown that health care provider recommendation is one of the strongest predictors of health behavior, including colonoscopy uptake [43, 44]. Therefore, at 9 months, we measured whether participants had received a recommendation for colonoscopy from their health care provider.

The Family CARE Project

The Family CARE Project demonstrated that a relatively brief phone-based intervention led to positive changes in screening behavior. However, the question remains of how the intervention brought about changes. Shedding light on the underlying mechanisms through which behavioral change is achieved in a theory-based intervention can help inform and validate theory and optimize intervention strategies [45, 46]. Strong interventions are grounded in theory and are often stronger when multiple theories are combined. Further, evidence-based models of behavioral change require rigorous measurement and analysis of the purported mediators underlying the behavior [47]. This study has incorporated these guidelines at all levels: theory-based intervention, deliberate measurement of mediating constructs, and in-depth analysis of intervention effects on primary outcomes via hypothesized mediational pathways. We predicted that the intervention would increase cognitive and affective constructs, leading to increased colonoscopy uptake. We hypothesized that the intervention would increase intentions to get colonoscopy and ultimately lead to increased colonoscopy uptake.

Methods

Participants and Procedures

Our study population (ClinicalTrials.gov, NCT01274143) consisted of 481 individuals 30–74 years old with either a single FDR diagnosed with colorectal cancer before age 60 or one FDR diagnosed at age 60 years or older plus an additional first- or second-degree relative diagnoses at any age (see Fig. 2). All participants were non-current with risk-appropriate screening and met criteria for colonoscopy according to national guidelines [5].

Participants randomized to the high-intensity TeleCARE arm received a tailored telephone-based colorectal cancer risk counseling session with a cancer risk specialist (i.e., genetic counselor), as well as tailored follow-up letters and reminder postcards [49, 50]. The TeleCARE intervention incorporated principles from the extended parallel process model and implementation-intention strategies described previously. Specifically, the telephone sessions were tailored to participants’ previously assessed perceptions of colorectal cancer susceptibility and severity, beliefs about the effectiveness of colonoscopy (response efficacy), and self-efficacy regarding
obtaining colonoscopy. The sessions incorporated risk communication and behavior change approaches based on raising perceptions of threat of familial colorectal cancer, thus leading to emotional arousal (i.e., increased fear/distress/worry). In addition, the session aimed to enhance beliefs about colonoscopy benefits (i.e., response efficacy), increase self-efficacy by helping patients develop solutions to overcoming self-identified barriers, and increase motivation to undergo colonoscopy. Based on implementation-intention principles, the participants were also asked to create an action plan for obtaining a colonoscopy. They were reminded of their stated plan in the follow-up tailored letter and postcard. The TeleCARE arm participants were also provided information on colorectal cancer to increase their general knowledge on the topic.

The low-intensity intervention arm received an educational brochure. Complete details of this study including the intervention protocol and study implementation are described elsewhere [18, 25, 49, 51, 52]. Surveys were administered at baseline, 1 month post intervention, and 9 months post intervention. To increase response rates, participants were given the option to respond via mailed (80%), internet (10%), or phone (10%) surveys. The at-risk relative enrollment response rate was 60.4% [51]. The Institutional Review Boards of participating institutions approved the trial, and informed consent was obtained for all participants.

### Measures

To better understand the underlying mechanisms accounting for the effects of TeleCARE on colonoscopy uptake, we evaluated whether perceived threat and efficacy, emotions (colorectal cancer fear, worry, distress), colorectal cancer knowledge, and intentions to get a colonoscopy mediated the intervention effects on colonoscopy uptake. We assessed responses on the baseline and
Developing colorectal cancer (1 = very low to 5 = very high) [53]. With a single item asking participants to rate their chance of taking the mean of standardized scores from the following scales: response efficacy mean score, self-efficacy mean score, and perceived risk. We did not conceptualize perceived efficacy and not three measures of the same type of efficacy. Since we wanted an overall efficacy score, taking the mean across these measures provided a global perceived efficacy score. Response efficacy \( (\alpha = 0.90, 0.90) \) was measured with four items on a five-point Likert scale \( (1 = \text{strongly agree}, 5 = \text{strongly disagree}) \) [28, 61] with statements such as “Colonoscopy works in preventing colorectal cancer.” Self-efﬁcacy \( (\alpha = 0.83, 0.83) \) was measured with four items on a five-point Likert scale \( (1 = \text{strongly agree}, 5 = \text{strongly disagree}) \) [28, 61] with statements such as “I can get a colonoscopy to prevent the onset of colorectal cancer.” Barriers were assessed with 21 items listing potential barriers that might prevent someone from getting a colonoscopy. The measure was adapted from Rawl’s (2005) ten-item measure assessing perceived obstacles of getting a colonoscopy [63] and based on our unpublished formative research with the target population. Examples of possible barriers include “I have a busy schedule and don’t have time” and “My doctor has not recommended a colonoscopy.”

Colorectal cancer knowledge \( (\alpha = 0.85, 0.94) \) was measured using an adapted measure from the Colorectal Cancer Knowledge Questionnaire [64], a 12-item validated scale that assesses colorectal cancer screening knowledge, risk factors, and colorectal cancer symptoms. This measure consists of true/false statements such as “You can have colorectal cancer even if you do not have symptoms.” It is best practice in health communication to try and increase knowledge.

Affective Variables Emotions—A latent variable for global negative emotions was estimated using the following measured indicators: cancer worry, psychological distress, and fear of colorectal cancer. In contrast to threat and efficacy, we did conceptualize negative emotions as a latent construct, where aspects of cancer-related worry, distress, and fear are all different ways to tap into the same underlying construct of negative emotions, thus constituting overall negative affect. Cancer worry \( (\alpha = 0.89, 0.84) \) was assessed with a three-item scale [65] measuring intensity and frequency on a five-point Likert scale \( (1 = \text{never or not at all}, 5 = \text{all the time or extremely}) \) with questions such as “How worried are you about getting colorectal cancer?” Psychological distress \( (\alpha = 0.87, 0.91) \) was measured using the Impact of Event Scale, a seven-item intrusion subscale [66]. Items were measured on a four-point Likert scale \( (1 = \text{not at all}, 4 = \text{often}) \) with statements such as “I thought about it [colorectal cancer] when I did not mean to.” Fear of colorectal cancer \( (\alpha = 0.94, 0.94) \) was assessed with an adapted six-item scale from the Negative Affect in Risk subscale of the Cancer Risk Beliefs Scale [67, 68] using a four-point Likert scale \( (1 = \text{strongly agree}, 4 = \text{strongly disagree}) \) with statements such as “I get frightened when I think I could get colorectal cancer.”

Intervention compared the TeleCARE arm versus educational brochure arm. Health care provider recommendation was measured by participants’ self-report of a recommendation from health care provider to get a colonoscopy.

Cognitive Variables To assess the four main extended parallel process model constructs (perceived susceptibility, severity, response efficacy, and self-efficacy), we adapted Cheah’s 16-item Risk Behavior Diagnosis Scale [61]. Cheah’s scale is based on Witte et al.’s original 12-item scale [28], with the addition of one item to each subscale to increase internal consistency \( (\alpha = 0.86–0.91) \) in a US sample.

Threat perceptions—A global threat score was achieved by taking the mean of standardized scores from the following scales and item: perceived severity mean score, perceived susceptibility mean score, and perceived risk. We did not conceptualize perceived susceptibility, severity, and risk as a latent variable. Although these all relate to perceived threat, they do so in distinct ways. Therefore, by taking an overall mean, all three are taken into account to provide a single measured construct for global perceived threat. Perceived severity \( (\alpha = 0.92, 0.95) \) was measured with four items on a five-point Likert scale \( (1 = \text{strongly agree}, 5 = \text{strongly disagree}) \) [28, 61] with statements such as “I believe that colorectal cancer is a significant disease.” Perceived susceptibility \( (\alpha = 0.86, 0.87) \) was measured with four items on a five-point Likert scale \( (1 = \text{strongly agree}, 5 = \text{strongly disagree}) \) [28, 61] with statements such as “I am at risk for getting colorectal cancer.” Perceived risk measured perception of cancer risk with a single item asking participants to rate their chance of developing colorectal cancer \( (1 = \text{very low to 5 = very high}) \) [62].

Efficacy beliefs—A global efficacy score was calculated by taking the mean of standardized scores from the following scales: response efficacy mean score, self-efficacy mean score, and reported barriers. Similar to threat, efficacy was not conceptualized as a latent variable. Response efficacy, self-efficacy, and barriers all constituted different aspects of efficacy and not three measures of the same type of efficacy. When appropriate, Cronbach’s alphas were calculated for demographic and social support variables in the model and directly assessed health care provider recommendation’s influence on colonoscopy uptake.

A description of specific measures is in the following. When appropriate, Cronbach’s alphas were calculated for scales at baseline and 1 month and are reported in that order.

Predictor Variables

Mediator Variables

Springer
Outcome Variables

Colonoscopy intention was considered an intermediate outcome and was assessed with self-reported intention [adapted from Witte] [27] to obtain a colonoscopy within the next 6 months on a seven-point Likert scale (1 = definitely will not, 7 = definitely will). Colonoscopy uptake within 9 months of the intervention was the primary outcome and was verified via a medical record report.

Statistical Analyses

T tests and chi-square tests were used to examine group differences in demographic and theoretical variables across several subsamples (see “Descriptive Statistics” section). PROC CALIS (SAS 9.4) was used for the structural equation model (SEM) analyses. To test the hypothesized theoretical pathways in the mediation model, general guidelines suggest that an estimated sample size of approximately 450 is needed for 80% power when considering both likely effect sizes and missing data [69–72].

Several covariates were partitioned from the model to simplify and increase interpretability including age, sex, income, ethnic group, health insurance status, urban/rural status, number of first- and second-degree relatives with colorectal cancer, and social support. Past research has found associations between these sociodemographic characteristics, as well as social support and colorectal cancer screening [15, 53–57].

Adequacy of fit was assessed using several fit indices, including the comparative fit index (CFI, >0.95 for good fit), the root-mean-square error of approximation (RMSEA, <0.05 for good fit), and the standardized root-mean-square residual (SRMR, <0.08 for good fit) [73]. Model modifications were theory driven and primarily based on removing non-significant pathways between latent and manifest variables. Results from the Lagrange multiplier (LM) and Wald tests were also assessed. The endogenous outcome variable of colonoscopy uptake at 9 months was dichotomous so we used the maximum likelihood robust twostage method of estimation to account for non-normality in this variable [74].

Results

Preliminary Analyses

Missing data for each scale were handled according to published recommendations [61, 64, 66–68]. When no published recommendations were available or if a participant had approximately a 25% or more of the items missing for a construct, the participant’s score was excluded from analysis. Before interpreting the final model, we confirmed that random assignment was maintained across time and that baseline measures were unrelated to TeleCARE versus educational brochure arm assignment.

Descriptive Statistics

Structural equation modeling will not tolerate missing data in the model analysis. Consequently, large, complex, and longitudinal SEMs have an increased likelihood of a reduced sample size due to missing data [75]. For this analysis, there were complete data for 231 participants out of the initial 481 possible participants. We compared major demographic variables (e.g., sex, age, income) between the complete (n = 481) and SEM sample (n = 231) to determine if our reduced sample resulted in significant group differences (Table 1). Chi-square tests showed that the demographic variables were not significantly different, with one exception; although the groups were not different in regard to reported levels of income, they were different in number of participants who did not report income.

We also considered it important to compare the complete versus SEM sample on the theoretical variables assessed in the SEM. T tests did not reveal statistically significant differences in mean scores between the complete sample and the SEM sample at baseline for cancer worry, psychological distress, fear of colorectal cancer, perceived severity, perceived susceptibility, response efficacy, self-efficacy, perceived risk, and number of reported barriers. Colorectal cancer knowledge did show a statistically significant difference (p < 0.001). However, this mean difference was by only one point (which is less than half of a standard deviation) out of a possible total of 17 points (full sample M = 10.10, SD = 4.34; SEM sample M = 11.35, SD = 2.98), and therefore, this difference was not considered clinically meaningful.

Finally, we examined the demographic variables between the TeleCARE arm versus the educational brochure arm within the SEM sample (Table 2). There were no significant differences between the two groups. The combined findings of similarity between the complete sample and partial sample based on demographic and theoretical variables are such that we believe the interpretation of the SEM can be extrapolated to the complete sample.

Structural Equation Modeling

SEM was used to test the hypothesized model that the intervention led to colonoscopy uptake through several mediation constructs (specifically, perceptions of threat, efficacy beliefs, emotions, knowledge, and intentions) (Fig. 3). The role of health care provider recommendation to get a colonoscopy was also evaluated. Baseline measures of threat perceptions, efficacy beliefs, emotions, and colorectal cancer knowledge were included in the model to account for variation in scores over time. This allowed us to estimate the association between the intervention and the theoretical variables at 1 month while...
simultaneously accounting for the relationship that the theoretical variables maintain over time. All scores or scales were standardized prior to testing the model. All reported coefficients are standardized $\beta$ coefficients.

First, an inclusive model was constructed in which all plausible (direct and indirect) theoretical pathways between the latent constructs and manifest variables were specified (e.g., a direct path between threat and intentions was initially considered). Second, a restricted model was created by removing non-significant pathways (e.g., the direct path between threat and intention) and examining the LM and Wald tests (see Fig. 3). The revised model fits the data very well and was theoretically coherent. The overall fit of the final model was very good (CFI = 0.95, RMSEA = 0.05, SRMR = 0.08).

Further, we found that the hypothesized pathways from the TeleCARE intervention to colonoscopy uptake were mediated through extended parallel process model and intention variables (see bolded arrows in Fig. 3). In Fig. 3, the SEM shows the standardized path coefficients and corresponding significance levels of the revised model. Specifically, the TeleCARE intervention increased perceptions of threat ($\beta = 0.12, p < 0.05$), which in turn led to increased negative emotions

**Table 1** Demographic characteristics at baseline for the full sample and SEM sample

<table>
<thead>
<tr>
<th></th>
<th>Full sample</th>
<th>SEM sample</th>
<th>$p$ value$^a$</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
<td></td>
<td>.34</td>
</tr>
<tr>
<td>Mean</td>
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</tr>
<tr>
<td>SD</td>
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<td>9.4</td>
<td></td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td>.95</td>
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<tr>
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<td>224</td>
<td>97.0</td>
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<tr>
<td>Other/unknown</td>
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<td>3</td>
<td>1.3</td>
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<tr>
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<td>10</td>
<td>4.3</td>
</tr>
<tr>
<td>Married/member of unmarried couple</td>
<td>363</td>
<td>183</td>
<td>79.2</td>
</tr>
<tr>
<td>Separated, divorced, widowed</td>
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<td>38</td>
<td>16.4</td>
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<td><strong>Education</strong></td>
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<tr>
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<td>Bachelor’s</td>
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<tr>
<td>Postgraduate</td>
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<td>16.5</td>
</tr>
<tr>
<td><strong>Household income (yearly)</strong></td>
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<tr>
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<td>$50,000–$69,000</td>
<td>73</td>
<td>42</td>
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<tr>
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<td></td>
<td>.53</td>
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<td>448</td>
<td>218</td>
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<tr>
<td>2 or more</td>
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<tr>
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<td></td>
<td>.88</td>
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<td>201</td>
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<tr>
<td>1</td>
<td>54</td>
<td>26</td>
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<tr>
<td>2 or more</td>
<td>6</td>
<td>4</td>
<td>1.7</td>
</tr>
</tbody>
</table>

CRC colorectal cancer, SD standard deviation

$^a p$ value calculated with $t$ test or chi-square statistic
leading to higher intentions to obtain a colonoscopy \((\beta = 0.22, p < 0.001)\), leading to higher intentions to obtain a colonoscopy \((\beta = 0.29, p < 0.001)\) and, ultimately, increased colonoscopy uptake at 9 months \((\beta = 0.28, p < 0.001)\). Additionally, TeleCARE increased efficacy levels \((\beta = 0.12 p < 0.05)\), which also led to increased intention to obtain a colonoscopy \((\beta = 0.14, p < 0.05)\) and colonoscopy uptake \((\beta = 0.28, p < 0.001)\). Finally, TeleCARE had a direct effect on colonoscopy intention \((\beta = 0.24, p < 0.001)\) and uptake \((\beta = 0.14, p < 0.05)\). There was a significant and direct effect from health care provider recommendation to colonoscopy uptake \((\beta = 0.31, p < 0.001)\). Colorectal cancer knowledge was not significantly related to the intervention or to the outcome variables.

Finally, an intent-to-treat model was tested where negative imputation was used to impute values for colonoscopy uptake. The fit statistics remained identical when rounded to two

| Table 2 Demographic characteristics at baseline by intervention arm assignment in the SEM sample |
|------------------|------------------|------------------|
| Variable                      | TeleCARE arm \(N = 102\) | Edu. brochure arm \(N = 129\) |
| Age (years)                  |                           |                               |
| Mean                         | 50.8                       | 51.2                           |
| SD                           | 9.7                        | 9.3                            |
| Gender                       |                            |                               |
| Male                         | 38                         | 61                             |
| Female                       | 64                         | 68                             |
| Ethnicity                    |                            |                               |
| Caucasian, not Hispanic      | 97                         | 95.1                           |
| Hispanic or non-white        | 3                          | 2.9                            |
| Other/unknown                | 2                          | 2.0                            |
| Marital status               |                            |                               |
| Never married/single         | 4                          | 3.9                            |
| Married/member of unmarried couple | 80                 | 78.4                           |
| Separated, divorced, widowed | 18                         | 17.6                           |
| Education                    |                            |                               |
| High school or less          | 20                         | 19.6                           |
| Post-high school             | 44                         | 43.1                           |
| Bachelor’s                   | 24                         | 23.5                           |
| Postgraduate                 | 14                         | 13.7                           |
| Household income (yearly)    |                            |                               |
| Less than $15,000            | 8                          | 7.8                            |
| $15,000–$29,000              | 8                          | 7.8                            |
| $30,000–$49,000              | 19                         | 18.6                           |
| $50,000–$69,000              | 20                         | 19.6                           |
| $70,000 or more              | 47                         | 46.1                           |
| Number of first-degree relatives with CRC |                        |                               |
| 1                            | 94                         | 92.2                           |
| 2 or more                    | 8                          | 7.8                            |
| Number of second-degree relatives with CRC |                        |                               |
| 0                            | 87                         | 85.3                           |
| 1                            | 15                         | 14.7                           |
| 2 or more                    | 0                          | 0.0                            |
| Health care provider recommendation at baseline |                        |                               |
| Yes                          | 41                         | 40.2                           |
| No                           | 61                         | 59.8                           |

CRC colorectal cancer, SD standard deviation

\( ^{a} p \) value calculated with \(t\) test or chi-square statistic
decimal points (CFI = 0.95, RMSEA = 0.05, SRMR = 0.08), and all significant pathways remained significant with virtually identical path coefficients.

**Discussion**

Colorectal cancer remains a leading killer of American men and women, and despite the recent attention to increase colorectal cancer screening behavior in the USA (e.g., media campaigns), rates still remain less than optimal, especially in those at increased familial risk. Interventions such as TeleCARE can increase screening behavior, but it is important that the hypothesized theoretical constructs that drive such interventions are analyzed to assess the extent of their influence on the outcome variable of interest. Such analyses will help researchers create and refine future interventions. Accordingly, a main aim of this study was to gain an understanding of the underlying constructs in TeleCARE that were derived from the extended parallel process model [26] and implementation-intention strategies [29–33, 35, 36].

The TeleCARE intervention effectively heightened perceived threat, leading to stronger cancer-related negative emotions (fear/distress/worry), which in turn increased intentions to get a colonoscopy. In addition, the intervention also instilled stronger efficacy beliefs in regard to colonoscopy uptake, leading to increased intention to get a colonoscopy within the next 6 months. Our analysis demonstrated the effectiveness of increased threat and efficacy in the TeleCARE intervention in mediating the effect of the intervention on intention to screen and, ultimately, colonoscopy uptake. These associations are modest, however. Future studies could incorporate a greater variety of measures to assess threat and efficacy to examine whether better measurement increases the association. Alternatively, future interventions could place more emphasis on increasing efficacy beliefs and threat perceptions, thus possibly increasing the association with intentions. Though the associations are modest, this is nonetheless noteworthy, as there is great variability in whether intentions lead to behavior [32]. Additionally, we found a direct effect of the intervention on colonoscopy uptake, indicating that other components of the intervention unrelated to the tested cognitive and affective mediators may be at work. For instance, reduced resistance to change might have been produced by the motivational interviewing component of the intervention.

Our results also indicate that, among the tested mediators, the pathway to intention via negative emotions is stronger than the one via efficacy perceptions. Such findings support the extended parallel process model in that individuals need to be motivated via increased perceptions of risk, which results in feelings of fear. With a high sense of efficacy, such fear will be channeled toward adopting the recommended action. These findings are important because cancer threat may often be overwhelming to individuals who have a family history of colorectal cancer. These individuals may have witnessed firsthand the negative impact of cancer in their own families and understand the high impact of cancer on families and finances.
The extended parallel process model asserts that if the threat is overwhelming (“My mother died of colorectal cancer and I am just like her!”) and efficacy is low (“I have no way to get a colonoscopy to help prevent colorectal cancer!”), then individuals may channel their fear into maladaptive responses, such as dismissing the message as “unimportant” or “not worth worrying about.” TeleCARE successfully addressed both threat and efficacy and led to proactive responses by increasing the colonoscopy uptake.

Some research suggests that increasing knowledge can help lead to better decision-making [37]; therefore, we tested colorectal cancer knowledge as a mediator for colonoscopy uptake. We found that increased colorectal cancer knowledge was not associated with participants’ intentions regarding colonoscopy or actual colonoscopy uptake. Future studies could examine the incremental amount of information given during a counseling session needed to show a difference between groups. Our findings, however, are consistent with another research which indicates that increased knowledge alone will not significantly affect behavior [76]. Our data appear to support the latter contention, at least for the case of promoting colonoscopy in this population. In fact, our data seem to indicate that colonoscopy uptake was an outcome of increased motivation rather than knowledge. This, too, is important to understand, as conflicting literature results may leave researchers unsure which constructs are most valuable for intervention inclusion.

In addition to the indirect and direct effects of the intervention on colonoscopy uptake, it is also clear that health care provider recommendation is an important predictor of colonoscopy uptake, consistent with prior research [77]. We did not detect a direct pathway between the intervention and health care provider recommendation; perhaps, this was because health care provider recommendation at 9 months was too distal a time point to detect a relationship. However, previous analyses showed that participants in the TeleCARE arm who consented to having their tailored letter and risk-based national screening guidelines mailed to their providers were three times as likely to get screened as those whose providers were not mailed the information (odds ratio = 3.1; 95% CI = 1.7–5.7) (unpublished data). This is particularly important and underscores the significance that provider awareness of their patients’ cancer history can have in increasing screening behavior.

Isolating the most important mediation variables can help further refine and tailor future interventions and minimize effort on constructs not found to be important in leading to the desired outcome. By focusing on the most influential targets, interventions can be simplified, leading to greater sustainability and dissemination [24, 78]. One of the best ways to assess theory’s role in an intervention is by directly measuring the purported mediating variables [24, 79]. Accordingly, our study has isolated and tested underlying theoretical mediators affecting behavior change used in our TeleCARE intervention. Interventions that incorporate strong theory lead to better cancer screening outcomes due to increased focus on the essential factors that lead to behavior change. Theory-based principles are an important driving force behind identifying core components in specific interventions [78]. Our Family CARE project has exemplified this approach and has been endorsed by NCI’s research tested intervention program (RTIP)—a platform for successful interventions to be available for public dissemination [50].

While our study has provided an important examination of the underlying mediating variables in behavior change, this study also has several limitations. First, although the complete sample and SEM sample do not appear to be substantively different, we did lose a substantial number of participants in our original sample due to missing data on at least one of the assessed mediating variables. This limitation could be addressed in future research by working to minimize missing data for theoretically essential variables. Second, we only asked participants about whether a health care provider had recommended a colonoscopy at baseline and 9 months. We were, therefore, unable to model the influence that health care provider recommendations may have on participants’ intention to get a colonoscopy. Third, for the purposes of this paper, we wanted to test threat and efficacy as they are conceptualized by the extended parallel process model. This requires a composite variable for each construct to be created using the different types of threat and efficacy in its composition. However, doing so limits nuanced interpretation of the separate aspects of each construct. This is a limitation and future research could examine the unique contributions of the types of threat and efficacy in more detail. Finally, our study consisted of primarily non-Hispanic whites. This limits our ability to generalize our findings to other groups, especially underserved racial and ethnic minority populations. Research has shown systematic differences between non-Hispanic white samples and samples with larger proportions of Hispanics and African Americans [80], specifically in regard to reported barriers [81], health care provider recommendations [82], and cultural and familial influences [83].

Future research should continue to incorporate theory-based interventions grounded in research that has specifically examined the purported mechanisms by which the intervention should work. Additionally, interventions aimed at not only motivating participants, but also work to directly increase health care provider recommendation, will likely prove to be the most effective interventions.

Acknowledgements We would like to thank Marc Schwartz, PhD; Antoinette Stroup, PhD; Lisa Pappas, MStat; Rebecca Simmons, PhD, MPH; and Randall Burt, MD for their contributions to the study design and execution. We also thank the interventionists who are genetic counselors in High Risk Clinical Research at Huntsman Cancer Center: Wendy Kohlmann, MS; Amanda Gammon, MS; Kory Jaspers, MS; Anne Naumer, MS; and Lisa Wadge, MS. We thank A.J. Figueredo, PhD, for consulting on the statistical analyses.
Compliance with Ethical Standards

Funding This manuscript included Family Colorectal Cancer Awareness and Risk Education (Family CARE) Project data obtained from the Kinney Research Group and is registered on the ClinicalTrials.gov website (NCT01274143). Family CARE was funded by the National Cancer Institute (1R01CA125194-0305; Kinney, PI) and the Huntsman Cancer Foundation. Family CARE was also supported by the Shared Resources (P30 CA042014) at Huntsman Cancer Institute; the Utah Cancer Registry, which is funded by Contract No. HHSN261201000026C from the National Cancer Institute’s SEER Program with additional support from the Utah State Department of Health and the University of Utah; the California Department of Public Health as part of the statewide cancer reporting program mandated by California Health and Safety Code Section 103885, the National Cancer Institute, and the Centers for Disease Control and Prevention; the University of Utah Department of Orthopaedics and the Genetics Network (HHSN261200744000C); the Huntsman Cancer and the Biostatistics Shared Resource (P30CA118100; C.L.W.); the New Mexico Comprehensive Cancer Center Support Grant: Development Funds awarded to the Public Health Institute; the Colorado Central Cancer Registry program in the Colorado Department of Public Health and Environment funded by the National Program of Cancer Registries of the Centers for Disease control and Prevention; the Cancer Data Registry of Idaho supported in part by the National Program of Cancer Registries of the Centers for Disease control and prevention; the University of New Mexico Comprehensive Cancer Center Support Grant: Development Funds and the Biostatistics Shared Resource (P30CA118100; C.L.W.); the New Mexico Tumor Registry which is funded by National Cancer Institute Contract No. HHSN261201000033C; the Rocky Mountain Cancer Genetics Network (HHSN261200744000C); the Huntsman Cancer Registry; the University of Utah Department of Orthopaedics and the Center for Outcomes Research and Assessment; and the Intermountain Healthcare Oncology Clinical Program and Intermountain Clinical Genetic Institute. This content is solely the responsibility of the authors and does not necessarily reflect the opinions or views of the funding and supporting agencies.

Authors’ Statement of Conflict of Interest and Adherence to Ethical Standards Authors Barbara H. Brumbach, Wendy C. Birmingham, Watcharaporn Boonyasirivat, Scott Walters, and Anita Y. Kinney declare that they have no conflict of interest. All procedures, including the informed consent process, were approved by the Institutional Review Boards of participating institutions and were conducted in accordance with the Helsinki Declaration of 1975, as revised in 2000.

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