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Impact of including quantitative information in a decision aid for colorectal cancer screening: A randomized controlled trial

Peter H. Schwartz[a,b,c,d,*], Thomas F. Imperiale[a,e,f], Susan M. Perkins[d,g], Karen K. Schmidt[a], Sandra Althouse[g], Susan M. Rawl[d,h]

[a] Department of Medicine, Indiana University School of Medicine, Indianapolis, USA
[b] Indiana University Center for Bioethics, Indianapolis, USA
[c] Philosophy Department, Indiana University, Indianapolis, USA
[d] Indiana University Simon Cancer Center, Indianapolis, USA
[e] Regenstrief Institute, Inc., Indianapolis, USA
[f] Center of Excellence for Implementation of Evidence-based Practice, Roudebush VA Medical Center, Indianapolis, USA
[g] Department of Biostatistics, Indiana University, Indianapolis, USA
[h] Indiana University School of Nursing, Indianapolis, USA

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ABSTRACT

Objective: Guidelines recommend that decision aids provide quantitative information about risks and benefits of available options. Impact of providing this information is unknown.

Methods: Randomized trial comparing two decision aids about colorectal cancer (CRC) screening with colonoscopy or fecal immunochemical test (FIT). 688 primary care patients due for CRC screening viewed a decision aid that uses words only (Verbal arm) vs. one that provides quantitative information (Quantitative arm). Main outcomes included perceived CRC risk, intent to be screened, and test preference, measured before and after viewing decision aid, and screening uptake at six months. Analyses were performed with ANCOVA and logistic regression.

Results: Compared to the Verbal arm, those in the Quantitative arm had a larger increase in intent to undergo FIT ($p = 0.011$) and were more likely to switch their preferred test from non-FIT to FIT (28% vs. 19%, $p = .010$). There were decreases in perceived risk in the Verbal Arm but not the Quantitative Arm ($p = 0.004$). There was no difference in screening uptake. Numeracy did not moderate any effects.

Conclusions: Quantitative information had relatively minor impact and no clearly negative effects, such as reducing uptake.

Practice implications: Quantitative information may be useful but not essential for patients viewing decision aids.

1. Introduction

Guidelines for the design of decision aids recommend disclosure of quantitative information such as, for screening tests, baseline risk of the condition, risk reduction provided by the intervention, positive and negative predictive values, and chance of negative outcomes [1,2]. Quantitative information may support informed decision making by increasing patient understanding [3,4]. Quantitative information may not help all patients, however, especially those with limited numeracy skills [5,6]. No well-powered randomized trial has measured the impact of disclosing the recommended types of quantitative information [7]. Heuristics and biases in human thought produce irrational responses to risk data including people's tendency to underestimate the risk of a bad outcome ("optimism bias") [8,9]. It would be unfortunate if disclosing quantitative information triggered heuristics or biases that reduced uptake of preventive measures that save lives [10–14].

In this study, we compared the effects of verbal information and quantitative information in a decision aid for colorectal cancer (CRC) screening. Screening is recommended for people ages 50–75 years old, and for those at average risk, several tests are recommended [15,16]. Colonoscopy is the most commonly performed screening test and provides the most complete examination of the colon, but it has risks and requires a rigorous bowel prep [15–17]. The second most common approach is annual stool blood testing, e.g. the fecal immunochemical test (FIT), which is easy to do and is performed at home [15–17]. A single application

* Corresponding author at: Indiana University Center for Bioethics, 410 W. 10th St., Ste. 3100, Indianapolis, IN 46202, USA.
E-mail address: phschwar@iu.edu (P.H. Schwartz).

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of FIT often fails to identify polyps and may miss a cancer, however, and a positive stool test requires colonoscopic evaluation. Lifetime risk reduction provided by regular FIT may be slightly less than that provided by regular colonoscopy, though there continues to be some uncertainty about the long-term effects [15,18]. The choice between colonoscopy, FIT, and other approved tests is "preference sensitive," resulting in the creation and testing of several decision aids [7].

The aims of the current study were to: 1) compare the impact of verbal information and quantitative information on outcomes of perceived CRC risk, CRC screening intent, colonoscopy intent, FIT intent, perceived benefits and barriers for colonoscopy and FIT, decision conflict, test choice (colonoscopy or FIT), and 6-month uptake of screening; and 2) determine whether numeracy moderates any of these effects.

2. Methods

2.1. Study setting

The study was conducted from June 2015 to June 2017 at 18 primary care sites in the Indiana University Health (IUH) and 6 primary care sites of the Eskenazi Health (EH) system in central Indiana. The study was approved by the Indiana University Institutional Review Board prior to data collection and is registered with ClinicalTrials.gov (NCT02477553).

2.2. Inclusion and exclusion criteria

Participants were screening-eligible male and female adults, 50–75 years old, who were scheduled or due to be seen by their primary care provider at participating clinics. Participants were eligible if they were not up-to-date with screening. We excluded patients who had: (1) a personal history of CRC, (2) inflammatory bowel disease or other condition or family history conferring elevated risk for CRC, (3) symptoms consistent with CRC, (4) difficulty reading English, or (5) been told by their provider to avoid CRC screening.

2.3. Recruitment process

Physician approval was obtained prior to contacting patients who appeared to be eligible based on electronic health record (EHR) review. Of 80 physicians approached, 70 (88%) agreed to have their patients contacted. Patients were sent an introductory letter and then contacted by phone to explain the study and assess eligibility. Eligible patients who agreed to participate met with a research assistant for approximately 1 h, often immediately preceding a provider appointment.

2.4. Study procedure

After confirming eligibility and providing written informed consent, participants were randomly assigned, using the REDCap database, to view the verbal decision aid (verbal group) or the quantitative decision aid (quantitative group). Stratification was based on age ($\leq$ 65 years old or $>$ 65 years old), gender (male, female), and health system.

Data were collected and managed using REDCap electronic data capture tools hosted at Indiana University [19]. Participants completed a baseline survey (T0) in REDCap using either a laptop computer or a paper version in the presence of a research assistant. They then viewed the decision aid to which they were assigned, and completed a self-administered survey post-intervention (T1). Six months later, participants were contacted by phone to complete a third interview (data not presented in this paper), and participants' EHR data were checked for completion of a colonoscopy, FIT, or other approved screening test within six months of enrollment.

2.5. Decision aids

Both decision aids consisted of PowerPoint slides with text, photos, and an audio track, viewed on a laptop controlled by the participant. The decision aids began with a $4^1/_2$ min slightly edited version of a video on CRC screening produced by the American Cancer Society [20], followed by 3 slides summarizing the advantages and disadvantages of colonoscopy and stool testing with the fecal immunochemical test (FIT).

The quantitative decision aid provided the following quantitative information regarding CRC and the comparative effectiveness of colonoscopy and FIT, generally presented as frequencies depicted on icon charts:

- Sensitivity of a single application of FIT and colonoscopy for CRC,
- Average lifetime CRC incidence and mortality with no screening and with regular screening with colonoscopy or FIT (depicted individually on icon charts and jointly on a bar chart),
- Frequency of a single FIT turning positive, and
- Frequency of complication from a colonoscopy (hemorrhage or perforation).

The verbal decision aid discussed each of these topics but used verbal descriptions only ("rare," "reduced," etc.) instead of numbers. Both decision aids used only verbal descriptions of the sensitivity of colonoscopy and FIT for polyps and the frequency of FIT yielding a false positive, i.e. negative colonoscopy after positive FIT. Appendix Table 1 lists the specific numbers and quantities disclosed in both decision aids. Decisions about which numbers to present and which terms to use in the decision aids were guided by recommendations from the International Patient Decision Aids Standards Collaboration (IPDAS) [1,21] and discussions with the research team, patient advisory board, and community advisory board.

The decision aids were updated from versions used in a pilot study [22] by the research team, which included experts in health communication, gastroenterology, epidemiology, risk communication, biostatistics, and bioethics. Scripts and visuals were circulated and discussed in biweekly meetings, and draft versions of the DAs were presented to patients and community members for assessment of acceptability, understandability, and satisfaction.

2.6. Measures

- *Perceived Risk of CRC* (T0, T1). Perceived personal risk of CRC was assessed by asking participants how likely they were to get colon cancer during their lifetime, in the next 10 years, and in the next 5 years. Each had response options: very likely, somewhat likely, somewhat unlikely, and very unlikely. Perceived comparative risk of CRC was measured with a single item assessing "compared to other women/men your same age, would you say your chance of getting colon cancer in the next 10 years is higher, about the same, lower, or don't know."
- *Benefits and Barriers* (T0, T1). Perceived benefits and barriers were measured for colonoscopy and FIT separately using scales developed by our team [23]. All scales had Likert-type response options where 5=strongly agree to 1=strongly disagree.
- *Screening Intent; FIT Intent; Colonoscopy Intent* (T0, T1). Intent to be screened for CRC with any test ("Screening Intent"), intent to undergo FIT ("FIT Intent"), and intent to undergo colonoscopy ("Colonoscopy Intent") were measured with 3 separate items: "Do you plan to get a [colon test/ stool test/ colonoscopy] within

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the next 6 months?" Each had response options of: 5=Definitely, 4=Probably, 3=May or May not, 2=Probably not, and 1=Definitely not.

- *Test Choice* (T0, T1). For those who answered the *Screening Intent* question – "Do you plan to get a colon test within the next 6 months?" with Definitely not, Probably not, or May or may not, *Test Choice* was categorized as "No screening." Those who answered the *Screening Intent* question with Probably or Definitely had their *Test Choice* categorized based on their answer to a single item: "If you have a colon test, which one would you choose?" Response options were: FIT, Colonoscopy, Other, or Don't know.
- *Decision Conflict (T0, T1).* Decision conflict was assessed using the Decision Conflict Scale, a 16-item instrument [24].
- *Numeracy.* Subjective numeracy was assessed with the Subjective Numeracy Scale (SNS) at T0 [25,26]. Objective numeracy was measured with the 8-item, short form of the Numeracy Understanding in Medicine Instrument (NUMi) at T1 [27,28].
- *Health Literacy (T1).* Health literacy was assessed using a 3-item health literacy scale [29].
- *Uptake.* Screening uptake was determined by documentation of a completed screening test within 6 months of enrollment in the participants' EHR.

2.7. Statistical analysis

The sample size was based on results of our pilot study of a similar decision aid that showed overall CRC screening rates differed by 12% between the control and quantitative groups (26.9% vs 39.3%) [22]. To detect a similar difference in this study with 80% power with a chi-square test ($\alpha = 0.05$), a sample size of 241 per group (482 total) was required. To examine the moderating effect of numeracy, the required sample size was based on calculations provided in Demidenko (2008) [30] for detecting an interaction between two binary covariates (intervention group and numeracy) in a logistic regression model. In this case, a total of 600 (300 per group) were required to have 80% power ($\alpha = 0.05$) to detect an interaction OR of 3.2, which was similar to the interaction OR estimated from our preliminary data of 3.7. Thus, to have sufficient power for both aims, we targeted a total of 600 evaluable patients.

All analyses were conducted using SAS Version 9.4 (Cary, NC) and the significance level set to $\alpha = 0.05$ for all statistical tests. Demographic information was summarized by frequencies and percents for categorical variables or by mean and standard deviation (SD) for continuous variables. Group differences for categorical variables were compared with the Chi Square test or Fisher's Exact test. Continuous variables were compared using two-sample t-tests.

All models included covariates for site (EH or IUH), gender and age (<=65 years and > 65 years) [31]. For aim 1, changes in perceived risk, screening intent, colonoscopy intent, FIT intent, benefits and barriers of colonoscopy and FIT, and decision conflict from baseline (T0) to post-intervention (T1) were compared between groups using ANCOVA with baseline scores treated as covariates. To check for changes in scores over time (i.e., assuming no interactions or main effects for group or numeracy), an intercept only model was used. *Test choice* was examined before and after intervention to see if there was a change in 1) intent to be screened (Test Choice = No screening vs. Screening (with FIT, colonoscopy, other, or don't know); and 2) Test Choice of something other than FIT at T0 (no screening, colonoscopy, other, or don't know) to FIT at T1 and tested between groups using logistic regression. CRC screening rates were compared between the two groups using logistic regression.

For aim 2, subjects were divided into two groups (above and below the median for total **subjective** numeracy and also for **objective** numeracy). First, moderation was tested by adding a main effect for numeracy and group by numeracy interaction term to the models used in aim 1. If the interaction term was not significant, it was removed from the model and the main effects model was used.

3. Results

A total of 728 patients were randomized to quantitative (n = 364) or verbal (n = 364) groups (Fig. 1). Forty patients were later excluded, resulting in sample sizes of 344 in each group. Mean age was 59 [s.d. = 7] years. Most participants were white and 60% were female. Except for employment status, there were no statistically significant differences in demographic variables between the groups (Table 1). Thus, employment status was a covariate in models.

3.1. perceived risk, screening intent, benefits, barriers, and decision conflict

Appendix Figures 1 and 2 shows changes in perceived risk, CRC screening intent, others from baseline (T0) to immediately post-intervention (T1). There were statistically significant increases in CRC screening intent, FIT intent, perceived benefits of FIT and colonoscopy, and significant decreases for decision conflict and perceived barriers for FIT and colonoscopy ($p < 0.001$) from T0 to T1 for both groups. There were no significant changes from T0 to T1 in perceived comparative risk, perceived personal risk, or colonoscopy intent.

As shown in Table 2, there were no group differences for changes in perceived comparative risk, CRC screening intent, colonoscopy intent, benefits or barriers for either colonoscopy or FIT, or decision conflict. Participants in the quantitative group had greater increases in FIT Intent ($p = 0.007$) and perceived personal risk ($p < .001$) compared to the verbal group.

3.2. Test choice

From T0 to T1, participants in both groups changed their test choice from 'No Screening' to one of the four screening options (colonoscopy, FIT, other, don't know/missing) (Appendix Table 2). As shown in Table 3, the proportion that made this change was higher in the quantitative group (85/176 [48%]) compared to the verbal group (60/158 [38%]; $p = 0.02$). A greater proportion of those in the quantitative group changed their test choice from non-FIT to FIT than the verbal group (29% vs 19%, $p = 0.005$).

3.3. Uptake

At 6-months, CRC screening uptake in the EHR for all participants was 29%. FIT uptake was 11%, and colonoscopy uptake was 19%, with no difference in uptake between groups (Table 4). In the quantitative group, uptake of any CRC screening test was 29%, FIT was 11%, and colonoscopy was 19%. In the verbal group, uptake of any CRC screening test was 30%, FIT was 11%, and colonoscopy was 20%.

3.4. Effect of numeracy

Since we found the same substantive results for subjective and objective numeracy, we report the results for subjective numeracy only. Although there were some main effects of numeracy, there were no significant interactions between group and subjective numeracy for perceived risk, screening intent, benefits, barriers, or decision conflict, thus no evidence of moderation (Table 5).

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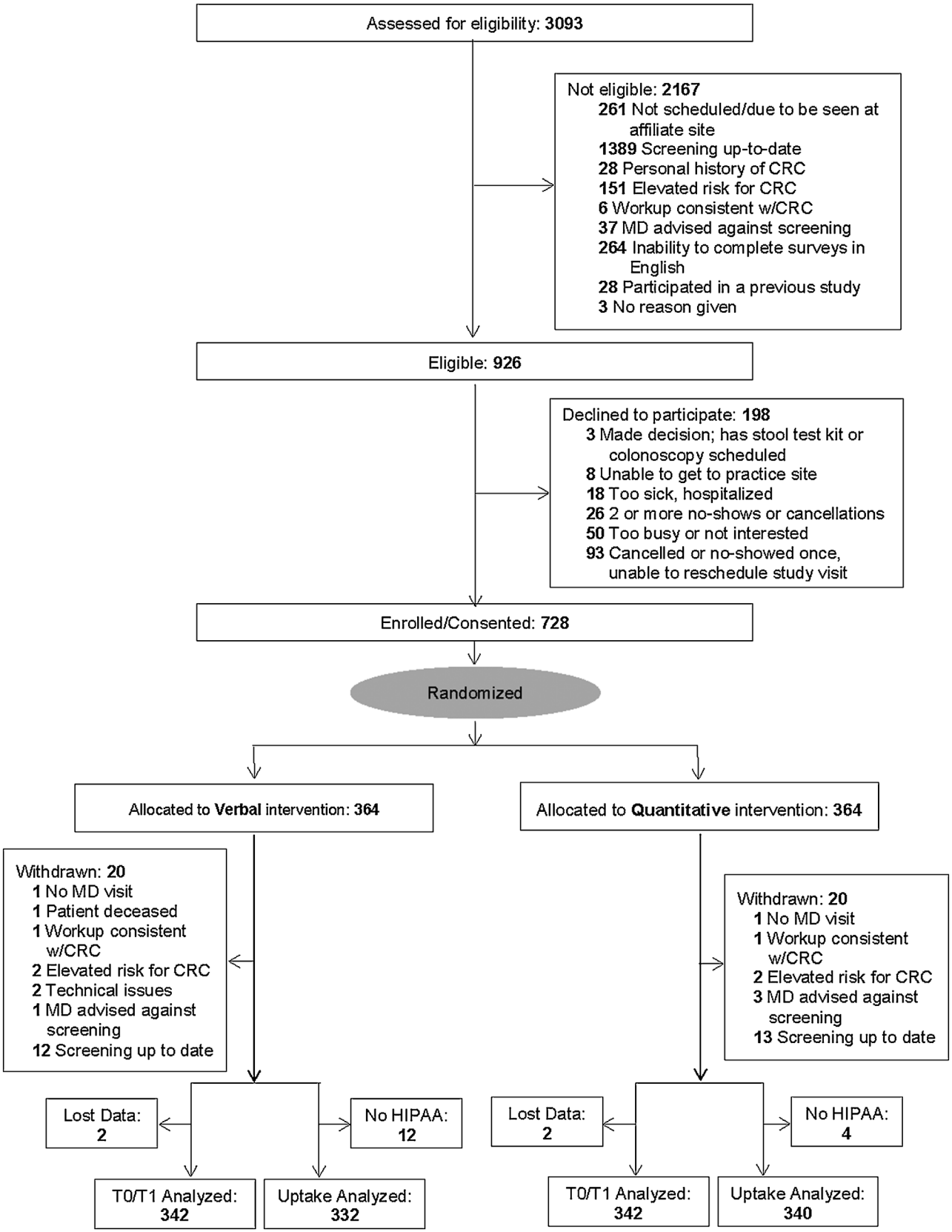

Fig. 1. Study flow diagram.

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Table 1
Demographics by Group (Mean [SD] or n [%]).

Category	Value	Verbal (N = 344)	Quantitative (N = 344)	p-value*
Site	Eskenazi Health	96 (28%)	93 (27%)	0.80
	IU Health	248 (72%)	251 (73%)	
Age	Mean (SD)	58.71 (6.49)	58.83 (6.66)	0.81
Age - Categorical	<= 65 y/o	288 (84%)	283 (82%)	0.61
	>65 y/o	56 (16%)	61 (18%)	
Gender	Female	206 (60%)	198 (58%)	0.54
	Male	138 (40%)	146 (42%)	
Race	American Indian or Alaskan Native	1 (0%)	1 (0%)	0.106
	Asian	3 (1%)	4 (1%)	
	Black or African American	98 (28%)	86 (25%)	
	Missing	12 (3%)	10 (3%)	
	Multiple	16 (5%)	5 (1%)	
	Native Hawaiian or Pacific Islander	1 (0%)	1 (0%)	
	Other race	8 (2%)	5 (1%)	
	White	205 (60%)	232 (67%)	
Ethnicity - Hispanic/Latino	Yes	12 (3%)	5 (1%)	0.112
	No	317 (92%)	329 (96%)	
	Do not know	4 (1%)	1 (0%)	
	Missing	11 (3%)	9 (3%)	
Education	Less than high school	25 (7%)	15 (4%)	0.38
	High school graduate/GED	75 (22%)	89 (26%)	
	Some college/technical school/trade school	92 (27%)	80 (23%)	
	Associate's degree school	35 (10%)	31 (9%)	
	Bachelor's degree	58 (17%)	68 (20%)	
	Professional or graduate degree	44 (13%)	51 (15%)	
	Don't Know	2 (1%)	1 (0%)	
	Missing	13 (4%)	9 (3%)	
Relationship	Single	71 (21%)	75 (22%)	0.21
	Married/living with partner	170 (49%)	168 (49%)	
	Separated	12 (3%)	10 (3%)	
	Divorced	61 (18%)	73 (21%)	
	Widowed	19 (6%)	8 (2%)	
	Missing	11 (3%)	10 (3%)	
Employed?	Yes	158 (46%)	188 (55%)	**0.037**
	No	170 (49%)	146 (42%)	
	Missing	16 (5%)	10 (3%)	
Health Insurance?	Yes	315 (92%)	317 (92%)	0.49
	No	13 (4%)	17 (5%)	
	Missing	16 (5%)	10 (3%)	
Income Level Subjective	Are comfortable	129 (38%)	145 (42%)	0.113
	Have just enough to make ends meet	117 (34%)	125 (36%)	
	Do NOT have enough to make ends meet	80 (23%)	59 (17%)	
	Missing	18 (5%)	15 (4%)	
Ever heard of FIT?	Yes	234 (68%)	242 (70%)	0.86
	No	78 (23%)	78 (23%)	
	Missing	32 (9%)	24 (7%)	
Ever heard of Colonoscopy?	Yes	295 (86%)	312 (91%)	0.094
	No	17 (5%)	9 (3%)	
	Missing	32 (9%)	23 (7%)	
Doctor ever recommend colon test?	Yes	190 (55%)	206 (60%)	0.64
	No	105 (31%)	105 (31%)	
	Do not know	16 (5%)	10 (3%)	
	Missing	33 (10%)	23 (7%)	
Doctor ever recommend colonoscopy?	Yes	172 (50%)	179 (52%)	0.88
	No	121 (35%)	129 (38%)	
	Do not know	16 (5%)	13 (4%)	
	Missing	35 (10%)	23 (7%)	
Doctor ever recommend FIT test?	Yes	88 (26%)	101 (29%)	0.39
	No	200 (58%)	197 (57%)	
	Do not know	21 (6%)	21 (6%)	
	Missing	35 (10%)	25 (7%)	

* p-value from t-test, Chi-Square, or Fisher's Exact Test, where appropriate. Missing and Do not know were not included in analysis.

4. Discussion and conclusion

4.1. Discussion

This study found that including quantitative information in a decision aid significantly increased intent to undergo FIT but not colonoscopy for screening and increased perceived CRC risk but not comparative risk in patients eligible for screening. Quantitative information had no impact on either uptake of screening or type of test at six months, and numeracy did not moderate the effect of quantitative information on any outcome. Both decision aids increased intent to undergo screening and reduced decision conflict, in pre- to post-testing.

Together, these findings help address concerns that quantitative information may have significant negative effects for patients overall, or for patients with limited numeracy skills. At

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Table 2
Between-Group Differences in Change in Perceived Risk, Intent, Benefits, Barriers, and Decision Conflict.

Variable	Group	Change (T1 – T0) N, Mean (SD)	Intervention Effect Estimate (95% CI)**	p-value*
Perceived Comparative Risk	Verbal	217, −0.04 (0.45)	0.06 (-0.02, 0.14)	0.173
	Quantitative	232, 0.05 (0.52)		
Perceived Personal Risk	Verbal	333, −0.08 (0.70)	**0.16 (0.07, 0.26)**	<**0.001**
	Quantitative	336, 0.08 (0.81)		
CRC Screening Intent	Verbal	342, 0.37 (0.84)	0.09 (−0.03, 0.20)	0.142
	Quantitative	342, 0.47 (0.84)		
Colonoscopy Intent	Verbal	341, 0.03 (0.81)	0.03 (−0.09, 0.14)	0.66
	Quantitative	338, 0.06 (0.80)		
FIT Intent	Verbal	341, 0.26 (1.13)	**0.22 (0.06, 0.37)**	**0.007**
	Quantitative	338, 0.46 (1.09)		
Colonoscopy Benefits	Verbal	324, 0.44 (0.62)	0.03 (−0.05, 0.11)	0.47
	Quantitative	332, 0.47 (0.62)		
FIT Benefits	Verbal	320, 0.44 (0.76)	0.07 (−0.02, 0.17)	0.138
	Quantitative	330, 0.52 (0.73)		
Colonoscopy Barriers	Verbal	322, −0.18 (0.47)	0.05 (−0.02, 0.12)	0.149
	Quantitative	330, −0.13 (0.45)		
FIT Barriers	Verbal	321, −0.18 (0.55)	−0.01 (−0.09, 0.07)	0.74
	Quantitative	327, −0.21 (0.54)		
Overall Decision Conflict Score	Verbal	316, −19.3 (17.77)	−0.12 (−1.95, 1.72)	0.90
	Quantitative	326, −22.0 (19.25)		

* p-value for Group from the model: T1 outcome = Group + T0 outcome + site + age + gender + employment.
** the Verbal Group is the reference group.

Table 3
Change in Test Preference from T0 to T1 by Group, Overall and by Subjective Numeracy Level.

Group	Change from not Screen to Screen			Change from not FIT to FIT		
	Overall	Low Subjective Numeracy	High Subjective Numeracy	Overall	Low Subjective Numeracy	High Subjective Numeracy
Verbal	60/158 (38%)	34/77 (44%)	25/79 (32%)	56/301 (19%)	31/147 (21%)	24/149 (16%)
Quantitative	85/176 (48%)	40/86 (47%)	44/88 (50%)	87/305 (29%)	42/140 (30%)	45/161 (28%)
Final Model (Main Effects) p-values	**0.022**	**Arm: 0.020*** Numeracy: 0.61		**0.005**	**Arm: 0.004*** Numeracy: 0.48	

* All results are from the main effects model since the interaction Group*numeracy was not significant in any of the interaction models.

Table 4
CRC Screening Uptake, Overall and by Group and Subjective Numeracy Level.

	Variable	Verbal n/N (%)	Quantitative n/N (%)	Final Model (Main Effects) p-values*	Odds Ratio (95% CI)
Overall	CRC screening uptake	99/332 (29.8%)	99/340 (29.1%)	0.74	0.94 (0.67, 1.33)
	FIT uptake	36/332 (10.8%)	38/340 (11.2%)	0.96	1.01 (0.62, 1.67)
	Colonoscopy uptake	64/332 (19.3%)	63/340 (18.5%)	0.72	0.93 (0.63, 1.38)
Below Total Subjective Numeracy Median	CRC screening uptake	43/167 (25.6%)	34/158 (21.5%)	Group: 0.70	Group: 0.94 (0.66, 1.32)
				Numeracy: 0.031	Numeracy: 1.48 (1.04, 2.11)
	FIT uptake	15/167 (9.0%)	8/158 (5.1%)	Group: 0.90	Group: 0.97 (0.58, 1.61)
				Numeracy: 0.013	Numeracy: 1.99 (1.16, 3.40)
	Colonoscopy uptake	29/167 (17.4%)	26/158 (16.5%)	Group: 0.78	Group: 0.95 (0.63, 1.41)
				Numeracy: 0.57	Numeracy: 1.13 (0.75, 1.69)
Above Total Subjective Numeracy Median	CRC screening uptake	53/157 (33.8%)	63/175 (36.0%)		
	FIT uptake	20/157 (12.7%)	29/175 (16.6%)		
	Colonoscopy uptake	33/157 (22.0%)	36/175 (20.6%)		

n= number screened; N = Total N.
By numeracy: p-value for Group and numeracy from the model: Uptake = Group + numeracy + site + age + gender + employment. All results are from the main effects model since the interaction Group*numeracy was not significant in any of the interaction models.
* overall: p-value for Group from the model: Uptake = Group + site + age + gender + employment.

the same time, the findings show relatively limited impacts of including quantitative information and leave questions unanswered about whether such information should be included in all decision aids. Since the study compared only one way of framing quantitative and verbal information about CRC screening, it cannot assess the impact of other methods of framing, or the impact of quantitative information on other medical decisions.

The only previous randomized trial that we are aware of that compared decision aids that differed only in their inclusion of quantitative information was a pilot study we conducted. In our study, 223 patients who were due for CRC screening were randomized to view four different decision aids, two that included quantitative information and two that did not [22]. Findings in the current study extend those of our earlier study but differ in certain ways, which we discuss here.

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Table 5
Between-Group Differences in Change in Perceived Risk, Intent, Benefits, Barriers, and Decision Conflict by Subjective Numeracy (Above/Below the Median).

Variable	Subjective Numeracy	Group	Change (T1-T0) N, Mean (SD)	Intervention Effect Estimate (95% CI)**	Final Model (Main Effects) p-value*
Perceived Comparative risk	Low	Verbal	94, 0.00 (0.46)	Group: 0.06 (-0.02, 0.13)	Group: 0.169
		Quantitative	98, 0.10 (0.55)	Numeracy: 0.14 (0.06, 0.22)	**Numeracy: 0.001**
	High	Verbal	121, −0.07 (0.44)		
		Quantitative	132, 0.01 (0.49)		
Perceived Personal risk	Low	Verbal	169, −0.04 (0.77)	Group: 0.17 (0.08, 0.26)	**Group: <0.001**
		Quantitative	159, 0.15 (0.86)	Numeracy: 0.17 (0.07, 0.27)	**Numeracy: <0.001**
	High	Verbal	161, −0.14 (0.63)		
		Quantitative	175, 0.03 (0.76)		
CRC Screening Intent	Low	Verbal	172, 0.38 (0.82)	Group: 0.09 (-0.03, 0.20)	Group: 0.137
		Quantitative	160, 0.48 (0.88)	Numeracy: −0.02 (−0.14, 0.10)	Numeracy: 0.70
	High	Verbal	164, 0.36 (0.88)		
		Quantitative	177, 0.47 (0.81)		
Colonoscopy Intent	Low	Verbal	172, 0.05 (0.82)	Group: 0.02 (−0.10, 0.14)	Group: 0.74
		Quantitative	158, 0.16 (0.80)	Numeracy: 0.08 (−0.05, 0.20)	Numeracy: 0.23
	High	Verbal	164, 0.02 (0.80)		
		Quantitative	176, −0.03 (0.79)		
FIT Intent	Low	Verbal	172, 0.21 (1.18)	Group: 0.21 (0.05, 0.36)	**Group: 0.011**
		Quantitative	158, 0.49 (1.13)	Numeracy: −0.03 (-0.19, 0.13)	Numeracy: 0.71
	High	Verbal	164, 0.34 (1.03)		
		Quantitative	176, 0.45 (1.06)		
Colonoscopy Benefits	Low	Verbal	162, 0.40 (0.62)	Group: 0.03 (−0.06, 0.11)	Group: 0.53
		Quantitative	156, 0.39 (0.60)	Numeracy: −0.15 (−0.24, 0.07)	**Numeracy: <0.001**
	High	Verbal	161, 0.49 (0.61)		
		Quantitative	174, 0.53 (0.64)		
FIT Benefits	Low	Verbal	159, 0.33 (0.68)	Group: 0.07 (−0.03, 0.16)	Group: 0.172
		Quantitative	156, 0.46 (0.75)	Numeracy: −0.19 (−0.29, −0.09)	**Numeracy: <0.001**
	High	Verbal	160, 0.56 (0.81)		
		Quantitative	173, 0.58 (0.71)		
Colonoscopy Barriers	Low	Verbal	161, −0.16 (0.46)	Group: 0.05 (−0.02, 0.12)	Group: 0.130
		Quantitative	155, −0.15 (0.48)	Numeracy: 0.01 (−0.06, 0.08)	Numeracy: 0.77
	High	Verbal	160, −0.19 (0.48)		
		Quantitative	174, −0.10 (0.42)		
FIT Barriers	Low	Verbal	160, −0.17 (0.55)	Group: −0.01 (−0.09, 0.07)	Group: 0.81
		Quantitative	155, −0.14 (0.57)	Numeracy: 0.10 (0.02, 0.19)	**Numeracy: 0.014**
	High	Verbal	160, −0.20 (0.55)		
		Quantitative	171, −0.27 (0.50)		
Overall Conflict Score	Low	Verbal	159, −18.0 (17.80)	Group: -0.05 (−1.87, 1.76)	Group: 0.95
		Quantitative	154, −18.2 (17.59)	Numeracy: 3.66 (1.79, 5.53)	**Numeracy: <0.001**
	High	Verbal	157, −20.6 (17.71)		
		Quantitative	172, −25.3 (20.08)		

* p-value from the model: T1 outcome =Group+ numeracy + T0 outcome + site + age + gender + employment. Only main effect models were used since Group*numeracy was not significant in any of the interaction models.
** the Verbal arm and High Numeracy were the reference groups.

One concern about disclosing the specific baseline risk for a cancer in a decision aid has been that it would lower people's perception of their risk which would lead to reduced intent and uptake of screening [10–12]. Another concern has been that disclosing the specific magnitude of absolute risk reduction provided by screening would reduce perceived benefit and, subsequently, reduce intent and uptake [10,11]. The current study does not support either of these concerns. While the change in perceived risk from T0 to T1 was significantly different for the two groups (p = .007), the changes were relatively small (+0.08 in the quantitative group and −0.08 in the verbal group, on a four-point scale) and, thus, have questionable clinical significance. In our pilot study, individuals who viewed the quantitative information also had a small increase in perceived risk (+0.15 on a seven-point scale). Changes in perceived benefit of colonoscopy or FIT did not differ between groups.

The quantitative decision aid may have increased perceived risk, in part, by disclosing frequencies over a lifetime rather than a shorter time period, such as 5 or 10 years. Incidence and mortality from cancer and the magnitude of absolute risk reduction provided by screening is higher over a lifetime than over shorter periods.

Previous studies found that providing quantitative estimates of baseline risk of cancer leads to lower perceived risk, perhaps because people started with higher estimates of their risk. When told their baseline risk of getting breast cancer in their lifetime (approximately 13% on average), women in a previous study had reduced perceived risk, in part since they estimated their risk beforehand as much higher (25% or more in many cases) [32]. In another study, perceived risk of getting an upset stomach as a reaction to a medication was lower after the numeric frequency was disclosed (14,000 per 100,000), than when it was described as "very common" [33]. In that case, perceived risk may have been lower after viewing the numbers since the term "very common" was associated by many subjects with a higher probability than 14%. In our study, in contrast, the quantitative information presented in our decision aid regarding incidence and mortality of CRC may have generated an impression of these risks that was similar to the ones subjects developed when viewing the verbal decision aid.

Viewing either the quantitative or verbal aid increased intent to undergo FIT, measured either as a response to a five-point Likert scale ("FIT Intent") or as planned screening behavior ("Test choice"). The increase was greater for both outcomes in the quantitative group than in the verbal group. Further, the changes in intent were clinically significant: the percent of patients choosing FIT as their test choice increased from T0 to T1 from 12% to 24% in

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the verbal group and from 11% to 34% in the quantitative group. These results match and extend findings from our pilot study, where mean FIT intent increased from T0 to T1 in both groups but the increase was significantly larger in the quantitative arm [22]. In the current study, the increase in selection of FIT as test choice resulted in an increase in intention to be screened overall that may be considered clinically significant (10% difference). The higher test choice of FIT at T1 and of being screened overall in the quantitative arm, however, was not reflected in an increased uptake of FIT or of screening at 6 months.

Viewing either decision aid resulted in a significant increase in patients' intent to have FIT in part since many patients eligible for CRC screening do not know about alternative tests because many physicians offer only colonoscopy [34–36]. Our decision aids explain that stool testing is an approved alternative to colonoscopy, allowing patients to choose this non-invasive approach. The quantitative decision aid may have resulted in a larger increase in FIT intent than the verbal decision aid because the numbers presented showed that the risk reduction provided by colonoscopy and FIT is similar: according to a leading model on which we based our presentation (SimCRC), colonoscopy reduces lifetime CRC mortality from 30 per 1000 to 4.6 per 1000, and FIT reduces it to 6 per 1000 [37].

As mentioned previously, there is concern that disclosing quantitative information about baseline risk in a decision aid for screening would decrease perceived risk, and thus decrease uptake [10–12]. In this situation, there would be difficult questions about whether the goals of disclosure before screening should prioritize improved understanding (respecting individual autonomy) or increasing uptake of screening (improved health outcomes) [13], and whether the decrease in uptake reflected the action of heuristics or biases rather than patients' informed preferences. The current study found no decrease in uptake. Our pilot study found that patients who viewed the quantitative decision aid had a significantly higher uptake of screening at six months than those who viewed the verbal decision aid [22], and we have no clear explanation for this difference in the studies.

Our study has several notable strengths including that: 1) it was a randomized, controlled trial with a large sample size, fully powered for our primary outcomes; 2) patients were recruited from multiple clinics and were diverse in terms of race, income, and education; and 3) screening outcomes were measured using the EHR. The main limitation is that it recruited only within a single city and surrounding area. Although we measured knowledge, we will report those results, along with other measures of decision quality, subsequently.

Finally, the study outcomes could have been impacted by the framing of words and numbers presented in the decision aids, a limitation that applies to any study involving decision aids. As mentioned above, the increase in perceived risk seen with the quantitative decision aid may have been the result, at least in part, of the team's decision to describe risk and risk reduction over a lifetime, rather than a shorter time period, such as 10 years. The magnitudes of predicted risk and risk reduction over a lifetime are larger and potentially more impressive than over shorter time frames. As another example, in keeping with recommendations, the decision aids described the sensitivity of a single application of FIT and of colonoscopy for CRC, using a frequency and icon graph in the quantitative arm and words in the verbal arm. It is possible that viewers could overestimate the importance of a difference in sensitivity. For many patients, there may be no negative consequence of FIT failing to identify a cancer or polyp on a single application, since many polyps do not progress to cancer and many polyps or cancers will be identified on later annual applications before they have progressed. The decision aids included an explanation of why a missed polyp or cancer might not have a negative effect. Future research should further study the impact of message framing in decision aids, building on the extensive body of research on framing [38].

5. Conclusion

In conclusion, this study showed that including quantitative information in a decision aid regarding CRC screening had significant, if moderate, effects on patient perceptions and intent to undergo screening, specifically intent to undergo FIT. The study did not show negative impacts on either intention or uptake of screening, and did not find large differences among patients with high and low numeracy. Additional studies will be needed to determine the impact of other sorts of quantitative information, potentially framed in other ways, in decision aids.

5.1. Practice implications

This study is the first adequately powered, randomized, controlled trial of the impact of quantitative information in a decision aid. The findings provide some support for recommendations that decision aids should provide patients with quantitative information about risks and benefits of available options. First, we did not find that quantitative information had negative consequences such as reducing uptake or negatively impacting decision-making of lower numeracy patients. Second, we found that quantitative information had the clinically significant impact of increasing the percentage of patients selecting FIT as their preferred test.

At the same time, these findings leave open the possibility that quantitative information should be an option for patients to view rather than a required part of decision aids. Further discussion of the place of quantitative information in decision aids will need to take these findings into account.

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Conflict of interest

The authors declare that they have no conflict of interest.

Author contribution

PHS, TFI, SMP, KKS, and SMR contributed to the study concept and design. KKS participated in acquisition of data. PHS, SMP, and SA analyzed and interpreted the data. All authors participated in drafting, revising, and approving the final manuscript.

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Appendix C. Supplementary data

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References

[1] G. Elwyn, A. O'Connor, D. Stacey, R. Volk, A. Edwards, A. Coulter, R. Thomson, A. Barratt, M. Barry, S. Bernstein, P. Butow, A. Clarke, V. Entwistle, D. Feldman-Stewart, M. Holmes-Rovner, H. Llewellyn-Thomas, N. Moumjid, A. Mulley, C. Ruland, K. Sepucha, A. Sykes, T. Whelan, C, The international patient decision aids standards, developing a quality criteria framework for patient decision aids: online international Delphi consensus process, BMJ 333 (7565) (2006) 417.
[2] L. Trevena, B. Zikmund-Fisher, A. Edwards, W. Gaissmaier, M. Galesic, P. Han, J. King, M. Lawson, S. Linder, I. Lipkus, E. Ozanne, E. Peters, D. Timmermans, S. Woloshin, Presenting probabilities, in: R. Volk, H. Llewellyn-Thomas (Eds.), Update of the International Patient Decision Aids Standards (IPDAS) Collaboration's Background Document, 2012 Chapter C., 2012.
[3] J. Paling, Strategies to help patients understand risks, BMJ 327 (7417) (2003) 745–748.
[4] G. Gigerenzer, A. Edwards, Simple tools for understanding risks: from innumeracy to insight, BMJ 327 (7417) (2003) 741–744.
[5] M. Kutner, E. Greenberg, Y. Jin, C. Paulsen, The health literacy of America's adults: Results from the 2003 National Assessment of Adult Literacy, U.S.D.o. Education National Center for Education Statistics, Washington, DC, 2006.
[6] NCES, National Assessment of Adult Literacy (NAAL): Key findings: Demographics: Overall, (2003) . (Accessed April 10 2013) http://nces.ed.gov/naal/kf_demographics.asp.
[7] D. Stacey, F. Legare, K. Lewis, M.J. Barry, C.L. Bennett, K.B. Eden, M. Holmes-Rovner, H. Llewellyn-Thomas, A. Lyddiatt, R. Thomson, L. Trevena, Decision aids for people facing health treatment or screening decisions, Cochrane Database Syst. Rev. 4 (2017) CD001431.
[8] J.A. Shepperd, E.A. Waters, N.D. Weinstein, W.M.P. Klein, A primer on unrealistic optimism, Curr. Dir. Psychol. Sci. 24 (3) (2015) 232–237.
[9] N.D. Weinstein, Unrealistic optimism about future life events, J. Pers. Soc. Psychol. 39 (5) (1980) 806–820.
[10] P.H. Schwartz, Questioning the quantitative imperative: decision aids, prevention, and the ethics of disclosure, Hastings Cent. Rep. 41 (2) (2011) 30–39.
[11] B.J. Zikmund-Fisher, The right tool is what they need, not what we have: a taxonomy of appropriate levels of precision in patient risk communication, Med. Care Res. Rev. 70 (1 Suppl) (2013) 37S–49S.
[12] H. McDonald, C. Charles, A. Gafni, Assessing the conceptual clarity and evidence base of quality criteria/standards developed for evaluating decision aids, Health Expect. 17 (2) (2014) 232–243.
[13] A.E. Raffle, Information about screening: Is it to achieve high uptake or to ensure informed choice? Health Expect. 4 (2) (2001) 92–98.
[14] L.J. Trevena, B.J. Zikmund-Fisher, A. Edwards, W. Gaissmaier, M. Galesic, P.K. Han, J. King, M.L. Lawson, S.K. Linder, I. Lipkus, E. Ozanne, E. Peters, D. Timmermans, S. Woloshin, Presenting quantitative information about decision outcomes: a risk communication primer for patient decision aid developers, BMC Med. Inform. Decis. Mak. 13 (Suppl 2) (2013) S7.
[15] U.S.P.S.T. Force, K. Bibbins-Domingo, D.C. Grossman, S.J. Curry, K.W. Davidson, J.W. Epling Jr, F.A.R. Garcia, M.W. Gillman, D.M. Harper, A.R. Kemper, A.H. Krist, A.E. Kurth, C.S. Landefeld, C.M. Mangione, D.K. Owens, W. R. Phillips, M.G. Phipps, M.P. Pignone, A.L. Siu, Screening for colorectal Cancer: us preventive services task force recommendation statement, JAMA 315 (23) (2016) 2564–2575.
[16] D.K. Rex, C.R. Boland, J.A. Dominitz, F.M. Giardiello, D.A. Johnson, T. Kaltenbach, T.R. Levin, D. Lieberman, D.J. Robertson, Colorectal cancer screening: recommendations for physicians and patients from the U.S. multi-Society Task Force on Colorectal Cancer, Gastroenterology 153 (1) (2017) 307–323.
[17] C.N. Klabunde, D.A. Joseph, J.B. King, A. White, M. Plescia, Vital signs: colorectal cancer screening test use — United States, 2012, Morbidity and Mortality Weekly Report 62 (44) (2013) 881–888.
[18] J.S. Lin, M.A. Piper, L.A. Perdue, C.M. Rutter, E.M. Webber, E. O'Connor, N. Smith, E.P. Whitlock, Screening for colorectal Cancer: updated evidence report and systematic review for the US preventive services task force, JAMA 315 (23) (2016) 2576–2594.
[19] P.A. Harris, R. Taylor, R. Thielke, J. Payne, N. Gonzalez, J.G. Conde, Research electronic data capture (REDCap)-A metadata-driven methodology and workflow process for providing translational research informatics support, J. Biomed. Inform. 42 (2) (2009) 377–381.
[20] A.C. Society, Get Tested for Colon Cancer. Here's how, American Cancer Society, Inc., 2008.
[21] I.D.A.S.I. Collaboration, International Decision Aid Standards (IPDAS) Collaboration - Resources, (2012) . (Accessed April 10 2013) http://ipdas.ohri.ca/resources.html.
[22] P.H. Schwartz, S.M. Perkins, K.K. Schmidt, P.F. Muriello, S. Althouse, S.M. Rawl, Providing quantitative information and a nudge to undergo stool testing in a colorectal cancer screening decision aid: a randomized clinical trial, Med. Decis. Making 37 (6) (2017) 688–702.
[23] S. Rawl, V. Champion, U. Menon, P.J. Loehrer, G.H. Vance, C.S. Skinner, Validation of scales to measure benefits of and barriers to colorectal cancer screening, J. Psychosoc. Oncol. 19 (3/4) (2001) 47–63.
[24] A.M. O'Connor, User Manual Decision Conflict Scale, (2005) . (Accessed April 10 2013) http://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_Decisional_Conflict.pdf.
[25] A. Fagerlin, B.J. Zikmund-Fisher, P.A. Ubel, A. Jankovic, H.A. Derry, D.M. Smith, Measuring numeracy without a math test: development of the subjective numeracy scale, Med. Decis. Mak. 27 (5) (2007) 672–680.
[26] B.J. Zikmund-Fisher, D.M. Smith, P.A. Ubel, A. Fagerlin, Validation of the Subjective numeracy scale: effects of low numeracy on comprehension of risk communications and utility elicitations, Med. Decis. Mak. 27 (5) (2007) 663–671.
[27] M.M. Schapira, C.M. Walker, K.J. Cappaert, P.S. Ganschow, K.E. Fletcher, E.L. McGinley, S. Del Pozo, C. Schauer, S. Tarima, E.A. Jacobs, The Numeracy understanding in medicine instrument: a measure of health numeracy developed using item response theory, Med. Decis. Mak. 32 (6) (2012) 851–865.
[28] M.M. Schapira, C.M. Walker, T. Miller, K.E. Fletcher, P.S. Ganschow, E.A. Jacobs, D. Imbert, M. O'Connell, J.M. Neuner, Development and validation of the numeracy understanding in medicine instrument short form, J. Health Commun. 19 (Suppl 2) (2014) 240–253.
[29] L.D. Chew, K.A. Bradley, E.J. Boyko, Brief questions to identify patients with inadequate health literacy, Fam. Med. 36 (8) (2004) 588–594.
[30] E. Demidenko, Sample size and optimal design for logistic regression with binary interaction, Stat. Med. 27 (1) (2008) 36–46.
[31] B.C. Kahan, T.P. Morris, Improper analysis of trials randomised using stratified blocks or minimisation, Stat. Med. 31 (4) (2012) 328–340.
[32] A. Fagerlin, B.J. Zikmund-Fisher, P.A. Ubel, How making a risk estimate can change the feel of that risk: shifting attitudes toward breast cancer risk in a general public survey, Patient Educ. Couns. 57 (3) (2005) 294–299.
[33] E. Peters, P.S. Hart, M. Tusler, L. Fraenkel, Numbers matter to informed patient choices: a randomized design across age and numeracy levels, Med. Decis. Mak. 34 (4) (2014) 430–442.
[34] A. McQueen, L.K. Bartholomew, A.J. Greisinger, G.G. Medina, S.T. Hawley, P. Haidet, J.L. Bettencourt, N.K. Shokar, B.S. Ling, S.W. Vernon, Behind closed doors: physician-patient discussions about colorectal cancer screening, J. Gen. Intern. Med. 24 (11) (2009) 1228–1235.
[35] B.S. Ling, J.M. Trauth, M.J. Fine, M.K. Mor, A. Resnick, C.H. Braddock, S. Bereknyei, J.L. Weissfeld, R.E. Schoen, E.M. Ricci, J. Whittle, Informed decision-making and colorectal cancer screening: is it occurring in primary care? Med. Care 46 (9 Suppl 1) (2008) S23–9.
[36] P.H. Schwartz, E. Edenberg, P.R. Barrett, S.M. Perkins, E.M. Meslin, T.F. Imperiale, Patient understanding of benefits, risks, and alternatives to screening colonoscopy, Fam. Med. 45 (2) (2013) 83–89.
[37] A.G. Zauber, I. Lansdorp-Vogelaar, A.B. Knudsen, J. Wilschut, M. van Ballegooijen, K.M. Kuntz, Evaluating test strategies for colorectal cancer screening: a decision analysis for the U.S. preventive services task force, Ann. Intern. Med. 149 (9) (2008) 659–669.
[38] A. Edwards, G. Elwyn, J. Covey, E. Matthews, R. Pill, Presenting risk information–a review of the effects of "framing" and other manipulations on patient outcomes, J. Health Commun. 6 (1) (2001) 61–82.

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