

COVER PAGE

Comparing Screener vs. Survivor Role Models
to Improve Colon Cancer Screening

NCT02485561

12/03/2015

CRC Narratives - Internet

PI: Amy McQueen

IRB ID #: 201501019

Project Details

1. Demographics

- 1.1 Project Title:
Evaluating Strategies to Present Colon Cancer Screening Information on the Internet
- 1.2 Short Title (required):
CRC Narratives - Internet
- 1.3 Project is primarily:
Social Science/Behavioral (includes History/Anthropology)
- 1.4 Type of Study:
Other Interventional
- 1.4.a Is your research study one in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes ([NIH clinical trial definition](#)).
Yes
- 1.5 Select how you plan to obtain consent:
- Sign a consent document or a consent letter
 - Letter or information sheet with no signature

2. Source(s) of Support

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1

Type/Source	Grant Title	Name of PI on Grant	Status
Federal Agency NIH, National 1	COMPARING SCREENER VS. SURVIVOR ROLE MODELS TO IMPROVE COLON CANCER SCREENING	Amy McQueen	AWARDED

Attachment Name	Category	Version	Date Attached
McQueen Narratives submission.pdf	Grant from funding source or private foundation/association	1	12/19/14

3. Research Team

3.1 Principal Investigator

Name	E-mail	Title	School
Amy McQueen	amcqueen@dom.wustl.edu	Assoc Prof of Medicine	School Of Medicine

3 Team Members

2

Research Team Members

Role	Name	Role Desc	Student	Email	Title	School	Department	Contact	Consent Process Involvement	Epic Contact Person
PI	Amy McQueen, PHD		No	amcqueen@dom.wustl.edu	Assoc Prof of Medicine	School Of Medicine	Int Med - Gen Medical Sciences	Yes	Yes	
	Charlene Caburnay, MPH, PHD			ccaburnay@email.wustl.edu	Research Assistant Professor	George Warren Brown School of	Health Comm. Research Lab	No	No	

						Social Work				
Balaji Golla, MS			bgolla@email.wustl.edu	Programmer/Databases Developer	George Warren Brown School of Social Work	Health Comm. Research Lab	No	No		
Matthew Kreuter, MPH, PHD			mkreuter@email.wustl.edu	Eugene S. and Constance Kahn Family Professor	George Warren Brown School of Social Work	Public Health-social Work	No	No		
Molly Loughran, BS			mloughran@email.wustl.edu	Non A&S Graduate Student	George Warren Brown School of Social Work	Health Comm. Research Lab	No	No		

	Julianne Sefko, MPH			jsefko@email.wustl.edu	Sr Clinical Research Coord	School Of Medicine	Orthopaedic Surgery	Yes	Yes	
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Team Member Financial Interest

Name	Financial Interests
Amy McQueen, PHD	none
Charlene Caburnay, MPH, PHD	none
Balaji Golla, MS	none
Matthew Kreuter, MPH, PHD	none
Molly Loughran, BS	none
Julianne Sefko, MPH	none

4. Other Institutional Reviews/Requirements

- 4.1 Do any of the objectives of this study involve the diagnosis, prevention, screening, evaluation, treatment or support of cancer patients?
Yes
- 4.2 Are more than 30% of the patients involved in this study likely to have an active cancer diagnosis?
No
- 4.10 Will a Certificate of confidentiality be used for this research?
No
- 4.11 Does this project need to be registered on [ClinicalTrials.gov](https://clinicaltrials.gov/)?
Yes
- 4.11.a Who is the Responsible Party for registering this study in ClinicalTrials.gov?
Principal Investigator
- 4.19 Mark all that apply to your study:
 Mark any service(s) you'd like to use:
 - Participant Recruitment Services available through [Recruitment Enhancement Core \(REC\)](#)

1. Protocol

1.1 Is there a separate, written protocol that will be submitted in addition to this form?
(Note: a grant application is not considered to be a protocol)

No

1.2 Select up to three key words below that best describe this research study:

• Education

1.3 Provide a short summary/abstract of the purpose and procedures of the study proposed in this IRB application.

- DO NOT include information on studies not proposed in this application.
- Use LAY terminology only. This must be easily understandable by IRB community members and nonscientists.
- DO NOT cut and paste technical abstracts from source of support applications that may not be understood by a general audience.

This is a web-based pilot study examining the effects of narratives about colorectal cancer screeners on intentions and steps to colorectal cancer screening (CRCS) among average-risk adults who are non-adherent to CRCS guidelines (pre-test study IRB# 201405069). Potential participants will complete a brief eligibility survey by phone or online then be invited to participate in the study. Eligible, consented participants will complete a baseline survey and read basic CRCS information then be randomly assigned within the website program to either 1) proceed directly to the post-intervention survey or 2) view a portrait and read a narrative from an individual who got a colonoscopy and either did (“survivor”) or did not (“screener”) have cancer, before completing the post-intervention survey. Narratives will be written as first-person testimonials based on similar stories posted online. Photos will be tailored to the participant (age group, gender, race/ethnicity). One month later, participants will be contacted to complete the follow-up survey online or by phone. A subset of these participants will be contacted for a three month follow-up survey online or by phone.

1.4 Specify your research question(s), study aims or hypotheses:

Aim 1. Examine the direct effect of narratives on intentions and steps to CRCS behavior.

Hypothesis 1: Narratives (vs. Information-only) will increase CRCS intentions and steps to behavior.

Hypothesis 2: Screener (vs. survivor) narratives will increase CRCS intentions and steps to behavior.

Aim 2. Examine mediators of narratives’ effects on intentions and steps to CRCS behavior.

Hypothesis 3: Screener (vs. survivor) narratives will produce greater identification and self-efficacy and less negative affect and counterarguing (mediators) to indirectly influence CRCS intentions and steps to CRCS.

Hypothesis 4: Survivor (vs. screener) narratives will produce greater perceptions of susceptibility to CRC, prevalence of CRC, social norms for CRCS, and negative affect, counterarguing (mediators) to indirectly influence CRCS intentions and steps to CRCS.

Exploratory Aim 3. Estimate potential moderating effects of audience characteristics (e.g., sociodemographics, psychological dispositions).

Hypothesis 5: People high in need for cognition will be more engaged and persuaded by narratives.

1.5 Background and significance and/or Preliminary studies related to this project: Colorectal cancer (CRC) is an important cause of morbidity and mortality in the US. Despite multiple recommended screening options, CRC screening (CRCS) rates are suboptimal. More effective interventions are needed to increase CRCS uptake. Narrative communications that depict events and consequences may have advantages over informational communication styles that present reasons and arguments. The inclusion of patient narratives in interventions and on the Internet are becoming ubiquitous and have far outpaced empirical research regarding how and for whom narratives are effective. Frequently, narratives take the form of role model stories or testimonials that promote behavior change. Breast cancer survivors' testimonials have positively influenced women's mammography use for early detection. However, survivors' stories also may be perceived as inherently dissimilar and raise defenses among those concerned about (or in avoidance of) their cancer risk. For CRC, focusing on survivors also may undermine the message of preventing CRC through screening. Most people who are screened for CRC do not find any cancer and these "screeners" may be more influential role models. To improve future interventions that incorporate narratives, we need to identify the best role models ("survivors" vs. "screeners") for increasing CRCS intentions and behaviors, and examine mechanisms of their influence.

1.6 Literature cited/references (if attaching a grant enter N/A):
N/A

1.7 Describe EACH of your participant populations

- Include description of any control group(s)
- Specify the Inclusion/Exclusion criteria for EACH group

Inclusion: Males and females adults aged 50-75 years old

• Exclusion criteria: Unable to read or speak English; prior diagnosis of cancer (except non-melanoma skin cancer), Crohn's disease, inflammatory bowel disease or colitis; and adherent to colorectal cancer screening (CRCS) guidelines defined as a sigmoidoscopy (SIG) in the past 5 years, or a colonoscopy (COL) in the past 10 years.

1.8 Check all materials/methods that will be used in recruiting participants:

- Telephone script
- Ads/Brochures/Posters/News Release/Fliers
- Email or letters
- Website or Social Media (printed pages)
- Other Materials - Potential participants may see study flyers posted through community organizations such as YMCAs, community centers, public libraries, public bulletin boards, health fairs, or other community events. They may also learn about the study through word of mouth or newspaper advertisements or newsletter announcements. We will also send flyers to Volunteer for Health registrants.
- Existing Registry/database
 - Other Existing Registry/database - Volunteer for Health, ResearchMatch.org

- Referral
- Medical Records or Other PHI

Attachment Name	Category	Version	Date Attached
Brief Internet post text.rtf	Recruitment Materials: Ads/Brochures/Posters/News Release/Fliers	1	06/25/15
Narrative poster modified.rtf	Recruitment Materials: Ads/Brochures/Posters/News Release/Fliers	9	06/29/15
Newspaper ad-option2.rtf	Recruitment Materials: Ads/Brochures/Posters/News Release/Fliers	1	06/25/15
Newspaper ad-option3.rtf	Recruitment Materials: Ads/Brochures/Posters/News Release/Fliers	1	06/25/15
Narrative phone script.rtf	Recruitment Script: Phone	1	12/18/14
Newspaper ad-1-1.rtf	Recruitment Materials: Ads/Brochures/Posters/News Release/Fliers	7	06/01/15
McQueen facebook ad 201501019.rtf	Recruitment Materials: Ads/Brochures/Posters/News Release/Fliers	1	06/19/15
McQueen201501019 RPR website.rtf	Recruitment Materials: Ads/Brochures/Posters/News Release/Fliers	1	06/19/15
McQueen - Centerwatch.rtf	Recruitment Materials: Ads/Brochures/Posters/News Release/Fliers	1	06/19/15
Internet post text.rtf	Recruitment Materials: Ads/Brochures/Posters/News Release/Fliers	1	06/25/15

- 1.8.a** List the individual data elements you will need to access/use from the patient or clinic records to identify potential participants for recruitment
Names, email addresses and phone numbers will be used from the Volunteer for Health or HCRL registry in addition to age in order to identify potentially eligible individuals.
- 1.8.b** What is the plan for participant identifiers obtained to identify participants for recruitment?
Identifiers for those who do NOT enroll will be destroyed at the earliest opportunity, consistent with the conduct of the research (for example when recruitment and enrollment are completed.)
- 1.8.c** Does the research team agree that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized

oversight of the study, or for other research for which the use or disclosure of the requested information would be permitted by the HIPAA Privacy Rule?

Yes

1.9 Will you use a screening log or other record that would include information on people who do not consent to participate in the study?

Yes

Attachment Name	Category	Version	Date Attached
Screening questions.docx	Screening: Screening Log	1	01/07/15

1.9.a Will the screening log be shared with individuals outside of the research team?

No

1.10 Describe where the consent discussion will occur (check all that apply):

- Online

1.11 Participants and/or their legally authorized representative will have (check all that apply to the consent process and explain process in Question 1.12 below):

- As much time as they desire to consider enrolling in the study, including:
 - An opportunity to thoroughly review the consent materials with knowledgeable members of the research team, and with family and/or friends as appropriate
 - Sufficient time to have all of their questions answered

1.12 Provide a description of the enrollment and consent process in sequential order and address EACH of the bulleted points below:

- Describe each study population separately including control population
- Describe when recruitment and consent materials are used
- Indicate how much time individuals will have to consider participation
- Use THIRD person active voice. For example, "the principal investigator will identify potential participants, the study coordinator will discuss the study with participants over the telephone and schedule the first study visit, etc..."
- Describe the steps that will be taken by the research team to minimize the possibility of coercion or undue influence during the consent process

Participants will be recruited through a variety of ways. They may see study flyers from clinicians, outpatient clinics, university buildings in the medical campus, employee health and wellness, or the Volunteer for Health office. They may also learn about the study through word of mouth or newspaper advertisements or newsletter announcements. Flyers may be distributed or posted through community organizations such as YMCAs, community centers, public libraries, public bulletin boards, health fairs, or other community events. The study will also be included in ClinicalTrials.gov and other volunteer research sites including the Volunteer for Health website, Facebook page, and Center Watch, and external sites such as ResearchMatch.org, ResearchRegistry.pitt.edu, CreateTheGood.org, SocialPsychology.org, StudyResponse.net, Psych.Hanover.edu/Research/exponent, and PioneersResearch.org. Participants using independent research study search engines

(often within university or health system websites) may find our study and others posted on ClinicalTrials.gov without going directly to that site. Participants may also be recruited through colleague referrals or by research staff in proactive recruitment calls to people in volunteer registries.

Interested individuals can learn about the study purpose, requirements, and compensation by reading the informed consent form on the website or speaking to research staff who can also answer any questions that individuals may have. Interested individuals will complete an eligibility survey on the website or by phone and if eligible, may consent to participate after reading an informed consent form. Participants may choose to complete the interview at a location of their choice using their own internet-enabled device. If they do not have access to a computer, they may complete the interview by appointment with study staff and use a University computer.

There should be no coercion or undue influence from research staff on potential participants as they have no relationship. Additionally, all staff are experienced with recruitment and protecting the rights of human subjects.

1.13 Provide a detailed description in sequential order of the study procedures following the consent process - DO NOT cut and paste from the Consent Document.

Describe study populations separately if they will be participating in different procedures

DESCRIBE:

- Control populations, if applicable
- Any randomization, if applicable
- What participants will be asked to do/what happens in the study (in sequential order)
- The time period over which procedures will occur
- Long-term follow-up and how it occurs

Participants will complete a baseline web-based survey and read basic CRCS information then, be randomly assigned within the website program to either 1) proceed directly to the post-intervention survey or 2) view a portrait and read a narrative of an individual who got a colonoscopy and either did (“survivor”) or did not (“screener”) have cancer, before completing the post-intervention survey. Interested participants without access to a computer may schedule a time to come to our office to complete the surveys on a study computer, otherwise participants can complete the study anywhere they have access to a computer and internet connection. This session will not exceed 30 minutes and participants will be paid \$20 for their time. One month later, participants will be contacted to complete a follow-up survey online or by phone. This one-month follow-up session will not exceed 10 minutes and participants will be paid \$10 for their time. A subset of participants may complete a six-month and twelve-month follow-up survey. Each of these additional follow-up sessions will not exceed 10 minutes and participants will be paid \$5 for their time.

1.14 Will participants be randomized?

Yes

1.15 Will any of the following be used to collect information from the participant or others?

- Screening questions or screening/eligibility questionnaires
- Surveys
- Questionnaires
- Stimuli
- Any other written assessments

Yes

Attachment Name	Category	Version	Date Attached
Post-Intervention survey.docx	Subject Data Collection Instruments	1	01/07/15
Baseline survey.docx	Subject Data Collection Instruments	1	01/07/15
Narrative_6moFollowupSurvey.docx	Subject Data Collection Instruments	1	10/29/15
Follow-up survey-1 (1) (2).docx	Subject Data Collection Instruments	5	10/29/15
Narrative_12moFollowupSurvey (5).docx	Subject Data Collection Instruments	6	06/27/16

1.16 Does this project involve creating any audio, video, or photographs?

No

1.17 Does the study include any form of deception (e.g., providing participants with false information, misleading information, or withholding information about certain study procedures)?

Examples:

- Procedure includes a cover story that provides a plausible but inaccurate account of the purposes of the research.
- Participants will be provided with false information regarding the particular behaviors of interest in the research.
- Procedures include a confederate pretending to be another participant in the study.
- Participants will be told that the research includes completion of a particular task, when in fact, that task will not be administered.
- Study is designed to introduce a new procedure (or task) that participants are not initially told about.

- No
- 1.18 Indicate any payments or reimbursements to participants (check all that apply)
 - Check
- 1.19 Does this study have a plan to have an individual or committee review combined data from all participants on a periodic basis (such as summary or aggregate safety and/or efficacy data)?

No
- 1.20 What have you done to minimize any risks?
 - No foreseeable risks
- 1.21 What are the potential benefits related to this project for:
 - the participant (if any)
 - benefits to society (if any)

Participants may or may not benefit from being in this study. Participants may gain knowledge of colorectal cancer and screening options.
- Our results may change how CRC screeners' narratives are valued, used, and potentially tailored for different audiences to promote CRCS among non-adherent adults. We hope that, in the future, other people might benefit from this study because we will learn better ways to present information to educate and motivate adults to get screened for colon cancer.
- 1.22 Provide a summary of the analysis methods you will use, including, if applicable, the data points or outcomes you will analyze.

Participants assigned to study arms are expected to be equivalent on baseline measures; any differences will be included as covariates in analyses. We also will test for differential loss to follow-up, and compare results from intent-to-treat vs. complete-data analyses. To test Aim 1 hypotheses, we will conduct analyses of variance or covariance in SPSS, as appropriate. Baseline intention will be included as a covariate of later intention. Planned contrasts will compare (1) the information only vs. the pooled narrative conditions, and (2) survivor vs. screener narratives. We chose intention as the main outcome in this pilot study because it is a necessary determinant of CRCS behavior. We will also examine steps to CRCS (e.g., using or seeking CRCS information, discussing CRCS with others) as important intermediate outcomes of CRCS adherence. For Aim 2, to test indirect effects of narratives and provide empirical support for our conceptual model, we will use structural equation modeling (SEM) with Mplus software consistent with our past work. We will use recommended criteria for assessing model fit and statistical tests for identifying the magnitude and significance of multiple mediators (indirect effects). SEM can parsimoniously evaluate multiple mediators and outcomes in a single model. To test our conceptual model, we will examine message elaboration and CRCS determinants as mediators (from the Post-intervention Survey) of the effect of narratives on intentions and behaviors (from the Follow-up Survey). We propose to use manifest variables and we will create exogenous dummy variables to compare study groups. We expect stronger

effects of study condition on mediators than on outcomes and are particularly interested in differences in perceived risk, worry, and prevalence of CRC, affective reactions to narratives, and defenses. For Aim 3, two-way interactions between study condition and individual characteristics will be explored using GLM analyses in SPSS for mediators and outcomes. Post-hoc group comparisons and interaction plots will be used to describe any significant associations. We are especially interested in noting any differences in narrative effects by gender or race to address the need for stratified interventions or analyses in a future R01.

- 1.23** Provide the rationale or power analysis to support the number of participants proposed to complete this study.
Using post-intervention intention as a main outcome for Aim 1, assuming a mean score of 3.5 and a standard deviation of 1.0 on a 1-5 scale, there is >80% power to detect a 0.3 mean difference between survivor vs. screener narratives (Hyp2) with a sample size of 360 (120 per condition) at $p < 0.05$. Thus, we propose to recruit 500 participants (~167 per condition) during the 2-year study to provide sufficient power for any loss to follow up (<20%). Assuming 400 participants provide complete data, we can test our conceptual model (Figure 1) using structural equation modeling. We will have sufficient power (>.80) to detect small associations ($\beta \geq .19$) with mediators, and indirect effects as small as $\alpha\beta \geq .07$ as statistically significant.
- 1.25** Will any data from this project be stored for use in future research studies?
No
- 1.26** Does this project involve the collection or use of biological samples?
No
- 1.27** Are you requesting institutional certification to contribute human data or samples to a repository or database for broad sharing (public or restricted access)?
No

2. Participants

- 2.1** Will there be any adult participants?
Yes
- 2.1.a** How many adult participants do you expect to consent or enroll under a waiver for this project?
600
- 2.1.b** What is the age of the youngest adult participant?
50.0
- 2.1.c** What is the age of the oldest adult participant?
75.0
- 2.2** Will there be any minor participants?
No
- 2.3** Will there be any emancipated minor participants?
No
- 2.7** Do you plan to recruit/enroll non-English speaking people?
No
- 2.8** Do you propose to enroll any of the following in this study as participants?

- Employee of the PI or employee of a research team member
 - Individual supervised by PI or supervised by member of research team
 - Individual subordinate to the PI or subordinate to any member of the research team
 - Student or trainee under the direction of the PI or under the direction of a member of the research team
- No
- 2.9 Is this project about pregnant women?
No
- 2.10 Will this project involve fetuses?
No
- 2.11 Does this project involve the use of fetal tissue from any source?
No
- 2.12 Does this project recruit adult participants who may be incompetent or have limited decision-making capacity on initial enrollment into the study?
No
- 2.13 Does this project involve prisoners as participants?
No

3. Performance Sites

- 3.1 Indicate type of site(s) where research will occur (check all that apply):
- Academic Institution
 - Other - Online
- 3.2 Where will project procedures take place (check all that apply)?
- School of Medicine
 - Other WUSTL campus site - Division of General Medical Sciences in the School of Medicine, Health Communication Research Laboratory at Brown School of Social Work
- 3.3 Is this project also being conducted by other researchers at their own sites (e.g. a multi-site collaborative project)?
No

5. Privacy & Confidentiality

- 5.1 Indicate your plans to protect the privacy interests of the participants during the conduct of the study (check all that apply):
- Only the minimum necessary private information is collected for the purposes of the study
 - Any procedures or interventions conducted as part of the study will be conducted in private setting to the extent possible

- Recruitment/consent will occur in a private setting
- Participants will be able to ask questions in a private setting

5.2 Are you collecting or using the Social Security Number of any participants for any purpose?

Yes

5.2.a Provide the intended usage of SSN:

- To provide compensation to participants

5.3 Project uses paper or hard copy consents, surveys, data collection forms, research subject binders, or other hard copy materials (check all that apply):

Yes

- All materials are stored in secured environment
- Access is limited to research team members only

5.4 Project collects, stores and/or transmits electronic data on mobile devices, desktop computers, servers including cloud servers, email, or any other information in electronic form (check all that apply):

Yes

- Access is limited to research team only
- Transmitted using recognized security for electronic submission

5.5 Project collects or uses biologic specimens (check all that apply):

No

5.6 Identify any additional protections in place for data and or samples (check all that apply):

- Formal research staff training process