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## Efficacy of a Telehealth Intervention on Colonoscopy Uptake when Cost is a Barrier: The Family CARE Cluster Randomized Controlled Trial

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### Abstract

**BACKGROUND**—We tested the efficacy of a remote tailored intervention (TeleCARE) compared to a mailed educational brochure for improving colonoscopy uptake among at-risk relatives of colorectal cancer patients and examined subgroup differences based on participant reported cost barriers.

**METHODS**—Family members of colorectal cancer patients who were not up-to-date with colonoscopy were randomly assigned as family units to TeleCARE (N=232) or an educational brochure (N=249). At the 9-month follow-up, a cost resource letter listing resources for free or reduced-cost colonoscopy was mailed to participants who had reported cost barriers and remained

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non-adherent. Rates of medically-verified colonoscopy at the 15-month follow-up were compared based on group assignment and within group stratification by cost barriers.

**RESULTS**—In intent-to-treat analysis, 42.7% of participants in TeleCARE and 24.1% of participants in the educational brochure group had a medically-verified colonoscopy [OR = 2.37; 95% confidence interval (CI) 1.59 to 3.52]. Cost was identified as a barrier in both groups (TeleCARE = 62.5%; educational brochure = 57.0%). When cost was not a barrier, the TeleCARE group was almost four times as likely as the comparison to have a colonoscopy (OR = 3.66; 95% CI = 1.85 to 7.24). The intervention was efficacious among those who reported cost barriers; the TeleCARE group was nearly twice as likely to have a colonoscopy (OR = 1.99; 95% CI = 1.12 to 3.52).

**CONCLUSIONS**—TeleCARE increased colonoscopy regardless of cost barriers.

**IMPACT**—Remote interventions may bolster screening colonoscopy regardless of cost barriers and be more efficacious when cost barriers are absent.

### Keywords

telehealth; colorectal cancer screening; family history; colonoscopy; cost barriers

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## INTRODUCTION

Screening is essential for the prevention and control of colorectal cancer (1-3), especially for people who are at increased familial risk of developing the disease (4). Despite an “A” rating from the United States Preventive Services Task Force (5), colonoscopies are underutilized among individuals who are considered at increased risk (6, 7). Approximately 40% of relatives of colorectal cancer patients adhere to screening guidelines (7, 8). Promoting colonoscopy use among family members of colorectal cancer patients is one efficient way to reduce colorectal cancer morbidity (9). However, increasing adherence to risk-based screening guidelines is a complex problem that requires addressing both structural (e.g., cost) and personal (e.g., motivation) barriers to screening (10, 11).

For many people, cost is a major factor in choosing whether or not to obtain a colonoscopy (12-15). According to the National Health Interview Survey (2010), only 21% of uninsured people in the United States are up to date with colorectal cancer screening—a stark contrast to the 59% of insured people who are up to date (8, 15, 16). Although the Patient Protection and Affordable Care Act eliminates *screening* colonoscopy co-payments for those with private insurance or Medicare, individual states can choose whether to offer no-cost colorectal screening for patients with Medicaid (16). State laws that mandate colorectal cancer screening coverage through insurance vary in the amount of coverage required for different screening services (17). State laws cannot require coverage from insurance plans that are self-funded by the employer and the Affordable Care Act does not apply to health plans that were in place before it was passed (17). Thus, cost is likely to continue to be a barrier to colonoscopy use.

Even when cost is not a barrier, colonoscopy screening uptake remains suboptimal (18), underscoring the need for behavioral interventions. Although behavioral interventions vary

in their delivery method and target populations, most are based on assumptions that patients should be educated about colorectal cancer screening, motivated to act, and assisted with overcoming barriers (16, 19-21). Most behavioral interventions have modest effects on colonoscopy uptake; however, few trials have examined how well intervention effects hold across population subgroups such as those with cost barriers (21, 22). The Family CARE trial took a pragmatic approach of targeting relatives of colorectal cancer patients to increase colonoscopy through evidenced-based communications strategies which addressed perception, barriers, motivation, and volition (23). Those in the intervention arm were nearly three times as likely to obtain a colonoscopy at 9-months post-intervention compared to those in the comparison group, with no differences based on rural residency or income (24). Given that cost is a known barrier to colonoscopy use, we sought to determine the intervention effect by the 15-month follow-up when cost barriers to colonoscopy were considered. We also examined the impact of providing resource information for overcoming cost barriers to colonoscopy for those who remained non-adherent at 9 months and identified the time frame in which most participants obtained a colonoscopy after the intervention.

## MATERIALS AND METHODS

### Trial Design and Oversight

We describe the Family CARE trial in detail elsewhere (23-25). Family CARE was a cluster randomized, two-group trial conducted in the United States that tested the efficacy of a remote, tailored intervention, TeleCARE, to increase colonoscopy uptake among relatives of colorectal cancer patients who were considered to be at increased familial risk of colorectal cancer (ClinicalTrials.gov #: NCT01274143). Random assignment began in 2009 and ended two years later. Primary outcome assessments (colonoscopy within 9 months following the intervention) was completed in September 2012 and 15-month colonoscopy uptake assessment was completed in April 2013 (23-25).

The Institutional Review Boards of participating institutions approved the trial. All participants provided informed consent.

### Participant Population

Primarily, population-based cancer registries (California, Colorado, Idaho, New Mexico, and Utah) identified colorectal cancer patients or their next of kin who were then contacted to request information about their relatives. Relatives were contacted about study participation. Relatives resided in 35 states.

Eligibility criteria included: 30 to 74 years of age, considered at increased familial CRC risk [having a first-degree relative diagnosed with colorectal cancer before age 60 years or one first-degree relative diagnosed at age 60 years or older plus an additional first or second-degree biologic relative diagnosed at any age (2, 26, 27)] for whom screening guidelines recommend colonoscopy, no colonoscopy within the last 5 years, a known family history of colorectal cancer, not a member of family with known hereditary cancer syndrome (28) or a candidate for germ line mutation testing, no previous counseling about familial cancer risk or participated in a family cancer trial, and no history of in situ or invasive cancer other than

non-melanoma skin cancer. We did not enroll individuals under age 30 to limit the possibility of erroneously enrolling members of families with high penetrance hereditary conditions such as familial adenomatous polyposis or Lynch syndrome. We did not enroll individuals over the age of 74 as the guidelines for screening at the time of the study did not apply to people 75 years of age or older.

## Randomization

After completing baseline measures, participants were randomized to study arm using a computer-generated allocation algorithm based on randomized block method (four to eight blocks). Family members were assigned to the same study arm to avoid study contamination. Staff collecting baseline assessments were unaware of the identity of a person's participating relatives to prevent them from predicting group assignment.

## Intervention

**Educational Brochure**—Participants assigned to the educational brochure group received a brochure that described colorectal cancer, the role of family history in determining risk, and the ability of colonoscopy to prevent and detect cancer early. It encouraged participants to discuss colorectal cancer and colonoscopy with healthcare providers. The brochure listed colonoscopy as the recommended screening test for their level of familial risk, but encouraged participants to seek some other form of screening such as stool blood testing if colonoscopy was not feasible. The brochure was designed specifically for the target population by the study investigators using investigator expertise and information gleaned from cognitive interviews conducted with colorectal cancer patients and close relatives representing the study's target population. The brochure was further reviewed by the study's community advisory board for acceptability. At the 9-month follow-up, a cost resource letter listing national and state-specific resources for free or reduced-cost colonoscopy was mailed to all participants who had not yet had a colonoscopy and had indicated that cost was a barrier at any of the assessment points. The educational brochure group received this cost resource letter at the 9-month follow-up as the brochure condition did not include communication with a study genetic counselor and therefore did not include a clinical encounter.

**TeleCARE (Tele-Cancer Risk Assessment and Evaluation)**—TeleCARE is a multi-faceted, remote risk-communication intervention. Participants assigned to the TeleCARE group received the same educational brochure plus mailed visual aids tailored from their baseline assessment of likelihood to engage in colorectal cancer screening (i.e., risk perception of cancer, self-efficacy for obtaining colonoscopy). TeleCARE participants discussed this information over the phone with one of five genetic counselors who were trained in cancer risk assessment, behavior theory, and motivational interviewing techniques (29, 30). Participants were mailed a tailored letter within one week after the telephone call that summarized the session and the participant's action plan to obtain a colonoscopy. Participants' healthcare providers were mailed copies of the letter and family history of cancer if participants consented to it. Consistent with usual care, if participants indicated that cost was a barrier during the telephone call, counselors addressed cost barriers and the same type of cost resource letter that was sent to comparison group participants at 9 months was

included in the post-phone call letter. Approximately 6 weeks after the intervention, participants received a reminder card with their personalized action plan for colonoscopy. If at 9 months participants remained non-adherent and indicated that cost was a barrier at a previous assessment point, a cost resource letter was sent again. As in the educational brochure group, participants were encouraged to seek some other form of screening if colonoscopy was not feasible.

### Outcome Specification and Data Collection

Primary outcome (medically-verified colonoscopy) was assessed at the individual level. Colonoscopies were verified through physician or clinic confirmation if participants provided a medical release. Participants who self-reported a colonoscopy but did not provide a release for medical verification were considered non-adherent to screening. Cancer screening, knowledge, cognitions, and screening barriers were assessed at baseline (pre-randomization), 1 month, and 9 months post-intervention. A 15-month follow-up questionnaire was mailed to participants who reported that they had not had a colonoscopy by the 9-month follow-up or if their screening status was unknown.

### Statistical Analysis

Differences in demographic variables between study arms were tested with  $\chi^2$  tests. Generalized mixed logistic regression models were used to account for the cluster (i.e., nuclear family) effect when evaluating the impact of intervention on colonoscopy uptake by the 15-month assessment. Data were analyzed using participants with known outcomes, negative outcome imputation, and multiple imputation. Family was considered a random effect variable. Negative outcome imputation and multiple imputation were used for intent-to-treat analysis and included all eligible participants who were randomly assigned. Negative outcome imputation assumed that colonoscopy did not occur if there was no documented verification of colonoscopy. Multiple imputation was based on data from age at baseline, sex, household income, and health insurance coverage. Five imputed datasets were used to provide a combined estimate for missing values. Odds ratios (OR) with 95% confidence intervals (CI) compared colonoscopy uptake at 15 months.

To estimate the cumulative incidence of medically-verified colonoscopy following the intervention to 15-month follow-up, curves based on Kaplan-Meier estimates were created along with associated 95% Hall-Werner confidence bands. Cumulative incidences were stratified by study arm. For outcome analysis involving cost as a barrier, stratified logistic regression estimated the intervention effect within those who indicated that cost was a barrier and those who indicated that cost was not a barrier at baseline. Those with missing data on cost as a barrier or colonoscopy use were excluded for this analysis. Family was not included as a random effects variable as clustering could no longer apply when stratifying based on cost as a barrier. The effect of receiving a resource letter describing low-cost options for colonoscopies was examined within the subgroup of people who had not yet received a colonoscopy by 9 months post-intervention. The model controlled for the intervention effect and a potential interaction between intervention and resource letter. Two biostatisticians (K.M.B. and L.M.P.) conducted the analyses using SAS (version 9.3; SAS Institute, Cary, NC).

Sample size and power calculations were based on the trial's primary outcome analysis at 9-month follow-up (24).

## RESULTS

Study enrollment, randomization, and retention data are shown in Figure 1. The TeleCARE group had 167 eligible clusters and the educational brochure group had 170 clusters. The number of family members enrolled per cluster did not differ significantly by treatment arm (24). Demographic characteristics did not differ between the study groups (see Table 1) or when further stratified by participant reported cost barriers to colonoscopy. The participants who received the 15 month assessment did not differ in demographics specified in Table 1 from those who received the 9 month assessment. Twenty-one participants (TeleCARE = 12; Educational Brochure = 9) reported another type of colorectal cancer screening.

### Colonoscopy Uptake at the 15-Month Follow-up

Overall, 42.7% of those in the TeleCARE group obtained a colonoscopy by 15-months post-intervention compared to 24.1% of those in the educational brochure group (OR = 2.37, 95% CI = 1.59 to 3.52; Table 2). The intervention effect was similar across known outcome and imputed models.

### Timing of Intervention Effect

As shown in the cumulative incidence curves (Figure 2), the TeleCARE group had higher cumulative incidence of colonoscopy throughout the 15-month follow-up period. The divergence of cumulative incidence slopes between the TeleCARE and educational brochure group appears primarily within the first nine months of the intervention (i.e., within 276 days after the intervention), suggesting that the intervention effect occurred primarily within those nine months. Thirty-six percent of the TeleCARE participants had a colonoscopy by 9 months and 44.3% by 15 months. Within the educational-brochure group, 16% had a colonoscopy by 9 months and 24.2% by 15 months.

### Impact of Cost as a Barrier and Financial Resource Letter

At 15 months, TeleCARE participants were more likely than those in the educational brochure group to obtain a colonoscopy even when cost had been indicated as a barrier at baseline. Among those who did not identify cost as a barrier [TeleCARE = 66 (37.5%), educational brochure = 89 (43.0%)], 51.5% of the TeleCARE group had a colonoscopy compared to 24.7% of the educational brochure group (OR = 3.66; 95% CI = 1.85 to 7.24; Table 3). Of the 228 people who identified cost as barrier [TeleCARE = 110 (62.5%), educational brochure = 118 (57.0%)], 38.2% of those in the TeleCARE group had a colonoscopy compared to 23.7% of those in the educational brochure group (OR = 1.99; 95% CI = 1.12 to 3.52).

Two-hundred eighty-seven participants (113 in TeleCARE group, 174 in educational brochure group) reported no colonoscopy by 9 months post-intervention. Colonoscopy uptake by 15 months was not increased by the addition of the cost-resource letter (OR = .80,



95% CI = .52 to 1.23), with no evidence of the effect of the letter differing based on group assignment ( $p = .50$ ).

## DISCUSSION

TeleCARE, a remote, tailored intervention targeted to people at increased familial risk for colorectal cancer, was effective in increasing colonoscopy screening even among those who reported cost barriers. However, the intervention effect was considerably stronger among those who did not report cost as a barrier, a particularly relevant finding in the context of the Affordable Care Act.

It remains to be seen what the full impact of the Affordable Care Act will be on risk-based colorectal cancer screening. Evidence to date suggests that eliminating co-payments has a modest effect on colorectal cancer screening (18, 31, 32). In addition to reducing colorectal cancer incidence and mortality, improving colonoscopy rates among those at increased risk may demonstrate to insurers the value of providing access to cancer screening and prevention services, including remote behavioral interventions. Insurer decisions to uniformly waive colonoscopy co-payments or extend waivers to situations in which a colonoscopy becomes diagnostic (i.e., removal of polyps) will likely be influenced by whether colonoscopies provide cost savings (33). If colonoscopy uptake among those with increased colorectal cancer risk is improved, it may become financially appealing to insurers to waive co-payments for colonoscopy because of the potential to avoid the costs of expensive cancer treatments (18, 33). Interventions such as TeleCARE are one way to promote colonoscopy use among people with higher risk.

The increase in screening rates between 9 months and 15 months was not attributed to the cost-resource letter, which raises questions as to other contributing factors. It is possible that some people needed the additional time to plan and overcome individual barriers to screening such as scheduling and making arrangements for work, childcare, or transportation. It is also possible that participants had a health maintenance visit with their provider which prompted a discussion about and completion of colonoscopy.

We are unable to identify which components of TeleCARE influenced the decision to undergo colonoscopy. A stepped-care approach should be evaluated to determine if the intervention can be streamlined and remain effective (e.g., waiting to send reminders until a person has not obtained screening by 3 months or providing telephone counseling to those who do not have a colonoscopy within 6 months of the intervention). It may be possible to increase the potency of TeleCARE by incorporating patient navigation for those who need it. Navigation services are likely to become more widely available due to the Centers for Medicare and Medicaid Services' 2014 rule offering state Medicaid agencies the option to reimburse for more community-based preventive services, including those of community health workers (34). Other third party payers are expected to adopt this reimbursement policy. Thus there is potential for community health workers to provide health promotion services, including navigation, to help patients overcome cost and other barriers to cancer prevention (35).

## Limitations

Our study was not designed to determine the effect of individual components of TeleCARE's intervention (i.e., telephone call, reminder card). Reminder cards may have some benefit (36), although their stand-alone effectiveness is unknown for people who are ambivalent about having a colonoscopy. TeleCARE is multi-faceted: all participants assigned to TeleCARE received more intervention-related contact than those in the educational brochure (three vs. one, respectively). Therefore, we cannot tease apart the effect of attention (i.e., dose) versus that of the intervention content and delivery (37).

The majority of our study population was non-Latino White, which precluded evaluation of TeleCARE's efficacy among ethnically diverse subgroups. Although motivational interviewing accommodates a wide variety of cultural beliefs, the intervention did not explicitly address cultural beliefs that may conflict with having colonoscopy (38, 39). People with additional sociocultural barriers (e.g. competing life concerns or cultural beliefs such as fatalism) may require patient-navigation interventions beyond the scope of TeleCARE (14, 38, 40). Our study was also not powered to examine differences in uptake by state, which is important as states and communities vary in their capacity for colonoscopy (10, 41).

Finally, it is important to note that although our intervention increased adherence to guideline-concordant colorectal cancer screening from 0% to 42.7%--which is higher than other intervention trials among individuals at increased familial risk (42-44)—the national goal for screening adherence in the general population is 70-80% (45, 46). Given the increased risk in relatives of colorectal cancer patients, screening adherence needs to be higher than what our intervention achieved. As highlighted previously, adherence to colonoscopy is a multi-faceted problem. The efficacy of TeleCARE may be improved by complementing it with an intervention that intervenes on system-level barriers such as provider communication about screening, increasing access to screening patient navigation, direct assistance with coverage for screening, and patient follow up in primary care (12, 16).

## Conclusion

Our results suggest that TeleCARE increases colonoscopy screening among relatives of colorectal cancer patients, especially, but not exclusively, when cost is not a barrier. Interventions such as TeleCARE may help maximize the impact of programs and policies that increase access to preventive services by bolstering cancer screening.

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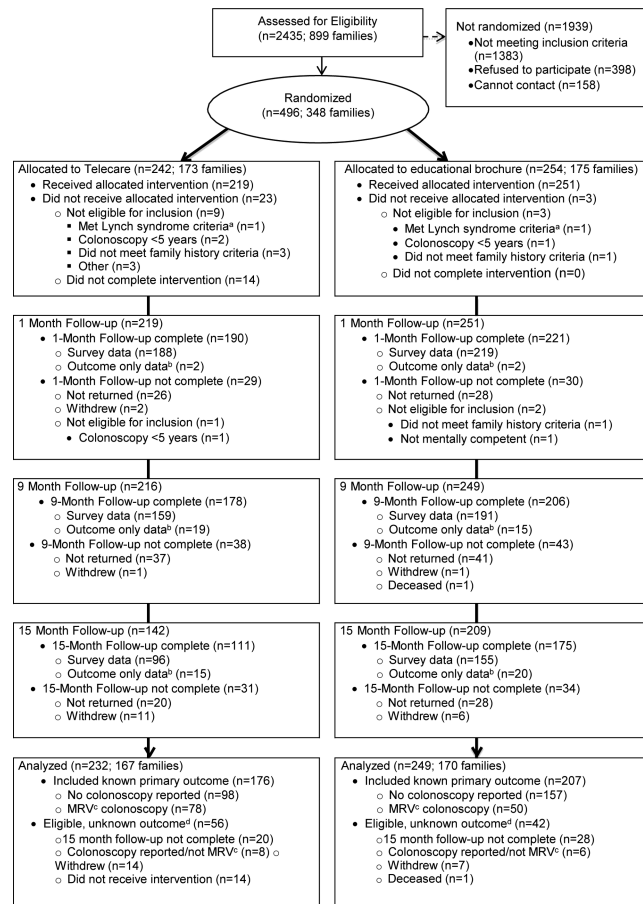
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**Figure 1.**  
Consolidated Standards of Reporting Trials (CONSORT) flowchart.

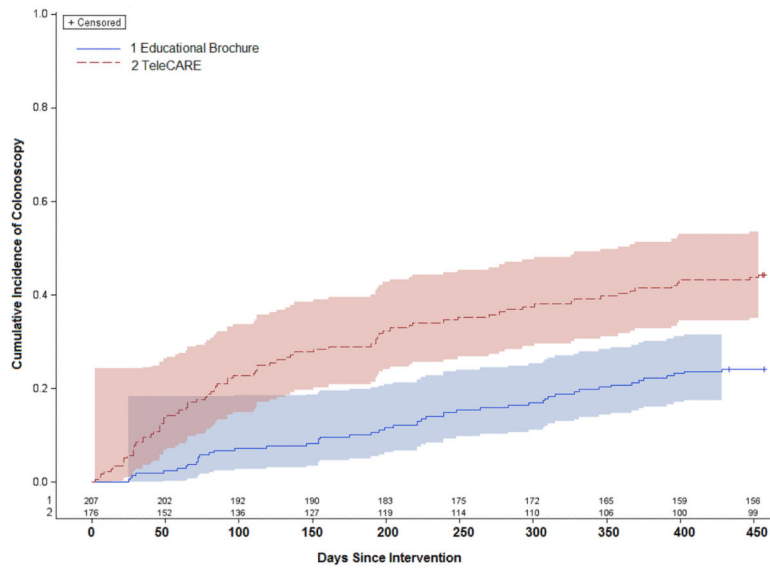
<sup>a</sup> Lynch Syndrome Criteria based on work by Tan et al.(28)

<sup>b</sup> Participants who did not complete a survey were asked to complete a very brief survey containing primary outcome questions only.

<sup>c</sup> Medical record verified

<sup>d</sup> Included in imputation analyses.

TeleCARE, Tele-cancer Assessment and Risk Evaluation



**Figure 2.** Cumulative incidence based on Kaplan-Meier estimates of colonoscopy uptake after intervention with number of participants at risk and 95% Hall-Wellner confidence bands.

**Table 1**

Baseline Characteristics by Intervention Group for Intent-to-Treat Analysis

Characteristic	TeleCARE (n = 232)	Brochure (n = 249)
Age—mean years (standard deviation)	49.9 (9.0)	50.8 (9.0)
Sex—no. (%)		
Female	91 (39.2)	114 (45.8)
Male	141 (60.8)	135 (54.2)
Race/Ethnicity—no. (%)		
Non-Latino white	215 (92.2)	239 (96.0)
Other/unreported	17 (7.8)	10 (4.0)
Marital Status—no. (%)		
Currently married or living as married	172 (74.1)	191 (76.7)
Not currently married or living as married	60 (25.9)	58 (23.3)
Educational Level—no. (%)		
High school or less	51 (22.0)	42 (16.9)
Post-high school	100 (43.1)	106 (42.6)
Bachelor's	50 (21.6)	64 (25.7)
Postgraduate	31 (13.4)	37 (14.9)
Residence <sup>a</sup> —no. (%)		
Urban	173 (74.6)	199 (79.9)
Rural	59 (25.4)	50 (20.1)
Yearly Income (\$) —no. (%)		
<\$30,000	46 (19.8)	42 (16.8)
\$30-49,999	42 (18.1)	49 (19.7)
\$50,000	119 (51.3)	134 (53.9)
Missing, refused	25 (10.8)	24 (9.6)
Employment Status—no. (%)		
Employed	166 (71.6)	172 (69.1)
Not Employed	66 (28.5)	77 (30.9)
Health Insurance—no. (%)		
Private	164 (70.7)	175 (70.3)
Public	31 (13.4)	23 (9.2)
No coverage	37 (16.0)	50 (20.1)
Missing	0 (0.0)	1 (0.4)
Relatives with colorectal cancer—no. (%)		
1 FDR, 0 SDR	188 (81.0)	202 (81.1)
2 FDR, 0 SDR	13 (5.6)	18 (7.2)
1 FDR, 1 SDR	30 (12.9)	22 (8.8)
1 FDR, 2 SDR	0 (0.0)	6 (2.4)
2 FDR, 1 SDR	1 (0.4)	1 (0.4)
1 FDR, 0 SDR	188 (81.0)	202 (81.1)
2 FDR, 0 SDR	13 (5.6)	18 (7.2)



Abbreviations: FDR, first degree relative, SDR, second degree relative, ERS, Economic Research Service; RUCA; rural-urban computing area; Tele-CARE, Tele-Cancer Risk Assessment and Evaluation; USDA, US Department of Agriculture; WWAMI, Washington, Wyoming, Alaska, Montana, and Idaho.

<sup>a</sup>Rural/urban residence was based on RUCA codes at the zip code level. RUCA codes were developed by the University of Washington Rural Health Research Center and the USDA ERS, with the support of the Federal Health Resource and Service Administration's Office of Rural Health Policy and the ERS using standard Census Bureau urbanized area and urban cluster definitions in combination with work commuting data to characterize census tracts and later zip codes.(47) The 10 RUCA categories were aggregated into urban (1-3) and rural (4-10), per the WWAMI Rural Health Research Center.

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**Table 2**

Results for Intervention Effect on Colonoscopy Uptake within 15 months

Model <sup>a</sup>	Odds of getting Colonoscopy	95% Confidence Interval	P Value	Medically Verified Colonoscopies	
	TeleCARE vs. Education	[Lower, Upper]		TeleCARE % (n)	Education Brochure % (n)
Cases with known outcome	2.50	[1.61-3.88]	<0.001	44.3% (78/176)	24.2% (50/207)
Negative outcome imputation <sup>b</sup>	2.02	[1.32-3.08]	0.001	33.6% (78/232)	20.1% (50/249)
Multiple imputation <sup>c</sup>	2.37	[1.59-3.52]	<0.001	42.7% (99/232)	24.1% (60/249)

<sup>a</sup>Each of the 3 separate models represents a different treatment of missing outcomes and included a random effect for family.

<sup>b</sup>Negative outcome imputation treated unknown colonoscopy outcome as no colonoscopy.

<sup>c</sup>Average number of colonoscopies based on 5 imputation sets from the SAS procedure MI

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**Table 3**

Stratified Analysis of 15-month Intervention Effect Based on Cost as a Barrier

Model <sup>a</sup>	Odds of getting Colonoscopy	95% Confidence Interval [Lower, Upper]	P Value	Medically Verified Colonoscopies	
	TeleCARE vs. Education			TeleCARE % (n)	Education Brochure % (n)
Cost not identified as a barrier	3.66	[1.85-7.24]	0.0002	51.5% (34/66)	24.7% (22/89)
Cost identified as a barrier	1.99	[1.12-3.52]	0.0189	38.2% (42/110)	23.7% (28/118)

<sup>a</sup>Each of the 2 separate models represents the subgroup analysis for those who did and did not identify cost as a barrier at baseline. Only those with known barrier information and known outcomes were included.

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